

TechCare – Mobile Assessment and
Therapy for Psychosis: Feasibility Study
of an Intervention for Clients within the
Early Intervention Service.

by

Nadeem Gire

G20310789

*A thesis submitted in partial fulfilment for the requirements for
the degree of Doctor of Philosophy at the University of Central
Lancashire*

January 2019



STUDENT DECLARATION FORM

Type of Award Doctor of Philosophy PhD

School School of Nursing

1. Concurrent registration for two or more academic awards

I declare that while registered for the research degree, I was with the University's specific permission, an enrolled student for the following award between, September 2017 to December 2017:

Bachelor of Medicine and Bachelor of Surgery (MBBS)

2. Material submitted for another award

I declare that no material contained in the thesis has been used in any other submission for an academic award and is solely my own work

3. Collaboration

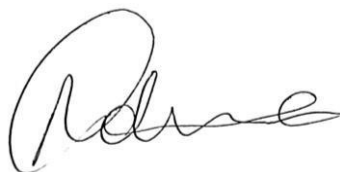
Where a candidate's research programme is part of a collaborative project, the thesis must indicate in addition clearly the candidate's individual contribution and the extent of the collaboration. Please state below:

N/A

4. Use of a Proof reader

No proof reading service was used in the compilation of this thesis.

Signature of Candidate



Print name: **NADEEM GIRE**

ABSTRACT

Background: Mobile digital health technologies, mHealth, is a growing field globally with a potential to improve mental health. Technological advances have shown promise across healthcare and particularly when delivering interventions for mental health problems such as psychosis. The use of mobile devices provides greater autonomy to service users who would otherwise be seen as a 'hard to reach group', with complex relationships between psychotic experiences, trust and engagement with services. A non-stigmatising approach is implicit within technological developments, as many service users experience mental health stigma, which can compound problematic engagement, treatment adherence and outcomes. This study was an original piece of work and has created new insights into mHealth technologies for individuals experiencing psychosis.

Aim: The aim of the project was to develop and conduct a feasibility study of the mobile phone application (App) 'TechCare' for individuals with psychosis in the North West of England.

Methods/Design: The feasibility study followed the National Institute of Health Research (NIHR) guidance on feasibility study design and consisted of both qualitative and quantitative components. The study was conducted across three strands as follows: 1) Qualitative work & Systematic review; 2) Test-run and Intervention refinement (developing the TechCare App); 3) Feasibility trial. The TechCare App assessed participants' symptoms and responses and provided for a personalised guided self-help based psychological intervention, with the aim of reducing participants' symptoms. In Strand 1 of the study, 16 service users and 16 health professionals from Lancashire Care NHS Foundation Trust, Early Intervention Service (EIS) were recruited to explore their experience of psychosis and give their opinions on the existing evidence based treatment (Cognitive Behavioural Therapy (CBT)) and how the mobile App could be developed (service users and staff). In Strand 2, a test-run with a small number (n= 4) of participating service users, was conducted to refine the mobile intervention (TechCare). Finally, in Strand 3 the TechCare App was examined in a feasibility study with a total of 12 service users. The study was also registered on ClinicalTrials.gov Identifier: NCT02439619.

Results: The systematic review, found 7 studies which met the inclusion criteria, from a total of 5690 records. The included studies describing the feasibility of using mHealth technologies for psychosis, functionality and access to mHealth interventions and study outcomes. Overall, the systematic review results suggested that mHealth for psychosis is acceptable and feasible in the target population. Furthermore, the TechCare App had

been developed, working alongside service users who consulted on the development of the App. The qualitative result of the study showed that the TechCare App was found to be an acceptable means of receiving interventions for the service users, with key themes around, the participant's experience of using the App, the further development and refinement of the intervention and the usability of the intervention. In addition, the Strand 3 feasibility study, results showed that out of the 12 participants, a total of 83.33% of participants completed the 6 week intervention. Overall participants responded to the App notifications on average 2.95 time per day (Range: 0-11), with a reduction in average scores on the TechCare App, from baseline to week 6 for the depression scale questions (Week 1, M=29.13 (SD=18.29); Week 6 was M=17.50 (SD=11.92)) and paranoia scale questions (Week 1 M=38.00, SD=28.27; Week 6, M=33.92, SD=27.88).

Discussion: The results of the study show promise in the feasibility and acceptability of the TechCare App. Based on these results I can now take the research forward as part of a future clinical and cost effectiveness trial. It has been suggested that there is a need, for a rapid increase in the evidence base for the clinical effectiveness of digital technologies, considering mHealth research can potentially be helpful in addressing the demand on mental health services in the UK and mental health inequalities.

Table of Contents

LIST OF FIGURES & TABLES.....	9
ACKNOWLEDGEMENTS	11
CHAPTER 1: INTRODUCTION	12
Patient and Public Involvement (PPI) -----	12
Statement of Originality -----	13
Thesis Structure-----	15
CHAPTER 2: BACKGROUND TO THE RESEARCH.....	17
2.1 Psychosis: The Theoretical Perspective-----	19
2.2 Early Intervention Service for Psychosis -----	21
2.3 EIS Care Pathway for First Episode Psychosis (NHS Trust, 2017)-----	25
2.4 Cognitive Behavioural Therapy for Psychosis in EIS-----	28
2.5 Overcoming Mental Health Inequalities Using Technology -----	30
2.6 Digital Inclusion: The Concept and Strategies for People with Mental Health Difficulties-----	31
2.7 The effects of digital exclusion on mental health -----	32
2.8 The use of mobile technologies for the treatment of psychosis -----	34
2.9 Chapter 2: Summary & Conclusion-----	36
CHAPTER 3: ASSESSMENT OF THE TECHCARE PROJECT USING THE NIHR CLAHRC NORTH WEST COAST HEALTH INEQUALITIES ASSESSMENT TOOLKIT (HIAT).....	38
3.1 Defining Health Inequalities and the Social Determinants of Health-----	38
3.2 Health Inequalities in the North West Coast-----	39
3.3 The Development of the HIAT tool-----	40
3.4 Section 1: Clarifying what aspects of health inequalities and their socio- economic drivers are relevant to the problem to be addressed in the proposed work. 40	
3.4.1 What evidence is there that this health problem is unequally distributed across people living in different socio-economic circumstances	42
3.4.2 What particular socio-economic drivers of health inequalities can be expected to impact on this problem.....	43
3.5 Section 2: Designing your intervention or activity to have maximum effect on reducing health inequalities -----	44

3.6	Section 3 - Evaluating and monitoring the effect of your activity on health inequalities and their causes-----	45
3.7	Section 4 - Planning for wider effects on health inequalities and avoiding negative ones-----	46
3.8	Chapter 3: Summary & Conclusion-----	47
CHAPTER 4: MHEALTH BASED INTERVENTIONS FOR THE ASSESSMENT AND TREATMENT OF PSYCHOTIC DISORDERS: A SYSTEMATIC REVIEW		50
4.1	Background to the Systematic Review-----	50
4.2	Systematic Review Methodology-----	51
4.3	Results of Systematic Review: Characteristics of the included studies -----	53
4.4	Discussion of systematic review findings-----	66
4.5	Chapter 4: Summary & Conclusion-----	70
CHAPTER 5: METHODOLOGY		72
5.1	Mixed Methods in Health services Research-----	72
5.2	Study Aims & Objectives-----	76
5.2.1	Design.....	77
5.2.2	Feasibility Studies	78
5.2.3	Sample.....	80
5.2.4	Inclusion/Exclusion Criteria	80
5.2.5	Overall Project Timeline	82
5.2.6	Overall Sample Recruitment.....	82
5.3	Strand 1: Systematic review-----	82
5.3.1	Strand 1: Qualitative component	83
5.3.2	Study setting and participant selection	83
5.3.3	In-depth Interviews – service users	83
5.4	Focus Groups – Health Professionals -----	84
5.5	Strand 2: Test-Run & intervention refinement-----	88
5.6	Strand 3: Feasibility Study-----	89
5.6.1	Outcome Measures.....	89
5.6.2	Quantitative Analysis.....	92
5.7	Defining the TechCare App Intervention -----	93
5.8	TechCare Intervention Modelling/theoretical basis -----	94
5.9	intelligent Real-Time Therapy (iRTT)-----	100
5.9.1	Equipment.....	101
5.9.2	TechCare Application Procedure & Set-up	101

5.9.3	TechCare App Usage.....	104
5.9.4	Web Application	104
5.9.5	Installation and Setup.....	105
5.9.6	TechCare App Usage.....	107
5.10	Patient and Public Involvement-----	107
5.11	Ethical Approval-----	109
5.12	Adverse event reporting-----	110
5.13	Finance-----	110
5.14	Data Management Planning-----	110
5.15	Chapter 5: Summary & Conclusion-----	111
CHAPTER 6: FINDINGS OF THE STRAND 1 (PRE-INTERVENTION QUALITATIVE WORK) AND STRAND 2 (TEST-RUN & INTERVENTION DEVELOPMENT AND REFINEMENT)		113
6.1	Findings from the Health Professionals Focus Groups (Strand 1) -----	113
6.2	Analysis of the Focus Group Data -----	114
6.3	Summary and Conclusion of the Health Professional’s Focus Groups -----	132
6.4	Findings of the Pre-Intervention Qualitative One-To-One Interviews with Service Users-----	134
6.5	Summary and conclusion for pre-intervention one-to-one interviews-----	145
6.6	Results: Strand 2: Test–Run & Intervention Development/Refinement -----	147
6.7	Strand 2: Results of the Test-run with participants-----	147
6.7.1	Test-Run: Preliminary Results.....	148
6.7.2	Analysis of the Test-Run iRTT Data	149
6.7.3	Refinements to the TechCare Software.....	149
6.7.4	Improvements to the Research Procedure	150
6.7.5	Initial Development of the TechCare App	151
6.7.6	Further Refinement of the TechCare App.....	153
6.8	Summary and conclusion of Test-run Findings Section -----	154
6.9	Chapter 6: Summary & Conclusion-----	154
CHAPTER 7: FINDINGS OF STRAND 3 (FEASIBILITY STUDY) & STRAND 1 (POST-INTERVENTION INTERVIEWS).....		157
7.1	Sample demographics-----	157
7.2	Recruitment and retention -----	158
7.3	Strand 3: Feasibility Study PANSS and PSYRATS Scores-----	159
7.4	Strand 3: analysis of weekly assessment data-----	161

7.5	Analysis of TechCare App derived participant data-----	166
7.6	Analysis of the iRTT data -----	168
7.7	Compliance to the iRTT intervention -----	170
7.8	Chapter 7: Summary & Conclusion-----	171
7.9	Findings of the Post- Intervention Qualitative Interviews with Service Users	173
7.10	Post-intervention qualitative work: Summary and conclusion -----	184
CHAPTER 8: DISCUSSION OF THE TECHCARE PHD PROJECT		185
8.1	mHealth for medication management-----	187
8.2	Access to digital technologies-----	188
8.3	mHealth Apps: The concept of usability and user experience-----	191
8.4	Risk and Benefits of mHealth -----	194
8.5	Adverse effects of mHealth and Internet use-----	196
8.6	Strengths and limitations of the research -----	197
8.7	Implications for future research-----	199
8.8	Conclusions -----	200
REFERENCES		203
APPENDICES		231
Appendix 1:	Digital Inclusion: The Concept and Strategies for People with Mental Health Difficulties.	231
Appendix 2:	mHealth Based Interventions for The Assessment and Treatment of Psychotic Disorders: A Systematic Review	232
Appendix 3:	TechCare: Mobile Assessment and Therapy For Psychosis–An Intervention For Clients In The Early Intervention Service: A feasibility study protocol.	233
Appendix 4:	Reporting and understanding the safety and adverse effect profile of mobile Apps for psychosocial interventions: an update	234
Appendix 5:	Early Intervention Service for Psychosis Care Pathway	235
Appendix 6:	TechCare Topic Guide.....	236
Appendix 7:	TechCare App Algorithm	239
Appendix 8:	NHS Health Research Authority Ethics Approval	242
Appendix 9:	TechCare Software Changes & Amendment Log.....	248
Appendix 10:	TechCare App User Guide.....	252

LIST OF FIGURES & TABLES

Figure 3.1: Planning for the wider effects on health inequalities	47
Table 3.1: Summary of key findings of the HIAT and development considerations.....	49
Figure 4.1: Consort diagram to show search results	54
Table 4.1: Main Findings of the Included Studies.....	56
Figure 4.2 : Risk of Bias Assessment Diagram	66
Table 4.2: Key Findings of the Systematic Review.....	71
Figure 5.1: Flow diagram of study strands	77
Table 5.1 : Study Procedure & Outcome Assessments.....	92
Figure 5.2: The intervention was based on the Kingdon and Turkington (2005) CBT model.....	98
Figure 5.3: Figure showing an example of ESM and iRTT in the TechCare App	103
Figure 5.4: TechCare Web Application System.....	105
Figure 5.5: TechCare Web Application Question Screen	106
Figure 5.6: TechCare Web Application Crisis Plan Screen.....	106
Table 5.2: File Type and Number of Records Collected	111
Table 5.3: Summary of PPI Activities and Input	112
Table 6.1: The roles and gender of participants in the focus groups.....	114
Table 6.2: Coding Framework for the Focus Groups with Health Professionals	115
Table 6.3: Coding Framework for the Pre-Intervention Interviews	135
Table 6.4: Strand 2: Test-run Participant Demographics	148
Table 6.5: Mean and Standard Deviation of Pre-and Post- Assessment Scores	149
Table 6.6: Strand 1 Feedback and the TechCare App Development/Refinement.....	156
Table 7.1: Demographic for Participants in Strand 3	158

Figure 7.1: Flow diagram to show Recruitment and Retention	159
Table 7.2: Table to show mean and standard deviations for the PANSS and PSYRATS at baseline and week 6 (End of intervention)	160
Figure 7.2: Graph to Show Mean Scores on the PANSS and PSYRATS at Baseline and Week 6 end of Intervention	160
Table 7.3: Table to show Mean and Standard Deviations for the Weekly Assessment Measures.....	162
Figure 7.3: Graph to show Scores on the Weekly Outcome Measures.....	165
Table 7.4: iRTT Depression and Paranoia Average Weekly Scores.....	167
Table 7.5: To Show Mean Scores on the TechCare Questions.....	168
Table 7.6: Interventions Selected and Presented to Participants on the App.....	169
Table 7.7: iRTT System Data.....	170
Table 7.8: Participant Usage of Helpful Links and Psychoeducation	170
Table 7.9: No. of Questions Answered and Engagement with App	171
Table 7.10: Coding Framework for Post-Intervention Interviews with Service User Participants.....	174

ACKNOWLEDGEMENTS

My journey in undertaking my PhD work has been one of the most meaningful experiences of my life. Firstly, I would like to acknowledge and thank my family and friends for their continued and enduring support. I have learnt many new skills and attributes and gained a deeper understanding of the need for robust, high quality research. Although this journey has been enjoyable, we all face challenges, and I have been mentored by the most inspirational scholars who have supported me throughout this journey.

I would like to firstly, take this opportunity to thank my supervisory team, Professor Joy Duxbury and Professor Mick McKeown, for getting me to this point and providing immense support and guidance. I know one of the highlights of my PhD journey was going to Spain with Professor Mick McKeown, to share the project findings at the European Psychiatric Association Conference in 2016.

I would like to also to extend my thanks and gratitude to my mentors Professor Nusrat Husain and Professor Imran Chaudhry, who instilled in me a passion to conduct research and have been an inspiration for me to develop myself as both a person and scholar.

Lancashire Care NHS Foundation Trust, have greatly supported my development and provided numerous opportunities for me to gain experience in research during my PhD studies. I also gratefully acknowledge the support and funding of the National Institute of Health Research Collaboration for Leadership in Applied Health Research and Care North West Coast.

CHAPTER 1: INTRODUCTION

The present study was conducted to establish the feasibility and acceptability of a novel intervention, the newly developed TechCare App for psychosis. The TechCare App was developed at an early stage of the project, engaging relevant service users and clinical staff in a participatory dialogue that informed the design process. Based on this preliminary work, I ultimately aimed to complete a feasibility study to determine how the TechCare App could be evaluated as part of a future effectiveness trial. My PhD work has been the result of collaborative working with health professionals and service users, who provided valuable information in relation to the most effective means of deploying the TechCare App. The results of this feasibility study helped in examining the potential for service users to engage with the App, and whether the App could potentially lead to improved access to psychological therapies. This in turn could have real implications for the way psychosocial interventions are delivered, by providing a novel medium for individuals to receive treatment, with the feasibility study providing promising preliminary data.

The study was focused on individuals with a diagnosis of psychosis, receiving treatment from the Early Intervention service (EIS). Psychosis is a Severe Mental Illness (SMI), consisting of a number of symptoms for instance; unusual experiences such as hallucinations, seeing or hearing things that other people do not, delusions, having fixed beliefs which are false or unreasonable or paranoia; a fear of others (McGorry, 2013). The key intended benefit of the TechCare App was the potential for improved treatment engagement and adherence, facilitated by the App being discrete and taking a non-stigmatising approach. This was highlighted in the pre-intervention development work with the service user representatives at an NHS Trust in the North West of England. The overall intention of the project was to develop and research an intervention that harnessed the potential of new digital technologies to tackle issues of stigma and difficulties in treatment concordance. This approach being congruent with a psychosocial ethos, hence being likely to be taken up by services and service users alike.

1.1 Patient and Public Involvement (PPI)

The project was developed with PPI planned from the outset, with key input from service users who consulted on the development and refinement of the App. An important contemporary ideal for services is the notion of co-production (Bettencourt, Ostrom et al, 2002; Needham and Carr, 2009). There has been much recent policy and practice energy behind the goals of increasing levels of involvement and the democratic voice of service users, carers and other public stakeholders. Particularly directed towards the

organisation and delivery of services and day-to-day clinical encounters, between individuals and care team members (Cayton, 2004). This turn has also been valued and evident in the research context and is something I have endeavoured to achieve within this project.

The decision to include service users in the development process stemmed from a combination of ethical principles and design imperatives. The ethical principles of respecting the diversity, rights and autonomy of patients and the public (Duncan, 2010; Gardinger et al., 2013). These values are an important means to empowering individuals or groups (Boote, Baird & Beecroft, 2010; Hanley, 2005), and underpin my commitment to involvement within this study. Furthermore, optimum design processes require thorough involvement of end-users (Ennis & Wykes, 2013). Gardinger et al., (2013) highlights that when conducting research, the values relating to PPI contributions are made explicitly clear. In my view, providing patients and the public a voice in decisions pertaining to the development of treatments enhances patient autonomy. This value is of greater importance within the context of mental health services, where previously the doctor-patient relationship was based on a very much paternalistic model of care.

However, things are beginning to change, with approaches based on autonomy, patient choice and independence, very much promoted within contemporary healthcare services (Trough, 2012; Cahn, 2000). These ideals of co-production have been extended to include PPI work in research, where there is also a heritage of participatory approaches (Realpe & Wallace, 2010), and may prove an additional route to supporting autonomy in service users. The development process involved the design, layout and identifying factors such as the logo, security of the device, access to the App, and an acceptable name for the App, through discussion with the service user representatives. Including service users in the process of conducting and evaluating the research had significant benefits, as it allowed for an exploration into the subjective experiences of the use of this innovative treatment approach within an EIS context. Thus, providing an indication as to whether the intervention was acceptable and could be progressed to a definitive trial. This would help enable me to answer further questions, in relation to the mechanisms of action and pathways to care for individuals who use the TechCare App intervention for experiences of distress associated with psychosis in service users.

1.2 Statement of Originality

Before reviewing the background research, I first address the originality of my research. Research focused on mHealth is a growing field globally, with a potential to improve individual and collective mental health. This study was novel and aimed to create new

insights into mHealth technologies for Severe Mental Illness's (SMI) such as psychosis. Current statistics in the UK state that 94% of adults in the UK personally own/use a mobile phone (Office of Communication (OFCOM) 2014), with 76% of adults owning a smartphone (OFCOM, 2014). Many service users experience mental health stigma and as a result are reluctant to engage with services, which can affect treatment adherence and outcomes (Henderson, Evans-Lacko and Thornicroft, 2013; Clement et al., 2015).

The mobile phone can be viewed as a discrete medium for service users to engage with mental health services; with a degree of privacy and at a distance from institutionalised services; thus, potentially reducing stigma. Moreover, the TechCare App looked to provide individual's greater access to psychological therapies, which are recommended by the National Institute of Health and Clinical Excellence (NICE) for the treatment of psychosis (NICE, 2014). Interventions which utilise mobile devices as an alternative medium to deliver psychological therapies can offer greater accessibility and improve engagement, thus tackling inequalities in mental health access and outcomes. Such approaches provide service users greater control over their care and treatment, as the App can be personalised to their specific needs.

The PhD project examined a new concept called intelligent Real-Time Therapy (iRTT) (Kelly et al., 2012), which monitors an individual's symptoms of mental health, and provides a tailored response in real-time. The iRTT concept had not been evaluated prior to this study, thus contributing to the knowledge base for real-time, real-world therapies. Mobile technologies which incorporate iRTT may well be a feasible medium to provide greater access and engagement to psychological therapies. The PhD project enabled me to work with both service users and health care professionals, bridging the gap between the clinical therapy setting and real-life. The proposed research aimed to help in addressing the demand on mental health services, by increasing access to psychological therapies and reducing mental health stigma. A systematic review of existing mHealth interventions for psychosis was conducted, to explore previous research in the area, with the findings being used to develop the TechCare App intervention. The PhD project used a feasibility study design and was conducted over three strands (1: qualitative work, 2: intervention refinement & development and test-run, and 3: feasibility study). Overall, the results of this feasibility study can aid the development of a future Randomised Controlled Trial (RCT) and provide an avenue to expand the research in this area, which at present is limited.

1.3 Thesis Structure

Based on the above rationale for conducting the study on the evaluation of the TechCare intervention, I have structured the thesis in the following chapters outlined below, and have provided a brief overview of the chapters, describing the different components of the research:

Chapter 1: The initial chapter described the background to the study and the development of a rationale for the research, taking into consideration the inclusion of service users and the public in the design of the study.

Chapter 2: Background: this chapter presents the background research with a description of the Early Intervention Service (EIS) and how the TechCare App fits into the service delivery model of the EIS. The chapter also provides the rationale behind the thesis in terms of 'digital inclusion' a concept, which infers the added benefits to society through increased engagement with digital technologies. This builds upon the research base for digital inclusion as a powerful tool in overcoming mental health inequalities. This can be more important for mental health service users as opposed to people using general health services, as in some ways they may be falling behind the rest of society who can use digital technology to their advantage. (Part of the background section relating to 'digital inclusion' has been published in 'The Australian and New Zealand Journal of Psychiatry' and is attached in Appendix 1).

Chapter 3: This chapter describes how the Health Inequalities Assessment Toolkit (HIAT) was used to appraise the study. The HIAT is a process initiated by the North West Coast CLAHRC in a context of researching public health and associated inequalities. In the TechCare study, the HIAT was utilised in conjunction with the study's PPI processes, to determine factors relating to the inequalities experienced by those with SMI's, the HIAT provided an understanding of the contributory factors related to health inequality and assessed the impact of the research.

Chapter 4: This chapter will present a systematic review of mHealth for psychosis, with a view to synthesising the available evidence to gain a better understanding of what has already been done in this area. It is important to assess previous literature within an evidence base, so as to allow for gaps in the research to be highlighted in addition to providing a platform to further develop what is known. (The chapter is a presentation of a systematic review, which has been published in the journal 'mHealth', see Appendix 2).

Chapter 5: Methodology: This chapter begins with a summary of the aim and objectives of the PhD project, which were derived from guidance by the National Institute of Health Research (NIHR) pertaining to feasibility study design. The chapter then presents the design and methodology of the study, taking in to consideration the 3 main components (Strands) of the study. The strands involve both qualitative and quantitative methods and thus the project enlisted a mixed methods design. One of the key things which is described in the methodology is the procedural aspects of the study and the overview of the TechCare App. The methodology section also describes the assessment questions used and their utility in determining the outlined objectives and aim. Ethics and governance are a crucial part of any research project, therefore factors around the ethical considerations of the TechCare App, its development and evaluation will be described. (The study protocol has been published in the journal 'SAGE Open Medicine', see Appendix 3).

Chapter 6: Findings, Strand 2: Intervention development and refinement: This chapter will present strand two of the research, accounting for the development and refinement of the TechCare App. This strand of the work involved service user participation in the early design and development and conducting a test-run of the TechCare App with a small number of four participants. When working with technological devices in particularly mHealth, there is a chance of faults occurring with the technology. Therefore, a test-run was conducted to ensure any faults were rectified prior to roll-out in the feasibility study (Strand 3).

Chapter 7: This chapter will describe and report the findings of the Strand 3 feasibility study. The study variables will be analysed to determine feasibility measures, which will then be presented in accordance with the outlined aim and objectives of the study. In addition, results of the post-intervention qualitative work will also be presented.

Chapter 8: The final chapter will provide a discussion and appraisal of the results of the study, the strengths and weaknesses and the implications for policy, practice and future research. Chapter 8 will look specifically at the process of measuring feasibility and lessons learnt from conducting the study. In health services research the majority of studies have reported the feasibility of an intervention using the NIHR guidance on feasibility study design. However, the chapter will argue on completing the TechCare project the importance of factors relating to usability and user experience. (A section of chapter 8 was published in the 'World Journal of Psychiatry', see Appendix 4).

CHAPTER 2: BACKGROUND TO THE RESEARCH

In this chapter, I will outline the context of the study in terms of the broader potential of digital technologies in the care and support of individuals diagnosed with psychosis, and the particular service setting within which the study was conducted. The chapter will also describe the current service provisions for psychosis within Lancashire and provide an overview of the psychosocial interventions used within the Early Intervention Service. In addition, I will also provide an overview of the concept of 'digital inclusion', and its potential implications regarding mental health inequalities, building a rationale for the use of mHealth technologies to support those with experiences of psychosis.

In the digitally connected world we live in, people now have access to the most up-to-date health information; there are millions of searches conducted across the globe using the Internet and search engines for terms related to health, treatment and wellbeing. As many as 75% of patients in the US use the web to seek information on available treatments for chronic illnesses (Ayers, & Kronenfeld, 2007). Similarly, in the UK the Department of Health (2012) has promoted the use of digital technologies such as the Internet, to provide patients with health information through websites such as www.nhs.uk. However, despite research, indicating increased usage of the Internet to retrieve health information (Dutton & Blank, 2011; Atkinson et al., 2009), there is a scarcity of research suggesting its clinical utility within practice (Bowes et al., 2012). The wealth of information available through search engines such as Google (www.google.com) and data already held on the Internet through mobile device applications (more commonly known as Apps) may hold some value in improving health services globally, as they allow for greater access to health information in real-time.

In the West, research in the area of mHealth, has shown much promise in the development of mobile phone interventions which look at the assessment and treatment in real-time of psychiatric disorders (Ainsworth, Palmier-Claus, Machin, et al., 2013, Spaniel et al., 2013 & Granholm, Ben-Zeev, Link, Bradshaw, & Holden, 2011). A study by Galizzi et al (2012) indicated that online rating websites provided a key role in supporting patient's choice of primary care providers in the UK, suggesting the utility of web-based tools to capture patient derived data. Furthermore, a systematic review conducted by Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, (2015) examined the impact of mHealth chronic disease management. It was found that out of the 107 studies included in the review, 57.9% reported the usability, acceptability and feasibility of mHealth interventions that were focused on adherence, in relation to chronic disease

management (Hamine et al., 2015). Hamine et al., (2015) concluded that mHealth tools have the potential to facilitate improved adherence in chronic disease management.

The typical experience of individuals diagnosed with psychosis in recent decades has been patterns of long-term illness. Newer developments in thinking about the potential course of psychosis have substituted a commitment to recovery for a previous therapeutic pessimism. The management of long-term illnesses such as psychosis in low resource settings, such as in deprived areas of the UK, face considerable challenges in providing high quality, cost-effective, widely accessible care (Lewis et al., 2012). In the 1960's Goffman, noted how the process of institutionalisation could be considered as a form of socialisation which reinforced the view that mentally ill patients could be transformed into 'dull, harmless and inconspicuous' individuals, with this process being synonymous with the notion of SMI's being chronic long-term experiences (Goffman, 1968; Lester, & Gask, 2006; Lieberman, Dixon & Goldman, 2013). Despite the societal view that SMI's are chronic, research has shown that recovery is attainable, particularly for those with a First Episode of Psychosis (FEP) (McGorry, Killackey, & Yung, 2008). However, for many mentally ill patients, recovery is far from an agreed end-point in their prognosis, with SMI recovery in its entirety being a difficult construct to define, and even more difficult to form a consensus agreement upon (Lester, & Gask, 2006). There are many differing models of recovery such as the theory of 'wood shedding' (Strauss, Hatez, Lieberman, & Harding, 1985) where a person, may improve for the initial periods, but may plateau for long periods with sudden improvements. The challenge that arises is that recovery for most is a subjective experience and can be interpreted differently by service users. Slade & Hayward (2007) highlight the notion and importance of the 'lived experience perspective', being the key driver of understanding recovery. However, these perspectives are not often meaningfully included in the current biomedically orientated mental health services.

Recovery in psychosis is an on-going process, with some service users experiencing a reoccurrence of symptoms, which can impede their pathway to recovery (Eisner, Drake, & Barrowclough, 2013). Relapse can be defined as a reoccurrence of symptoms (Alvarez-Jimenez, Parker, Hetrick, McGorry, & Gleeson, 2011; Reed, 2008), with relapse prevention being an important area of mental health practice research. Van Meijel (2002) suggested relapse prevention as an essential element of psychosis work. Furthermore, Eisner et al., (2013) also reported that relapse in first episode psychosis is common and has profound effects on service users, such as suicidal ideations, self-harm, increased distress, depression and anxiety, recurrence of positive symptoms of psychosis, loss of work, increased family distress and hospitalisation. Communication and understanding

between health professionals and service users in the reporting of distress and reoccurrence of symptoms is highly essential in reducing the chances of relapse. Therefore, how distress is communicated within the EIS can be different for each service user (Covington et al., 2005), suggesting a need for a non-stigmatising pathway in which service users feel confident in accessing. Providing real-time experiential data and support has the potential to enhance the well-being and potentially prevent relapse, the involvement of the crisis team or hospital admission. An alternative pathway which uses mobile technology to engage with services, may hold the key to gaining a deeper understanding of the lived experiences of those with mental health difficulties, in particular experiences of recovery from SMI's.

Moreover, the increase in usage of mobile devices such as mobile phones which are rapidly developing and reducing in price and availability globally, may provide a unique platform in bridging this gap. Research published in the Bulletin of the World Health Organisation (WHO), by Lewis, Synowiec, Lagomarsino, & Schweitzer (2012), suggested that digital health innovations could improve treatment outcomes by extending geographic access to care and support, facilitating patient communication and improving diagnosis and treatment. In addition, benefits may also extend to reduction in the cost and usage of natural resources, such as is the case in the UK. The UK Department of Health 2020 vision aims for health services within the UK to go paperless by 2020. Savings in costs associated with the maintenance and cost of paper based medical records, can be utilised in treatment development which may look at overcoming mental health inequalities.

2.1 Psychosis: The Theoretical Perspective

It has been reported that one in four individuals experience mental health problems in their life time (Mind, 2014). Early psychosis is most prevalent in young males between the ages of 15-25 and in women around the age of 25-30 years. Those with a diagnosis of psychosis encounter a number of symptoms for example, perceptual experiences such as auditory hallucinations and delusional ideation or disturbances in thinking (Van Os et al., 2009). At later stages of the illness there may be a marked deterioration in an individual's functioning (Keshavan, DeLisi, & Seidman, 2011). Psychosis is most common in inner city populations and in deprived communities, with psychotic disorders leading to major healthcare service burden (NIHR CLAHRC, 2012).

A first episode psychosis is assessed by the EIS using the Positive and Negative Syndrome Scale (PANSS) based on information pertaining to a specified period, usually one week (Kay, Fiszbein, & Opfer, 1987). The diagnosis of schizophrenia according to

the ICD-10 is a presence of at least one first rank symptom or bizarre delusions, or at least 2 symptoms from a) persistent hallucinations (Daily for a month) with delusions or overvalued ideas, b) neologism or thought disorder, c) catatonia, or d) negative symptoms. In addition, there has to be no organic disorder or substance misuse. Furthermore, symptoms have to be present for one month, most of the time or some time most days (World Health Organization, 1993). Individuals with a first episode of psychosis, often come to mental health services after a long period of illness due to the result of a drop in functioning (Birchwood, Todd, & Jackson, 1998). In contrast, in the USA the Diagnostics Statistical Manual (DSM-5) is slightly different, in that criterion A lists 5 symptoms 1) delusion. 2) disorganised or catatonic behaviour, 3) disorganised speech, 4) hallucinations and 5) negative symptoms. However, only one of the 5 symptoms are required if delusions are bizarre or hallucinations are running commentary (DSM-5).

The more commonly distinguished paradigms which aim to provide an understanding of psychosis are the illness paradigm, stress-vulnerability model and symptom-focused paradigm (Morrison et al., 2004). I will describe these as follows, with the aim of gaining an understanding of the approaches to care which have resulted from these paradigms. Firstly, the illness paradigm (Kraepelin, 1915, 1990), described a clear distinction between normality and abnormality with particular importance given to the biological aspects of illness namely an inherited genetic predisposition, or the result of infections such as syphilitic mental disorders (Hagen, Turkington, & Berge, 2010). There is, much support currently amassed for the biological aetiology of psychosis, namely the role of the neurotransmitter dopamine and genetics (Howes & Murray, 2014). However, as the illness paradigm focuses solely on biological aspects of psychosis, limitations relate to the use of psychosocial interventions or Individuals who are given antipsychotic medication without being given the autonomy to make a decision on their best course of treatment. Bracken et al., (2012) plausibly argue that it would be implausible to discard the biomedical model completely but thinking in biological terms should not dominate service delivery.

Another paradigm which aimed to explain psychotic symptomatology is the Stress-Vulnerability Model (Zubin & Spring 1977). The model suggests that individuals may be more prone to biological or psychological susceptibility to stress, with early stressful experiences potentially leading to symptoms of psychosis. This paradigm gave rise to understanding how therapeutic interventions that alleviated stress, and at the same time increased coping would be a valuable means of reducing the experiences of psychosis. In contrast, Bentall (2003) advocated an alternative to the Stress-Vulnerability Model,

which had an emphasis on each specific symptom or actual experiences of distress. Bentall (2003) further suggested that treatment approaches needed to provide the best way to help people understand, or cope with their illness throughout both the social and professional aspects of life. Of great importance is the subjectivity of psychosis, with no discernible line between abnormal and normal mental states, resulting in a continuum based approach to psychosis. Treating each of the specific symptoms of psychosis has the most potential in treating SMI's within a continuum (Hagen et al., 2010), with a cognitive behavioural approach being the most important means of both treating and understanding psychosis. This also makes the case for dropping a categorical diagnostic approach to classifying mental distress in defined categories of disorders such as schizophrenia.

Current mental health services in the UK on the whole are very much geared towards a biomedical model of service delivery, based on a Kraepelinian approach to understanding mental illness. Psychiatric services use diagnostic classificatory systems such as the DSM-V and ICD-10 to diagnose mental illness. However, there is growing concerns against this form of service delivery model due to limited considerations of the psychological and social aspects of care, which are crucial to those suffering from psychosis (Bentall 2003; Van Os & Kapur 2010). It has been argued that having a dimensional approach, which takes into account the continuity between mental illness and mental health, would serve as a more effective model of service delivery as highlighted by Bentall (2003).

2.2 Early Intervention Service for Psychosis

Early Intervention services (EIS) were introduced into the NHS in the early 1990's, for people with a first episode of psychosis (Lester et al., 2011; Wallcraft, & Nettle, 2009; Lloyd & Carson, 2012; Bennet, & Baike, 2003; Singh, 2013). The primary aim of EIS's was to reduce the Delay in Untreated Psychosis (DUP), with the rationale being that early treatment of psychosis could result in a greater chance of recovery, and a reduction in the psychosocial impact of the illness (Pelosi & Birchwood, 2003; McGorry et al., 2008). Previous research has shown that these services are cost effective, and are highly successful in reducing relapse, leading to reductions in hospital admissions (McCrone, Craig, Power, & Garety, 2010; Craig et al., 2004). The Early Intervention service (EIS) has been established in Lancashire for 10 years, and in the UK as a whole for fifteen years. The EIS philosophy is 'person-centred' based on therapeutic engagement and recovery (Martinez et al., 2011; Byrne & Morrison, 2010; Dilks, Tasker & Wren, 2010; Killackey, 2009; Vanderplasschen, Rapp, Pearce, Vandavelde, & Broekaert, 2013;

Reed, 2008). This approach is based on therapeutic interactions, which promote service user recovery from First Episode Psychosis (FEP).

The EIS way of working, is based on helping the service user to recover from mental health difficulties by using talking therapies, social support and medication. However, some service users experience relapse. It is suggested that relapse can be a gradual process taking place over time, and can disrupt the recovery journey (Dilks et al., 2010; Byrne & Morrison, 2010). Often relapse can be detrimental in the long term to service users, therefore making it crucial to get the appropriate support at the earliest time possible, with early intervention preventing a full relapse occurring (Bird et al., 2010). This can be challenging, due to the service users' difficulty in communicating their experience of distress, which can have an impact on accessing support and increasing the chance of relapse (Gumley, Craig & Power, 1999; Lester et al., 2012; Alvarez-Jimenez et al., 2011; Hatfield, McCullough, Frantz, & Krieger, 2010; Pitt, Kilbride, Nothard, Welford, & Morrison, 2007).

Furthermore, evidence has suggested that the EIS has been successful in reducing admissions (due to relapse) to acute psychiatric units (Wallcraft, & Nettle, 2009, Eisner et al., 2013), with the EIS having increased employment retention in recovering service users, along with an additional reduction in suicide levels, equating to savings of £27,000 per service user over the past few years (Alvarez-Jimenez et al., 2014). This is of importance, as it has been reported that the cost of treating psychotic relapse is four times more compared to a service user experiencing recovery (Bird et al., 2010). The cost of an acute psychiatric hospital bed is between £300- £500 per day and an EIS health professional visit to a service users home ranges on average between £40 - £100. Therefore, the major goal of all interventions in First Episode Psychosis is reducing the number of relapses leading to hospital admissions (Eisner et al., 2013), which can impede the pathway to recovery for service users (Marshall et al., 2015).

Despite the reduced costs of EIS in comparison with inpatient care, and the cost savings attendant on promotion of recovery, overall mental health services operate under increasing resource pressures. Digital technologies and self-help strategies promoting service user autonomy and control, may also assist in making the resources of EIS go further, supplementing face-to-face practitioner time with service users. Even more importantly for those service users who do not engage with services due to lack of trust with services, or for those experiencing difficulties in accessing services due to stigma. The mobile technology might be an alternate way of engaging and supporting these service users, by enhancing self-management and increasing the accessibility of support.

The TechCare App was thus developed to provide real-time therapy targeted at reducing symptoms of psychosis, allowing appropriate interventions to occur in real-time and thereby reducing the possibility of relapse. Examples of these interventions could be problem-solving, use of crisis planning, or behavioural activation, enabling the service user to remain in work or at school whilst accessing support on their mobile phone. In this context a mobile App is a familiar and friendly concept to young people, who may not want to say how they feel but would be more comfortable using SMS messaging. OFCOM reported that in 2012, 96% of 16-24 year olds used some form of texting to communicate with others on a daily basis, indicating that SMS is a medium most young individuals feel confident in using, and is increasingly used across age groups. The proposed App pathway in this study was designed to monitor the level of service user distress and use of self-help interventions targeted at reducing the chance of relapse (Trevena, Davey, Barrett, Butow, & Caldwell, 2006; Byrne & Morrison, 2010; Stewart, 2013; McGorry, 2013; Hatfield et al., 2010). Although service users and carers are always provided with crisis plans and emergency phone numbers as part of a relapse prevention strategy, these do not take into consideration the service user experience of distress or the potential loss of the crisis plan itself. Whereas an App can be downloaded to the service user's mobile phone for day-to-day usage.

In addition, there is limited research investigating mental health professionals' application of Psychosocial Interventions (PSI) within their role (Hardy, Dickson & Morrison, 2009) specifically psycho-education. Psychosocial interventions can be defined as a therapeutic approach to address psychological, social, interpersonal and vocational problems associated with mental health disorders (Ayers & De Visser, 2010). Typical interventions include those with a focus on the social network of service users, such as family therapy, or Cognitive Behavioural Therapy (CBT) targeting psychotic experiences. A component of PSI can be working to support individuals to marshal their own coping resources and strategies, for example using music to distract from voices.

Thus, psychosocial approaches to therapy address both symptoms associated with mental health disorders as well as issues which arise as a consequence of the mental health problem. For example, within psychosis; fearful thoughts associated with delusions and hallucinations are carefully re-evaluated and mitigated, social withdrawal is gradually reversed, and feelings of hope and self-worth are nurtured (Santos, & Teixeira, 2016). However, it has been reported that there is a reluctance or inability by service users to communicate this distress (Byrne & Morrison, 2010). In tackling this difficulty, it has been reported that young people are more likely to take up simple methods of communication, specifically using technology that they are most familiar with,

such as mobile phones (Depp et al., 2010). This in turn bridges this communication gap, with communication being a vital component of the recovery process (Byrne & Morrison, 2010).

A study by Lester et al., (2011) showed the importance of technology in engagement within EIS, as clients preferred contact via email and text rather than by letter (Lester et al, 2011). This again demonstrates how the use of technology in care is increasingly fundamental to effective engagement. Furthermore, Lester et al., (2011) found one-third of the participants interviewed to deem an 'overemphasis' on engagement within the EIS. The clients believed that care coordinator visits were too frequent at times and that these reminded them of their illness. This is important in drawing attention to the fact that for many clients, just having access to support at their fingertips when needed was sufficient reassurance for them.

A meta-analysis of research on Internet-based psychotherapeutic interventions found them to be as efficacious as face-to-face therapy in the treatment of certain mental health difficulties (Barak, Hen, Bonell-Nissin, & Shapira, 2008). This shows that the effectiveness of the therapy is not necessarily diminished by changes in medium. Barak et al., (2008) found CBT a much more effective therapy than others for the online treatment of psychological difficulties. Doze, Simpson, Hailey, & Jacobs (1999) also investigated telepsychiatry, allowing clients more accessibility to their psychiatrists via videoconferencing. They gave a choice of which psychiatrist the client saw as giving the client a better sense of control of their care. They established the ease of use and found that clients were particularly satisfied in areas of less stress linked to travel, quicker access to support and feelings of confidentiality and privacy. Staff also expressed their satisfaction with the service. This highlights the potential benefits of e-health services in reducing health inequalities, through providing a means to access support and treatment without geographical restrictions.

However, due to the fast-developing nature of mHealth, difficulties and criticisms have been reported. For example, Mallen, Day, and Green, (2003) found that clients using a face to face intervention, compared with online chat, overall felt more satisfied, had a better sense of closeness and were more comfortable in disclosing their difficulties. Such issues are important to address, as each play a key role in contributing to a therapeutic relationship, which has been highlighted as important in delivering efficacious treatment and encouraging engagement (Lester et al., 2011). Additionally, Rees and Stone (2005) found clinical psychologists rated therapeutic alliance lower in videoconferencing compared to face-to-face interventions. This shows therapeutic alliance to be less fully developed within telehealth interventions, which could have a negative impact on

treatment. In contrast, Cook and Doyle (2002) found that clients reported feeling satisfied with the therapeutic alliance within an online therapy intervention.

2.3 EIS Care Pathway for First Episode Psychosis (NHS Trust, 2017)

The following Section will provide an overview of the care pathway within EIS to gain a better understanding of how interventions can be developed within this care pathway. Early intervention in psychosis services can improve clinical outcomes, such as admission rates, symptoms and relapse, for people with a first episode of psychosis (Birchwood, & Florillo, 2000). They do this by providing a full range of evidence based treatments including pharmacological, psychological, social, occupational and educational interventions under an umbrella of psycho-social therapy. Treatment from EIS is recommended to be accessed as soon as possible to reduce the duration of untreated psychosis. In the following section I have outlined the LCFT care pathway for psychosis to provide an understanding of current practice (please see Appendix 5).

The NICE Quality standard [QS80] provides the recommendation that adults with a first episode of psychosis should start treatment within 2 weeks of being referred to an early intervention service (NICE, 2014). The service provides support and treatment to help people with symptoms of psychosis. Early treatment (within 2 weeks) in these services is often successful at treating symptoms and preventing symptoms from coming back and helps to reduce the number of people who need to be admitted to hospital.

The NICE Quality Standards (2015) and Mental Health Access and Waiting Times Standards (2015/16) state that:

- Adults with first episode psychosis will be treated with a NICE Approved care package within 2 weeks of referral. This is measured by allocation of a care coordinator in a service which provides the range of NICE approved treatments.
- Adults with psychosis or schizophrenia are offered cognitive behavioural therapy for psychosis.
- Family members of adults with psychosis or schizophrenia are offered family interventions.
- Adults with psychosis or schizophrenia that have not responded adequately to treatment with at least two antipsychotic drugs are offered Clozapine.
- Adults with psychosis or schizophrenia who wish to find or return to work are offered supported employment programmes.

- Adults with psychosis or schizophrenia are offered combined healthy eating and physical activity programmes and help to stop smoking.
- Carers of adults with psychosis or schizophrenia are offered carer-focused education and support programmes.

The Early Intervention service (EIS) delivers specialist interventions through a modular programme, which aims to provide new opportunities for service users and their carers and promote optimism in their journey to recovery. The EIS service in the Northwest is delivered on a hub and spoke model across the Lancashire footprint. There are three multi-disciplinary spoke teams and a hub team. EIS services focus on the importance of the early detection of symptoms in order to allow the greatest opportunity for recovery. Specialist mental health professionals (care coordinators) have allocated dedicated time for assessments with a focus on the first two weeks following referral. The aim of assessments in these first two weeks is to determine if the individual who has been referred is:

- Suitable for treatment from EIS as they present with first episode psychosis
- Suitable for support from EIS as they present with an At Risk Mental State (ARMS), those who are at greater risk of transitioning to psychosis
- Not suitable for treatment in EIS
- Has declined treatment in EIS despite being suitable
- Has a complex presentation; so being offered a prolonged assessment

One of the key ways care coordinators support service users is through Psychosocial Intervention (PSI) work. PSI is critical to the way Early Intervention Services support individuals who are experiencing psychosis or who are at risk of psychosis to have the best chance of recovery. The EIS service uses a tiered system for the delivery of CBT informed therapy, meaning services users are offered CBT from a qualified therapist. Each individual under the care of the EIS team will have a PSI care plan which describes the service being offered.

In addition, support for carers is also offered. Providing carer focused education and support reduces carer burden and psychological distress and may improve the carers quality of life. As part of the initial process of assessment and engagement, carer focused education and support programmes can also help cater for adults with psychosis and schizophrenia, to be able to identify symptoms of concern. Within the EIS care pathway

there is a baseline assessment of carer understanding of psychosis at 4 weeks and an offer of psycho-education at 12 weeks.

Also included in the NICE (2014) recommendation is the use of Family Interventions for individuals with psychosis. Family intervention can improve coping skills and also relapse rates of adults with psychosis and schizophrenia. Family interventions should involve the person with psychosis or schizophrenia if practical and form a broad-based approach that combines different treatment options tailored to the needs of individual service users. Family interventions are core to the work of the EIS team and the aim is for all care coordinators to be trained in providing family interventions.

Other important components of the care pathway include physical health assessments, as life expectancy for adults with psychosis or schizophrenia is between 15 and 20 years lower than that of the general population. This may be because, psychosis or schizophrenia patients often have physical health problems, including cardiovascular and metabolic disorders, such as type 2 diabetes, that can be exacerbated by the use of antipsychotic medications (Nuevo et al., 2011; Lambert & Chapman, 2004). Comprehensively assessing physical health will enable health and social care practitioners to offer physical health interventions if necessary. Physical Health monitoring is initiated at baseline when a patient joins the EIS service. Any changes for example, weight gain due to the use of anti-psychotic medication will be proactively managed, with a combined healthy diet and physical exercise plan offered when needed.

Rates of diabetes in adults with psychosis or schizophrenia, are higher than those for the general population (Nuevo et al., 2011; Lambert & Chapman, 2004). Rates of tobacco smoking are also high in people with psychosis or schizophrenia (Gurillo et al., 2011). These factors contribute to premature mortality and higher rates of morbidity than the population at large (Casey et al., 2011). Offering combined healthy eating and physical activity programmes and help stopping smoking, can reduce these rates and improve physical and mental health.

Adults diagnosed with schizophrenia who have not responded adequately to treatment with at least two antipsychotic drugs are offered clozapine. The EIS approach uses a combination of medication and psychosocial approaches, with evidence that optimising prescriptions enables people to make the most of psychosocial interventions, and effective PSI improves concordance with medication (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008). EIS teams recognise the importance of clear and honest information to service users about benefits and side effects of medication. The medical staff within the teams ensure that facts about medication and all options are discussed.

Medical reviews are completed with the individual at least every 6 months. CBT in conjunction with antipsychotic medication, or on its own if medication is declined, can improve outcomes such as psychotic symptoms. It should form part of a broad – based approach that combines different treatment options tailored to the needs of individual service users.

On providing a descriptive overview of the current care pathway within the early intervention service, it can be seen that the development of an intervention that can be imbedded within this pathway would allow for easy integration. Considering the long waiting times for specialist CBT with a therapist and the use of antipsychotic medications, which can have a detrimental impact on an individual's physical health, a rationale can be derived for the implementation of mHealth interventions to overcome this gap by providing an alternative to pharmacological treatment and the long treatment delays for CBT for psychosis. Of importance is the use of psychological therapies such as CBT, however as I have mentioned above long waiting times, coupled with difficulties in engaging with this group of individuals may benefit from real-time CBT based interventions, thus potentially reducing waiting times and enhancing engagement with the CBT treatment approach. (see Appendix 5 for EIS care pathway for psychosis).

2.4 Cognitive Behavioural Therapy for Psychosis in EIS

Over a century ago Emil Kraepelin, first diagnosed individuals with 'dementia praecox', an illness we now know as schizophrenia (Kennerley, Kirk, & Westbrook, 2016). As I highlighted above in the EIS care pathway, the biomedical model of illness has led to pharmacological interventions being the mainstay of treatment for SMI's, particularly the use of antipsychotic medications. Antipsychotic medications were first introduced in the 1950's, due to reports that they could help in alleviating the symptoms of psychosis (Kennerley et al., 2016). However, the usage and efficacy of antipsychotic medications has been the centre of much debate. Moncrief (2015) highlighted that factors such as long-term usage, adverse effects and discontinuation-related adverse effects were factors rarely investigated. It has also been reported that 80% of individuals with a diagnosis of schizophrenia have on-going social disabilities (Wiersma et al., 2000). In the UK, the growing rise of such differing viewpoints in the treatment of psychosis has led to alternatives. CBT is one such treatment for psychosis, which is a form of psychotherapy that emerged in the 1970s (Kennerly et al., 2016).

During the cognitive revolution of the 1950s, the Freudian approach to psychotherapy was losing support due to the lack of evidence indicating its efficacy (Eysenck, 1952). During the same period, behavioural and cognitive approaches to treatment were gaining

traction. The behavioural therapy approach first developed by Wolpe (1967), examined the internally constructed ideas within an individual, which were thought to be only observable through a person's behaviour (Kennerly et al., 2016). On the contrary, the cognitive therapy approach, which was developed by Beck in the 1960s, looked at thought processes, with Beck in 1978 publishing his work on Cognitive Therapy (CT) for depression and conducting research, which suggested CT was just as effective as antidepressant treatment for depression. Over the years, the interlinking and integration of both approaches gave rise to CBT as we know it today. CBT can be described as a psychological therapy, which looks at gaining an understanding of a person's thoughts and behaviours (Kennerley et al., 2016). The cognitive component of CBT examines an individual's emotional or behavioural reactions and the cognitive processes, which are amenable to our experiences, thoughts, schemas, mental images and beliefs. The behavioural aspect of the model, examines how our behaviour is the fundamental part of changing our psychological state (Kennerley et al., 2016).

CBT has been a popularised treatment approach in the UK, in particular in England and Wales due to the Increasing Access to Psychological Therapies (IAPT) initiative. IAPT was spearheaded by Lord Layard in 2006, who presented an economic case to the UK government suggesting that investment in mental health services and the improvement of access to psychosocial interventions such as CBT would increase prosperity and economic success of the country, as mental health problems were becoming highly prevalent (Kennerley et al., 2016). After a successful pilot of the initiative in 2007 for common mental disorders such as depression being conducted, the following year, in 2008 the government announced that £170 million would be available for the project over a three year period. This had immense implications in relation to evidence-based psychological therapies and the need for the training of therapists to deliver the IAPT programme. Evaluation of the effectiveness of IAPT was completed in 2009 by Clark et al., (2010) and has further strengthened the inclusion of CBT in NICE clinical guidance (Clark, 2011), and supports the use of CBT with service users with psychotic disorders.

It can be argued, that within a cognitive behavioural framework, symptomatology is based on experiences of distress associated with the symptoms. Taking into account the individual's beliefs and experience would be an important part of the treatment process. However, despite this as I have outlined, current services are very much psychiatry laden with significant focus placed on the biomedical model. Furthermore, as Bentall and Morrison (2002) and Morrison et al., (2010) have asserted, labelling service users with diagnostic terms may potentially lead to unnecessary treatment with antipsychotic medications. EIS's are based within the community and include a multidisciplinary team

of staff and are focused on a non-stigmatising youth-centred approach to intervention (Lester et al., 2011). Research found that the majority of early intervention clients held positive opinions towards the service, particularly stating that it was 'youth friendly' by keeping up to date with modern day technology (Lester et al., 2011). CBT is commonly used for the treatment of early psychosis (Wykes, Steel, Everitt, & Tarrier, 2008), and it can be implemented at three different levels depending on severity. Tier 1 CBT is provided by non-specialists in that particular area. This first Tier would be applicable within an early intervention setting if the CBT was implemented by a care coordinator. Tier 2 is carried out by a specialist such as a psychologist or counsellor who is usually employed by an NHS Trust or local authority. Tier 3 is treatment by a team of specialist's including clinical psychologists', psychiatrists, and social workers.

Tier 1: is delivered by all staff who have undertaken the 3 day Psycho-Social Interventions (PSI) training. This is at the level of guided self-help interventions. It consists of understanding principles of recovery and hope, basic CBT thought-feeling-behaviour relationship, stress vulnerability models, techniques for managing mood, goal setting, SMART goals and relapse prevention. There is a manual to support this work. Tier 2: is specific pieces of psychological work, usually delivered in a manualised or specific protocol driven way, undertaken by case managers or staff who are studying for or have completed a PSI course. Tier 3: An individualised, bespoke psychological formulation of one or more complex difficulties delivered by a trained CBT therapist or qualified doctoral level clinical psychologist over 16-20 sessions. Sophisticated use of models of psychosis and other problem based models, including historical formulations of difficulties.

2.5 Overcoming Mental Health Inequalities Using Technology

One way of tackling mental health inequality is through the use of mobile and wireless technologies, which have the potential to transform mental healthcare. With digital technologies becoming an important way to gain access to the social determinants of health (RCN, 2012; Marmot et al., 2010; Marmot & Allen, 2014). Many people living with mental health difficulties have yet to realise the potential benefits of technology in enhancing their lives.

Most importantly, inadequate access to digital technologies may hinder self-management and self-help, which can significantly assist recovery from long-term conditions such as asthma and diabetes (Pinnock, Slack, Pagliari, Price & Sheikh, 2007; Arsand, Tatara, & Hartvigsen, 2010). Patient and service user e-communities can make a significant contribution to aiding individuals in managing and learning about their own

health conditions. The Internet has created a way for people who would not normally meet to exchange information, experiences of treatment and insights and interact with each other (Jackson, 2013). Mobile based interventions have benefits not only for potentially reducing stigma felt by clients in accessing mental health services, but also improving accessibility and engagement.

Digital inclusion can be a key aspect of social inclusion with the potential for an immensely positive impact on mental health. People can develop effective networks, gain access to employment, social groups and the community. The barriers however include connectivity (lack of access), capability (capacity to engage) and content (tailored content for specific groups) (Office of the Deputy Prime Minister, 2005).

2.6 Digital Inclusion: The Concept and Strategies for People with Mental Health Difficulties.

Digital inclusion is defined as the best use of digital technology to improve the lives and life chances of all citizens and the places where they live (HM Government, 2008). It is suggested, that the direct access to technologies such as computers, Internet, smart phones and digital TV offer significant advantage to gain skills, employment and better access to services. This results in wider choice and empowerment, with better integration in society and the potential to overcome health inequalities. In contrast, a lack of access and knowledge of how to use Information and Communication Technology (ICT) can result in digital exclusion and can be considered as an important indicator of economic inequity (Norris, 2001).

Widespread use of mobile and wireless technologies has the potential to transform health care (Boulos, Wheeler, Tavares, & Jones, 2011; Bunyan & Collins, 2013). Digital technologies such as smart phones, the Internet and digital TV are increasingly becoming an important way to gain access to the social determinants of health; including employment, housing, education and social networks (Bunyan & Collins 2013). Furthermore, since the major overhaul of the welfare system in the UK, has resulted in the introduction of universal credit which is the UK government benefits system (HM Government, 2013a) and a new requirement to apply for benefits online (HM Government, 2013b). However, this may have implications for those individuals who do not have access to digital technologies, particularly for those who are in need of governmental benefits.

Digital inclusion, can allow people to develop effective networks, gain access to employment, social groups and community. People suffering from mental health

problems should be a key target in delivering digital inclusion. A large number of people use mobile phones simply to make calls, missing a number of highly useful features. Most programs to help service users have focused on providing IT training and computer literacy. Anecdotally, these do not seem to work and instead can create more anxiety and skepticism around technology. Training programs would benefit from a wider focus on life skills. Differentiating between individuals having possible access to digital technologies and individuals actually using them, can be a key outcome measure of policy initiatives and future research studies. Predictors of what encourages people to become online users can be very personal. One intervention to boost online uptake might involve an assessment which identifies the individual interests of people and demonstrated how “going online” could further enhance areas they already enjoy. Different incentives could be provided to encourage patients to visit health websites with reliable and up to date information.

This leads onto how there is limited consideration being given to the quantity and quality of access to these technologies, the possible effects of this on people from socially disadvantaged groups and for those experiencing severe mental health difficulties such as psychosis, bipolar disorder and depression. Research in the west, from the United States Census Bureau highlights that 15.9% of the American population have no use of the internet use anywhere or access to a PC at home (File, 2013). Furthermore, in the United States, it is estimated 15.9% to 25% of homes (File, 2013) do not have an Internet user (US Department of Commerce, 2010), accounting for millions of individuals. Similarly, over seven million adults in the UK do not use the Internet (ONS, 2013), with Fox (2012) reporting that there was a lack of motivation in 59% of non-Internet users under the age of 65 from going ‘on line’. However, in contrast 97% of 18-29 year olds own smart mobile phones with 81% using their phones to send or receive text messages (Fox, 2012). With millions of people having never used the Internet, these issues pose a major challenge for social and mental health care services (Milner, 2014).

2.7 The effects of digital exclusion on mental health

Socially disadvantaged people, not only lack in access to digital technologies, and have been reported to be falling further behind the rest of society who use technology to their advantage (The Deputy Prime Minister, 2005). This increases, both widens and deepens the divide. Digitally excluded people are increasingly at risk of becoming ‘invisible’, as the key platforms for discussion and social participation (e.g. e-petitions) are also digitally driven. This leads to a vicious cycle in which those excluded from the digital advantage suffer from higher costs of living (Morris, 2007) (loss of online retail discounts) and often restriction to access from services (The Deputy Prime Minister, 2005).

There are a number of studies describing Internet-based therapy (Reger & Gahm, 2009) and quality of information on mental health websites (Griffiths & Christensen, 2000). However, existing studies are limited to cross-sectional surveys based on convenience samples from outpatient populations without comparison groups (Borzekowski, Leith, & Medoff, 2009; Ennis, Rose, & Dennis 2012). A relatively larger US study found that only one-third of those with serious mental illness reported having used the Internet and less than a third of Internet users had ever searched for health information. This was in stark contrast to Internet use by chronic physical condition groups, where half went online regularly, and the majority were avid consumers of online health information (Borzekowski, & Rickert, 2001).

A number of these issues could be considered risk factors for poor mental health. Clayton (2009) assessed the extent to which people with psychiatric disorders search for health information on the Internet and found that among Internet-using patients with psychiatric disorders, 64.7% had used the Internet to find health-related information. He reported the most common reasons for this searching, was that the information was perceived to be “useful” and “relevant to people like me”. The barriers reported relate to the expense of mobile Apps and poverty of specific information. That ISM Institute (2013) argue that most health related Apps can be downloaded free of charge, never- the -less there are over 1,980 therapy specific mobile Apps, with the mental health and behavioral Apps costing the most money. Furthermore, it is reported that up to half of all the Apps on offer for downloading to mobile phones do not provide instructions on App usage, which makes them less available and accessible to non-tech users (IMS Institute for Healthcare Informatics, 2015). Lui, Zhu, Horoyd, & Seng, (2011) suggests that mobile Applications that rely on text based interventions have symbol restrictions compounded by service user’s ability to understand the content of the text, specifically if there are problems with literacy or if English is not their first language.

Overall there is a strong association between social disadvantage and digital exclusion (Dutton & Blank, 2011). A report by the Oxford Internet Institute found that as many as one in four adults can suffer deep social exclusion and have no relationship with Internet services (Dutton & Blank, 2011). Disability groups and patients remain key groups who experience digital exclusion. Internet use by people with disabilities is reportedly at 41%, and is about half that of non-disabled individuals (78%) (Dutton & Blank 2011). It can therefore be argued, that digital exclusion parallels social exclusion in many ways. It has been shown that three out of four of those who suffer ‘deep’ social exclusion, have only limited engagement with Internet-based services (Helsper, 2008). The evidence from general health care shows that those who lack digital access and are unable to use the

technology effectively, suffer from increasing health inequities (Baum, Newman, & Biedrzycki, 2012). The concept of social exclusion and its relationship with poor mental health are already well documented (Morgan, Burns, & Fitzpatrick, 2007). This is worrying as a recent study based on a large dataset from 26 European countries, found that both 'economic/employment' and 'social/welfare' dimensions of social exclusion, significantly influenced suicide mortality among males patients (Yur'yev, Varnik, & Sisask, 2013). Whilst there are initiatives to address the digital exclusion for a number of disadvantaged groups (Norris, 2001), those with mental health difficulties are often overlooked.

Never the less the most popular area of research appears to be that of the mobile phone use and associated mobile phone Apps. Jones et al., (2014) suggest that mobile phone technology offers a new and promising form of communication for mental health providers to link into providing mental health services. IMS Institute for Healthcare Informatics (2015) indicates that there are over 40,000 health Apps already on the market and available for download. Alvarez-Jimenz et al., (2014) argue that computerised technology has advanced rapidly over the past 20 years ,with the advent of mobile technology and mobile phones, which they state should be considered.

2.8 The use of mobile technologies for the treatment of psychosis

The emergence and continual development of technology in this era cannot be ignored. Socially, professionally and personally, technology encroaches upon all aspects of daily life. Consequently, telehealth and mobile health is a novel and emerging field in psychiatric and psychological care and in the treatment of mental health difficulties. It involves the use of telecommunications to provide health care, support and intervention from a distance (Nickelson, 1998). Whilst telehealth has been implemented in the treatment of chronic illnesses including diabetes, congestive heart failure and asthma (Hebet, Korabeck & Scott., 2006). Barak et al., (2008) found Internet-based interventions to be more successful for the treatment of psychological problems rather than for physical or medical problems. Using technology to advance psychological treatment is "a developing professional reality" (Barak et al, 2008).

Research in the area of mHealth, which is a form of eHealth, has shown much promise in the development of mobile phone interventions, which look at the assessment and treatment in real-time of psychiatric disorders such as psychosis (Ainsworth et al., 2013, Spaniel et al., 2012 & Granholm et al., 2011). These interventions use methodologies such as Experiential Sampling Methodology (Myin-Germeys et al., 2009) which examines the context and natural flow of daily occurrences in the lives of people who

suffer from psychosis. Through recording the differing moods, thoughts and psychotic symptoms of individuals in the real-time life course of the individual. In addition, not only do mobile devices allow for the assessment of symptoms but for the real-time treatment of symptoms using therapies such as CBT (Granholm et al., 2011).

The method looks at the differing moods, thoughts and psychotic symptoms of individuals, which occur in their day-to-day lives. The method is used to construct an understanding of individual's psychotic symptoms with a view to understanding the aetiological underpinnings of psychosis in the real-world context (Myin-Germeys et al., 2009). There have been a number of studies, which have investigated real-time assessments within the ecological environment of an individual's day-to-day life course (Palmier-Claus et al., 2012). The ESM Methodology has been validated by Palmier-Claus et al., (2012), which resulted in the development of a smartphone App. The ClinTouch system developed by Palmier-Claus et al., (2012) is a novel mobile assessment App, which uses ESM technology to assess individual's symptoms of psychosis. The system prompts service users to respond to a number of tailor-made questions about their symptoms. The key beneficial aspect of the system, is that the data gathered is recorded in real-time on a database which is useful in monitoring symptoms and allowing for warning signs to be highlighted to the team.

The concept of providing interventions in real-time was formulated by Kelly et al., (2012) and is known as intelligent Real-Time Therapy (iRTT). It can consist of differing iRTT formats such as media, MP3, images and hyperlinks (Kelly et al., 2012). Although there is research which suggests the efficacy of the use of mobile technologies to collect the longitudinal data on individual's symptoms and views of their illness (Granholm, Loh, & Swendsen, 2008), there is little research suggesting the use of mobile devices to deliver interventions (Spaniel et al., 2008). The iRTT conceptual model outlines the use of mobile technologies to deliver interventions for severe mental illnesses; this system goes beyond the momentary assessment of symptoms real-time by providing service users a CBT based intervention to help reduce the distress being experienced due to their symptoms (Kelly et al., 2012). The system also uses differing iRTT media formats to convey video messages, recordings, text messages, poems and images, providing an interactive interface for service users to engage with and provide better engagement with health professionals working in this field. The importance of such methods and technologies is known as the therapy-practice gap as described by Kelly et al., (2012). The idea behind this concept is to go beyond the confines of the therapy setting and bringing real time treatment in to an individual's day-to-day life.

2.9 Chapter 2: Summary & Conclusion

This chapter has reviewed the background and context, for the conceiving of a mobile phone Application (App) to better support individuals diagnosed with psychosis in the community. The material presented in this chapter assisted in forming the rationale for the intended research study and largely consists of information pertaining to the broader usage of mobile technologies and associated health usage and benefits. As the project progressed, this information was cascaded into discussions with service users who were involved in informing the construction of a specific mobile phone App intervention for psychosis, which was one of the objectives of my study.

Available literature suggests the global use of mobile phones has increased significantly. This increase provides a strong rationale for both overcoming digital exclusion for individuals with mental health disorders and providing a means for accessible monitoring and treatment of Severe Mental Illnesses (SMI) such as psychosis (Palmier-Claus et al., 2012, Granholm et al., 2008). EIS's have been found to provide a means to recovery for those experiencing mental health difficulties. The key factor which inhibits this is stigma, with stigma related factors having a detrimental impact on service users. Mobile technologies may be able to bridge this gap, by increasing self-management and accessibility to support. This rationale is further predicated on the increased usage of mobile devices, with SMS messaging being a preferred medium for young people to communicate on. The adoption of mHealth interventions is thus grounded in a clinically compelling case, for a simple but clear and jointly developed form of monitoring experiences of distress, so that appropriate psychological and self-help interventions can occur at the earliest contact point. This may contribute to enhanced engagement with clinical teams, relapse prevention and recovery.

Moreover, this approach is further strengthened through the concept of digital inclusion. The increasing availability of mobile technology has transformed the way people communicate with each other in the wider community and the Internet has become a powerful source of information (Alvarez-Jimenez et al., 2014). From the background literature, the current care pathway within the NHS for psychosis and NICE guidance pertaining to the usage of psychological therapies, the rationale for the need of mHealth for psychosis is strengthened. Additionally, in terms of the PhD project I wanted to develop and feasibility test the TechCare project keeping in mind health inequalities. To facilitate this, I employed the use of the Health Inequalities Assessment Toolkit (HIAT), which is a bespoke appraisal tool for addressing the capacity of proposed research activity to attend to health inequalities. This was developed within the North West Coast CLAHRC and enabled me to first conduct an evaluation of the potential impact the

intervention would have on reducing health inequalities. The following chapter presents how I have utilised the HIAT process, to ensure that mental health inequalities were thoroughly attended to in the course of the project.

CHAPTER 3: ASSESSMENT OF THE TECHCARE PROJECT USING THE NIHR CLAHRC NORTH WEST COAST HEALTH INEQUALITIES ASSESSMENT TOOLKIT (HIAT)

The following section outlines the methodology I used to formulate my research aims and to assess the potential impact, the TechCare project may have in tackling health inequalities in the North West Coast region. The Health Inequalities Assessment Toolkit (HIAT) was developed by the NIHR CLAHRC North West Coast to ensure that work carried out in the region had the ability to contribute to reducing health inequalities. I completed the HIAT in conjunction with service user representatives who provided useful comments related to the TechCare project and how it could potentially reduce health inequalities. I will outline the structure of the HIAT tool, and the methodology I used to complete the assessment of the TechCare project in relation to health inequalities.

There has been a vast amount of research in the field of psychological interventions primarily in the efficacy of Cognitive Behavioural Therapy (CBT), for a range of severe mental health disorders. Technological advances in health care have shown promise when delivering health interventions for mental health problems. However, due to inequalities, most individuals with SMI's are not offered psychological therapies. The National Institute of Health Research (NIHR) established nine Collaborations for Leadership in Applied Health Research and Care (CLAHRC) across the UK, funded by the Department of Health, with the aim of tackling such health inequalities. The current project is in line with one of the six main themes of the CLAHRC in the North West Coast region of the UK and will look to assist in improving the mental health of individuals with psychosis by improving access to psychological therapies.

3.1 Defining Health Inequalities and the Social Determinants of Health

Health inequalities arise from the widening gap between the poor and wealthy, resulting in poorer health outcomes for those from disadvantaged backgrounds (Marmot & Bell, 2012; Royal College of Nursing, 2010; Marmot, 2005). The Marmot Report (2010) found that people living in the most deprived neighbourhoods in the UK, on average die 7 years earlier than those living in the more affluent areas. Factors such as poor housing, social isolation and education can contribute to health inequalities, with the annual cost of health inequality in the UK reported as being between £36 billion and £40 billion, as a result of loss of welfare payments, NHS costs and loss in taxes (Marmot et al., 2010).

The World Health Organization (WHO) defined health inequality as a 'difference in health status or in the distribution of health determinants between different populations' (World

Health Organization, 2014). Both societal and economic inequalities have been reported to be related to poorer health outcomes for those living in the most deprived areas of the country (Marmot & Bell, 2012; Royal College of Nursing, 2010; Marmot, 2006). The social determinants of health are defined as being the conditions an individual grows up in or lives in, and are related to factors such as housing, education, financial stability, access to health care and the environment (WHO, 2014). There is now a large evidence base relating to social determinants and their impact on health inequality (Marmot & Allen, 2014; Braveman & Gottlieb 2014). The greater the gap between differing populations in terms of social determinants; such as highlighted above, the greater the health inequality.

3.2 Health Inequalities in the North West Coast

It has been reported by Whitehead et al., (2014), that individuals in the North suffer from higher levels of chronic illness, with poverty being associated with an increased risk of mental and physical illness. In England 30% of the population, live in the North, with the North consisting of 50% of the most poorest neighbourhoods in the country (Whitehead et al., 2014). Research by Husain et al., (2013) found that there was a higher incidence of psychosis in the most deprived areas of the North West, with ethnic minority populations significantly impacted by health inequity. Individuals from ethnic minorities have a number of social detriments which contribute to this heightened mental health inequity, such as language barriers, acculturation, low level of detection of mental health problems and less access to mental health services (Archie et al., 2010; August et al., 2011; Sentell et al., 2007; Bhui et al., 2003). In addition, it has been reported that waiting times for the Improving Access to Psychological Therapies (IAPT) service for individuals who have experience of mental health difficulties, is longest in the North West, with one area in the North West having roughly more than 4000 people waiting over 28 days for an initial treatment session (Health and Social Care Information Centre, 2013).

One way of tackling this health inequality is through the use of mobile and wireless technologies which have the potential to transform mental healthcare. Digital technologies such as smart phones, the Internet and digital TV are becoming an important way to gain access to the social determinants of health (Royal College of Nursing, 2012). Globally estimates suggest close to 5 billion mobile phone subscriptions worldwide (WHO 2011), with over 85% of the world's population being covered by a commercial wireless signal (WHO 2011). In the UK it is estimated that 94% of adults own/use a mobile phone and 76% owning a smartphone (The Office of Communications (OFCOM), 2017), with 92 million mobile phone subscriptions in the UK and 52.4 million 4G mobile subscriptions (OFCOM, 2017).

3.3 The Development of the HIAT tool

The HIAT tool was developed by NIHR CLAHRC NWC staff and collaborators as a part of a series of workshops during the period of 2014-2015. I actively participated in the workshops on the 27th of February 2015 and 29th of April 2015 and a further training session on the 8th of March 2017. Through my participation, I was able contribute to this process, as the development was based on a multi-stakeholder participatory approach and involved individuals from differing background and specialities, in addition to PPI representatives. The use of multi-disciplinary participatory research is a social process, which enables translation and exchange of knowledge (Fazey et al., 2014). They are becoming increasingly important when conducting complex implementation research, which aims to directly improve healthcare services (Hinchcliffe, Greenfield & Braithwaite, 2014). The HIAT was developed as a tool which could be applied flexibly to differing research methodologies and designs and is centred around application in collaboration with patients and the public.

The HIAT is comprised of the following four sections: -

- **Section 1** - Clarifying what aspects of health inequalities and their socio-economic drivers are relevant to the problem to be addressed in the proposed work.
- **Section 2** - Designing your work to maximise potential to reduce health inequalities
- **Section 3** - Evaluating and/or monitoring the impact of your activity on health inequalities and the drivers
- **Section 4** - Planning for wider impacts on health inequalities and its drivers

I now turn to reflecting upon my study using the different sections of the HIAT tool:

3.4 Section 1: Clarifying what aspects of health inequalities and their socio-economic drivers are relevant to the problem to be addressed in the proposed work.

The differences in socio-economic and environmental factors have been reported to lead to health inequalities, which arise as a result of the difference between the underprivileged and wealthy (Whitehead & Dahlgren, 2006). Results from The Global Burden of Disease 2010 study (Whiteford et al., 2013) reported estimates of individuals who suffer from mental health disorders globally; depression (400 million), anxiety (272

million), bipolar (59 million), schizophrenia (24 million), alcohol and drug use disorders (140 million) and people and children with behavioural disorders (80 million).

In the UK, there has been a widening gap between the health outcomes of individuals living in the wealthiest and most deprived areas of the country (Royal College of Nursing (RCN), 2012). Recent estimates suggest those living in the poorest areas of England, on average die 7 years earlier than those living in richer areas (Office for National Statistics (ONS), 2014), this is increased to 11 years for men living in Scotland (RCN, 2012). One region within the UK, which has increased levels of deprivation, is the Northwest of England. Areas such as Blackburn with Darwen, Manchester and Liverpool are some of the most deprived areas in the UK (ONS, 2015). This has a huge impact on health inequality in this region with life expectancy being lower than the UK equivalent (ONS, 2015). In the UK mental illness is a major source of disease burden costing in the region of £105 billion pounds (Bhugra, 2010), with mental illnesses being related to deprivation, low income, unemployment, poor education and poorer physical health (Bhugra, 2010).

The CLAHRC programme of research is aimed at addressing health inequalities within a public health frame. This study, hence, is concerned with some particular aspects of health inequalities for mental health service users, and the extent to which mHealth approaches can address these, in a context of improving symptoms of psychosis and enhancing engagement with services. Applying the HIAT tool in the early stages of project development, enabled full consideration of health inequalities to be taken into account in the design and execution of the project, and to consider the impact of the intervention with regard to equality in the long term.

Therefore, one problem the research aims to address is mental health inequalities and is targeted at individuals who have experience of severe mental illnesses such as psychosis. Initially the research question was formulated based on the clinical work of health professionals who worked as part of NHS Early Intervention Service in the North West. As a whole, the service user representatives highlighted that stigma surrounding mental health was the main barrier restricting them to proactively seek help and get access to treatment, in addition to difficulties in communicating their experience of distress to their case manager. They voiced that the TechCare App would be very resourceful in bridging the gap in getting treatment, as it was a less stigmatised and discrete approach of receiving treatment as opposed to having mental health workers visit their homes.

3.4.1 What evidence is there that this health problem is unequally distributed across people living in different socio-economic circumstances

There are a number of factors, which are implicated with the unequal distribution of mental illness across differing socio-economic factors. Firstly, individuals suffering from mental illnesses have been profoundly impacted by health inequalities due to factors such as stigma. Service user representatives involved in the TechCare project reported stigma surrounding mental health as the most important factor impeding them to seek and participate in treatment. Byrne (2000) described stigma as a negative attribute to social relations that may impede participation in treatment. Stigma reduces the self-esteem of individuals with mental health problems and also robs individuals of social opportunities (Corrigan, 2004). Goffman (1963) described stigma as an attribute, which reduces a person from 'a whole person to a tainted or discounted one' (Goffman 1963). Those with a lived experience of psychosis have been denoted as being one of the most stigmatised groups in society (Wood et al., 2015) and as a result 87% of individuals with a diagnosis of schizophrenia reporting experiencing stigma (The Schizophrenia Commission, 2012). The major implication of this is that many individuals may feel discouraged in seeking help (Thorncroft, Rose, & Kassam, 2007), with this inhibiting educational attainment and employment opportunities (Thorncroft et al., 2007). It has been highlighted by Hatzenbuehler, Phelan and Link (2013), that stigma has a 'corrosive impact' on the health of the population particularly for those with mental health difficulties and should be considered as part of research on the social determinants of health. Although a major contributor to health inequality, stigma is not the only socioeconomic factor associated with this unequal distribution.

The lack of funding and resources for mental health research has major implications to the development of novel interventions for mental illness. In the UK, the research budget for health has been estimated at £115 million, with only a 5.8% of this budget being spent on mental health research (MQ, 2015). Putting this into context MQ which is a mental health research charity, reported that the average spend per person is £9.75 for mental health compared to physical illnesses such as cancer which have an average spend of £1571 per person (MQ, 2015; UK Clinical Research Collaboration, 2015). Furthermore, on breakdown of the different mental health disorders, a greater variation in research spending has been reported, for example for research in depression £1.55 is spent per adult in comparison to £0.15 per adult for eating disorders (MQ, 2015).

In addition, individuals who live in either rural or coastal areas may be impacted by a lack of access to mental health services. It is estimated that individuals suffering from mental illnesses on average have to travel 300 miles to access treatment when in crisis,

suggesting a huge inequality in access to mental health services (Rethink, 2014). This again being more so for individuals living in rural or coastal regions of the North West. McGorry, Bates and Birchwood (2013) have reported that in the UK mental health services are difficult to access, and when services are accessed, there is great delay and restrictions in what individuals with SMI's can access.

The North West region of the UK has some of the most deprived localities, primarily areas of East Lancashire and Blackpool. This has a greater propensity to impact the mental health outcomes of individuals living in these communities. An audit completed as part of my earlier work (Husain et al., 2014) within the Lancashire area, found that individuals being referred to the Early Intervention Service for a first episode of psychosis were more likely to reside in areas of high deprivation. This has been further supported by Bhavsar, Boydell, Murray, and Power, (2014) who reported that area level deprivation was associated with incidence of psychosis.

Additionally, it is also well documented that access to psychological services in England have been improving within recent years through schemes such as Improving Access to Psychological Therapies (IAPT) which have had a positive impact on waiting times for treatment for individuals suffering from mental health difficulties. However, within England, 1 in 5 individuals still have to wait for over a year to access psychological therapies such as CBT (MIND, 2010), with the North West consisting of the largest proportion of individuals waiting for an initial CBT session.

3.4.2 What particular socio-economic drivers of health inequalities can be expected to impact on this problem

The concept of digital inclusion as described earlier is a key driver of the social detriments of health. This is primarily due to many of the key platforms, which allow for access to social care support to be based on technology. Therefore, access to digital technologies may have an impact on health inequalities. Individuals who do not have access to technologies, may be further behind individuals who have access to technologies. In the context of psychosis Torous, Friedman, and Keshavan, (2014) reported, that in a sample of 100 patients from an outpatient psychiatry clinic in Boston USA, 97% had access to a mobile phone with 72% reporting that their mobile phone was a smartphone. Firth et al., (2015), reported that recent trends in smartphone uptake has suggested the rate of smartphone ownership increasing over the last 10 years. As smartphones become cheaper, there is a greater propensity to gain a better understanding of how digital technology can overcome mental health inequality.

Another issue, which arises, is the lack of referral to psychological services for individuals with psychosis. It may be noted that differing service user groups experiencing mental health conditions may be less likely to be referred for psychological therapies. This may impact recovery, as some service users may prefer psychological support in comparison to pharmacological intervention. Although in the UK, the National Institute for Health Clinical Excellence (NICE; 2002, 2014) has advocated the use of both Cognitive Behavioural Therapy and family intervention for schizophrenia. However, actual referrals to psychological services are far and few between. This reported as being the result of a multitude of barriers to implementation, such as the individual's perceptions and lack of training of health professionals (Ince, Haddock & Tai, 2016; Berry & Haddock, 2008), with reluctance to participate in psychological therapies due to feelings of disempowerment, blame and stigma (Berry & Haddock, 2008). Furthermore, individuals who are socially isolated, may experience diminished social interactions due to symptom related factors, such as social withdrawal and negative symptoms related to cognitive impairments. Deficits in communication may also result in unemployment, financial difficulties and a reduction in opportunity to engage in social interactions.

Research has suggested that social status is one of the key factors which disproportionately affect the poor and disadvantaged in relation to mental illness, with individuals from low and middle class backgrounds having higher rates of common mental health disorders (Campion, Bhugra, Bailey, & Marmot, 2013). In *Bridging the Gaps*, the World Health Organization (1995) states, 'The world's most ruthless killer and the greatest cause of suffering on earth is extreme poverty'. Evidence has suggested that there is an increased incidence of psychosis in individuals from black and minority ethnic (BME) communities. The EMPRIC study (Das-Munshi et al., 2012), also highlighted the social environmental factors associated with increased risk of psychosis and higher own-group density, with a reduction in social risk factors for psychosis. Poverty is a multidimensional phenomena, with approaches to tackling poverty taking into consideration socio-economic factors.

3.5 Section 2: Designing your intervention or activity to have maximum effect on reducing health inequalities

The project aimed to utilise mobile technology in the form of an application (App), a commonly used familiar platform for many individuals in the UK. The use of mobile devices could potentially provide, greater autonomy to service users who would otherwise be seen as a 'hard to reach group' by taking a non-stigmatising approach. The delivery mechanism would be targeted at overcoming the main drivers of mental health inequality such as stigma and access to psychological therapies. Current services are

geared to a very much biomedical model of health care delivery. However, the problem arises that mental illness is stigmatised resulting in a reduced level of engagement with services, potentially delaying treatment and thus early intervention. In addition, the wider socio-economic factors which play a role in widening the health inequality divide can be digitally driven, an example of this is the UK's benefits systems (Universal Credit). Increasing access to digital clinical technologies may help in overcoming this inequality through greater access to mental health care in the real-world lived environment of individuals experiencing psychosis.

From the above identified socio-economic factors I found in consultation with the PPI group that a possible solution to these health inequalities, would be through the mobile phone platform and the utilisation of an App, which would be available to individuals in real time. Providing them with a discrete medium, which they would enable them to access mental health care. In addition, the App would help in providing greater access to the Internet, so that individuals could potentially access resources such as governmental benefits (Universal Credit; www.gov.uk) and educational resources such as online courses (Coursera, HavardX, Futurelearn).

There were a number of considerations, which had to be taken in to account. Firstly, the level of digital literacy, if individuals did not have access to technology, or were unable to use technology, they would more likely be digitally excluded. However, based on previous research, Firth et al., (2016) have described mobile ownership in those that experience psychosis. Although access is high, I was mindful of those that may not have the ability to pay for credit and Internet charges, thus I factored this into the study. The study was conducted with input from both NHS staff and Maywoods limited, with future integration of the TechCare system benefiting future impact, and development of the system to meet the requirements of the NHS.

3.6 Section 3 - Evaluating and monitoring the effect of your activity on health inequalities and their causes

The study examined the feasibility of a mobile App intervention for those individuals with a diagnosis of psychosis. In the short term, the intervention will provide an avenue for participants to access psychological support for distress associated with psychosis. In the longer term, the mobile App may hold importance in bridging the gap between the socio-economic causes of mental health inequalities, such as access to digital technologies. This may enable individuals to gain support in real-time within rural or coastal area, where access to specialist mental health care is limited. In examining these variable factors, which I have highlighted above it, is prudent that we examine the

evidence base for mHealth interventions, which are directed towards addressing the socio-economic drivers of mental health inequalities. To investigate this, therefore the focus of the evidence synthesis was mobile interventions for psychosis.

Social status is not only a driver of mental health inequalities, gender also plays a major role with mental health disorders being higher in women (Allen, Balfour, Bell & Marmot, 2014). In addition, low educational attainment, financial and material disadvantage and unemployment can also have an impact on mental health inequalities (Fryers, Melzer, Jenkins, & Brugha, 2005). The acceptability, motivation and attitudes towards the use of digital devices by people suffering from mental health difficulties is also poorly understood, with individuals often failing to see the individual relevance of the technology and considering it a possible threat to person centered care. The distressing experiences of unusual beliefs and delusions associated with psychotic disorders, possible interference with patient-clinician communication and anxiety associated with using digital devices can result in distorted perceptions and suspiciousness regarding computers and mobile phones. In contrast, a qualitative study involving 24 individuals with psychosis, found that participants perceived mobile technology as non-stigmatizing, thus suggesting a potential benefit (Palmier-Claus et al., 2012). However due to the scarcity of research in this area, the actual wider beneficial effects on mental health care await the results of further studies. Patients have advocated that mobile assessment could be a useful method for improving communication between service users and clinicians. From this feasibility work, I plan to scale up the project to a larger clinical and cost effectiveness trial, in the future to focus on mental health inequalities, which has been the key theme, that has been at the foundation of the work carried out. I will ensure that the tackling mental health inequalities will be a core component of the scale up work.

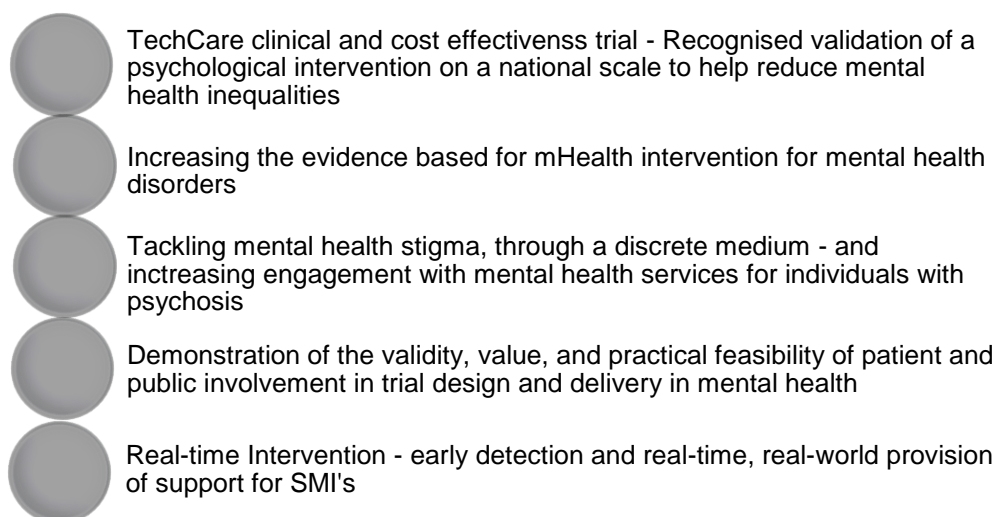
3.7 Section 4 - Planning for wider effects on health inequalities and avoiding negative ones

It is estimated, that individuals suffering from mental illnesses on average have to travel 300 miles to access treatment when in crisis, suggesting a huge inequality in access to mental health services (Rethink, 2014). Social determinants of health such as employment, housing, education and social networks, have been reported to be potentially responsible for the increased levels of health inequalities (Marmot et al., 2010; Marmot 2013; RCN, 2012). The aim of this preparatory work is to understand the feasibility and acceptability of the TechCare App intervention, with a focus on addressing mental health inequalities. The target population are those with mental health difficulties due to stigma, and work been conducted in increasing awareness of mental health

(www.change.org.uk). The wider impact of the project is to enable the ease of access to services for individuals with mental health difficulties, and to increase the benefits of access to technology, to overcome the socio-economic barriers for those who suffer from mental health difficulties. In the view of the service user representatives, stigma surrounding mental health may deter individuals seeking or adhering to treatment. However, a more discrete approach to treatment through the TechCare App may overcome this problem.

Globally there is a growing focus on digital technologies, including within the mental health context, with an increasing evidence base reporting positive outcomes. Despite the acknowledged exclusionary dimensions of internet access for disadvantaged groups, a case can be made for expanding internet access via mobile phone technologies, given the extensive patterns of ownership and access to such technologies amongst mental health service users. Future policy development should involve consultation with service users from diverse backgrounds and socio-economic status. In addition, overcoming health inequalities in the UK, requires the conduct of high quality robust research and collaborative multidisciplinary working, with the aim of creating a fair and equitable society for all those living in the UK with mental health difficulties. I have provided an overview of the wider outcomes, which are planned as part of the pathways to impact of the study in Figure 3.1 below.

Figure 3.1: Planning for the wider effects on health inequalities



3.8 Chapter 3: Summary & Conclusion

This chapter has presented a discussion, of my use of the HIAT to appraise relevant health inequality issues for the proposed study, reflecting a commitment to ensure that

work carried out in my project had the potential to overcome health inequalities. The method of the HIAT was chosen as the core ideals of service user involvement are ingrained within the methodology and hold true to a participatory ethos. PPI members provided valuable feedback during the process of conducting the HIAT. This was an empowering means of engaging with the target population and provided insights into the challenges faced by service users. As part of this component of the research, the PPI representatives completed the HIAT alongside myself and provided their own experiences relating to mental health inequalities.

Pertinent issues identified by application of the HIAT, resonate with wider commentary on mHealth technologies; these notably include factors relating to access and stigma. Factors identified by the HIAT can represent both potential barriers and opportunities. Research has provided insight into how barriers can be overcome, and opportunities capitalised upon. For example, improved training procedures and better distribution of information regarding technology based interventions, could improve attitudes towards this evolving field. Improving the access to digital clinical technologies, in low resourced or deprived localities can be of great benefits to providing a step-change in the utilisation of low cost mobile technologies, to address the huge treatment gap in mental health care. Overall, mHealth services have benefits of potentially reducing stigma felt by clients in accessing mental health services, improving accessibility and cost benefits.

Importantly, the key findings of the HIAT provided grounding for the project, within the context of health inequalities. From the findings of the HIAT the rationale for providing a real-time intervention for individuals experiencing psychosis, may help overcome identified and previously acknowledged mental health inequalities. A summary, of the key areas which were highlighted from the HIAT process and the developmental considerations for the project are presented in Table 3.1 below.

Table 3.1: Summary of key findings of the HIAT and development considerations

Summary of key areas highlighted in the HIAT	Development considerations for the project and intervention
1. Deprivation in the North West region and its impact on mental health	The App could potentially contribute to digital inclusion, which may benefit individuals with mental health difficulties
2. Difficulties faced by service users due to stigma	The TechCare App would be discreet thus potentially helping overcome stigma
3. Long waiting times for psychosocial interventions and lack of referrals to psychological services	Delivery mechanism targeted at overcoming the main drivers of mental health inequality, such as referral to psychological therapies.
4. Lack of access to mental health services	The mobile phone App may potentially increase access to mental health services, through providing an alternative means of access to support.
5. Improved engagement with mental health services	The TechCare App could potentially enhance engagement with the EIS and would supplement the work of the care coordinators.

A starting point for the next stage of the project would thus entail a synthesis of evidence of real-time interventions for psychosis. This was to examine what research had been done previously in this area, and whether lessons learnt from previous work could be used to develop the TechCare intervention. I aimed to conduct a systematic review to examine whether mHealth interventions had been used in the treatment of psychosis, and to take note of key factors, which would help contribute to the design, and operationality of the TechCare App. The systematic review is presented in the following chapter.

CHAPTER 4: MHEALTH BASED INTERVENTIONS FOR THE ASSESSMENT AND TREATMENT OF PSYCHOTIC DISORDERS: A SYSTEMATIC REVIEW

This chapter presents a synthesis of the existing evidence in the form of a systematic review; describing the methodology used in addition to the findings. The aim of this chapter was to conduct a synthesis of the evidence, to inform the development and refinement of the intervention. The key themes, which were found, related to feasibility and acceptability of mHealth for psychosis, with the seven included studies reporting a range of outcome measures.

4.1 Background to the Systematic Review

The relative burden of mental health disorders is on the rise in terms of prevalence, disability and mortality globally (Whiteford et al., 2010) with limited controlled data, available to guide treatment choices for clinicians. Since the 1990s, electronic service delivery within healthcare has expanded significantly (Oh, Rizo, Enkin, & Jadad, 2005). Initially, this area of service delivery initially received a number of titles like 'Telemedicine', 'Telehealth' and 'Telecare' but with the merging of different technologies, the whole area is becoming more encompassing and the term 'eHealth' has emerged.

One particular form of eHealth is mHealth (mobile Health). The Global Observatory for eHealth (GOe) defines mHealth or mobile health as '*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*' (Kay, Santos, & Takane, 2011). mHealth technologies utilise components and functionalities of mobile devices such as Short Messaging Service (SMS), general packet radio service (GPRS), Bluetooth, Global Positioning Systems (GPS), mobile connectivity (3g and 4g) and smartphone applications more commonly known as mobile Apps. mHealth has been successfully used in delivering treatment modalities in a variety of settings, predominantly in High Income Countries (HICs). In recent years, there have been studies on the successful use of a variety of mHealth interventions for Severe Mental Illnesses (SMI). More recently, a number of Apps for psychosis have been launched e.g. Actisist and ClinTouch (Palmier-Claus et al., 2012, Bucci et al., 2015).

Mental, Neurological and Substance-use (MNS) disorders constitute 14% of the global burden of disease (Collins et al., 2011). Low resourced countries face greater challenges to overcoming this burden due to lack of resources and limited availability and access to mental health care (Ajradi, Nauta, Chowdhary, & Bockting, 2015). The treatment gap for

MNS disorders is estimated to be over 75% in many Low and Middle Income Countries, due to the inequitable and insufficient usage of resources (Van Os, Linscott, Myin-Germeys, Delespaul, & Karabbendam, 2009). mHealth technologies may be a potentially beneficial avenue to bridging this large treatment gap, through improved access to self-management and self-help interventions using digital clinical technologies, which may also significantly assist in recovery from Severe Mental Illnesses (SMI) such as psychosis.

Those with a diagnosis of psychosis may experience a number of symptoms, such as auditory hallucinations and delusional ideation (Walker, McGee, Druss, 2015). Research has suggested the prevalence of psychosis to be roughly 1% globally with psychotic illnesses usually preceded by a prodrome which can last anywhere from one to three years (Ruhmann et al., 2010). This period is characterised by a range of non-specific behavioural and psychological symptoms, functional deterioration and/or attenuated, brief limited intermittent psychotic symptoms (Stafford, Jackson, Mayo-Wilson, Morrison, & Kendall, 2013). Interventions that delay or prevent transition to psychosis from this prodromal syndrome could be clinically and economically important (Alvarez-Jimenez et al., 2014).

mHealth interventions have been used in the assessment and treatment of psychosis. A recent review by Alvarez-Jimenez et al., (2014) highlighted a number of mobile interventions for psychosis; however, the focus of the paper was in relation to web-based and social media interventions and did not take into account mobile devices as defined above. Another review conducted by Kasckow et al., (2014) also reported the feasibility of telephone, the Internet and videoconferencing interventions. However, these reviews focused more on eHealth interventions, which are in most cases dependant on an Internet connection. Globally only 34.3% of the global population have access to the Internet, whereas the International Telecommunication Union (ITU) (2014) estimates roughly 7 billion mobile phone subscriptions being held worldwide, with an estimated penetration of 96% of individuals having access to mobile phones globally (Internet World Stats, 2015). It can therefore be seen that mobile devices could be a potentially effective modality to providing health interventions, by bridging the gap for those individuals who do not have access to the Internet in low resourced settings.

4.2 Systematic Review Methodology

The aim of the review was to search the literature systematically for studies utilising different mHealth interventions for psychosis, and to assess what kind of interventions had been used globally. I believed a synthesis of available information would lead to a

better understanding of the feasibility and effectiveness of these techniques in the treatment and assessment of psychotic illnesses. The results of this strand of the research would help in the development of the TechCare App intervention, and also provide an understanding of the health inequality considerations outlined in chapter 3.

Inclusion and exclusion criteria

I followed the Cochrane collaboration guidelines on conducting systematic reviews (Higgins et al., 2011). The inclusion criteria included studies which: i) Described the use of mobile device intervention in patients who were suffering from psychosis defined as ii) At least one outcome measure of the assessment and treatment of psychosis iii) Was a controlled trial (randomised or quasi-randomised). Studies were excluded if they used Internet or other technologies without utilising mobile devices such as smartphones and tablets.

Literature search

I searched the following databases Embase, Medline, PsychINFO and Evidence Based Medicine Reviews. A number of keywords were searched in each of the databases from inception to May 2016; the search criteria was initially configured and deployed in Medline and the same search criteria was then extrapolated to other databases. The key words that were searched included; 'mHealth' 'Mobile Health' or 'Severe Mental Illness' or 'Schizophrenia' or 'Schizo-Affective Disorder' or 'Intervention' or 'Assessment' or 'Treatment'. I also searched for relevant systematic reviews in the Cochrane Database of Systematic Reviews and the Cochrane Database of Abstracts of Reviews of Effects (DARE) and randomised controlled trials were searched in the Cochrane Central Trials Register (CENTRAL), and any relevant grey literature was searched. Grey literature is normally used to describe documents not formally published in academic databases, and can take the form of; conference proceedings, factsheets, policy documents and governmental/organisational reports (Godin et al., 2015). The same search strategy was deployed in OpenGrey which is a European wide database consisting of grey literature.

Assessment of Methodological Quality

The methodological quality of the included randomised controlled trials and clinical controlled trials was assessed using the list from the Cochrane Risk of Bias Tool (Higgins et al., 2011) which included four domains comprising of 11 criteria which assess internal validity of the selected studies. The four domains that were examined and the criteria used are as follows; 1) Selection bias; this domain looked at whether an adequate

randomisation procedure was used, similarity in baseline data on the primary indicator and whether treatment allocation was concealed. 2) Performance bias; this included blinding of patients to the intervention, whether intervention compliance was adequate, and whether health professional/therapist were blinded to intervention groups. 3) Attrition bias; this domain looked at whether the study included an intention to treat analysis and whether the study had an acceptable level of dropout rate at baseline. 4) Detection bias; this domain examined whether the study used similar or the same outcome measures across the study groups, and whether the outcome assessor was blinded to the study groups. Overall, the studies were scored independently by myself and another researcher (Dr Pardeep Singh Kundi) across each of the 4 domains, the studies were scored either with a 'Yes', 'No' or 'Unclear'. Studies which scored more than six across each of the four domains were classed as high quality otherwise the remaining studies were classed as low quality. Any disagreements were discussed with my supervisory team until a consensus was reached. This process was enlisted to ensure resolution of any discrepancies between myself and the co-rater (PSK).

Data Synthesis

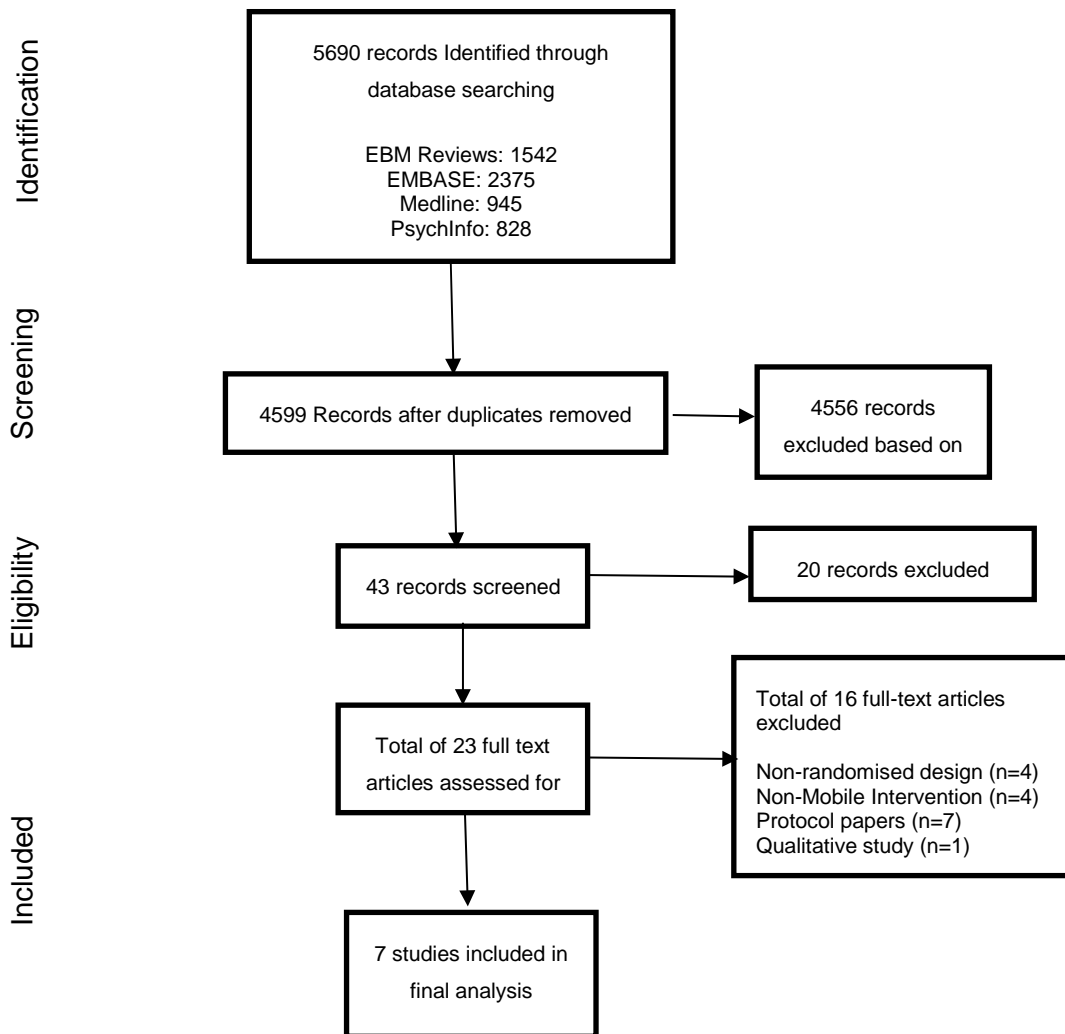
The data was extracted from the databases and all abstracts were read. Those studies which met the inclusion criteria were then extracted using a standardised data extraction sheet. The following variables were extracted from the included studies; mobile intervention used, type of study, outcome measures, duration, diagnostic criteria and results. In addition, based on the HIAT assessment carried out in chapter 3, variables such as access to mobile devices, stigma and improving access to services, outlined as contributory factors to reducing health inequalities were also noted. Any disagreements were resolved through discussion with my supervisory team until a consensus was gained.

4.3 Results of Systematic Review: Characteristics of the included studies

I found a total of 5690 titles across the databases I searched, using the search strategy. From these, 43 studies were selected based on the title and abstract for further scrutiny. I selected 23 studies which I read full text, with 16 studies being excluded (see Figure 4.1). Out of the excluded studies, four studies were excluded as they did not include a randomised controlled design, these included a study by Pijnenborg, Withaar, Evans, Van Den Bosch, & Brouwer (2007) which investigated an SMS text message intervention for cognitive rehabilitation in schizophrenia. A study by Depp et al., (2010), which looked at the mobile assessment of psychotic symptoms coupled with a low intensity intervention and Ben-Zeev, McHugo, Xie, Dobbins, and Young (2012) who looked at

retrospective multiple real-time/real-place assessments using a dual methods design, in individuals with schizophrenia and a non-clinical group. Another excluded study by Palmier-Claus et al., (2012) investigated ambulatory assessment of psychotic symptoms. Other reasons for the excluded studies are given in Figure 4.1.

Figure 4.1: Consort diagram to show search results



The seven included studies examined different parameters. One of the studies used an Experiential Sampling Methodology (ESM), which looked at monitoring symptoms real-time, one looked at medication adherence, two looked at cognitive impairments, one looked at social functioning, another looked at suicidal ideation in veterans with schizophrenia, one looked at mobile phone text message reminders and finally one examined relapse prevention and early warning signs. In view of the widely different interventions and outcome measures, it was not possible to conduct a meta-analysis. Therefore, I decided to give a descriptive account of the results.

Main Findings

The characteristics of included studies are given in Table 4.1. The majority of studies were conducted across Europe and the United States with one in China; one was conducted in the UK, two in Spain, one in Finland and one in the Netherlands. Four of the studies were conducted in outpatient psychiatric settings, and three studies in an inpatient psychiatric unit. The total population across all studies was 1105 (Mean= 158, SD = 197.20), with 637 males (Mean = 91, SD = 92.58) and 468 females (Mean = 67, SD = 107.27), the mean age of participants was 35.35 (SD = 8.73). Five studies used a randomised controlled trial design, one used a prospective randomised open-label controlled trial and one was quasi-randomised (please see Table 4.1 for the main findings of the included studies).

Table 4.1: Main Findings of the Included Studies

Author	Year	Population	mHealth delivery method & content	mHealth support in practice	Outcome measures used	Main Findings
Ainsworth et al.,	2013	N= 24	Mobile phone based SMS text messaging in comparison to a Smartphone Application (ClinTouch). Real-time monitoring of psychotic symptoms.	Researchers contacted participants 1-2 times a week to offer App related support and to check whether participants had encountered any technical difficulties.	Purpose-designed Quantitative Feedback Questionnaire to assess the acceptability and feasibility of these methods was used. Positive and Negative Symptom Scale (PANSS)	Participants in the smartphone Application condition took significantly less time to complete the assessment questions (Mean =68.4 seconds SD=39.5) compared to the SMS only condition (Mean=325.5 seconds SD=145.6) ($\beta = .78$, SE= .09, $P<.001$). There was also a significant difference in data points completed in the smartphone App group compared to the SMS only group ($\beta = -.25$, SE=.11, $P=.02$). There was no significant difference in PANSS score across the domains Hallucinations Anxiety Grandiosity Delusions Paranoia, Hopelessness.
Dang et al.,	2014	iPad assisted cognitive	Tablet device - iPad-assisted cognitive training (User-friendly	Participants were provided face-to-face support and training on how to play the	N-Back performance was recorded as an accuracy rate, composed of the percent of	Patients in the experiment group improved significantly in accuracy rate at 2-back ($Z = -3.27$, $P_{corrected} < 0.01$),

training group: N = 8	iPad cognitive training games).	cognitive training games by nursing staff.	correct responses (%) and reaction time for each response (ms).	and reaction time in 0, 1 and 2-back (Z = -2.89, Pcorrected = 0.012; Z = -2.60, Pcorrected = 0.048; Z = -2.98, Pcorrected = 0.012, respectively) from baseline to week 4, as compared with those in the control group.
Control group: N = 9				

Kasckow et al., 2016	Telehealth (Health Buddy) group: N = 25 Control group: N = 26	Intensive Case Monitoring with daily Health Buddy (mobile device, providing psychoeducational support)	Participants could contact support staff via telephone during the trial period for assistance relating to equipment problems or if they had any questions.	Questionnaire items assessing participants positive or negative views on the telehealth intervention and the Beck Scale for Suicidal Ideation (BSS), 17 item Hamilton depression scale, Calgary depression rating scale, Mini mental status exam, Scale for assessment of positive symptoms, Scale for assessment of negative symptoms.	Monthly adherence to the Health Buddy system was 83% (n=20), 92% (n=19) and 89% (n=15) for month 1, month 2, and month 3 respectively. Both groups exhibited improvement in suicidal ideation. The health buddy group BSS score reduced from 9.8 (SD = 6.15) at baseline to 2.44 (SD = 5.52) at endpoint, whilst the control group score reduced from 10.7 (SD = 8.24) at baseline to 2.88 (SD = 6.71) at endpoint. For the subgroup of participants who had a life time history of suicide attempt, a trend for a higher rate of remission at the 3 month period for those in the Health Buddy condition (16/18) as compared with those in the ICM condition (14/19; log rank=2.82; df=1; p=0.093).
-------------------------	----------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Kauppi et al.,	2015	N= 562	Mobile phone based SMS text messaging intervention. Participant selected messages relating to 'medication', 'treatment appointments' and 'free time'.	Research Nurse provided face-to-face support to participants. In addition, participants were also provided with a booklet to note any changes they would like to be made in the frequency and content of messages.	Demographic data and readmission to psychiatric services measured by no. of healthy days.	Overall a total of 2112 text messages were sent to participants, the mean no. of messages selected per month was 10 (SD 4.0, range 2-25). There was a significant difference found in gender and age, with older females and younger males preferring greater number of messages. The most popular day to receive messages was found to be Monday and the least popular timing for messages was the weekend.
Montes et al.,	2012	Total 254 patients. SMS Group N=100 Control Group N=154	Mobile phone based SMS text messaging intervention. SMS messages sent to participants 3 times a day, consisting of medication reminders.	Researchers supported participants face-to-face at personal website visits, to check SMS reception status and to resolve any technical difficulties	Morisky Green Adherence Questionnaire (MAQ)	Mean change in MAQ Score in IG was -1.0 (95% CI -1.02, -0.98) while in the CG the change was -0.7 (95% CI -0.72, -0.68) (P=0.02). Improvement was also noted in negative and cognitive symptoms and attitude towards medication.

Pijnenborg et al., 2010	N = 62	Mobile phone based SMS text messaging intervention, consisting of SMS based goal-setting messages and psychoeducational sessions	Participants were provided support in the usage of the intervention by either a nurse or family member who had regular interaction with the participant.	Client Motivations for Therapy Scale, several scales to measure the cognitive functioning, PANSS, Social Functioning Scale and Rosenberg Self-Esteem Questionnaire.	Overall the mean success percentage was 47% across all the goal categories during baseline (SD 27.9), this increased to 62% during the intervention (SD 20.1) and reduced to 40% at follow-up (SD 31.7). Participants who responded to the alerts and achieved their goals had significantly lower positive symptoms compared to the non-responders (t = 2:11, p = 0.4).
Spaniel et al., 2012	Active Group: N = 75 Control Group: N = 71	Mobile phone based SMS text messaging intervention; participants completed a weekly 10-item Early Warning Signs Questionnaire (EWSQ).	No specific training on the use of intervention. Participants were provided with a user-manual.	CGI-S and CGI-I Scales, Hayward 7-item Medication Compliance Rating Scale and GAF Scale.	Overall, the return rate for the EWSQ was 80% (active = 79.8%, controls = 81.3%), it was reported that the individuals who did not receive an increase in antipsychotic medication following a Pharmacological Intervention Requiring Event (PIRE) had an increased risk of hospitalisation (hazard ratio [HR] = 10.8; 95% confidence interval [CI] 1.4–80.0; p = 0.002).

mHealth Interventions

The included studies used a number of differing delivery platforms. Ainsworth et al., (2013) aimed to compare two differing mediums of receiving assessment notifications on a mobile phone device. The smartphone was loaded with a software application which provided questions to assess symptoms of psychosis. The system either utilised SMS text messages or smartphone based App to deliver the assessment questions. The study used a repeated measures crossover design which assigned the 24 study participants to either undergo the SMS condition first and then the smartphone App condition or vice versa. Both conditions used the same assessment questions which were based on the Positive and Negative Syndrome Scale (PANSS).

Another included study conducted by Dang et al., (2014) examined the effects of an iPad assisted cognitive training programme on working memory in a group of male First Episode Psychosis (FEP) patients. The training programme included user-friendly iPad games such as “Shanghai Mahjong”, “Little Ace and the Ten Commandments”, “Math vs. Brains” and “Brain Teaser Extreme. Participants engaged in the cognitive training for 60 minutes a day, 5 days a week. Assessments of working memory were carried out at baseline (Week 0) and follow-up (week 4) via the N-Back task.

In addition, a total of four studies used a SMS based system as a delivery platform for the intervention (Pijnenborg et al., 2010; Spaniel et al., 2008; Kauppi et al., 2015; Montes, Medina, Gomez-Beneyto, & Maurino, 2012). Pijnenborg et al., (2010) investigated the efficacy of SMS messages to provide prompts to participants to achieve goals in their daily lives. These goals included medication adherence, appointments, activities, attending training sessions and inhibition of undesired behaviours. Achievement of goals was based on an observer filling in a score sheet which indicated whether the goal had been achieved or not. The study used a tailor made system of assigning goals which was based on the participant’s preference. The Information Technology Aided Relapse Prevention in Schizophrenia (ITAREPS) (Spaniel et al., 2012), used a multicentre randomised controlled trial design to examine the detection of early warning signs, through the use of SMS based alerts delivered using a mobile phone. The clinicians were provided alerts to increase pharmacological intervention if there was an increase in scores on the Early Warning Signs Questionnaire (EWSQ).

Kauppi et al., (2015) utilised SMS based user defined prompts, relating to medication, follow-up appointments and daily issues such as hygiene, physical exercise, symptom management and other supporting messages during discharge from a psychiatric60

inpatient setting. The frequency and timing of the SMS prompts were also defined by the user. A total of 562 participants enrolled in the study with participant's receiving a mean total of 10 messages a month (SD 4.0, range 2-25) over the 12 month study period. Montes et al., (2012) used an SMS based mHealth delivery modality for medication adherence; a total of 254 participants took part in the study. Similarly, Montes et al., (2012) used an SMS based mHealth delivery modality for medication adherence. In this study participant in the Intervention Group (IG) condition received daily reminders to take their medication.

In contrast, Kasckow et al., (2016) assessed the feasibility of a telehealth monitoring intervention known as 'Health Buddy' for suicidal behaviour in a population of recently admitted inpatient US veterans aged 18 to 64, diagnosed with schizophrenia or schizoaffective disorder and recent suicidal ideation. The Health Buddy was a daily use system that facilitated symptom assessment and patient-staff communication during weekly visits for veterans following an Intensive Case Monitoring program (ICM). The study assessed, whether augmentation of ICM with the Health Buddy system would result in a significant reduction in suicidal ideation relative to a group that only received ICM. This was assessed using the Beck Scale for Suicidal Ideation (BSS).

Medication Adherence

A total of 4 studies looked at medication adherence, with a combined sample size of n=921 participants, although the study by Kasckow et al., (2016) more specifically investigated suicidal ideation in veterans with schizophrenia using the Health Buddy system. The daily monitoring of participants using the Health Buddy system included queries about medication adherence, which was described by participants as being an effective means of improving their medication adherence. In addition, the study by Pijnenborg et al., (2010), reported that participants who responded to the alerts and achieved their goals had significantly lower positive symptoms compared to the non-responders ($t = 2:11, p = 0.4$). It was found that participants showed an increase in leisure activities and keeping to appointments with their health professionals. However, this was not the case for medication adherence and attendance at training sessions. These results differed from the study by Kauppi et al., (2015), Kasckow et al., (2016) and Montes et al., (2012), who found improvements in medication adherence.

Kauppi et al., (2015) utilised SMS based user defined prompts, relating to medication, follow-up appointments and daily issues such as hygiene, physical exercise, symptom management and other supporting messages during discharge from a psychiatric61

inpatient setting. The frequency and timing of the SMS prompts were also defined by the user. A total of 562 participants enrolled in the study, with participants receiving a mean total of 10 messages a month (SD 4.0, range 2-25) over the 12 month study period. The results showed that the most preferable timing for the selected messages was at the beginning of the week, with participants less likely to prefer receiving messages on a weekend. The most selected messages related to medication (175 participants), follow-up appointments (149 participants) and physical exercise (82 participants). Furthermore, in the Montes et al., (2012) study participants who were in the Intervention Group (IG) significantly improved in medication adherence compared to those in the Control Group (CG) Mean change in score in the intervention Group (IG) was -1.0 (95% CI -1.02, -0.98) while in the Control Group (CG) the change was -0.7 (95% CI -0.72, -0.68) ($P=0.02$). In addition, Montes et al., (2012) reported that participants in the intervention group held more positive views about medications.

Experiential Sampling Methodology (ESM)

Only one of the studies utilised an ESM based methodology (Ainsworth et al., 2013). The system collected randomly selected data points to obtain participant's symptoms through either smartphone notifications or SMS. This in effect constructed a daily record of the participant's symptoms, enabling them to produce a day-to-day symptom profile. Participants in the smartphone application condition took significantly less time to complete the assessment questions (Mean =68.4 seconds SD=39.5) compared to the SMS condition (Mean=325.5 seconds SD=145.6) ($\beta =.78$, $SE= .09$, $P<.001$). It was also reported that individuals completed significantly more notifications in the smartphone condition compared to the SMS only condition. There was also a significant difference ($\beta = -.25$, $SE=.11$, $P=.02$) in data points completed in the smartphone application condition compared to the SMS group, with the smartphone application group completing 69% of entries, (mean = 16.5), compared to the SMS condition (56% of entries, mean = 13.5). There was no significant difference in PANSS scores across the domains, hallucinations anxiety, grandiosity, delusions, paranoia and hopelessness.

Cognitive Functioning

The study by Dang et al., (2014) examined cognitive functioning and used the N-Back task to assess cognitive functioning. In addition, the Wechsler Memory Scale-Revised (WMS-R) and full versions of the Wechsler Adult Intelligence Scale-Revised (WAIS-R) were administered to all participants at baseline. The results showed that patients in the experiment group improved significantly in accuracy rate at 2-back ($Z = -3.27$,

Pcorrected ≤ 0.01), and reaction time in 0, 1 and 2-back ($Z = -2.89$, Pcorrected = 0.012; $Z = -2.60$, Pcorrected = 0.048; $Z = -2.98$, Pcorrected = 0.012, respectively) from baseline to week 4, as compared with those in the control group. In addition, Montes et al., (2012) also looked at cognitive functioning and reported improvements in negative symptoms (Baseline=3.3 vs 3 months= 3.5) and cognitive symptoms (Baseline=3.3 vs 3 months= 3.5) $P < 0.05$, in the IG compared to the CG group on the Severity of illness subscale of the Clinical Global Impression-Schizophrenia Scale (CGI-SCH-SI).

In contrast, the study by Pijnenborg et al., (2010) looked at the efficacy of SMS based prompts to compensate for cognitive impairments in schizophrenia. This was done through SMS based prompts aimed at improving their everyday functioning through setting goals. Pijnenborg et al., (2010) reported that the mean success percentage was 47% across all the goal categories during baseline (SD 27.9), which increased to 62% during the intervention (SD 20.1) and reduced to 40% at follow-up (SD 31.7).

Engagement with mHealth technology

Kasckow et al., (2016) looked at monthly adherence to the Health Buddy system which was reported to be 83% ($n=20$), 92% ($n=19$) and 89% ($n=15$) for month 1, month 2, and month 3 respectively. Adherence rates were calculated monthly by adding for each participant the number of days they filled out the questions divided by the number of days the participants were in the study that month. Both groups exhibited improvement in suicidal ideation. The Health Buddy group BSS score reduced from 9.8 (SD = 6.15) at baseline to 2.44 (SD = 5.52) at endpoint, whilst the control group score reduced from 10.7 (SD = 8.24) at baseline to 2.88 (SD = 6.71) at endpoint. No group differences were found when examining time to remission (defined as having a BSS score = 0), however for the subgroup of participants who had a life time history of suicide attempt, a trend for a higher rate of remission at the 3 month period for those in the Health Buddy condition (16/18) was found, as compared with those in the ICM condition (14/19; log rank=2.82; $df=1$; $p=0.093$). No significant differences were detected between groups in scores on Calgary Depression Rating Scale, Hamilton Depression Rating Scale, Scale for Positive Symptoms and Scale for Negative Symptoms were found. However, in contrast it was reported in the Spaniel et al., (2008) study, that despite the fact that over the study period 17,082 SMS messages were sent by participants, the authors reported the study to be largely unsuccessful, due to poor adherence by investigators to the protocol. They reported that only 39% of participants received an increase in antipsychotic medication in response to increased scores on the EWSQ (Spaniel et al., 2008).

Feasibility and Acceptability

One of the main results of the included studies was the feasibility and acceptability of the mHealth interventions. Montes et al., (2012) concluded that due to the ease of implementation, using mobile phones to prompt medication was feasible and acceptable. In addition, Ainsworth et al., (2013) reported that mobile phones and smartphones were acceptable forms of technology, however there was a greater preference by participants to a smartphone App compared to a mobile phone. It was reported that participants took longer to complete each entry in the SMS condition (325.5 seconds SD145.6) compared to the smartphone App condition (68.4 seconds SD39.5). Overall 67% of participants preferred using the smartphone App compared to 13% who preferred SMS, whilst 21% of individuals had no preference on the delivery method. Furthermore, it was reported that 71% of participants found using the smartphone App easier than the SMS delivery modality, 17% found the SMS condition to be easier and 13% had no preference (Ainsworth et al., 2013).

The studies that used mobile phones were primarily used for the sending and receiving of SMS messages. These mobile devices had basic functionality such as voice calling, gaming, alarm, SMS and vibrate alerts (Pijnenborg et al., 2010; Spaniel et al., 2008; Montes et al., 2012). The studies also reported positive evaluations of using mobile phone based interventions. Pijnenborg et al., (2010), found that the 70% of participants viewed the SMS intervention as positive, 20% were neutral and 10% held negative views (Pijnenborg et al., 2010). In addition, Pijnenborg et al., (2010) reported that 41% of the participants found the intervention effective, 33% were neutral and 26% evaluated the intervention as ineffective. However, in contrast, Spaniel et al., (2008) reported that feasibility could only be gauged once there had been acceptance of computerised methods and a change in clinical thinking.

In addition, feasibility of the Health Buddy system was examined over a 3 month period, with 20 of the 25 participants able to set up the Health Buddy system (Kasckow et al., 2016). Of the 25 participants, it was reported that four individuals required some assistance with setting up the Health Buddy system. A number of reasons were reported for the five participants who did not set up the device, such as permission from landlord, substance misuse, cognitive impairment, phone company debt and transportation problems. In addition, Kauppi et al., (2015) reported that participants preferred messages at the beginning of the week. It was suggested that individuals preferred messages early

in the morning and in accordance to a working week format, running from Monday to Friday.

Health Inequality Considerations of mHealth interventions

From the HIAT assessment carried out in chapter 3, I examined factors relating to health inequalities such as access to mobile technology for those taking part in the included studies. The mobile phones were primarily used for the sending and receiving of SMS messages (Montes et al., 2012, Spaniel et al., 2012, Pijnenborg et al., 2010, Spaniel et al., 2012). These studies also reported positive evaluations of using mobile phone based interventions. Pijnenborg et al., (2010), found that the 70% of participants viewed the SMS intervention as positive and only 10% held negative views. These findings are important and demonstrate that even the simple mobile devices can be used for offering interventions using functions such as SMS alerts, voice calling or alarms. This is relevant for areas where access to smartphones maybe limited, such as areas high in deprivation where access to mobile devices with basic functionality is more common. In regard to connectivity, the Montes et al., (2012) study, used a system which provided the investigators with information pertaining to whether the participant had a mobile phone signal. In the study by Ainsworth et al., (2013), which was conducted in the UK, participants were given a smartphone for the purposes of the study. However, in the SMS study condition participants received questions on their own mobile phones. A similar procedure was also used in the Pijnenborg et al., (2010), with a total of 30 participants given a basic mobile device (Nokia 8310 or 8210) and a total of 24 participants using their own mobile phone in the study. Devices were also provided to participants in the Dang et al., (2014) and Kasckow et al., (2016) studies, highlighting important data on the access to mHealth technologies.

Risk of Bias Assessment

I used the Cochrane collaboration risk of bias instrument (Higgins et al., 2011) to measure the risk of bias in the assessment of quality of the trials (see Figure 4.2). Only one study had low risk of bias (Spaniel et al., 2008). All studies included were randomised trials, however, one was a quasi-randomised trial (Pijnenborg et al., 2010). Three of the studies described an appropriate method to generate the sequence of randomisation or gave the details, however the method used in the Pijnenborg et al., (2010) was scored as high risk. All studies gave the details of withdrawal and dropout rates. Ainsworth et al., (2013) did not report the PANSS outcome measures highlighting a risk of bias when reporting data on outcomes used in their trial. The study by Dang et

al., (2014) indicated that the methods of the study were described in an earlier paper (Lu et al., 2012), however it was unclear as to what methods of randomisation and allocation to treatment arm were employed highlighting a risk of bias.

Figure 4.2: Risk of Bias Assessment Diagram

Ainsworth et al., 2013	+	+	-	-	-	+	-
Dang et al., 2014	?	?	-	?	-	+	+
Kasckow et al., 2016	?	?	-	-	+	+	-
Kauppi et al., 2015	+	+	-	+	+	+	+
Montes et al., 2012	+	-	?	?	-	+	+
Pijnenborg et al., 2010	-	-	-	-	+	+	-
Spaniel et al., 2012	+	+	+	+	+	+	+

Key	
Low Risk	+
High Risk	-
Unclear	?

<i>Random Sequence Generation</i> <i>Allocation Concealment</i> <i>Blinding of Participants and personnel</i> <i>Blinding of Outcome Assessment</i> <i>Incomplete Outcome Data</i> <i>Selective Reporting</i> <i>Other Bias</i>

4.4 Discussion of systematic review findings

The systematic review conducted was the first to look at mobile device interventions for the treatment and assessment of psychosis and had a focus on how future research can inform the use of mHealth technologies to increase access to treatments for SMI such as psychosis both in the UK and globally. Previous reviews have focused on telehealth, web based and Internet interventions (Stafford et al., 2013; Alvarez-Jimenez et al., 2014). However, these reviews investigated a range of differing delivery systems such as through the Internet and telephone based landlines. Considering the increasing access to mobile devices globally, mHealth may potentially increase access to appropriate mental health care for individuals with SMI's.

In view of the limited literature on the subject, the findings of the review could only help to comment on feasibility and acceptability of the mHealth interventions. Most studies

found that mobile based interventions were feasible. Overall, it appeared that the strongest evidence found, was related to mHealth technologies for medication adherence. Kauppi et al., (2015) and Montes et al., (2012) found that using mobile phones to prompt medication was feasible and acceptable. Similarly, Kasckow et al., (2016) reported no significant difference in the clinical measures between the groups, however qualitative analysis of end-point surveys revealed a mainly positive response from participants in the Health Buddy condition with participants describing the program as effective in terms of improvement in medication adherence, and symptom reduction for anxiety and depression.

The included studies reported a variety of outcomes. These included treatment adherence (Montes et al., 2012), social functioning, (Pijnenborg et al., 2010), mobile text messages preferences for people on antipsychotics (Kauppi et al., 2015), experiential sampling (Ainsworth et al., 2013), cognitive impairment (Dang et al., 2014) relapse prevention (Spaniel et al., 2016) and suicidal ideation (Kascow et al., 2016). This combined with limited literature on the subject means that it is not possible to have any definitive findings on the effectiveness of mHealth based interventions in improving these outcomes. There was an increase in medication adherence; Montes et al., (2012) study, and Pijnenborg et al., (2010) reported improvement in social functioning. This is consistent with literature in other branches of medicine (Yellowlees, 2003), where mobile devices have successfully been used to improve adherence.

The mobile phones were primarily used for the sending and receiving of SMS messages. (Pijnenborg et al., 2010; Spaniel et al., 2008; Montes et al., 2012). These studies also reported positive evaluations of using mobile phone based interventions. Pijnenborg et al., (2010), found that the 70% of participants viewed the SMS intervention as positive and only 10% held negative views (Pijnenborg et al., 2010). Although the majority of studies provided smartphones to participants or the use of participants own, phone to receive SMS messages. These findings are important and demonstrate that even a simple mobile device can be used for interventions, which utilise functions such as SMS alerts, voice calling or alarms. This is relevant for low resourced settings, where large populations may have access to mobile devices with basic functionality such as in the rural areas of the North West coast.

However, it must be noted that, delivery of assessment questions in the Ainsworth et al., (2013) study utilised either a mobile App or SMS text messages. It was reported that participants took longer to complete each entry in the SMS condition compared to the

smartphone Application condition. Overall 67% of participants preferred using the smartphone Application compared to 13% who preferred SMS. This may suggest factors such as usability and user experience may be key factors in ensuring a user friendly medium to deliver mHealth intervention, which goes beyond basic SMS messaging.

An innovative use of mHealth is the real-time assessment of psychosis using an ESM methodology, which was conducted by Ainsworth et al., (2013). The study was based on the mHealth interventions engaging with participants in real-time. Research, in the real-time assessment of psychosis has been conducted by Myin-Germeys et al., (2009) who described the method as ESM. The method looks at the differing moods, thoughts and psychotic symptoms of individuals which occur in their day to day lives. The method is used to construct an understanding of individual's psychotic symptoms with a view to understanding the aetiological underpinnings of psychosis in the real-world context (Myin-Germeys et al., 2003). Methods such as experiential sampling provide greater insight into SMI's, constructing a picture of individual's experiences of psychosis in day-to-day life. These uses, however, need to be evaluated in larger well designed studies.

The utility of mHealth has been shown in number of Non-Communicable disorders globally. For example, Piette et al., (2010) reported that mobile technologies can be used effectively in self-management of hypertensive patients to improve outcome. Tran et al., (2012), investigated teleconsultation with a software-enabled mobile telephone for common skin diseases by a dermatologist, where it was found that mobile technology enabled greater access to dermatological expertise where access is limited. It may be possible to employ these methodologies for providing teleconsultations with mental health professionals, in areas where there is limited access to specialist mental health care. This potentially may be of huge benefit to those individuals who live in remote or rural areas and areas of high deprivation. Similarly, it may be possible to employ the cheap and widespread use of SMS messages for public health interventions such as reducing stigma associated with psychosis.

Limitations of the systematic review

The major limitation of the present review is that I was only able to identify 7 studies with relatively small sample sizes. It is unlikely that I missed any studies as I used a comprehensive search strategy. However, the limited literature shows that it is possible to design and conduct studies using mHealth interventions for improving treatment adherence, monitoring symptoms, and social functioning. Although this data is useful in providing evidence on the feasibility of mHealth, and the potential benefits and

applicability of mHealth for psychosis, however this has not been properly evaluated. Furthermore, I was unable to find studies, which examined at both the assessment and treatment of psychosis, using a Randomised Controlled Trial (RCT) design. This is important, as interventions which can provide assessment and treatment for psychosis in real-time; such as the study by Depp et al., (2010) can be hugely beneficial to individuals with severe mental illnesses particularly in low resourced settings.

A further limitation of the review was that I did not register the systematic review protocol on PROSPERO, which is a database of prospectively registered systematic reviews. This is an important part of conducting evidence synthesis work as it provides an audit trail of the original plans for a systematic review and safeguards against reporting bias and most importantly can inhibit the duplication of work (Booth et al., 2012). In addition, due to the scarcity of research in the area and limited number of trials found, I did not contact authors to locate missing full text manuscripts. This is an important point for consideration, due to the considerable time lag between research and its publications, relying solely on published papers may have resulted in the exclusion of relevant work (Pappas & Williams, 2011). Although I did search the grey literature using the same search methods employed in the other databases, it has been reported that there is no 'gold standard' for systematic grey literature searching (Godin et al., 2015) and thus my search strategy may not have been able to locate the relevant grey literature.

Finally, another important limitation was that I only included papers which described trials of mHealth interventions, as the aim of the review was to search the literature to see whether any trials had been completed which described mHealth for psychosis. I excluded other study designs such as qualitative studies and feasibility studies from the review, which would have potentially provided important data on the views and perspectives of mHealth technologies and factors related to feasibility study design. In addition, I only included studies, which were published in the English language; this could have been a limitation of the review as I may have excluded relevant papers, which were in other languages. Broadening the search criteria to include different language articles and studies with both qualitative and feasibility studies, may have increased the number of articles found and would have improved the methodological robustness of the systematic review.

4.5 Chapter 4: Summary & Conclusion

This chapter has presented findings from my systematic review of research into mHealth interventions for psychosis. Such research has taken place in a context where the relative burden of mental health disorders is increasing globally, in terms of prevalence and disability. There is limited data available to guide treatment choices for clinicians in low resourced settings, with mHealth technologies being a potentially beneficial avenue to bridging the large mental health treatment gap globally. The aim of the review was to search the literature systematically for studies of mHealth interventions for psychosis globally. A systematic literature search was completed in Embase, Medline, PsychINFO and Evidence Based Medicine Reviews databases from inception to May 2016. Only studies with a Randomised Controlled Trial (RCT) design, that investigated an mHealth intervention for psychosis were included. A total of 5690 records were identified with 7 studies meeting the inclusion criteria. The majority of studies were conducted across Europe and the United States with one being conducted in China. The 7 included studies examined different parameters such as experiential sampling methodology, medication adherence, cognitive impairment, social functioning and suicidal ideation in veterans with schizophrenia.

One of the PPI members was actively involved in the systematic review, examining the content of papers alongside myself, contributing to critical discussions, and meriting co-authorship of the relevant published paper (Appendix 2). Other service users became involved at the stage of acting upon the findings to inform the development and refinement of the App. The objective of this part of the research was to conduct a systematic review of existing mHealth interventions for psychosis to further develop the TechCare intervention taking the social detriments of health into consideration. The key findings of the review are summarised below in Table 4.2, with reference to how these findings were drawn upon to inform the development and refinement of the App.

Table 4.2: Key Findings of the Systematic Review

Key Findings of the Systematic Review	Refinement of the TechCare App
mHealth was found to be most commonly used for medication adherence (Kauppi et al., 2015; Montes et al., 2012; Pijnenborg et al., 2010)	Messages relating to medication reminders could be added on the App
Real-time monitoring of symptoms, using ESM (Ainsworth et al., 2011)	I used the assessment questions, validated by Ainsworth et al., (2011) in the ClinTouch trial.
Some participants may not have access to a smartphone, therefore as part of the Ainsworth et al., (2011) study a loan phone was provided	Participants who did not have access to a smartphone, would be provided with a smartphone for the duration of the study.
SMS messaging was found to be a beneficial means of communication and intervention delivery	The App would allow participants to communicate via SMS to preselected contacts based on participant preference.
Participants in the studies were able to set their own goals (Pijnenborg et al., 2010)	The App was refined to add goals which were set by the participant in conjunction with their care coordinator.
Inclusion of psychoeducation (Kasckow et al., 2016)	Psychoeducational information developed by Kingdon and Turkington (1998), was available to access on the App home screen.
Intensive case monitoring (Kasckow et al., 2016)	I refined the App to include the participants crisis plan
Managing daily activities (Kauppi et al., 2015)	The App was developed with components of behavioural activation, with participants being able to add activities that they enjoyed doing.
Technical support for participants (Montes et al., 2012; Ainsworth et al., 2011)	I was the main contact for any difficulties encountered by the participants

Overall as highlighted, although I looked to ensure robustness of the systematic review methodology there were some limitations, of particular importance was the limited number and quality of studies found, with only one study (Ainsworth et al., 2011) examining the assessment of psychotic symptoms in real-time. This in its entirety is an important result as it provides an indication of a gap in the research and a rationale can be built that the next logical step for the TechCare project would be to develop and feasibility test an App to deliver a real-time therapeutic intervention as well as assessment within the iRTT conceptual model. This in turn would both increase the evidence base for mHealth technologies for psychosis but also allows for the feasibility evaluation of the iRTT conceptual model.

CHAPTER 5: METHODOLOGY

The following chapter will provide a detailed account of the methodology, which was used to conduct the feasibility study of the TechCare App. This takes into account the philosophical worldview, which provided the grounding for the study. The rationale for taking a pragmatic philosophical view is presented with the study using a mixed method approach, thus utilising both qualitative and quantitative methods of research. The research also had a core participatory component, enlisting the expertise of key stakeholders throughout the design and implementation of the research methodology. A version of this chapter was published in SAGE Open Medicine (see Appendix 3).

5.1 Mixed Methods in Health services Research

In addition to the distinct methods required to conduct research we have to take in to consideration of the wider philosophical assumptions that underline the research. Crotty described these philosophical worldviews as epistemologies and ontologies (Crotty 1998) however; other authors have referred to these as 'broadly conceived methodologies' and 'paradigms' (Lincoln, Lynham & Guba 2011). In contrast, I will describe these epistemologies as described by Creswell (2014) as philosophical worldviews. This takes in to account the description given by Guba (1990) who suggested that the key to preparing or planning any research was to be mindful of the philosophical view taken when deciding on the specific method that will be employed in the research.

Furthermore, Creswell (2014) suggests that it is important when conducting research; particularly in the planning phase of a study, that the following considerations should be taken into account. Firstly, the philosophical worldview assumptions that are brought to the study, the design of the research which is connected to this philosophical worldview, and the particulars of the procedures of the research translated to the approach in practice. In the research process, the declaration of philosophical view tends to be lacking in the majority of cases, with the underlying philosophical ideas not always present despite being referred to as the foundation of the research process (Creswell, 2014). Crotty (1998) provided a description of four elements, which came together in providing the rationale for undertaking social health research. This taking into account the method, methodology, the theoretical perspectives and the epistemologies that inform these perspectives. Bringing these core factors together enables researchers to outline a unified approach to delivering the research. However, as Crotty (1998) explains, within

the social research context the differing approaches, which I will discuss further on in this section tend to be clumped together, despite for all intent and purposes not being entirely comparable (Crotty 1998). Rather each are elements, which inform each other in a constructive manner. Taking this in to account, and as described by Creswell 2014, it is important to outline explicitly the larger philosophical worldviews when developing a research proposal to employ the most appropriate epistemological approach to the research.

There are a number of philosophical worldviews, which are described by Creswell (2014) as being well established in the literature. The key approaches I will discuss, related to social research are post-positivism, constructivism, and pragmatism. Each of these provide a particular philosophical view to the research context and can thus help in determining the most appropriate research methodology to employ. Firstly, I will discuss post-positivism, which is based on the notion that we can measure reality in a quantifiable manner, and that as a result inferences can be made in relation to whether a theory is correct or incorrect through a process of gathering data (Creswell, 2014). Some of the key considerations of post-positivism is that that the knowledge gathered through research is fallible. Hence, as Karl Popper (1959) discusses, the truth advocated by our research is just our belief in the truth of our tested hypothesis (Popper, 1959). Furthermore, Ernst (1994) suggested that through the principle of falsification we can never prove scientific theory, with Popper similarly claiming, “every scientific statement must remain tentative forever” (Popper, 1959). This philosophical worldview of research is particularly associated with quantitative research, allowing for theory verification through empirical observation and measurement. However, this philosophical worldview has its weaknesses, as it was developed to gain an understanding of the natural world, thus has limitation when gaining an understanding of the social aspects of reality (Scotland, 2012).

The second philosophical worldview that I will discuss is the constructivist worldview, this epistemological approach to research is based on interactions between individuals within society and the inference that phenomena can be constructed through experiential subjective discourses. Thus reality is constructed through language which shapes and moulds reality (Frowe, 2001). Crotty (1998) described constructivism as primarily based on the generation of meaning through social interaction with humans within a community. With the data gathered in the field being used in an inductive manner to generate meaning from the data collected. The constructivist worldview is more commonly denoted as an approach to qualitative research methodologies. Limitations due to the

subjective nature of the data gathered may not be entirely reliable (Creswell, 2014). Subjective experiences can differ from person to person, thus reaching consensus and inferring generalisability can be problematic (Scotland, 2012).

Finally, I will now discuss the pragmatic worldview, which arises from the understanding of actions, situations and consequences within a real-world context (Creswell, 2014). The main aspect of a pragmatic worldview is the application of, and solutions to problems (Patton 1990). Instead of focusing on a particular methodological approach, a pragmatic approach would utilise all viable methodological approaches to answer the research question (Creswell, 2014). Tashakkori & Teddie (2003) have highlighted the importance of mixed methods research. As there is a greater focus on the problem being investigated within social science research, through generating all sources of knowledge available to derive such knowledge. The methodological approach most commonly associated with pragmatism is mixed methods.

On critique of the differing philosophical worldviews, which were an important factor in formulating my methodology and provided grounding for the research methods that I used to answer my research questions. As I have described above post-positivism holds truth accountable to quantifiable observable measures. However, my study aims were more directed to examining the feasibility aspects of the TechCare App, hence the post-positivist worldview did not apply to my research in this context. Furthermore, although constructivism does investigate the natural interaction between individuals within society through discourse, it lacks the quantitative variables which would help in answering my research question. Particularly, the recruitment and retention rates, which would be crucial indicators of feasibility. It was therefore decided that the most appropriate philosophical worldview, which would help in answering the research question would be by taking a pragmatist worldview. As the combination of both qualitative and quantitative methods, would be most viable in answering my research questions. Andrew and Halcomb (2007), have described mixed methods in nursing and health care research as a 'comprehensive, new epistemological position' which views mixed methods as existing on a continuum (Andrews & Halcomb 2007; Foss & Ellefsen 2002). The philosophical basis of the mixed method approach has been suggested to be more commonly aligned to pragmatism (Johnson & Onwuegbuzie 2004; Tashakkori & Teddlie 2003). Pragmatists hold the view, that the specific research question is more important than either the philosophical basis of the methods of data collection method. Therefore, pragmatism infers that if combining qualitative and quantitative methods is the most appropriate

means of elucidating the answer to the research question, then a 'mixed method' approach is justified (Johnson & Onwuegbuzie 2004; McAuley et al. 2006; Morse, 2003).

Purely evaluating an intervention through quantitative methods may result in a number of errors, such as measurement errors, measurement bias and limitations on the generalisability of the findings. The addition of qualitative methods provides a further dimension to gaining an understanding of the phenomena being investigated (Leech & Onwuegbuzie, 2009). In the past, combining methods such as qualitative and quantitative methods in one study, was called 'between-method triangulation' (Halcomb & Andrew 2005). However due to criticisms around the misuse of the term (Tashakkori & Teddlie 2003), there has been a need for a more concise terminology, which provides a clear description of the methods used. This approach to research using both qualitative and quantitative components is now more commonly known as 'mixed methods research' (Andrew and Halcomb, 2007). However, it has been highlighted that research utilising mixed method approaches exist along a continuum from purely monomethods to fully mixed method designs (Onwuegbuzie and Johnson, 2004). In addition, the procedural aspects of conducting mixed methods studies have been shown to follow a particular format. The mixed methods design can be conducted, either concurrently, whereby one stage of the research may use one particular methodology (either qualitative or quantitative) or sequentially where both qualitative and quantitative components of the research are conducted simultaneously (Leech et al., 2009). Forming a categorisation of a studies mixed methods design, has been reported to have its own challenges such as, to what extent is the study actually 'mixed' and where on the mixed methods continuum does the research design lie (Small, 2011).

Furthermore, despite a lack of consensus on the definition of 'mixed methods design' (Smith, 2008; Paluck, 2010), the key factor in determining the research design of a study, is the alignment of the methodology to the research questions and the general orientation to the phenomena being investigated (Small, 2011). However, conducting mixed methods research can be difficult, due to factors such as, which methodological approach holds greater weight, and issues relating to how the results of each of the approaches are connected and integrated into the research (Ivankova, Creswell & Stick 2006).

It is therefore important to note the typology of the mixed method approach used, to ensure that the study being conducted as part of my thesis was 'mixed methods'. Based on this it was evident that a sequential mixed method approach would not necessarily

provide a robust evaluation of the feasibility of the TechCare App. I decided that rather than a sequential exploration of the TechCare intervention, a concurrent approach would enable both methodologies to be conducted simultaneously. Thus contributing to the evaluation, of each of the stages of the research. The underlining philosophical basis to the study was based on pragmatism, as the TechCare App was being evaluated within a mental health service and therefore provided a basis for a workable solution to the research question, as it would be conducted within the real-world environment of the Early Intervention Service. Furthermore, the need for combining the differing approaches to data collection and analysis is based on practicalities and provides an explicit purpose for the mixed methods employed. The pragmatist view accepts, that the research is located within social, historical, political, cultural contexts, and holds more bearing on the research question and phenomena being investigated, rather than the methods or paradigm being used (Andrew & Halcomb, 2007).

5.2 Study Aims & Objectives

The aim of the project is to develop and conduct a feasibility study of the mobile phone Application 'TechCare' for individuals with psychosis in the North West of England.

The specific objectives of the research were to:

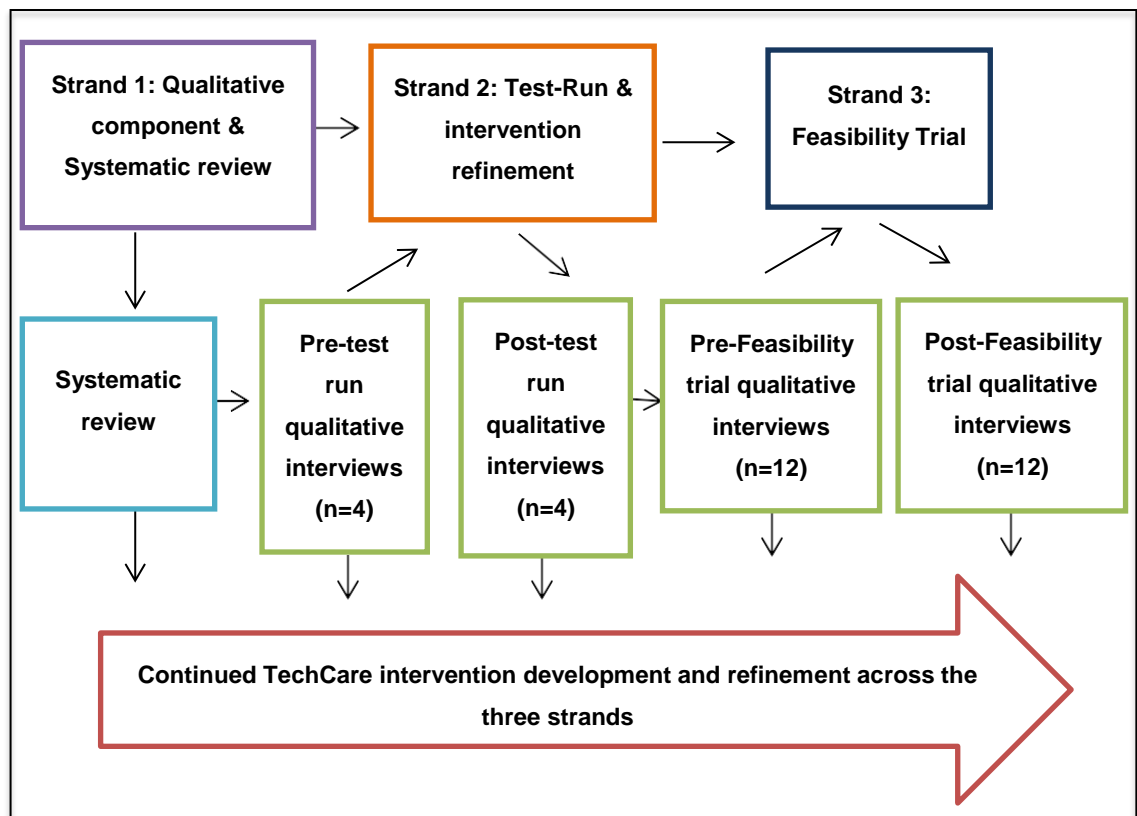
- 1) Conduct a synthesis of evidence through a systematic review of existing mHealth interventions to further develop the TechCare App intervention, taking into account the social detriments of health.
- 2) Explore the views and perspectives of health professionals and service users on the acceptability of the design and procedures, and to what extent do these need refining for the feasibility study by specifically examining;
 - a. The opinions of health professionals, on how to best deliver the TechCare App intervention within the Early Intervention service
 - b. An understanding of the challenges to delivery of the TechCare App and the possible refinements to overcome these challenges
 - c. The experiences of services using the TechCare App to assess feasibility and acceptability
 - d. Opinions on how digital technologies can help those with mental health difficulties overcome mental health inequalities

- e. A better understanding of barriers to access to services for those with mental health difficulties
- 3) Compile follow-up data to examine recruitment and retention rates to the feasibility trial
 - 4) Analyse preliminary data to provide grounding for a future larger scale Randomised Controlled Trial
 - 5) Determine the feasibility and acceptability of the intervention

5.2.1 Design

This feasibility study followed the NIHR guidance on feasibility study design (NIHR, 2014) and consisted of both qualitative and quantitative components. Feasibility studies are conducted prior to conducting large studies in order to assess whether the study can be done. Vital parameters are examined that are needed to design the main trial. The study ran across three strands as follows 1) Systematic review and Qualitative work, 2) Test-run and Intervention refinement and 3) Feasibility study (see Figure 5.1 below).

Figure 5.1: Flow diagram of study strands



5.2.2 Feasibility Studies

In the initial design of my PhD project, I referred to guidance set out by the NIHR on the design of feasibility studies. The majority of existing research, investigating psychosocial interventions is evaluated based on the current MRC framework for the evaluation of complex interventions (MRC, 2000). This primarily consists of feasibility and acceptability testing as a precursor to conducting a phase III effectiveness trial. In this context 'Complex Interventions' have been defined by Oakley et al., (2006) as being those interventions which do not include drug or surgical treatment, however consist of numerous components or 'active ingredients' (Oakley et al., 2006; Campbell et al., 2000). Previous attempts at defining feasibility studies have resulted in difficulties in gaining a consensus definition of feasibility studies, with many researchers using feasibility and pilot studies interchangeably.

Bowen et al., 2009, assert that feasibility studies are required to produce a set of findings, which can help in drawing inferences on whether an intervention should be recommended for efficacy testing. Lancaster (2015) reported that the objectives of pilot or feasibility studies should be different to those of the definitive trial, and that they should aim to reduce uncertainties around the design and development of the future definitive trial. Guidance on this has also been given by Tickle-Degnan (2013) as follows:

'The outcomes of most feasibility and pilot studies should be measured with descriptive statistics, qualitative analysis, and the compilation of basic data related to administrative and physical infrastructure' (Tickle-Degnan, 2013)

Bowen et al., (2009), make the recommendation that feasibility studies should focus on eight areas (Bowen et al., 2009). These are; acceptability (are the target population accepting of the intervention), demand (usage of the intervention in the population or clinical setting), implementation (whether the intervention is implementable), practicality (whether the intervention is deliverable even in low resource settings), adaptation (is the intervention adaptable to differing clinical groups and settings), integration (what changes are required to integrate a new program or process into an existing infrastructure), expansion (the potential success of an already-successful intervention with a different population or in a different setting) and Limited-efficacy testing (most feasibility studies test an intervention in a limited way). Bowen et al., 2009 also suggest three vital questions in designing feasibility studies, (1) Can it work? i.e., is it feasible and acceptable, (2) Does it work? i.e. does it work under the ideal conditions, and finally (3), Will it work? that is testing the intervention in real life settings.

NIHR Guidance on Feasibility Study Design (2014)

The NIHR has also outlined key areas of focus relating to feasibility studies, with the main reason for the conduct of feasibility studies to ascertain prior to completing a full trial “Can this study be done?” Feasibility studies thus provide vital parameters, which allow estimates to be made relating to the design of the main study. The following parameters are taken from the NIHR guidance on feasibility study design.

- Standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- Willingness of participants to be randomised;
- Willingness of clinicians to recruit participants;
- Number of eligible patients; carers or other appropriate participants;
- Characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCS in cluster trials, etc.
- Availability of data needed or the usefulness and limitations of a particular database; and time needed to collect and analyse data.

However, in real life, feasibility of psychosocial intervention is usually assessed through recruitment, retention and engagement, while acceptability is measured through feedback from participants and professionals regarding their experience of the intervention. Participants, at the end of the new intervention are typically asked to describe their experience, usually using qualitative methods. It is important to note that the data compiled and reported in my PhD project, took these considerations into account and followed guidance set by the NIHR (2014). I will describe the data collected through basic descriptive statistics, in-depth qualitative analysis and assess the procedural aspects of the study to ensure feasibility and acceptability for a future definitive randomised controlled trial. It is also highlighted by Degnan-Tickle that feasibility studies themselves do not require large sample sizes, as the aim would not be to conduct statistical hypothesis testing. This brings us to considerations of the sample size and the potential feasibility of randomisation. On the consultation with the Lancashire Clinical Trial Unit (LCTU), I was able to build a greater understanding on the

development of feasibility studies particularly, in relation to scaling up of the research work to a definitive trial. LCTU advice was that the project itself would be a feasibility study rather than a trial and that the purpose of my PhD project was to do an in-depth analysis of the TechCare App in preparation for a larger phase III effectiveness trial, with inbuilt feasibility pilot. Based on this the study became an in-depth analysis of the TechCare study, through investigation of feasibility factors such as descriptive statistics and qualitative data which would provide evidence to infer the feasibility and acceptability of the intervention.

5.2.3 Sample

The sample for the study was recruited from the East, Central and North Early Intervention service for Psychosis Teams (EIS) within an NHS Foundation Trust in the Northwest of England. At any one-time Lancashire, wide EIS teams are working with approximately 800 service users. Potential participants were volunteers who had already shown interest in the study, plus additional service users, carers and EIS case-managers who were invited to take part in the study. The participants, who would undergo Strand 2 and Strand 3, were individuals under the care of the EIS due to experiencing psychosis. I will now describe this sample in relation to the criteria for acceptance into the service.

5.2.4 Inclusion/Exclusion Criteria

The inclusion and exclusion criteria for the study was based on current service provisions for the Early Intervention Service for psychosis. The inclusion of participants from the 18-35 year old group, was based on the age range of service users accepted into EIS in Lancashire. To ensure informed consent and adherence to Good Clinical Practice in research, participants were only recruited to the study if they were able to provide fully informed consent and if a risk assessment had been completed by their case manager.

The risk assessment is routinely conducted by the EIS care coordinators for each service user and is recorded on the individuals care records. The risk assessment involves a formulation approach, based on a process of enquiry, which enables health professionals to understand the risk profiles of each service user. Risk assessment in this context looks at possible threats or hazards such as violence and suicide/self-harm behaviour, which are not fully understood and can thus only be forecast with uncertainty and a level of clinical judgement by the health professional (Department of Health, 2007). The 5P's formulation is used to elicit the problem (symptoms of psychosis), predisposing factors (past experiences/history), precipitating factors (triggers), perpetuating factors (on-going

difficulties) and protecting factors (factors which help in reducing risk) (Weerasekera et al., 1996). In addition to the 5P's formulation, complex scenarios are discussed within the multi-disciplinary team, taking a team approach to completing the 5P's risk formulation.

Based on the risk assessment and safety of the potential participants to enter the study, participants were assessed based on the following inclusion and exclusion criteria before acceptance on to the study.

Inclusion Criteria

- Each client must have been accepted into the Psychosis Group of the Lancashire Early Intervention service.
- Ages 18 – 35 years
- Medication stable for previous two months
- Clients must be currently stable-The Lancashire Early Intervention Team uses a traffic light system to indicate current symptomatology and risks of each client. For this study, I included only clients with a Green Light, signifying that they were currently stable
- A score of three or more on positive symptoms on the PANSS
- Minimum score of one on the Calgary depression scale

Exclusion Criteria

- Drug induced psychosis
- An acquired brain injury or learning disability
- Clients who are undergoing assessment, not formally diagnosed and accepted into the service
- Lacking capacity for informed consent
- Ultra-High Risk of developing psychosis group (i.e. Prodromal, not first episode)

5.2.5 Overall Project Timeline

The PhD project required a detailed understanding of the key milestones and timeline of the study. I had to take into consideration the differing strands of the study and develop a coherent work plan to ensure completion of the study to time and target. Putting this into context, Bower, Wilson and Mathers, (2007) have reported that one-third of trials in primary care have extended timescales due to recruitment delays. I ensured monitoring of timescales with my supervisory team to ensure the study was completed on time.

5.2.6 Overall Sample Recruitment

As part of the recruitment process, I contacted potential referrers (care coordinators, clinical psychologists and psychiatrists) at the NHS Trust EIS. I provided information about the study and requested the health professionals to share this with potential participants. In addition, information sessions were offered at the recruitment sites. If participants were interested and wished to be approached to receive further information about the research, a risk assessment was carried out with the service users care coordinator. This assessment informed the best way to approach participants. I also recruited health professionals such as care coordinators, clinical psychologists and EIS doctors from the NHS Trust EIS using a purposive sampling strategy, as I was seeking to maximise the range of views accessed. I left participant information sheets and consent forms with the clinical teams so that potential participants could contact myself directly. I also recruited participants via posters, which were distributed to the NHS Trust, EIS care teams with potential participants being recruited through their care coordinator/psychiatrists, as these health professionals would be able to ensure participant eligibility and safety for taking part in the study. A total of 16 qualitative interviews were conducted with service users who took part in strand 2 (test-run) (n=4) and Strand 3 (feasibility trial) (n=12). In addition, I also carried out two focus groups with 8-10 health professional (e.g., nurses, psychologists, psychiatrists, social workers). Interviews and focus groups explored feasibility, acceptability and the further development and refinement of the TechCare intervention.

5.3 Strand 1: Systematic review

As part of Strand 1, I conducted a systematic review; the aim of the review was to search the literature systematically for studies of mHealth interventions for psychosis globally, and to examine whether mHealth for psychosis has been investigated. The methodology and findings of the systematic review were presented earlier in chapter 4.

5.3.1 Strand 1: Qualitative component

The following section will outline the methodological aspects of the Strand 1 qualitative work, which was split into focus groups with health professionals and one-to-one participant interviews, pre- and post-intervention in Strand 2 and Strand 3.

5.3.2 Study setting and participant selection

The study took place in an Early Intervention service (EIS) within an NHS Trust in the United Kingdom. It was proposed that all the three EIS Spokes would be involved in this research, due to geographical and other diversities (ethnicity, transient populations), although all spokes work with service users experiencing First Episode Psychosis. The inclusion of all three teams, North, Central and East EIS would help provide rich data due to differing characteristics.

5.3.3 In-depth Interviews – service users

Service users who consented to participate in the study, were asked to take part in semi-structured interviews in order to obtain insight into their experience of using the TechCare intervention. The semi-structured interviews with the participants were digitally recorded and transcribed verbatim. I recruited 16 participants into the study, through permission from the participants, I was able to answer any questions or discuss any feedback with carers or family members. I also worked closely with health professionals who ensured that participants were safe to participate. The health professionals also worked with the participants and myself to develop appropriate brief, person-centred, guided, self-help interventions which were translated to the App.

A sample size of 16 was chosen as this reflected the number of individuals that would be taking part in both Strand 2 and 3. Ritchie, Lewis, & Elam (2013) have suggested that the sample size of a qualitative study is relatively small and do not tend to go over 50 participants. This is because there is a point where adding further data may not yield any new insights and evidence (Ritchie et al., 2013). Within the TechCare study 16 participants took part in Strand 1 (n=16) and 16 took part in Strand 2 and 3 (n=16) giving a total sample size for the qualitative component of the feasibility project of n=32. There are a number of factors, which I had to take into consideration when determining the sample size. Ritchie et al., (2013) suggested that the sample being investigated is a key indicator of the sample size calculation, as if the population is homogenous then there is a reduced need for diversity of views being accessed and thus data saturation is likely

to be gained with a smaller sample size (Ritchie et al., 2013). Furthermore, qualitative research can be intensive in terms of human resource (Ritchie et al., 2013), and increasing the sample size, could take significant timescales to collect and analyse the data, which in the case of the PhD project would not be feasible and attainable.

5.4 Focus Groups – Health Professionals

I conducted a total of 2 focus groups with a total of 16 health professionals (e.g., nurses, psychologists, psychiatrists, social workers), who work with service users who experience psychosis. The focus groups were digitally recorded and transcribed verbatim. The focus groups were based on a topic guide, which was developed by reviewing the literature. Drawing on the experiences and contributions from the advisory group, enabled me to explore fully issues of particular relevance to participants in each of the stakeholder groups. For example, with health professionals the focus might be on knowledge and beliefs about how to respond to their distress compared to the service users view of distress, conversely the case coordinators group may be related to delivery of the intervention in the EIS.

The focus groups each consisted of 8 participants comprising a variety of professionals ranging from psychiatrists, mental health nurses, social workers, low intensity, support worker's and mental health professionals. A fully written informed consent was obtained from all professionals to consent to be audio recorded. Once the interviews and focus groups were completed, they were fully transcribed in order to be analysed. From the audio recordings and field notes, I looked for themes emerging in areas of feasibility, the experience of using the App, acceptability and further development of the intervention through the use of qualitative Framework Analysis (Spencer & Ritchie 1994).

5.4.1 Recruitment Strategy for Health Professionals Focus Groups

Participants for the health professionals focus group were recruited through secondary care services in the Northwest of the UK, the EIS includes a multidisciplinary team, consisting of psychiatrists and mental health professionals, ranging from nurses, occupational therapists, psychologists and administrators. In order to meet the needs of a diverse clinical workforce, a purposive sampling (Luborsky & Rubinstein, 1995) strategy was used to ensure that a range of views were explored from the multi-disciplinary team. This was done to enable any further refinement of the intervention. Furthermore, to promote the study further in Lancashire, meetings were arranged with team leaders from the EIS. Individual psychiatrists/RMN's were invited to participate in

focus groups. Every opportunity for potential participants to contact me were explored. All participant information sheets and consent forms were provided to clinical teams for referral to the study.

5.4.2 Qualitative Research Method

Qualitative research focuses directly on the interpretation of the language expressed by participants, using an inductive process to form a conclusion, and to gather information (data) that will permit a conclusion to be formed. The aim of the study was to explore the perspectives and opinions of health professionals who provided care for service users within the EIS. A qualitative approach was adopted for data collection, which in return allowed me to gain an understanding of factors in relation to the development of the intervention itself. The spoken rhetoric was examined resulting in further understanding into the views of the health professionals.

The initial focus of this strand of the research entailed looking at the areas, which could be developed and refined further with the hope of enhancing the delivery of the TechCare intervention. The second key part of this strand of the research looked at the current service delivery, determining whether or not the TechCare intervention would be a feasible option for both health professionals and service users. Key questions highlighted were in direct relation to the challenges I may have come across when conducting the study along with the solutions to these challenges, with and aspects that could have been more refined, ensuring a more acceptable approach to the delivery of the intervention. An important factor in health service research is the acknowledgement and consideration of the opinions and viewpoints of key stakeholders, as it provides a unique perspective to the study within a real-life setting. In total, 16 participants took part in the focus group interviews.

There are a number of differing methods of conducting qualitative research such as Grounded Theory (Strauss & Corbin, 1998), which aims to develop theory through the process of examining the subjective experiences of participant's taking into account a more constructivist approach to building a conceptual understanding of the phenomena being investigated. Grounded theory lends itself to developing theory. In contrast, Framework Analysis lends itself to an inductive approach whereby the results emerge from the data and provide an understanding of the subjective experiences of an individual. Both methods of qualitative research have been used widely in many disciplines from psychology, medicine to sociology. The Framework Analysis was first developed in the 1980s and was primarily used in applied policy research (Ritchie &

Spencer., 2013). In deciding the most robust method to analyse the results of Strand 1, the process of Framework Analysis entails a structured process, which ensures an audit trail of the evidence, thus creating a favourable means of evidencing the research particularly for funding bodies.

5.4.3 Development of the topic guide

A topic guide was designed, with reference to previous research and in line with the project aims. I ensured the guide was flexible, allowing for maximum opportunities to explore open questions with participants. The topic guide was focused on understanding participants own perceptions, on their challenges and concerns, particularly the barriers and difficulties face when accessing appropriate treatment. This was developed in conjunction with service users and based on previous research in both evaluating feasibility studies of psychosocial interventions and from research in the area of eHealth and mHealth. The topic guide was further refined through discussions with senior researchers (supervisory team) and in line with the HIAT. The topic guide provided a structured approach to eliciting responses to questions, and as described by Whittaker (2009) prompted the natural flow of conversation. The topic guide was developed to help enable participants to provide their own subjective experiences of the TechCare App (see Appendix 6).

To ensure data credibility and to enhance the validity of the research the topic guide was reviewed by the PPI group members to ensure consistency and accuracy (Creswell & Miller 2000). An interview schedule (Creswell, 2007; Silverman, 2011) sets the likely questions in the most appropriate order that will encourage a purposeful conversation. The conversation facilitates the researcher's understanding into the subjective experience of the participants. The questions in the schedule were designed so that the interviews lasted a minimum of 45 minutes to a maximum of 90 minutes (Creswell, 2007).

The aim of qualitative research is to bring meaning to phenomena, rather than searching for truth, which tends to be the ultimate aim of quantitative approaches to research. This said within a mixed methods paradigm both methods complement each other and compensate for the limitations of each other. Therefore, it may be said that qualitative approaches are able to 'reach the parts other methods cannot reach' (Pope & Mays 2006), through providing an inductive means of gaining insight into the experiences of the participants within the given research context.

5.4.4 Data Collection

Data collected from the service user one-to-one interviews and focus group interviews was digitally recorded and transcribed. Data was analysed for emergent themes relevant to the development of TechCare App intervention across the one-to-one interviews and focus groups. The identified themes were also reviewed by the PPI advisory group ensuring that emergent, participant-generated themes were explored fully. Members of the service user groups also collaborated on the interpretation of the findings, to ensure they resonated with their knowledge and experience.

5.4.5 Data Gathering

Qualitative research also considers that purposeful conversations between participant and researcher will enhance the quality of the data gathered (Balls, 2009; Bryman, 2012). It is further considered, that a face-to-face semi-structured interview will facilitate this process (Bryman, 2012). Semi-structured interviews require that key questions are asked in the same way each time whilst permitting some flexibility in exploration of unexpected areas of information that are of interest to the research question (Smith et al. 2009).

5.4.6 Qualitative data analysis

Data obtained from the interviews and focus groups was transcribed. An analysis was completed to search for emerging themes, focusing on feasibility, acceptability and further development. These aspects provided information to develop the intervention further. Framework Analysis was used to analyse the data (Ritchie, Spencer, Bryman, & Burgess, 1994). The Framework Analysis started with the process of familiarisation, where data from all transcripts was read a number of times to gain an understanding and familiarity with the content the next stage of the analysis involved key Ideas and themes that were recurring being noted, with the final themes being compiled into a thematic framework. The process of Indexing (Srivastava & Thomson, 2009) was then carried to identify sections of the data that corresponded to a particular theme, in individual transcripts and then in the whole data set. This was followed by charting (Ritchie et al, 1994), whereby the indexed data was lifted from its original textual context and placed under the headings and subheadings drawn from the thematic framework. The final process included mapping, where all the data from the transcripts including the newly found themes and subthemes, were analysed and interpreted, under the supervision of

my supervisory team. Any discrepancies were discussed and resolved, and the final themes were read for congruence and reliability.

Each transcript was analysed and highlighted for recurring themes. Themes that were consistent across many of the transcripts, allowed me to compile sub-themes, often utilising smaller themes and combining these to give the final theme. Both the main themes and the subthemes were used to form the conceptual framework. All relevant data from the original manuscript, was then placed into these selected headings.

According to Silverman (2011), reading and re-reading the interview text is paramount to becoming familiar with the words and phrases used by the participants, so that vital statements about participant's experiences can be identified. Researcher notes can be written in margins of the text to identifying relationships between statements. These notes will help to pinpoint patterns and themes when linked to identified and agreed codes. Themes identified should then be grouped into units of meaning and collated into a table.

5.5 Strand 2: Test-Run & intervention refinement

As part of Strand 2, I completed a test-run of the TechCare intervention with a small group of four participants who I recruited from the EIS. This allowed me to preliminarily test the intervention. I also gathered feedback from the participating individuals, therapists and associated staff (psychiatrist/care coordinators) on the relevance and acceptability of the TechCare approach. This informed the further refinement of the intervention to the local NHS context and how best to run the TechCare intervention in the feasibility trial. I undertook semi-structured, one-to-one interviews with all participants in the test-run to obtain their opinions on the intervention, its feasibility, its acceptability, its impact on their lives and their thoughts about its ability to reduce symptoms of psychosis. All interviews were carried out by myself and were digitally recorded and subsequently transcribed.

The interview schedule included some pre-determined questions (based on the findings from Strand 1) and open-ended questions to facilitate the emergence of new themes. I investigated the acceptability of the treatment exploring participant's expectations of the intervention, its relevance to their psychotic symptoms, problems and social circumstances, their experience of the delivery method, what they found helpful or less helpful, and potential changes that could be made to improve their overall experience of the TechCare intervention.

5.5.1 Recording refinement/fieldwork data

All data pertaining to feedback on the TechCare App along with any technical difficulties which needed to be resolved by the software development team was recorded. This allowed me to keep a record of the ongoing feedback from the test-run part of the study. This was then utilised in consultation with the PPI team members to make any refinements to the TechCare App. Any technical difficulties were initially trouble-shooted by myself and if the problem could not be resolved, the Head Software Engineer would investigate and endeavour to resolve any technical difficulties.

5.6 Strand 3: Feasibility Study

As part of strand 3, 12 service users were recruited from the Lancashire Early Intervention Team for the feasibility trial. Each client's care coordinator played a key role in the development of the individualised Tier 1 psychological intervention. For the App, as mentioned earlier feasibility studies do not tend to consist of large sample sizes as outlined by Tickle-Degnan (et al., 2013). As a result, it was decided that although the sample size was small, it would provide an in-depth evaluation of the feasibility of the TechCare App which could then be evaluated in a larger definitive trial. There were a number of pragmatic factors, which I considered when determining the sample size of 12 participants for this strand. These were factors such as time constraints and the achievability of the study, considering I was the sole person conducting the research.

5.6.1 Outcome Measures

As part of Strand 3, feasibility study I selected a number of outcome measures which were used in previous research, in addition to routine measures currently being used within the EIS and IAPT for psychosis service in the UK. The rationale for this was that study outcome measures, were being implemented in current services. In addition to providing a pragmatic approach to evaluating feasibility with the current service context. The measures would be evaluated based on their feasibility and acceptability taking into account objective measures such as time taken to complete. The outcome measures were as follows:

PANSS (The Positive and Negative Syndrome Scale (PANSS) for Schizophrenia) (Kay, Fiszbein, & Opler, 1987) PANSS, is a clinician administered 30 item semi-structured interview which provides balanced representation of positive symptoms and negative symptoms over a two week period and gauges their relationship to one another

and to global/general psychopathology. The use of PANSS in mHealth interventions has been validated by Palmier-Claus et al., (2012) through the ClinTouch Application.

The Psychotic Symptom Rating Scales (PSYRATS; (Haddock, McCarron, Tarrier, & Faragher, 1999) The PSYRATS is a semi-structured interview measuring dimensions of delusions and hallucinations. The auditory hallucinations sub scale has 11 items (including frequency, intensity, duration, disruption and beliefs about origin and control) and the delusions sub scale has six items (including conviction, preoccupation, disruption to functioning and distress). All items are rated by the interviewer on a 5-point ordinal scale, higher scores indicate greater distress. This instrument has been validated against the PANSS by Drake et al., (2007).

Choice of Outcome In Cbt for psychoses (CHOICE) (Greenwood et al., 2010). This is an outcome measure, which reflects the aims of cognitive behavioural therapy for psychosis and the priorities of service users. It was developed with service users and this shortened version is utilised in the National Improving Access to Psychological Therapies (IAPT) for psychosis programme. Lancashire Care EIS is one of two national demonstration sites for the programme.

Warwick-Edinburgh Mental Well Being Scale (WEMWBS) (Tennant et al., 2007). The WEMWBS is a measure of mental wellbeing which focuses entirely on positive aspects of mental health. It consists of 14 items on one page, is quick to administer and is psychometrically robust (Stewart-Brown et al., 2009). It is also a core measure with the IAPT for psychosis project and measured potential improvements in positive aspects of mental health as a result of the TechCare mobile Application.

Brief Core Schema Scales (BCSS) (Fowler et al., 2006): This is a 24 item measure of core beliefs regarding self and others. Four scores are obtained: negative self, positive self, negative others and positive others. Fowler et al., (2006) found the BCSS to have good psychometric properties.

Calgary Depression Scale (Addington, Addington, & Schissel, 1990). The CDS was developed to measure the level of depression in schizophrenia. It is a nine item scale which allows for the quantitative and subjective dimension of depression in schizophrenia. Items are scored on a scale of 0-4 with a minimum score of 0 and maximum score of 27 for an assessment. The CDS is psychometrically robust and has been validated against the Hamilton Depression Scale (Schenach et al., 2012).

The Work and Social Adjustment Scale (WSAS) (Mundt, Marks, Shear, & Greist, 2002). This is a five-item measure of perceived impairment in five areas: work, home management, social life, private leisure and relationships. Each item is scored from 0 (no impairment) to 8 (very severe impairment) with a total score of 40.

EuroQoL-5 Dimensions EQ5-D - Health-related quality of life was measured using the EuroQoL-5 Dimensions (EQ-5D) (Sobocki et al., 2007). The measure is a standardised instrument looking at quality of life across five health domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The measure has been widely used in psychosis research.

The above assessment measures were chosen as they align with measures currently being used within the IAPT for psychosis demonstrator site. The EIS in the North West was one of the key demonstrator sites for the IAPT for psychosis programme. The rationale for using measures which are closely aligned to current practices provides a pragmatic approach to evaluating the feasibility of the TechCare App in terms of future integration into services. The outcome measures were determined based on feasibility and time taken to complete. The number of times the assessments are completed by the participants is highlighted in Table 5.1 below.

Table 5.1: Study Procedure & Outcome Assessments

Procedure	No. of times procedure completed	Duration of Procedure (Mins)	Description
Feasibility trial Consent form	1	5	I provided consent forms to participants, which were completed by participants, either at a trust base, voluntary organisation or at the participants' home.
Demographic Data Questionnaire	1	5	Demographic data was collected at baseline from each participant
Focus group	2	60	I facilitated the focus groups with 810 health professionals both pre and post intervention, the focus groups were held at a trust base lasting in the region of 45-60mins.
Qualitative Interview	2	60	Participants who took part in the study were invited to take part in a topic guided interview which lasted up to 60 mins. Participants took part in both pre and post intervention qualitative interviews
The Positive and Negative Syndrome Scale (PANSS)	2	40	The PANSS and PSYRATS were completed at baseline and end-of intervention (Week 6). Assessments were carried out at a trust or voluntary base, or in the home of the participant.
The Psychotic Symptom Rating Scales (PSYRATS)	2	30	
EuroQoL5 Dimensions (EQ5D)	6	5	The study questionnaire/ assessments were completed at baseline and then weekly across the 6 week study period. Assessments were completed at the trust or voluntary base, or in the home of the participant.
CHOice of Outcome In Cbt for psychosEs (CHOICE)	6	2	
Warwick Edinburgh Mental Well Being Scale (WEMWBS)	6	5	
Brief Core Schema Scales (BCSS)	6	5	
Calgary depression scale (CDS)	6	7	

5.6.2 Quantitative Analysis

As this was a feasibility study, no formal hypothesis testing was undertaken. To meet the objectives of the study, I aimed to recruit up to 16 service user participants. Data obtained

from the study was presented using summary statistics, which were used to define and compare the data (SD, mean, Confidence Intervals). One of the main objectives of this study was to gather preliminary data for the outcome measures in order to perform a sample size estimate for a larger definitive trial. In this regard, feasibility outcomes such as understanding the proportion of dropouts in the study would be a relevant indicator of feasibility and acceptability of conducting a larger definitive trial. All analyses were conducted in SPSS v20. The TechCare mobile psychological intervention ran over a 6 week therapy window period, and targeted a reduction of distress associated with psychotic symptoms, and strategies to improve low mood, adherence to medication, social functioning and the acceptability of the psychiatric assessments at different time points through analysis of means and standard deviations.

Preliminary analysis was performed to compare the baseline and post-intervention scores on the outcome measures. In the feasibility context, I investigated whether the TechCare App led to poorer outcomes and whether the post intervention scores were at least no worse than at pre-test. In addition to calculating recruitment and retention figures, the iRTT data gathered allowed for the analysis of participant responses and selection of interventions over the intervention period. Providing important insights into the feasibility of the iRTT system.

5.7 Defining the TechCare App Intervention

Treatment and relapse prevention in psychosis are considered a vital research area due to the considerable burden of disease. The prevalence rate of schizophrenia in England is reported to be 5 per 1000, with a projected figure of 243,931 individuals living with psychotic disorders by the year 2026 (McCrone et al., 2013). Evidence consistently suggests that CBT is effective in treating people with psychosis (Turkington et al, 2006; Trower et al., 2004). A number of meta-analyses (Rector & Beck, 2001; Zimmerman, Favrod, Trieu, & Pomini, 2005; Wykes et al., 2008) and a systematic review (Rathod et al., 2008) reported CBT with medication to be effective in the management of psychotic symptoms. CBT is commonly used for the treatment for early psychosis (Wykes et al., 2008), and is a recommended treatment for first episode psychosis, (National Institute of Health and Care Excellence (NICE), 2014). In the Early Intervention Service (EIS) Tier 1 CBT is delivered by all case managers who have undertaken the three day Psychosocial Intervention (PSI) training and is at the level of guided self-help interventions. These consist of understanding principles of recovery and hope, basic CBT thought-feeling-behaviour relationship, stress models, techniques for managing

mood, goal setting, SMART goals and relapse prevention. The overall intervention was informed by the work of Kingdon and Turkington (1994).

In accordance with NICE (2014) at least 16 sessions should be provided with self-monitoring of thoughts, feelings and behaviours and the therapist promoting alternative ways of coping with symptoms. Despite CBT being recommended by NICE (2014), the Schizophrenia Commission report (2012) found that only 10% of individuals that should have access to CBT interventions actually get access to it. Garety, Kuipers, Fowler, Freenman and Bebbington (2001) and Morrison (2001), have offered cognitive models of positive aspects of psychotic symptoms that individuals may experience. The formulation should be developed collaboratively with the person and aspects that are most appropriate for their stage of therapy should be shown to them. Formulations are often used within CBT as a basis to assist in describing the underlying difficulties that cause the individual's symptoms and are based on theoretical underpinnings (Hagen et al., 2010).

5.8 TechCare Intervention Modelling/theoretical basis

The TechCare intervention is based on the iRTT theoretical model, which was conceptualised by Kelly et al (2012). The theoretical basis of this model is that a change in mental state can increase resilience in another mental state. Therefore, providing an intelligent real-time response could theoretically reduce symptoms and mental states. I aimed to develop the iRTT framework, and to embed a therapy component which could be utilised in reducing symptoms and increasing resilience. The following details provide insight into the modelling and theoretical basis of the TechCare Intervention. Recent research has suggested the importance of daily life stressors being a major contributor to the manifestation of psychotic experiences, both positive and negative symptoms. This perspective is based on the stress-vulnerability model (Zubin & Spring, 1977). The model suggests that the onset of psychotic symptoms is due to increased vulnerability to stress. Many people in their day-to-day lives encounter stressful situations; however, it has been found that individuals with psychotic symptoms are more likely to be less able to cope with these stressors. Furthermore, it has also been suggested that biological factors such as inflammation (Lisiecka et al., 2015) within the brain could lead to symptoms of psychosis. This was reported to be the case in a preliminary study by Chaudhry et al., (2012), who found that minocycline an antibiotic could reduce the negative symptoms of psychosis. This is further being looked into, to shed light and understanding of biological component of schizophrenia.

Bentall (2003) suggested that there is no clear differentiation between a psychotic state and a non-psychotic state, and that the majority of the population encounter symptoms of psychosis such as hallucinations and delusions. The models of schizophrenia have shown differing precipitating factors such as social environment and biological factors, which increases the chance of an individual presenting with psychotic symptoms. The present study will utilise the CBT model proposed by Kingdon and Turkington (1994), which is based on the Stress-Vulnerability Model of psychosis (Zubin & Spring, 1977). This theoretical model suggests that all individuals encounter stressful situations in their lives, however some people are more vulnerable to, and less able to cope with stressors. There are a number of differing vulnerabilities which are attributed as being precipitants in the onset of psychotic symptoms such as sexual abuse, trauma in childhood and substance misuse (Kingdon & Turkington, 1994).

As discussed in chapter 2, several models have been developed in order to provide an understanding of psychotic illness, which are based on psychological, biological and social conceptualisations. However, none of these models have gained universal acceptance within psychosis research due to various limitations in the current evidence base (Kingdon & Turkington, 2005; Hagen et al., 2010). These models jointly form the 'biopsychosocial model' (Kingdon & Turkington, 2005), and are based upon interactions between an individual's vulnerabilities and stress (Kingdon & Turkington, 2005; Hagen et al., 2010). In addition, it is reported within research that a genetic predisposition may be implicated in the vulnerability of developing psychosis. This predisposition is evident within studies conducted on identical and non-identical twins (Kingdon & Turkington, 2005) and within individuals who have suffered from birth trauma (Geddes and Lawrie, 1995). Although biological vulnerabilities may play a role within the aetiology of psychosis, many individuals present no observable biological or genetic susceptibility; therefore, there is a need to consider psychological and social vulnerabilities in the development of psychosis.

The stress-vulnerability hypothesis of psychosis suggests that the association between both stressors and vulnerabilities interact to form the symptoms characteristic of the disorder. Thus, the type of vulnerabilities and stressors experienced by an individual will in turn determine the nature of the symptoms (e.g. voices). In light of this, individuals with certain vulnerabilities from genetic weighting and negative schemas may in turn become psychotic, through the manifestation of environmental stressors such as drug use or compilation of social problems. Additionally, seemingly healthy community samples have commonly reported experiencing transient psychotic symptoms including auditory

hallucinations or paranoid ideas (Johns & Van OS, 2001). As a result, these symptoms are generally perceived in a highly stigmatised way especially within the western culture and can exacerbate stress, as they tend to be interpreted in a negative manner leading to an individual being convinced that they are different from others.

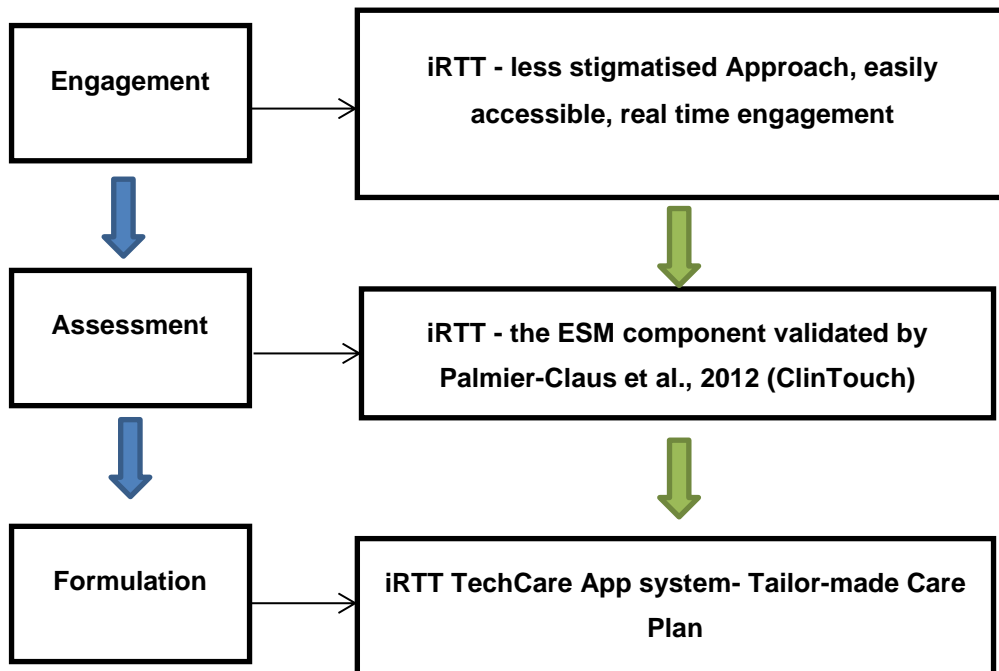
The process of therapy as outlined by Kingdon et al., (2005) initiates an understanding of the mechanisms associated with the service users' experiences of distress. The process of normalising aims to provide a means of assisting in building a strong therapeutic alliance, through maintaining an understanding of psychosis as a continuum of experience in line with ordinary human experiences (Hagen et al., 2010). Moreover, normalising provides an insight surrounding circumstances where such experiences occur. As a result, the occurrence of psychotic experiences is more easily understood within the lens of individuals undergoing extreme stress (e.g. hostages) as their symptoms are attributed to the stressful experience. However, these individuals tend not to be seen as 'different' by society as the exposure of these particular types of stressors may even cause healthy individuals developing similar psychotic symptoms. Thus, normalising explanations illustrate that any given person under certain types of stressors may develop similar symptoms they are experiencing, enabling psychotic individuals to feel that they are not so different from others. This technique has proved successful, as it has shown to lead to a reduction in anxiety and improved collaboration with psychotic patients (Kingdon & Turkington, 1994). In addition, Kingdon and Turkington (2005) have also highlighted the importance of psychoeducation in the normalising process as it provides a means to educate service users on the myths that surround psychotic illness (Hagen et al., 2010). Psychoeducation forms a vital component of the intervention, as the evidence based psychoeducational help sheets will be linked to the App home screen.

The next phase of therapy as outlined by Kingdon and Turkington (2005), is the assessment and formulation of the psychotic experiences. Kingdon and Turkington (2005) discuss how the process of assessment which aims to gather information on the persons experiences, thus helping develop a case formulation which is personalised to the individual. The final phase of the treatment process looks to bring together the information gathered in the assessment phase to develop a treatment plan. The aim of the treatment plan is to help the individuals to gain a better understanding of the illness and formulate coping strategies for the specific symptoms of psychosis.

The project investigated a unique platform for delivering interventions for psychosis. The core component of the intervention is the real-time assessment and delivery of interventions. As stated earlier the project was based on the CBT approach to psychosis by Kingdon and Turkington (2005). The following section will aim to break down the constituent parts of the intervention and the differing modalities that the intervention consists of such as multimedia CBT focused self-help strategies.

The delivery of the intervention was based on a shared formulation approach to CBT through discussion with the participant's case manager. From this shared care plan approach CBT informed strategies were developed for the participant, ensuring a personalised tailor-made approach to treatment. For the feasibility part of the study, the case managers selected from a list of pre-selected intervention types; social media, social networking, goal setting, problem-solving, the ABC model, behavioural activation and positive things to say to yourself. The interventions chosen were based on self-help strategies taken from the CBT for Psychosis manual by Kingdon and Turkington (2005). I have outlined below the different strategies which were available to participants in the study and how the iRTT conceptual model aligns to the Kingdon and Turkington (2005) model (see Figure 5.2). The intervention utilised a basic formulation wizard, which informed the selection of interventions by the participant's case manager. The program utilised a basic formulation process, which then highlighted the targeted response as outlined in Kingdon and Turkington (2005).

Figure 5.2: The intervention was based on the Kingdon and Turkington (2005) CBT model



Goal Setting: the goal setting intervention looked at developing a clear set of goals in conjunction with the participant. Goals were set and agreed through discussion with the participant, which could be achieved during the treatment period and were tailor made and intrinsic to the actual individual's needs. Each participant was given the opportunity to discuss what goals they would like to achieve in a given time period and what steps they had to take to achieve their goals. This took into consideration understanding of the participant's insight, positive behaviours, and negative thinking associated with a lack of achieving goals. The goals were noted on the system in a list format and used the participants own language. This was to ensure participants would engage with achieving their goals, as they themselves had developed the goals. On a weekly basis, myself and the care coordinator would discuss with the participant how they had been getting on with their goals and offer encouragement. Any amendments to the goals were also made at this time point based on participant preference.

Social networking: Social networking has been reported to have a profound impact on reducing symptoms of psychosis (Turkington et al., 2010). This has been predominantly due to people being able to seek the support of family member's, friends and associated networks. This particular intervention provided the participant with an opportunity to note down two numbers for individuals that they would be able to contact in the case that the

TechCare App detected that they were experiencing low mood or paranoia. The intervention prompted the participant to call their family members or other members of their social support network to discuss any difficulties that they may be facing, as well as prompting the participant to increase their level of socialisation.

Behavioural Activation: behavioural activation is one of the core concepts within CBT and looks to see how activities can increase motivation, self-confidence and self-awareness. These strategies are particularly beneficial for those who may be asocial and lacking motivation due to depressive symptomatology. In the context of the study, the behavioural activation strategies were developed to prompt participants to increase the level of their chosen activity. Individuals were provided with certain activities or practices which they enjoyed, with this helping in understanding the differences of when they were feeling low to engage in activities they enjoyed.

Problem-solving: This intervention was to help individuals who may have negative thinking related to dealing with problems, and who may have difficulty in cognitive functioning related to problem-solving. The intervention would thus allow individuals to overcome a problem through breaking it down into smaller constituent parts.

Helpful links and psychoeducation: The home screen on the App also provided a 'helpful links' section which included psychoeducation. Being on the home screen it was easily accessible for participants and was in the form of a service user developed psychoeducation. This detailed cognitive therapy for psychosis, information about paranoid thoughts and information about psychosis. In addition, a series of helpful web links were also available in case participants required support such as the Samaritans or Mind.

Crisis Planning: The crisis plan took in to consideration the current practices within the Early Intervention Service. Each service user is provided with a crisis plan, which provides details of the out of hours emergency contacts for the Crisis Team and also the duty team in hours. Each crisis plan is personalised to each service user and provides a step-by-step guide to overcoming a mental health crisis. The crisis plan was developed to be accessible via the TechCare App and was developed in conjunction with the participant's care coordinator.

5.9 intelligent Real-Time Therapy (iRTT)

A total of three notifications were sent between 10 a.m. and 10 p.m. If low mood/paranoia was detected by the App, it re-notified the participant every 60 minutes to assess symptoms in real-time, with personalised interventions being displayed to participants. The system re-notified participants a total of three times with an agreed crisis response being displayed on the App if low mood/paranoia was detected for a prolonged duration of time (a period of ≈ 4 h). Crisis planning is a routine part of EIS treatment with all service users working with their health professionals to agree a plan of action, which they can follow if they are in crisis. The crisis plan was displayed via the TechCare App. The crisis response consisted of an agreed plan of action in the case participants were in distress due to their symptoms and also prompted the participant to contact the EIS service or an agreed designated contact. In the feasibility context, I examined response rates to notifications, questions and also the participant's selection of the intervention in the findings section.

The TechCare App ESM and iRTT system utilised intelligence at two levels:

- 1) Intelligently increasing the frequency of assessment notifications if low mood/paranoia is detected. This was done through feedback loops, which monitored symptoms over time, with the deployment of a personalised crisis plan, if prolonged duration of low mood/paranoia was detected (≈ 4 h).
- 2) An intelligent machine learning algorithm (see Appendix 7) provided interventions in real time based on breach of assessment thresholds and also provided recommendations on the most popular interventions. Recommendations were based on the most selected interventions by the cohort of participants on the study, with the most popular listed interventions in rank order.

Current advances in treatment approaches for psychosis have vastly developed in the past 25 years, particularly in the area of pharmacotherapies. In the 1950s reduction in symptoms of psychosis through antipsychotic medication was found to be only marginally beneficial, in that although there was found to be a treatment response, full recovery was limited to only a few. This was due to the limited use of treatment approaches to the psychosocial aspects of the illness. The evidence base for CBT as an effective treatment approach for psychosis has been an area of much debate with some critics describing CBT as being an 'oversold' treatment approach. Despite this CBT has

become a part of clinical discourse and practice for the treatment of SMIs and as a treatment recommended by NICE (NICE, 2014).

5.9.1 Equipment

The TechCare software, was developed by an NHS Trust in the North West, software development department specifically for use on touch screen Windows mobile phones. As part of the study, service users who had compatible smartphones were able to upload the App to their phone. To ensure that those who wished to participate but did not have a smartphone, preloaded phones were available. The TechCare software was developed for use on a touch screen mobile phone. The service users who had compatible smartphones were able to upload the App to their phone. The team lent a preloaded phone to those who wished to participate but did not have a smartphone. If participants encountered any technical problem with their device, they were advised to directly contact myself.

5.9.2 TechCare Application Procedure & Set-up

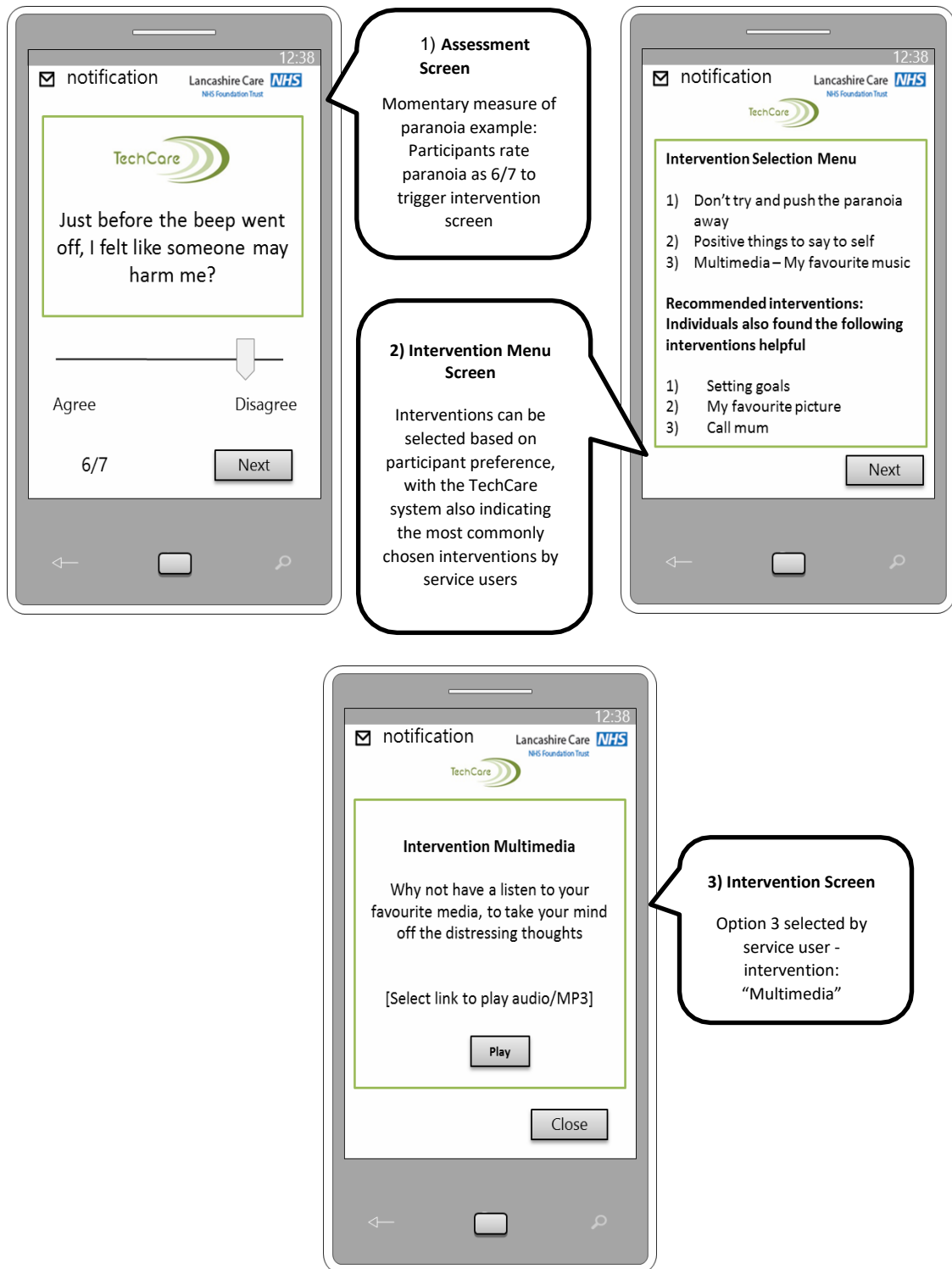
Individuals accepted into the North West EIS were eligible to take part in the study. A leaflet and participant information sheets were given to potential participants who had been referred and met the inclusion criteria. Participants were then approached to give informed consent, with individuals being given a minimum of 24hrs to consider their decision. Participants were reminded that they were free to withdraw at any stage without providing a reason, up until the data had been anonymised and analysis was complete. Participants were asked to sign the consent form and were given a photocopy of their completed consent form to keep. They then completed the study outcome measures at a suitable location (e.g. GP practice, clinic, etc).

Individuals who consented to take part were given a briefing session and completed the PANSS and PSYRATS interviews. They were then introduced to the TechCare App either on their own smartphone or a low-cost Windows device provided by the research team. At the end of the session, the participant number, alarm volume preference, and specific symptoms were entered onto the device via the setup screen. The App was then activated the morning following the briefing session. The App assessment items were designed to be equivalent to the 12 items of the PANSS and 5 items of the Calgary Depression Scale and are derived from the "ClinTouch" assessment software (Palmier-Claus et al., 2012). Participants were asked to respond on an analogue scale indicating the degree to which they agreed or disagreed with statements relating to their symptoms

on a likert style sliding scale from 0-7 as described by Kelly et al., (2012). In order to reduce the number of items and length of time to complete, the questions were divided into two sets and displayed at alternative time points.

A range of unusual or paranoid beliefs are reported by individuals with psychosis. The TechCare App were equipped with a “delusions” menu in the setup section, where the researcher in collaboration with the participant’s care coordinator could personalise to which delusions the participant was currently experiencing and was based on the initial Positive and Negative Syndrome Scale (PANSS) interview and other self-report questionnaires. This delusional belief was the basis for TechCare questions asked and scored for level of preoccupation, distress and impact on behaviour. Up to two delusions could be entered for each person. For those with more than one delusion, the delusions with greatest conviction and distress rating were utilised. Depending on the threshold of response, the assessment questions triggered the intervention screen (Figure 5.3 displays a mock-up of the TechCare App).

Figure 5.3: Figure showing an example of ESM and iRTT in the TechCare App



The TechCare App triggered the mobile handset to display a notification alarm/vibrate at randomly generated time points between 10am and 10pm. This triggered the first set of App questions. Participants were given an option to try again in 15 minutes if they were busy and could not complete the questions. If the response from the participant was

above a pre-agreed threshold, this triggered the interventions menu for low mood or paranoia. Participants could then select a brief personalised self-help psychological intervention to reduce the distress of the particular symptom they were experiencing.

Participants were texted via SMS, or phoned twice during the first week, to gauge how they were finding things, to offer encouragement, and reminders to charge their phone. I anticipated the phone App would have wireless connectivity or 3/4G connectivity and be able to transmit the responses back to the TechCare Web App. On a weekly basis, I met with the participants to readminister the outcome measures and to ensure safety.

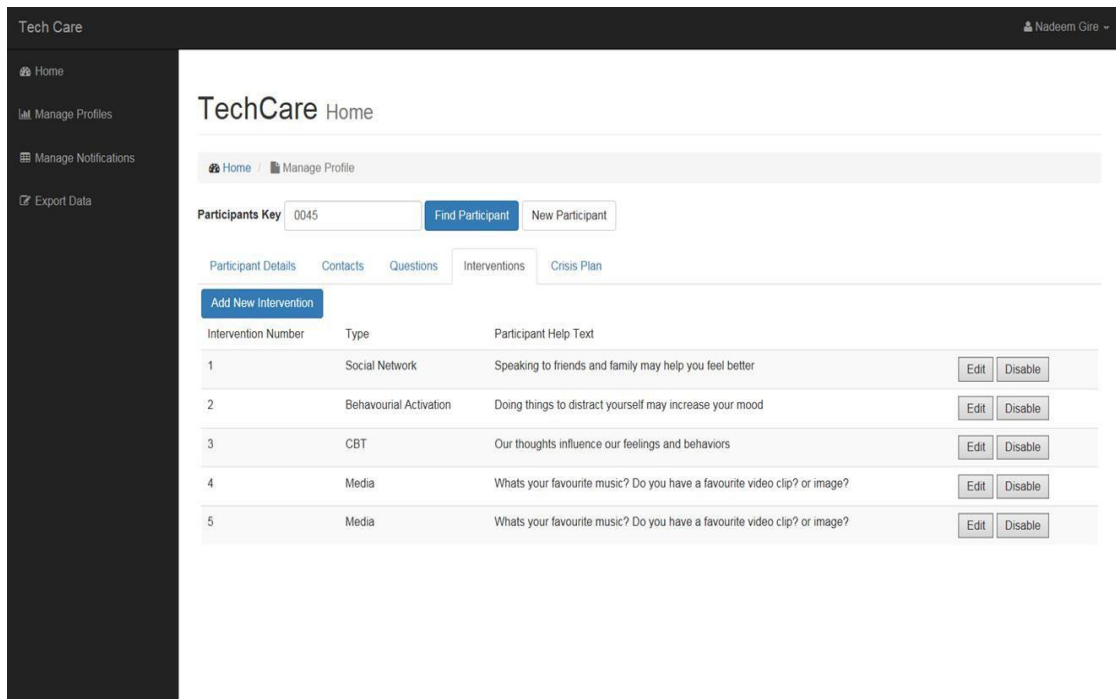
5.9.3 TechCare App Usage

The mobile Application was designed to allow health professionals the ability to monitor their service users' symptoms on a day-to-day basis. Once the windows device was set up, the user took daily questionnaires, with results logged on a central server held within the NHS Trust. The researcher and care coordinator were able to view participant responses and selection of interventions by the participant over the intervention period. This data provided critical points, which indicated the service users were experiencing symptoms on a particular day in addition to providing an objective means of observing participant ongoing recovery.

5.9.4 Web Application

Administrator access was through the website, admin control panel on the login screen. Once logged in, administrators could view a list of all users currently saved in the database. Clicking on a user displayed more information about that user, including currently active questions and the user's previous attempts at their questions. Again, the questions could be activated or deactivated on this screen (in the questions tab) by toggling the checkbox. User accounts were created on a central server website, which then allowed participants to login in to the mobile App. Once an administrator logged in, they were able to see a list of users by clicking on the users link in the top right of the screen. Data collected via the App could only be viewed via the online Web Application. (see Figure 5.4).

Figure 5.4: TechCare Web Application System

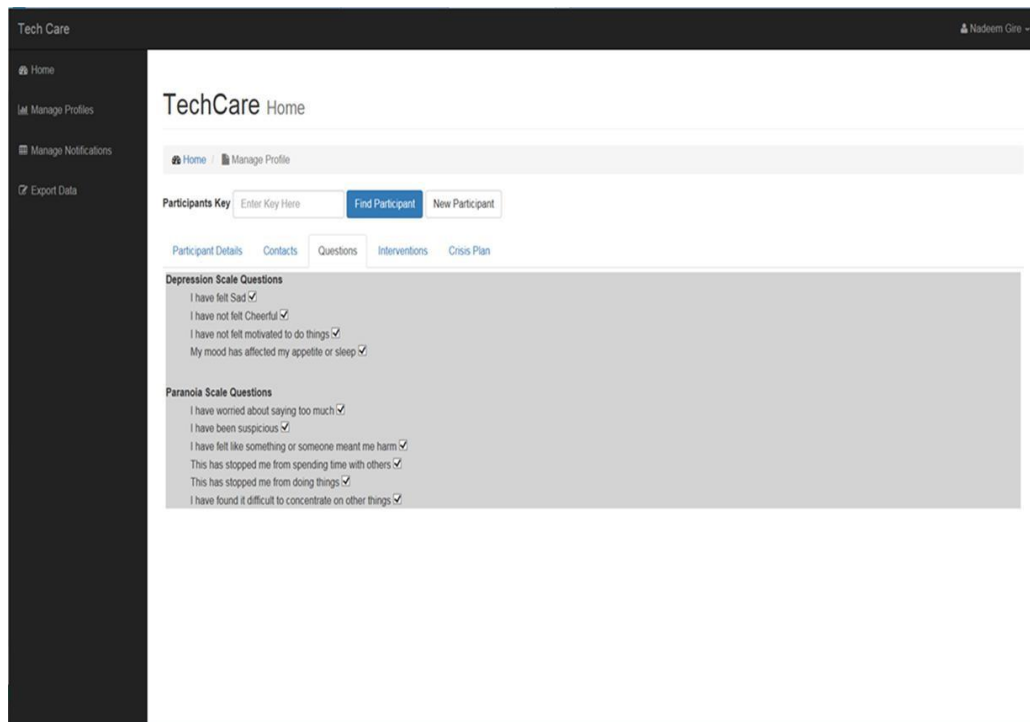


5.9.5 Installation and Setup

Once installed and opened, the App would load the login screen. In order to create a new user. I would access the Web Application and click on the sign-up button in the menu in the top right-hand corner. The signup screen had four tabs, the profile tab which required a PIN (four digits) to gain access to the system. Additional fields, such as 'personalised contacts' were optional. Upon signup, the user was directed to a settings screen, where each question could be viewed and activated by toggling the checkbox. Active surveys were available for the user to take at random hours throughout the day.

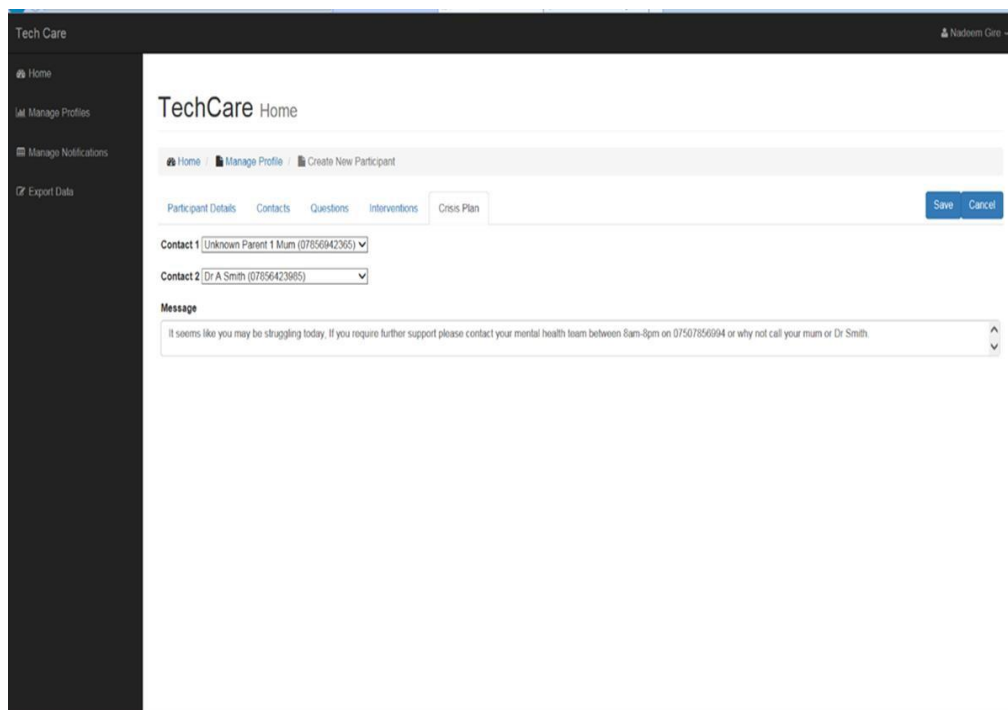
The contacts tab required information about personalised contacts for the participant, it could also be used in the event of a crisis intervention to display useful numbers such as for the crisis team. The questions tab allowed for the modification of the questions that would be presented to the participant, to ensure tailored questions specific to the service user's needs (see Figure 5.5).

Figure 5.5: TechCare Web Application Question Screen



In the interventions tab, in conjunction with the service user and care coordinator, I was able to develop personalised strategies for the participant. The last tab was used to include the tailor-made crisis plan, which was added on this tab (see Figure 5.6).

Figure 5.6: TechCare Web Application Crisis Plan Screen



Once the save button was clicked, a user account was created on the mobile device itself, and also online, providing the device was connected to the Internet. The new user account could be viewed by visiting the URL: TechCareadmin.azurewebsites.net and through obtaining a login PIN for the App.

5.9.6 TechCare App Usage

The participant would log in with their valid 4-digit PIN any time that they wished to use the App. Once logged in, they were directed to the welcome screen, which contained useful information, including websites/contact links. When the user clicked on the notification to complete the questions, they were directed to the question screen, where they could move the slider to indicate how much they agreed with the statement on the screen. If it was determined that the user has breached the threshold for distress, then the intervention list was triggered. If not, then the user would be re-directed to the welcome screen where they could close the App. If, however the intervention screen was triggered, the participant was shown the list of interventions that were added to the online Web Application. The participant was able to pick an intervention from the list and, were shown a list of interventions that other users had found helpful via a list of recommendations. This screen had a 60 second timer which shut the App down if it was not active during that time.

5.10 Patient and Public Involvement

On defining PPI activities within health services research, Brett et al., (2014) conducted a systematic review on the impact of PPI work, on health and social care research. The key findings reported from the 66 included studies, was that patient and public involvement was facilitated at differing stages of the research. PPI members being involved in the development of research objectives, service user resources, topic guides, and the enhancement of the dissemination and implementation of the research (Brett et al., 2014). In contrast, Domecq et al., (2014) conducted a similar review, reporting that PPI work was less likely to be conducted during the execution and translational phases of research (Domecq et al., 2014), which is an equally important part of the research process. Domecq et al., (2014) further describing that the process of PPI can in most cases be very much 'tokenistic'. Taking these considerations on board in the TechCare PhD project, I ensured that the PPI advisors were not engaged in a tokenistic manner and were given the opportunity to gain skills in research in addition to taking part at different stages of the project, with the App development phase having a participatory

ethos. One example of this was a PPI consultant requesting to participate in an art course at the local college to help share the findings of the research through art.

In its entirety, the process of working with PPI members has strengthened my understanding of the research, in particular the sensitivities around working with mental health service users. In detail, the PPI members contributed significantly in the process of identifying the problem, but also helped develop the research question. Discussions with the PPI members highlighted areas of importance, which I could target, to address the socio-economic inequalities related to mental health. PPI team members were also involved in a number of ways during the study period. The PPI representatives for the study were involved in the design of the study, development of the intervention, developing the Participant Information Sheet (PIS), analysis of findings and dissemination of research findings. The PPI representatives were also present at the ethics meeting and were able to provide a unique insight into difficulties that may be faced by individuals who were eligible to take part in the study. The study used a feasibility design to evaluate the feasibility, acceptability and trial readiness for the TechCare App intervention. PPI team members also assisted in the analysis of the results of the study and I supported PPI participants in learning new skills in dissemination and writing for publication. PPI members reported feeling empowered and valued, as their input had helped develop an intervention, which in their view, could potentially help other individuals with similar experiences.

Mental health stigma is one of the primary drivers of mental health inequalities, with economic difficulties such as living in a deprived, urban locality and poor access to mental health services also contributing to the widening of health inequalities. Before the feasibility study, the PPI members recommended that an affordable smartphone App would help in overcoming these drivers of inequality, as the support would be placed in a commonly used, familiar platform and would likely increase engagement with mental health services. With the planned TechCare study being able to actually determine the feasibility and acceptability of this.

Overall, the project has benefitted significantly from the contribution of the PPI representatives. One of the key impacts was the empowerment and engagement of the target population in the study. The PPI members used the TechCare platform to share their experiences. One of the study participants was able to use art, to express herself indicating that involvement in research can have a hugely positive impact on individuals.

The further impact of PPI was through the dissemination of the research findings and the impact of capacity building with the PPI members.

Furthermore, the project required the input of the service users throughout all stages of the research project, including membership of the research team and project advisory group. The choice of a mixed methods research design placed the service user at the heart of the research project. There are many assessment tools that can measure different therapeutic concepts, however these tools are generally developed only from a clinician's perspective (Simons, & Gaher, 2005; Antoine, Antoine, & Nandrino, 2008; Buchy, Bordeur, & Lepage, 2012,) and are subject to mainly a professional interpretation of service user experience. The TechCare (App) for this proposed study would be specific to each service user and their individual experience of distress, and thus provide novel insights into the real-world implications of the TechCare App.

The Schizophrenia Commission (2012) acknowledged that embedding service user experience into the development of interventions for use at the earliest stage of psychosis is important for recovery (Schmidt, 2011). The proposed study aimed to align itself with this philosophy, by thorough involvement of service users at all stages of the research and promoting collaborative engagement between service user and mental health professionals.

5.11 Ethical Approval

Ethical Approval was obtained from the NRES Committee North West - Preston REC reference: 14/NW/1192 (see Appendix 8). It is important to note the ethical considerations related to research in the area of developing mHealth interventions. When conducting any form of health research, it is imperative for researchers to follow principles and guidelines set out by the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (WHO, 2001) and in the UK the National Health Service Health Research Authority guidance (NHS, 2014). These guidelines ensure safety of participants, the right by participants to withdraw from the study, recruitment of participants and confidentiality. However, research in the mHealth field gives rise to ethical considerations which are more specific to mHealth such as the control of data held by mHealth Apps, privacy protection, freedom to use/not use the App, technical difficulties, sending data over 3G & 4G connections and the safety and functionality of mobile technologies.

5.12 Adverse event reporting

I adhered to principles of Good Clinical Practice in reporting adverse events. The adverse events in digital interventions are generally not well reported (Farooq et al., 2016). Monitoring of any serious adverse events (SAEs) was carried out throughout the study. The site-specific supervisor Professor Nusrat Husain was directly notified of all adverse events, with all SAEs being reported to the NHS Research Ethics Committee (REC). In the light of the limited literature on adverse events in digital technology, I explored these further through the qualitative work and the data on the side effects such as worsening of symptoms and/or mood, which were assessed at the weekly review assessment and reported to the care coordinator.

5.13 Finance

Individuals were provided with a mobile device for use in the study. The device was a Nokia Lumia smartphone, which included functionality such as email, WIFI, social media and a multimedia player. Participants were given an allocated allowance, which included 250 minutes of call time, 5 GB of data and unlimited SMS texts. This cost in the region of £15 worth of credit through a pay as you go sim card. A number of participants went over this allowance during the study period and were provided with an additional credit to their mobile phone of £15. Any additional costs such as travel to the study site for follow-ups was reimbursed to the participant.

5.14 Data Management Planning

The following section outlines the data management arrangements for the TechCare study. The study collected demographic data in addition to data collected through clinical assessments/outcome measures (quantitative). This also included momentary assessment data, gathered via a participant smartphone Application (App) (mobile device). Qualitative data was also collected from participants through both semi-structured interviews and focus groups, with digitally recorded qualitative data being transcribed verbatim. The transcribed data was then collated using MaxQDA with any participant identifiable data being deleted. The recordings were stored in a locked office and destroyed in line with the qualitative data management guidelines at the NHS trust. The data collected was anonymised and collated primarily in Microsoft Office to ensure file sharing ability, with all data being encrypted and password protected. Table 5.2 shows the number and file formats used in the study.

Table 5.2: File Type and Number of Records Collected
Quantitative: - No. of Records: n=16 participants File type: SPSS V.20
Qualitative: - No. of Records: a) Participant semi-structured interviews b) Health professionals semi-structured focus group interviews File type: MaxQDA, Microsoft Word, Microsoft Excel.

Data was generated using questionnaires (both momentary assessments and face-to-face assessments) and face-to-face interviews. Data for each participant was collected at the relevant time points (baseline and weeks 1-6). In terms of data, I collected momentary assessment data via a mobile device, whereby participants were able to self-report their experiences via a smartphone App. Data gathered in this format was anonymised and held on a secure online server. I maintained consistency and quality of all data by adhering to the study protocol. In accordance to the MRC guidance (2017) on good research practice, the study pertained to data assurance principles as outlined by the ICH good clinical practice guidelines (www.ichgcp.net).

Consent forms and paper copies of assessment tools were stored in locked filing cabinets in secured offices within the participating site. All computerised data was encrypted, and password protected and replicated on the NHS secure computer system. All personal information collected and stored after selection into the study was assigned by a reference number. Hardcopy data files were stored securely at the NHS Trust research office. I employed standardised operating procedures for the capture and management of metadata and adhered to the MRC metadata standards. Published data from the study was deposited and available on the UCLan Clon data repository and was allocated a Digital Object Identifier. Funding bodies such as the NIHR and MRC enforce an open access policy for sharing data with the least possible restrictions.

5.15 Chapter 5: Summary & Conclusion

In the above Chapter 5, I outlined the differing components of the project and design considerations related to the chosen research methodology. Of note was the need to ensure that the work carried out as part of my PhD project used a robust research methodology. I decided to use a design, which used a mixed methods approach and consisted of three strands. As I have outlined earlier the two core components of the project that informed these decisions were the HIAT assessment and systematic review.

Through these research activities, I was able to gain an understanding of the impact the research would have on health inequalities and then subsequently, a synthesis of available evidence on mHealth for psychosis identified the value of developing and testing the novel TechCare App. The methodology was thus designed grounded in the findings of chapter 3 and 4, with the design of the feasibility study following guidance by the Medical Research Council (MRC, 2000) in the development of new complex interventions, which recommends the conduct of a phase II or feasibility study prior to conducting a Phase III effectiveness trial (MRC, 2000). This feasibility work intended to inform the design of a larger trial, which would examine important parameters such as, the identification of appropriate outcome measures, follow-up periods and estimates of recruitment and acceptability of the TechCare App intervention. In addition, I also describe how the intervention was developed based on the work of Kingdon et al., (1998). An important part of the research was PPI, as the PPI was an integral part to the research, Table 5.3 below provides a summary of the key activities and contribution of the PPI members to the project.

Table 5.3: Summary of PPI Activities and Input

PPI Activity/input	Description
Reviewing the content of the intervention	The PPI members worked closely with myself, to review the App content and resources
Ethical considerations/developing Ethics	PPI members supported the development of the NHS ethics form, and were also present at the ethics review meeting
Refinement of the intervention	This was an iterative process where I met with PPI members regularly to provide updates and seek input/advice on areas which needed refining
Development of the participant resources	The PPI members assisted in developing the user manual and case vignettes
Design of the App layout	Through an iterative process in collaboration with the PPI members, I was able to examine and refine the layout of the App. This included having a home screen with access to helpful resources and also, refinement of the general layout of the question and notification screens
Design of the App logo	I had originally used the NHS logo on the App however due to possible stigma concerns, we collaboratively developed a new discreet logo for the App
Reviewing the research procedures and development of the research protocol	Working collaboratively with the PPI members, I looked at the research procedures to examine areas for refinement/development

CHAPTER 6: FINDINGS OF THE STRAND 1 (PRE-INTERVENTION QUALITATIVE WORK) AND STRAND 2 (TEST-RUN & INTERVENTION DEVELOPMENT AND REFINEMENT)

The following chapter will present the findings of the pre-intervention qualitative component of the study (Strand 1) test-run and the development/refinement of the intervention (Strand 2). The chapter is split into two sections, with the first section describing the qualitative findings of the focus groups, which were conducted with health professionals and one-to-one interviews with the service user participants pre-intervention. The second section will present the findings of the test-run and the further development and refinement of the intervention, in preparation for the Strand 3 feasibility study. I will present in turn the relevant findings, beginning with the health professional's focus groups.

6.1 Findings from the Health Professionals Focus Groups (Strand 1)

A total of two focus groups were held with professional staff to elicit their views on optimising the utility of the TechCare App within EIS. The total sample size for the focus groups was n=16 with a total of 6 males and 10 females. The majority of participants were Registered Mental Nurses/Care coordinators who worked with service users in the EIS. The focus groups were conducted in the North and East EIS sites in Lancashire, between September 2015 to November 2015. I made note of the differing specialities in regard to the health professionals, with the majority of participants being Registered Mental Nurses (RMN) who were predominantly females (n=10). Data on the role and gender of participants is reported in Table 6.1 below.

Table 6.1: The roles and gender of participants in the focus groups

Participant ID	Role	Gender
FG1-1	Mental Health Nurse	Female
FG1-2	Support Worker	Female
FG1-3	Mental Health Nurse	Male
FG1-4	Mental Health Nurse	Female
FG1-5	Mental Health Nurse	Female
FG1-6	Mental Health Nurse	Male
FG1-7	Mental Health Nurse	Female
FG2-1	Support Worker	Male
FG2-2	Mental Health Nurse	Male
FG2-3	Mental Health Nurse	Female
FG2-4	Psychiatrist	Male
FG2-5	Mental Health Nurse	Female
FG2-6	EIS Support Team	Female
FG2-7	EIS Support Team	Female
FG2-8	Mental Health Nurse	Male
FG2-9	Mental Health Nurse	Female

6.2 Analysis of the Focus Group Data

The focus group data was analysed using Framework Analysis, which proceeds through a number of stages. Once the data had been collected and transcribed verbatim, I familiarised myself with the data. This entailed listening to the tapes and gaining an understanding of the context in which the participants responded to questions. The familiarisation step in the Framework Analysis was an important part of the analysis, as it allowed me to ‘relive’ the experience of conducting the focus groups. Once I had completed the familiarisation of the focus group data, I thoroughly read and re-read the transcripts in cycles of identification of thematic material. In this Framework Analysis, the process involved identifying, indexing and charting of key themes. Through the process of indexing and charting, I was able to then determine the key themes and subthemes, which were developed into the following framework matrix, which I used to code the transcripts. Table 6.2 below shows the coding framework matrix and the main themes and subthemes found.

Table 6.2: Coding Framework for the Focus Groups with Health Professionals

	Themes	Subthemes
Coding framework	<i>Theme 1: They are on it constantly: Access & usage of digital technologies</i>	<ul style="list-style-type: none"> a) Ease of access b) Barriers to Access c) Complications of Stigma
	<i>Theme 2: Being in control: implications for clinical practice</i>	<ul style="list-style-type: none"> a) Impacting professional work b) Integrating service users' Care Plans onto the smartphone App c) Tailoring intervention content d) Enabling ownership and self-management
	<i>Theme 3: A bloody nightmare: Challenges & barriers to usage</i>	<ul style="list-style-type: none"> a) Connecting or not connecting b) Lost, Stolen, Damaged or Sold c) Confidentiality & security d) App notifications & questions e) Adverse effects
	<i>Theme 4: Can we put up things like: Development and Refinement Considerations for the TechCare App</i>	<ul style="list-style-type: none"> a) Amending current functionality b) Future Directions

From the above table the key themes that emerged from the data were; access and usage of digital technologies, implications for clinical practice, challenges & barriers to delivery and development and refinement considerations for the TechCare App. The key themes and subthemes are described further as follows:

1) They are on it constantly: Access & Usage of Digital Technology

This theme accounts for the health professionals' views of mental health access inequality, in terms of access to digital technologies, and how this had an impact on service users. It was highlighted by the health professionals that service users within EIS had ease of access to mobile technologies and that the use of digital devices such as smartphones was common place in the service users' day-to-day life. These access

issues appeared to interact with concerns about stigma, which was seen as an important factor in both supporting the case for uptake and implementation of digital technologies and influential in engagement with services and social inclusion. There was evidence that service users already relied upon basic mobile phone functionality, such as texts, to cement and facilitate their engagement with the clinical team, and this fed into a view that newer technologies could further improve engagement and make a positive contribution to their transaction of support.

1a) Ease of access

This sub-theme describes how the EIS professionals understood current ease of access by service users to digital technologies and indeed, how these were already impacting upon patterns of communication with the team. The consensus across participants was that mobile phones played a major role in gaining access to support for many service users, and even when health professionals would see service users they would have their phones visibly with them. This suggests the importance of digital technology being a possible platform to engage service users within the EIS:

"P1: Yeah, they're on it constantly, aren't they? Constantly. Facebook, social media. Yes. The phone's never that far away from young people's hands, are they?" [Focus Group 1]

"P2: Sometimes even to the extent to when you're seeing them [in a clinical appointment] and they still have a mobile phone in their hand." [Focus Group 1]

On the contrary, although access to digital technologies was seen as increasing for many, it was voiced that not all participants had access to smartphones. There were some mixed views regarding the particular technologies available to service users engaged with the EIS. One participant suggested that most service users had a basic phone whereas another reported that 95% of service users had a smartphone. At the very least, this suggests that service users do have access to mobile device, even in the case a service user did not own a smartphone they would likely have a basic device.

The overall need for improving access to the EIS was also discussed, with reference to current issues around difficulty in communicating with service users. Despite a range of difficulties, the most common means of communicating with service users was via Short Messaging Service (SMS). This was regarded as being the normative means of service users making contact with their care coordinator, and further supported the view that

service users had access to digital technologies, but also that mobile phones were a familiar communication medium:

"P4: They text normally isn't it?" [Focus Group 2]

"P3: Yeah text." [Focus Group 2]

"P1: Yeah they are always texting." [Focus Group 2]

Although these results suggest a substantial potential for the mobile technology in improving access to services, in practice face-to-face contact was seen as an important and valued part of the health professionals role.

1b) Barriers to Access

In this sub-theme the health professionals discussed potential barriers to using the App, mainly concerning themselves with practical issues such as difficulty with signal connectivity, accessibility via a cellular network, costs using the App and the procedures for the study. One example of the practicality issues was difficulties in obtaining signal or a connection to the internet, this was related to some areas of the North West having limited internet access:

"P2: I was just about to say it's more practicality isn't it [Connection to the internet]" [Focus Group 2]

Other matters which were suggested as potential barriers to utilising digital technologies were factors relating to the type of technology used such as laptops and tablets. Due to the increasing usage of alternate technologies such as laptops and tablets within this population, the health professionals were of the view that to be more inclusive the App should be available across mobile based platforms such as Apple and Android, with the added accessibility to the TechCare App via laptops and tablets.

"P5: If people who are quite a lot on headphones on their computers, would they, because one is people on their phones and App and others are the people who are mostly at home and they're constantly on their laptops, on the net. Would they be able to, is there a possibility of them being able to tap into this resource?" [Focus Group 1]

"P3: So is it just on the Windows or would it work on an iPad.... Because I think a lot of people have Apple..." [Focus Group 1]

1c) Mental Health Stigma

In this sub-theme the health professional's express views regarding their concerns about mental health stigma, with possibly contradictory ideas that the App might expose individuals to stigma or be a mechanism by which they can avoid some of the stigma which is attached to being in contact with services. Stigma was seen as particularly of relevance due to the implications of having a mental health App on your device, as there was potential for this being seen by third parties such as family members and friends, raising possibilities for negative reactions or social embarrassment:

"P4: I was looking at more from a stigma perspective, if you've got TechCare on your [Phone]" [Focus Group 1]

"P4: Talking about stigma, if you're out with your friends.... and this Apps on your phone" [Focus Group 1]

This might be more likely with inadvertent visibility of using the App in public spaces and risking exposure to strangers. From a psychosocially inclined service such as the EIS, family members witnessing use of the App might prompt support or affirmation as much as stigma or disapproval, depending upon their attitudes and level of engagement in the service. Experiencing stigma as a result of using the App was not necessarily a concern of all staff, given the ubiquitous usage of mobile phones in the public domain these days. Such concerns may prove to be unfounded with most people affording other phone users a degree of privacy or indifference to their business on their phone.

The challenges posed by stigma attached to mental health in society was also felt to be important in a broader sense for continued engagement with services. Staff conveyed that some service users found it difficult to communicate via face-to-face contact due to stigma related to accessing services and as a result were less likely to engage with the EIS. Interestingly, in this context the availability of an App that can ensure a more 'private', independent contact with services, not dependent on attendance at a clinic, was seen as a valuable way of navigating stigma and maintaining engagement:

"P6: I think some of the patients basically which.... Uh, sometimes say, is that they don't want to make contacts I think, from the service..... so, we basically don't have anyone in contact with them.....so this App might help" [Focus Group 1]

The stigma of the clinic could also extend to domicillary visits. Recommendations were made in relation to reducing stigma, due to mental health professionals attending service users houses. This provided support for the non-stigmatising approach to delivering support via the TechCare App:

"P6: Minimising face-to-face contact. I think... that could be also a stigma issue like having to meet people, having to meet professionals coming over to see them or something, you know." [Focus Group 1]

2) Being in Control: Implications for Clinical Practice

This theme accounts for the professionals' views of the implications for clinical practice and how they deliver care. The TechCare App was deemed as a novel platform to delivering mental health care services. Key points which were discussed related to the clinical input and configuration of the TechCare App. An important dimension of this theme was consideration of matters of control. The professional staff had concerns regarding the impact and implications for their work. This included reflections on personal agency, and control over their work and the related challenges and opportunities posed by the introduction of new technology. In addition, the ultimate value of the technology was framed in terms of its potential to realise control and autonomy for service users over their own care and recovery, chiming in with progressive professional and service ideals.

2a) Impacting professional work

The health professionals viewed the App as a possible means for reducing the burden of calls from service users, with time savings being utilised in increasing patient contact in those experiencing mental health crisis. There were also concerns around the configuration of the App and its set up, with some participants requesting further clarity in the usage and working of the TechCare App system. The health professionals were of the view that they would need some assistance in managing the online application system initially:

"P4: Because I would struggle with that, I would learn but, I would'nt be able to run with it from the beginning" [Focus Group 2]

"P3: So do we do that when were out with people? Do we alter? Or do they do that themselves? or how do you manage that?" [Focus Group 2]

"P5: Because I think from that point of view, then it is also at that it will also have a fairly significant impact on resource in terms of care providers' time for case managers so instead of sitting and taking half a dozen calls, it may come down to three calls a day, you know. It depends. So, if they're able to get most of their answers, they can get from the [Care-coordinator] it'll be filtered through till it comes to a form, actual you know, a face-to-face, a phone-to-phone conversation and hence it's going to have an impact on that resource as well." [Focus group 2]

In addition, staff expressed the sort of anxieties about introduction of new technologies that are common across a range of workplaces and occupational groups, notably fears of substitution of technology for skilled, professional input. From a service delivery point of view the health professionals highlighted that although they could see the utility of the App in their clinical practice, it was recommended that the TechCare App should not be a sole means of delivering interventions and that service users should still have the ability to access support from their health professionals:

"P2: I think it is good from what I have seen though but. I wouldn't want it, just the services that this is all that was required in terms of interventions and still access me." [Focus Group 2]

Also highlighted was the impact, lack of face-to-face contact would have on service users, as there would be instances or situations where face-to-face contact was a vital component of care, as it ensured service user's problems or distress were not being missed:

"P3: What I'm just thinking is, what about the things we'll miss, the things you need face-to-face contact for" [Focus Group 1]

These worker anxieties differ from other contexts in the value placed upon the interpersonal aspects of job role, with concerns over therapeutic alliance grounded in the effective use of self, seen as an essential part of a psychosocial service. Wrestling with these issues, staff could see that rational planning could lead to having the best of all worlds, with time for face-to-face contact backed up with the benefits of between-time contact using technology and this balance playing out differently depending upon the needs and wishes of different service users:

"P3: Yeah, I'm just thinking about the contact, the face-to-face contact. Sometimes when someone rings you up, or you see someone..... If it gets to a

phone call, if phone and they've decided not to ring, they'll be things that we'll be able to pick up on the phone call" [Focus Group 1]

The health professionals also detailed their views in relation to the workplace practicalities of their interaction with information generated by service users' usage of the TechCare App. This included interest in professionals gaining access to the App content, and whether the App would need to be connected to a network. Similarly, the real-time access to self-help information, as and when required by the service user was deemed a useful functionality of the App:

"P2: Yeah, so even if they feel no matter what time of day it is if they need to access the self-help information; it's on there" [Focus Group 2]

The health professionals were also keen to put forward possible participants who would be suitable for the study. This was indicative of the acceptability of the TechCare App for the health professionals.

2b) Integrating service Users' Care Plans onto the Smartphone App

The integration of individual care plans was an important subtheme. The health professionals held the view that a Care Plan Approach (CPA) was the core treatment approach within the EIS, thus centring around a psychosocial ethos. The ability of the App to integrate the service users tailored care plan, was identified as a feasible means of the TechCare App to support the current EIS care pathway. This means of intervention delivery was referred to as an 'interactive care plan' by one of the health professionals:

"P1: Yeah, I'm feeling this way so what does my care plan say, it'll give you a link to so-and-so that you can try" [Focus Group 1]

"P4: So, I suppose this is accessible and sort of, a care program like that. So, it answers sort of that one, right" [Focus Group 1]

References were also made to the App being similar to a 'mood diary' which was easily accessible for service users. Health professionals held the view that the App would be a useful aid in complementing the Psychosocial Intervention (PSI) work which they currently conducted with service users in the Early Intervention Service. It was also noted that the App would thus provide greater personalisation, in regard to the PSI work, which would be tailored to each individual. Also, of note was the integration of the service users

care plan on the mobile phone, allowing participants easy access to their crisis plan, as in most cases a paper copy tended to be misplaced by the service users:

"P3: I think it can be very useful if you can adapt it as a care plan, if it tops up our care plans that would be rather than having to write another care plan" [Focus Group 2]

"P9: Yeah because the good thing is that people with the care plan they're not bothered where they put or they lose it, or its actually on the floor when we see em..." [Focus Group 1]

2c) Amending the intervention content

The professionals were dynamically interested in the extent to which they could influence and edit the content of the App. A feature of the App is indeed the facility to adapt and edit the available intervention content. As well as being able to tailor the content of the TechCare App, changes made to the App can be initiated through a laptop or computer, resulting in these changes appearing on the participant's device. The ability to tailor the App content was a useful means to provide alterations by the health professionals based on the clinical needs of service users, and this was valued by the professionals. For example, if a service user's symptoms began to improve, alterations could be made by the health professionals, allowing for clinical input into developing a tailored care plan, which was reactive to the needs of the service user. Professional interest in these characteristics of the App were evidenced in the following questions:

"P1: So is there a facility if they start to improve? To make alterations to what you got on there [the care plan]?" [Focus Group 2]

"P6: Sorry, may I just be really awkward and just ask one more question about the editing. Can the individual edit it alone so if they felt that they wanted to change [a self-care prompt] to swimming." [Focus Group 2]

The latter point extended professional interest in the functionality of the App to whether service users themselves could be in control of editing the content material.

2c) Enabling ownership and self-management of care

Another important focus of professional interest was the ability of the App to enhance self-management of service users within EIS, emphasising the value placed upon individual autonomy within this service committed to recovery ideals. This was seen as

beneficial in a number of ways, most importantly in terms of giving service users a sense of 'ownership' in their personal care:

"P4: Would you say it's a good way of giving them ownership of it?" [Focus Group 1]

"P2: That's a good word [Ownership]" [Focus Group 1]

"P6: So that will be very positive for them, you know, the feeling of being in control" [Focus Group 1]

It was further noted that the App represented the potential for providing an alternative medium of communication, rather than having to wait until face-to-face contact had been arranged. To a certain extent, the enablement of service user control and self-management was also seen as a means to manage the level of demands made upon professional time:

"P1: It's giving people the opportunity, isn't it, to try and manage their own feelings and illness instead of ringing every time they feeling a certain way" [Focus Group 1]

Ideally, this recalibration of relationships, supported by the technology, results in mutual benefit, making best use of limited staffing resources at the same time as service user control supports positive outcomes that build upon professional inputs:

"P3: It's also reinforcing, if we go out to see someone Tuesday and then go see them on think following Tuesday its reinforcing what we've discussed and they can look at it and think, yeah" [Focus Group 1]

The extension of self-management also offered possibilities to change the ways certain practices were currently undertaken, perhaps with further positive consequences for staff workload:

"P1: You have that questionnaire thing as well. So you keep a lot of things you try to get people to do. It might be easier for people to go on their phones and fill that in" [Focus Group 1]

It can be seen that in the view of the health professionals, supporting service users in the self management of their symptoms could have a positive impact, due to enhancing

autonomy and control of their symptoms and feelings and altering the way they interact with services to achieve these ends.

3) A bloody nightmare? Challenges & Barriers to Usage

The professionals flagged up a number of possible barriers they could foresee, that could impede usage of the TechCare App by service users. These included matters of connectivity impeding interaction, loss, damage or theft of the mobile device, concerns regarding confidentiality and security, issues regarding App notifications and questions, and potential adverse effects.

3a) Connecting or not connecting

Staff could envisage a number of problems for use of the App that, broadly speaking, are indicative of failures to connect. These include the simple concern of impeded access to the App because of variable internet connectivity and the more complicated matter of failing to connect fully if individuals may have difficulties with literacy. There was a view that the geographical area covered by the team was not best for internet coverage:

"P3: It is not too good for internet down here...Is it? [signal]" [Focus Group 1]

There were other concerns regarding people's ability to read, and whether this would impact engagement with the App content:

"P3: what about people who can't read and write, is there going to be anything on the App for them? I'm thinking, sort of, you know, for the people who are less literate" [Focus Group 1]

3b) Lost, Stolen, Damaged or Sold

One of the consensus points highlighted by the health professionals, was that service users commonly lost or damaged their phones, and that furthermore, during the study there was a likelihood of the participating services users either not returning the phones or selling the mobile phones:

"P3: I think the thing is they use the smartphones or sell them or damage them but I think this group, the problem is that all smartphones, they'll sell them or damage them as well" [Focus Group 1]

"P3: I suppose it depends on how much more often they lose a smartphone for those periods of time. Because, it could, some of them destroy the phones weekly. Others don't. So there's a grey area..." [Focus Group 1]

However, the health professionals advised that if the TechCare App was downloadable onto the service users' personal phone, then even if they were to lose their phone then they would be able to redownload the App on an alternative device, and continue usage:

"P1: I was thinking it's an App at the end they'll use. Very easy to just download onto a new phone, isn't it?" [Focus Group 1]

3c) Confidentiality & security

Security of the device was discussed, with the health professionals reporting concerns around access to the TechCare App. They were particularly concerned or uncertain over possibilities of service users losing their phones, and whether they would be able to still access support on the App, or whether a third party could then gain access to their personalised content:

"P3: Even if you've lost the phone, you're still logged in even if you lose the phone" [Focus Group 1]

"P1: So I'm just wondering, so if you log in, you stay logged in?" [Focus Group 1]

One way that was suggested to be a viable means of providing secure access to the device was via a mobile fingerprint scanner, which would be built into the phone. This was highlighted as making access to the App more efficient and user friendly with the potential to enhance service user satisfaction with the App. In contrast, there was feedback from the health professionals that suggested that fingerprint scanners were not commonly found on mobile devices although they were becoming more and more common:

"P5: Give them [finger] print accessjust put in their thumb impression...."
[Focus Group 1]

"P2: That all depends on their device. It all depends on their device" [Focus Group 1]

"P3: They all have it at the moment to use. All these new phones will have this, all these finger-print scanners on them in a couple of years" [Focus Group 1]

It was also highlighted by one health professional (P2-FG-2), that they had experienced difficulties when using the fingerprint scanner on their mobile device. Although this was not the consensus view, it did highlight issues around difficulties in accessing the support on the App, particularly during time critical periods when timely support would be crucial, such as in the case of service users experiencing suicidal ideation. One health professional (P3-FG-1) suggested that if fingerprint access failed then alternate pin access should also be available:

"P2: Oh no, do you know I had that on that phone. It got locked, it took about half an hour to get onto my phone. for the time i just wanted to ring somebody, well It never got it right honest to god it was a bloody nightmare" [Focus Group 2]

"P4: You may just be putting on the wrong side.....I think my understanding is that any kind of finger App should be like the moment you actually touch it, basically in the middle, it should open" [Focus Group 2]

"P3: Yeah, still a pin code [necessary]" [Focus Group 2]

Furthermore, participants highlighted the importance of ensuring anonymity and confidentiality. It was suggested that the tailored support held on the App, should not be amendable by anyone thus ensuring confidentiality. On a different, but in some ways related point, health professionals held the view that any tracking of location would hinder engagement with the App, and that participants should be reassured that their location was not being tracked through the App:

"P9: Just wondering how this would work in terms of like say confidentiality..... person added to their crisis plan can come add in or whatever. what if like their family were like sort of involved with that person, could they also be involved with it" [Focus Group 1]

"P2: Can the other side of it could be for them to think that this means we know their whereabouts all the time, where they are and that's one thing. So how do we reassure them, because this is a question that's very likely to come up that why do you know all the time where I am.....So we need to be careful. So the reason I think, the reverse, it's a counter-argument but something that we need to be prepared with an answer so when it's in in practice we're able to satisfy them that no, that's not what it does. It's not a device, it's not like a tracking device" [Focus Group 1]

3d) App notifications & questions

Participants in the focus group also discussed the notifications and the delivery period of assessment questions that are aspects of the functionality of the App. It was recommended that assessments should be time appropriate, with the contents of the questions being alligned to designated timings.

"P2: So everyday they would get set questions throughout the day?" [Focus Group 2]

"P3: So i'm thinking perhaps the question should be time appropriate" [Focus Group 2]

"P3: Some questions are more suited for the morning and some to the evening" [Focus Group 2]

Another key theme which was emphasised was the view that continually notifying participants may cause annoyance to service users. It was recommended that a pre-agreed notification schedule which included the service users set preferences along with functionality to switch the notifications on and off being more acceptable. The example given was if the participant was going out they would have the ability to turn off the notifications, enabling greater control over the App.

"P4: The other thing to ask about is the annoyance as well. Because as we were talking about before, if you've got a phone and it's blinking all the time... always a new message coming up, it'll add on to it if there's something going on" [Focus Group 1]

"P2: Orientated to like sleep hygiene questions at night...have some information about relaxation" [Focus Group 2]

"P1: I think when they're going out, they might think I want to turn this off, these notification. It can get quite annoying. You know, just thinking about Facebook, constantly getting notifications. Every five minutes, somebody said this and somebody said that" [Focus Group 1]

Moreover, the timings of the notifications were also suggested as being an important part of the TechCare App delivery, with concerns related to notifications occuring at 10pm when services were at reduced resource capacity, and that there was the potential that many service users may go to sleep before 10pm and may not want to recieve

notifications at 10pm at night or after. Recommendations for an 8 hour window for the App to deploy messages was deemed a possible option. The health professionals also provided insights into the consequences of missed notifications and the monitoring by health professionals of non-engagement with the App which may enable the real-time detection of a deterioration in symptoms:

"P3: Just one thing, will we be getting a prompt if people decided to decline to do anything? Will we get a prompt back saying, that this persons not engaging in the App. It is not being that useful. Is that not a sign of deterioration" [Focus Group 2]

"P2: I dont know if 10 o' clock is late just very much like [Participant 8] said if it maybe triggers something at 10 o' clock at night when services are at a minimum level, its still a lot of time to do you know what I mean. I know everything else is on the App to support the person" [Focus Group 2]

"P2: Alot of my service users are in bed at 10 O'clock at night" [Focus Group 2]

"P3: Eight hours would be better" [Focus Group 2]

"P1: Personally, I just think at ten o'clock at night you really won't be posing questions about the way a person feels or generally relaxing in bed" [Focus Group 2]

3e) Adverse effects

The health professionals also emphasised safety considerations related to adverse effects, such as whether the TechCare App could actually cause a deterioration in symptoms. This was viewed as being an important factor which should be taken into consideration when carrying out research in this area. Although it was noted, that due to the system logging real-time experiences of symptom deterioration, the health professionals would gain a better understanding of the service users' experiences of distress:

"P3: Just one thought out of it, in some ways can it not actually increase paranoia?" [Focus Group 2]

"P2: But at the same time, you know, the data would be coming to the case manager. So you would know about symptoms..." [Focus Group 1]

"P8: I suppose it depends what the emphasis is. If the emphasis is how is your paranoia you know at this time then its going to triggers that sort of thought process isnt it" [Focus Group 2]

"P8: I think there is a great use for it in terms of being inspirational getting people motivated and what have you..... We dont want to be distracting them away from the problem. You know, as well as dealing. but not living their problem everyday....We don't like the asking every 15 minutes, how is their day now? hows your mood is it still low, doing my head in that" [Focus Group 2]

4) Can we put up things like: Development & refinement of the TechCare App

There were a number of key areas which were highlighted by the health professionals for further development or refinement of the App. This included identification of some key areas of the App that could be developed to make it more acceptable to service users. There were two broad areas of ideas, the first involved development of functions already present in the App as it was presented to the professionals at this stage, the second involved novel suggestions for functions not already incorporated in the App.

4a) Amending current functionality

One of the suggestions made was the ability to provide self-help in a stepped manner, with the intervention of health professionals if required, in a time-frame best suited to the service user. In addition, it was also suggested that the ability to target specific symptoms with tailored responses would be more feasible for some service users, however some service users would prefer face-to-face contact and this should be managed in accordance to individual needs.

"P5: This is tailored. In the sense that, as I understand it, they're actually involved in developing because when we are developing a care program, we tailor-make it to each one of you, us, who have like twenty odd patients, each CPN, their care plan is not the same as the other, just tailored to their individual" [Focus Group 1]

"P1: Could you, have a prompt set in it at maybe each step, if you've tried this and this doesn't work, contact your team and they'll be on their way....So try this you know, twice or something, and then" [Focus Group 1]

"P5: I think that's a very valid point, just to keep on it... because you know, and there are a certain number of people that we know that they are facing

communication of voices so their plan can be tailored around it so instead of people like that having four hours wait, it could be just two contacts, or one contact, then generating that so we have a smaller threshold of direct contact in such people in comparison to those who are more resilient...and again it can be tailored. It doesn't necessarily need to be four hours, it doesn't necessarily...it could be eight hours, it could be two or it could be one. So it could be tailored around that" [Focus Group 1]

In addition health professionals held the view that the App would be a means for the service users to manage their own symptoms, and would aid in the teaching of CBT principles and that a real-time intervention would reduce the time needed to contact services or reduce waiting time lists for CBT:

"P4: I think the purpose I think of this App should be actually for, for them to actually umm manage their own symptoms and distress and all yeah. Rather than..the time to get in touch with the case manager and CBT" [Focus Group 2]

"P8: Its like a teaching aid in a way because what your showing them that if you increase your activities thats.....thats the education our service users need" [Focus Group 2]

4b) Future directions

There were also suggestions by the health professionals of novel developments which could be incorporated into the App. These were developments such as inspirational quotes, a dream board, meditation and relaxation, side-effect monitoring, reminders to take medication and appointments and sleep hygiene, examples included:

"P2: I think there could probably be a way you could report your side effect on Monday, you could have a headache, or on Tuesday ..." [Focus Group 2]

"P1: Next appointment dates as well." [Focus Group 1]

The main type of self-help which was advocated as being important, was behavioural activation, with the App being referred to as an 'activity tracker'. It was also suggested that prompting participants with suggestions relating to activities they could engage in would be a valued addition. This could be further developed to include alternative activity suggestions, with completion of activities corresponding with weekly goals and rewards:

"P1: Just to ask, so general notifications, what does that really do? You might look at what sorts of things people need to be doing every day to keep themselves well. So you know, a list of things like that could come up. You know, have you done this, have you done that?" [Focus Group 1]

"P8: in fact there is something that could like a point system. So they've got all the things they want to do that week, do an activity, engage in some kind of meditation something like that and they agree to that start the week and if they hit it, it can form part of a calendar or something like that, and you know by the end of the week they've you know, I don't know" [Focus Group 2]

It was reported by health professionals that Internet resources, particularly helpful websites such as Minds Matter and the hearing voices network, were resources which were recommended to service users. However the uptake and impact of such resources had never been fed back to the professionals:

"P4: You know most time I think they look into medications and things" [Focus Group 2]

"P2: Yeah I have recommended hearing voices websites and things like that but whether.... I have never actually done it with them or spoken to them about various websites that they can access" [Focus Group 2]

"P4: Links you put in your talking about, like hearing voices, minds matter and you know...and umm there are other links that are useful" [Focus Group 2]

It was also suggested websites such as a Rethink provided useful information that would be beneficial to service users:

"P4: I think the links basically... Rethink. When you go on to www.rethink.com There will be a lot of, what do you call, suggestions from that as well. What will be useful and all" [Focus Group 2]

In addition to the Internet resources it was suggested that social media-based platforms on the Internet were also important means of communicating and socialising for service users, on platforms such as Facebook:

"P2: Facebook is huge now, just the basic way of communicating. People find news out, family members find Facebook. Don't they" [Focus Group 2]

The use of other forms of multimedia were also discussed such as videoclips and images:

"P2: You can add images or clips in there?" [Focus Group 2]

6.3 Summary and Conclusion of the Health Professional's Focus Groups

Results of the focus group with health professionals provided a unique perspective of conducting mHealth research within an EIS context and the differing challenges health professionals anticipated facing in delivering the TechCare App intervention. Moreover, key areas of modification and refinement of the TechCare App also emerged from the focus group discussions, providing important considerations for development in Strands 2 & 3. The main finding of the focus group was that professionals saw the potential for the TechCare App to increase access to digital technologies, providing service users with an alternative medium to communicate with the EIS health professionals. However, these staff felt that despite mHealth Apps being a useful platform to deliver interventions, face-to-face contact should remain an important aspect of routine care.

Key Findings: Professional staff reports

- The majority of service users have access to mobile phones, with mobile phones providing an important means of communication between service users and health professionals.
- Stigma is a major factor in impeding access to services, with the TechCare App potentially providing an alternative to having health professionals conducting home visits.
- The TechCare App was deemed a viable platform, which could be integrated with the current service delivery pathway within EIS.
- The App was viewed by the health professionals as an interactive care plan, with the benefit of being accessible in real-time.
- The personalisability of the intervention was viewed as providing the ability for the service to facilitate self-management of symptoms and enabling a sense of ownership.
- Scepticism that service users would make best use of the mobile App, as they commonly lost, sold or damaged their phones.
- Factors relating to the security and access arrangements on the device are important issues relating to concerns about confidentiality.
- The timings of the App notifications and questions should be dependent on service user preference.

- The TechCare App was seen as supplementing the work of the health professionals, with continued face-to-face support deemed of paramount importance in ensuring effective care for service users.
- Ensuring adverse events such as a deterioration in symptoms are monitored was seen to be an important potential function.
- Ideas for further refinement of functionality included incorporating the following in the further development of the TechCare App:
 - Inspirational quotes
 - Meditation and relaxation
 - Side effect monitoring and medication
 - Sleep hygiene
 - Appointment scheduling and reminders
 - Planning and behavioural activation
 - Internet resources such as Rethink.org, and mind and social networking websites such as Facebook
 - The importance of allowing personalisability of the intervention, to the specific needs of the participant

6.4 Findings of the Pre-Intervention Qualitative One-To-One Interviews with Service Users

The following section will present the findings of the Strand 1, one-to-one interviews with service users. The interviews were conducted to gain an understanding of the subjective experiences of the individuals taking part in the study. With reference to the study objectives the interviews broadly investigated the feasibility and acceptability of the intervention. This pre-intervention qualitative work was also aimed at gaining a better understanding of the health inequalities associated with mental health with particular interest in any relationship between mHealth and equalities concerns. At this stage of the research, I wanted to examine factors relating to acceptability, with particular reference to informing the development and refinement of the intervention (Strand 2) but also to gain the perspectives of participants to be included in the Strand 3 feasibility study, prior to undertaking the intervention.

The interview participants provided wide-ranging, relevant views regarding these questions, furnishing rich data grounded in their personal experiences of mental health difficulties, engagement with services, and use of mobile technologies. Overall, the key themes that were identified in the analysis were organised into a coding framework as follows: accessing support for psychosis, mobile phone usage and ownership, the acceptability of the TechCare intervention, confidentiality and security and areas of development and refinement of the App. The following Table 6.3 shows the coding framework used.

Table 6.3: Coding Framework for the Pre-Intervention Interviews

	Themes	subthemes
Coding Framework	Pre-intervention	
	1) <i>It weighs you down: Accessing support for psychosis</i>	a) Experiences of inadequate access b) Mental health stigma c) Feelings of isolation
	2) <i>You're always on your phone: Mobile phone access and usage</i>	a) Communication via mobile devices b) Financial considerations and implications c) Connectivity to the internet/Going online
	3) <i>It's a brilliant idea: Acceptability of the TechCare App intervention</i>	a) TechCare App layout and design b) Acceptability of proposed study procedures
	4) <i>We don't want people knowing: Confidentiality and security</i>	a) Personal information b) Pin codes, passwords and biometric scanners
	5) <i>Keep it Live: Intervention development and refinement</i>	a) Development considerations b) Incorporating multimedia

The data was coded using the above framework. The next section presents the findings of the analysis of this pre-intervention qualitative work with service users, providing a description of each theme illustrated with quotes taken from the data.

1) *It weighs you down: Accessing support for psychosis*

This account presents participants' views regarding accessing support for their mental health difficulties, specifically highlighting complications and problems in accessing support. Sub-themes explore individuals' experiences of various factors that impede access to appropriate and valued support. These include, failings in support and frustrated access to services, a lack of understanding of their needs, the role of stigma in complicating access, and experiences of isolation. Throughout, the participants call attention to possible benefits that a helpful mobile App might generate in addressing the highlighted problems.

1a) *Experiences of inadequate access*

This sub-theme highlights participants' experiences of a lack of support available for individuals with psychosis and frustrations with services. Of note was the perceived need for greater accessibility to mental health services particularly the need for information relating to services available for service users. TC10 described how difficulties in obtaining the right help, had been a factor, which 'weighs you down', as there was a tendency to be passed from organisation to organisation, resulting in a delay in receiving care:

"TC10: I found in the past that... to be able to get the right help that you need is very difficult because you have to end up going through so many different people it sometimes weighs you down until you get to the right person. In my situation, it was being passed from different organisations you know to eventually to [EIS] that's the outcomes of it at the minute."

Furthermore as indicated by TC5, participants held the view that the level of help available was limited and that providing service users with an App would be better than being left alone. In the illustrative quote below, despite the lack of awareness of support available, it was felt providing an alternative medium would allow greater access to support, with the App enabling access to support and bridging this gap.

"TC5: I think they would think it was good because theres not a lot of help that's out there for people that are having like difficulties and stuff, so the fact that you are making something, so you can just like, I just need some help, like you even have to contact anyone, you can just like look at it and look through different things...its better than just being left alone"

In addition to the above quotes further subthemes emerged from the data, relating to access to support for service users. The subthemes which emerged related to; service users understanding of psychosis, mental health stigma and feelings of isolation.

1b) Mental health stigma

Stigma was an important theme expressed by the participants; it was made clear by the participants that mental health stigma was commonly experienced by those with psychosis, with the App being a potentially discrete medium for accessing support. Participants felt that stigma should be a major factor in developing the App, with the App being a feasible medium to access support for those who affected by stigma.

"TC4: I had names called because of illness...a phone is discrete no one will know"

"TC4: Probably young people, would benefit....its more discreet"

"TC8: it's a good idea yeah, because like you said theres a lot of stigma around it, with mental health issue, like people start looking at you differently"

Areas relating to stigma as referenced suggest that the anonymity and ability for the App to log itself out when not being used for 60 seconds, was a beneficial function in helping address stigma by enabling the information to disappear from the screen within a 60 second window. Furthermore, TC5 described how stigma around mental health had made it difficult to talk about their experiences, as people who did not know them would automatically be scared of them highlighting the impact stigma had on service users:

"TC5: Like if anyone ever asks me like, people who don't know me, if they ever ask me, like what was wrong with me and then I explained it to them, they're automatically scared, like they're just scared of me straight away, but im not a scary person [Stigma]"

1c) Feelings of isolation

Participants held a consensus view that in their experience they had felt isolated, with this resulting in not being able to access support. In addition the view that an App could allow service users to feel less alone. Futhermore an intresting finding which emerged form the data was having the ability to share experiences with other service users, would allow them to normalise their experience and provide a sense of not being the only one with psychosis:

"TC10: Sometimes you feel isolated and you think sometimes you're the only one with this illness or you're only one that can't get help for this and stuff but there's hundreds and thousands of people out there with the same thing sharing their experiences so it's really good"

"TC8: It's a good idea isn't it, in essence I suppose like help people know they're not on their own"

"TC5: it would make me feel less alone"

Furthermore TC7 described how their mobile phone had been a useful means of allowing them to engage in some form of activity on their device when alone:

"TC7: It doesn't get in the way, in a way like say when theres no one around I have something to do....other then that I dont feel like I have anything to do"

2) *You're always on your phone: Mobile phone access and usage*

One interesting finding of the qualitative interviews was that there was a feeling that although mobile devices were an important part of day-to-day life, there was a need for moderation in usage. Mobile devices were reported to be easily accessible, with all participants engaging in mobile phone usage throughout the day. This inferred that mobile devices could potentially be a familiar medium for accessing support. Furthermore, participants reported using their phones a couple of hours a day. This was an experience shared by all participants except one who advised not using his phone much, although they advised it was helpful for keeping track of bill payments and for calling people. Participants described using their mobile phones regularly, with the main functions being to text message people. Also reported by the participants was the financial implications of mobile ownership and connectivity to the Internet.

2a) *Communication via mobile devices*

The participants described using their mobile phones regularly, with the main function being to text message people. Furthermore, it was reported that communicating or talking about their distress had been a difficult experience for them, with SMS text messaging helping bridge the communication gap. This view related to the text messaging providing an alternative way to communicate with people. It was also highlighted that owning a mobile phone gave a sense of reassurance, as they could use their phone to get support if needed. In contrast TC16, held the view that although texting allowed for easy communication, face-to-face communication was helpful in building a dialogue and was deemed an empowering experience.

"TC16: Texting is easier, sort of still need face-to-face as it helps to build a dialogue and is empowering"

"TC9: Umm I think I be.... Sometimes someone might be more honest in a text message....because they might not really want to say how they feel on the phone"

"TC2: because you've got psychosis you don't like talking to other people because you've got other people in your head if you get what I mean, so like if you've got a phone, then you know you're typing not speaking it"

2b) Financial considerations and implications

Some of the participants voiced their concerns of the financial implications related to ownership of the mobile devices. However, only a minority of the participants held this view, with participants highlighting the affordability and low cost of mobile ownership. Furthermore, it was noted that costs of ownership varied based on the prime usage of the mobile device, with factors such as costs relating to data for internet connectivity and the cost of call time being dependent on service user preference. TC7 advised that in their view, of primary importance was data costs relating to accessing the internet:

"TC9: Um I think smartphones are really expensive"

"TC7: It depends as well I think I mostly use unlimited text....data is most important, so I think it depends on using internet.... it can be cheap on costs, using the phone but it depends on what you use and what's important to you like some people might use internet, they might call a lot, but I don't so that's like bare minimum for me and again the type of phone are you using so it really depends"

2c): Connectivity to the internet/Going online

References to the internet connectivity of mobile devices, and the ease of going online were also described by participants. One of the major implications of this was the experience of TC16 who lived in a rural area of the North West and was unable to obtain a mobile network signal although had access to Wi-Fi/broadband. In addition, social media was found to be mostly a useful aspect of the experience of going online, however there were some concerns that you could post things online and be judged by people.

"TC9: Yeah definitely...Um I think everyone uses the internet nowadays because it is so readily available um I use like you said I use Google"

"TC12: Yeah I use the internet....right now its looking for jobs, I don't know why I keep, because that's what I keep doing..."

"TC15: I use the phone for Facebook and messenger"

"TC9: Umm I think nowadays you can umm use them in a lot of things. Umm like productivity umm there is also the social side of it, social media"

Participant TC12, suggested that although mobile technologies could help people, there were some concern relating to social media. TC12 highlighted implications of posting things on social media, with the impact this could have on service users whilst in crisis.

"TC12: It could be because it would ruin their reputation, especially if you're south Asian, you know like, being a muslim as well, its not, it has its downside. Because when people find out, it makes you feel even worse and do you know all this paranoia that ive got, its because I created it myself by using Snapchat, Instagram, people finding out, people talking...But it helped me in way, but in another way it didn't help me..."

TC12 also commented that there was a need for balance, and that apps such as Instagram, allowing only select people to view a service user's profiles would be more acceptable. It can be seen that although there are potential negative consequences of engaging with mobile technology, greater control and enforcing confidentiality is key.

3) *It's a brilliant idea: Acceptability of the TechCare App intervention*

On providing a demo of the App, feedback obtained from the participants was highlighted as being an acceptable form of intervention. The App was described as a 'brilliant idea', and that treatments delivered in this way would be acceptable. All participants provided feedback detailing that they did not envisage service users being averse to using the TechCare App. However, factors such as the App layout and design features were crucial areas for considerations.

3a) *TechCare App layout and design*

Design related factors such as the logo and name were also examined to ensure acceptability; it was found that participants felt that the logo and name of the TechCare App was acceptable. On analysis of the data, the reasons for this can be seen in the following participant quotes. The views held by the participants, related to the TechCare name and logo not holding any obvious sign related to mental health or illness, thus a less stigmatised approach:

"TC3: Umm I don't know. Its just abit normal init [TechCare Logo]...Its like anonymous, you can't tell.. You can't tell what it is, if it was like a medicine sign people would know what it means"

"TC12: TechCare, I like TechCare because its, if its something with...it doesn't have any stigma attached to it TechCare, its just an App called TechCare.... no one would know what TechCare is"

3b) Acceptability of proposed study procedures and processes

I also investigated factors relating to the acceptability of the research procedures and processes, which would help in the development of the proposed future trial. Participant TC3, provided some insight into this by presenting the view that the ability to quit at any time would give participants no reason to not partake in the study. This suggests the importance of ethical principles such as autonomy when conducting research, and ensuring suitable withdrawal processes are in place and the reassurance that participation is voluntary. In addition, participants were also asked if they would involve their family/carers in the TechCare App process. TC3 advised of how their social support network was available if they needed support, and that they would be happy to involve their family/carers in the TechCare App process:

"TC15: I will be happy to involve my family"

"TC9: Um I think for some people, I think the family support would help. Umm but some people might want to make it a personal experience.....and might not want anybody else involved in it"

"TC3 My family do it, yeah. But other families might not. I know my family would do it, It would be good yeah"

The above participant quotes suggest that inclusion of family/carers was acceptable in the TechCare App intervention. However, providing service users with a choice and preference was important, as there was a possibility that some service users may not want to include their family/carers in the intervention process.

4) We don't want people knowing: Confidentiality and Security

Participant views relating to confidentiality were also discussed in the one-to-one interviews. There was specific reference to the security access on the device and how it would play an important role in people accessing personal information on the individuals. In addition, as outlined by TC9, having a privacy policy on the App would provide further details on the confidentiality arrangements of the intervention. Having this explained by a health professional helped reassure service users around the confidentiality of data:

"TC8: Yeah we don't want people knowing sort of thing"

"TC9: Umm cause I know some people like me who might not want our information to be [shown] to everybody...um I think if it was explained by a care worker or...yeah umm maybe have the privacy policy on the App...just so they can read it"

4a) Personal information

In addition, one of the subthemes that emerged was security considerations in relation to the service user's personal information held on mobile devices. Participants highlighted their concerns around having their sensitive information on the device, with TC7 noting that they had their email account, bank account details and social media accounts on their mobile phone. Furthermore, TC10 reported that they allow for the health care team to view their personal details, but would not want unauthorised access to their personal details:

"TC7: I have quite a lot of things like I have my email account on my phone and I have my bank account App on the phone as well so it is really important that its properly secure I do have a pin code on it but sometimes a lot people get through that so I need to keep alot of security codes on my phone and phone Apps well specially even like your social media Apps theirs alot of stuff that like you have personal stuff like you would'nt want anyone to see"

"TC10: Not really, only concern I would have if you had to put your full name in it for other people to see that would be the only concern that I would have in case other people could see. I don't mind the organisation [NHS] to see but someone that could log on from I don't know the other side of the world and see it"

4b) Pin codes, passwords and biometric scanners

Another subtheme which was referenced in the one-to-one interviews was the importance of ensuring security and access to the App, with suggestions being made regarding the use of pin code or passwords. Security options such as passwords or biometric fingerprint scanners to gain access to the App was viewed in a positive light. Ensuring enhanced security procedures such as pin code or finger print access were advocated as a suitable approach to securing the device:

"TC12: Confidentiality, you should put like a password on or something"

"TC8: Yeah obviously, you set that yourself don't you..... its just a four digit passcode well it stops anyone else getting on it doesn't it"

"TC16: Ensuring that data is encrypted, fingerprint scanner, improve the user experience make it more user friendly"

5) Keep it Live: Areas for development and refinement of the App

There were a number of ideas projected by the participants in relation to the development and refinement of the App. Firstly the language, the App would need to be multilingual to be accessible to those who could not speak English. Some of the key areas of development and refinement of the App which were suggested by the service users were; enabling personalisable settings in the TechCare App, inclusion of helpful websites, suicide support helplines, calendar reminders for medication and appointments with health professional, the ability for service users to note down how they are feeling using the App, and information on mental illness and medication side-effects.

5a) Development considerations

Areas of development were highlighted by the participants, these were ideas such reminders to take medication and attending appointments, being made easier if this could be recorded on the App. This was an interesting finding which indicated the importance of mobile phone reminders and notifications having the potential to increase engagement with both treatment and mental health services.

"TC15: For medication reminders maybe I need like a video of the service so you know what to expect"

"TC15: Calendar to take your medication and appointments"

"TC8: Yeah I suppose. Sometimes I struggle like it's when like a week or whatever between my appointments, its hard work remembering things that have gone on, so I suppose it keeps you up to date, it keeps it live like you said"

In addition, there was a general consensus that service users had a limited understanding of psychosis and had difficulties in explaining their experiences to family and friends. Recommendations were made to include helpful information on the App relating to gaining a better understanding of psychosis:

"TC5: You see like my partner, ive been with him three and a half years and I still cant explain it to him properly, he still doesn't understand what it is or like he

doesn't even, he just doesn't get it at all....Not many people understand [Psychosis] it can be difficult. They have the experience they are going through but don't know what it is"

"TC4: Peoples experiences/stories what other people are going through"

"TC9: Umm things like videos explaining mental illness umm"

"TC8: Well just, not just less broad, when I got diagnosed with psychotic disorder I looked it up online and theres loads of psychotic disorders, so I was thinking which ones me....its just all very broad and vague"

A further area which participants suggested could be developed, was having a function on the App which would allow them to view other service users experiences and stories. This signifies the potential of mHealth Apps to provide a means for normalising the experience of mental illness, through a shared medium such as mobile device. In addition, an interesting suggestion which was advocated by the participants was the ability for service users to make notes within the App, as a means of keeping a diary of their experiences. Most notably this was indicative of being most beneficial in recollecting their experiences of distress. This was an important factor as many participants were of the view that remembering their experiences of distress was difficult:

"TC9: Umm I think umm for me writing down how I feel would be...would be helpful umm because sometimes even though I write down how I feel, I might not really take much out of it. Umm.....I think that would be helpful...because umm sometimes I do remember to write down my thoughts and sometimes I don't.....And I think it would be helpful if I don't remember"

"TC8: What's going on at the moment, and then you don't forget it do you then because its down in the app history and that"

Other development and refinement ideas presented by the participants centred around the inclusion of coping strategies and motivational pictures. These were interesting additions to the TechCare intervention, and its further development in the next phase of the research.

"TC15: Coping strategies such as listening to music and talking to friends using a mobile phone. When feeling unwell activity ideas how to learn from other people who have had similar difficulties"

"TC16: Coping strategy information about medication side-effects"

"TC9: Yeah um I think there is a positive side to it umm for example like motivational pictures. Things like pictures, like that have motivational quotes on them"

"TC3 Umm I don't know. It could post links you know to sites, what could offer you help and stuff, offer you information and advice"

5b) Incorporating multimedia

From the service user's personal experiences, it was highlighted that access to multimedia was a commonly used means of helping with symptoms, particularly experiences of low mood. Participant TC14 described how watching humorous comedy clips on YouTube was an uplifting experience, as this had a positive impact on their mood. An interesting use of multimedia was reported by TC8, who suggested incorporating informational videos to help understand experiences of psychosis:

"TC8: Well I find watching something that you enjoy is a good distraction, but yeah...it's a good idea yeah "

"TC9: Just to support people about everything and umm so videos like they display what's happening when you are psychotic"

"TC14: Yeah multimedia....it makes me feel better.....its just uplifting"

6.5 Summary and conclusion for pre-intervention one-to-one interviews.

On analysis of the pre-intervention one-to-one interviews, the main themes that emerged related to the access to mobile phones, the acceptability of the intervention and areas of development and refinement of the TechCare App. Mobile phones were seen as familiar part of life by the participants, with the main usage being to communicate via SMS. The TechCare App was seen as an acceptable means of delivering interventions for those with an experience of psychosis. The results of this Strand were used to further develop and refine the TechCare App in the subsequent Strand 2. Other important considerations which were made related to the stigma faced by the service users, and concerns about confidentiality. I will now note down the key findings of the pre-intervention qualitative work in preparation for the test-run.

Key findings from the pre-intervention one-to-one interviews

- Participants reported difficulties in gaining access to support for psychosis, with the service user participants describing feelings of isolation.
- The TechCare App was deemed an acceptable means of delivering interventions and provided an alternative means of seeking help.
- Participants described easy access to mobile devices, however reported the financial implications of mobile phone ownership
- Having access to the internet was deemed an important factor for consideration in the development of the TechCare App, with one participant highlighting difficulties in connectivity due to living in a rural location.
- Possible negative implications of mobile technology was also highlighted pertaining to use of social media.
- Some of the key areas for development were noted by the participants as follows;
 - Multilingual functionality of the App
 - Personalisable settings
 - Inclusion of a suicide support helpline and useful websites
 - Helpful Information on psychosis
 - Ability for participants to note down how they felt
 - Incorporating calendar reminders and appointments into the App
 - Information relating to medications and side effects
 - Multimedia, such as humorous comedy clips

6.6 Results: Strand 2: Test–Run & Intervention Development/Refinement

The following section will provide details of the findings of the Strand 2 test-run and intervention development & refinement. I will firstly present the quantitative results of the test-run, to examine the preliminary assessment of feasibility of the TechCare App. Taking into account the test-run results, I will then examine the recommendations made by the service users and health professionals in Strand 1, and outline the changes made to the App as part of the intervention development and refinement component of the project.

I have outlined a number of key areas of refinement below in the development of the TechCare study, working alongside both participants and service user representatives at an NHS Trust in the North West. Feedback from the participants in Strand 2 provided insight into the refinement and further development of the App, both in terms of the intervention content, design and the research process and procedures. The key aim of this component of the research was to ensure that any design flaws or procedural aspects of the intervention delivery were examined.

6.7 Strand 2: Results of the Test-run with participants

A total of $n=4$ participants took part in the test-run, with 3 participants being male and 1 female. The mean age of the participants in this strand of the project was $M=22.5$. All participants were receiving treatment from the EIS for psychosis; the demographic data is presented in Table 6.4 below:

Table 6.4: Strand 2: Test-run Participant Demographics

		Total
Gender	Male	3
	Female	1
Age	Mean Age	22.5
	Range	19-30
Ethnicity	British - White	4
	British - Indian	0
	British - Pakistani	0
Work	Self-employed	1
	Part-time employment	0
	Unemployed	3
	Student	0
Living situation	Living with family	3
	Lives on own	1
Marital Status	Single	3
	Partner/Married	1
	Separated/Divorced	0
Diagnosis	Psychosis	4

6.7.1 Test-Run: Preliminary Results

Preliminary analysis was conducted on the test-run data to gain a perspective of the feasibility of the intervention and data collection via the web application system. On analysis of the outcome data, the PANSS and PSYRATS were both conducted pre- and post- intervention, with data gathered on the 3 Subscales of the PANSS (Positive, Negative and General Psychopathology), and the 2 subscales of the PSYRATS (Voices and Delusions). The mean scores on both measures was calculated at baseline (PANSS Positive Scale ($M=15.25$, $SD=3.30$; 95% CI , 9.99 to 20.51), PANSS Negative Scale ($M=16.00$, $SD= 7.44$; 95% CI , 4.16 to 27.84), PANSS General Psychopathology ($M=33.00$, $SD=5.10$; 95% CI , 24.89 to 41.11), PSYRATS Voices ($M=19.00$, $SD= 14.54$; 95% CI , -4.13 to 42.13) and PSYRATS Delusions ($M=13.50$, $SD= 6.02$; 95% CI , 3.91 to 23.09)) and at Week 2 end of test-run ((PANSS Positive Scale ($M=14.25$, $SD=4.65$; 95% CI , 6.86 to 21.64), PANSS Negative Scale ($M=14.25$, $SD= 7.89$; 95% CI , 14.25 to 1.70), PANSS General Psychopathology ($M=28.25$, $SD=5.56$; 95% CI , 19.40 to 37.10), PSYRATS Voices ($M=17.75$, $SD= 15.28$; 95% CI , -6.57 to 42.07) and PSYRATS Delusions ($M=6.00$, $SD= 7.66$; 95% CI , -6.19 to 18.19)) and can be seen in Table 6.5 below.

Table 6.5: Mean and Standard Deviation of Pre-and Post- Assessment Scores

Strand 2: Test-run		Mean	Std. Deviation
PANSS Positive Scale	Baseline	15.25	3.30
	Week 2	14.25	4.65
PANSS Negative Scale	Baseline	16.00	7.44
	Week 2	14.25	7.89
PANSS General Psychopathology Scale	Baseline	33.00	5.10
	Week 2	28.25	5.56
PSYRATS Voices	Baseline	19.00	14.54
	Week 2	13.5	6.03
PSYRATS Delusions	Baseline	17.75	15.28
	Week 3	6.00	7.66

From the above table it can be seen that there was a reduction in mean score between baseline and week 2 on both measures.

6.7.2 Analysis of the Test-Run iRTT Data

I collated the data from the iRTT system and conducted preliminary analysis of the iRTT data on the 4 participants who took part in the test-run. Over the 2 week period a total of 515 questions were answered by the participants. The participant who answered the most number of questions was TC2 (316), followed by TC1 (108), TC4 (70) and finally TC3 (21). Other findings of the test-run data showed, that over the test-run period a total of 114 notifications were clicked by the participants, an average of 2.04 times a day. Furthermore, the data also showed that the most commonly used intervention by the participant was multimedia, which was accessed a total of 26 times. Participant also accessed the helpful links section on the App home screen a total of 28 times, tapping into the psychoeducational information and links.

6.7.3 Refinements to the TechCare Software

Part of Strand 2 also examined any software difficulties or faults that occurred during the test-run. The mobile App software and integrated web portal were coded using the Microsoft Azure Server. In addition to the participant related recommendations, the software code was monitored by the software engineers, with errors in the code being sourced and corrected. The main software problems encountered are summarised in Table 6.6 below, with a brief description of how the faults were resolved by the engineer outlined. A more extensive log of the changes made by the software engineer is attached as part of Appendix 9.

Table 6.6: Software Errors and Modifications: Event Log

Date	Software Errors and Modifications: Event Log
14/01/2016	Moving from Windows Phone 8.1 to 10 resulted in small tweaks in the user interface due to different screen sizes.
28/10/2015	Provided visual feedback to users when logging in. A 'Please Wait' message lets users know that tasks are being processed in the background
23/09/2015	Debugging the live notification process is difficult- To resolve this write to logs at key points within the process. Logging added to the mobile Application
21/09/2015	Alterations to how the random notification algorithm worked. Notifications were randomly spaced; therefore, the algorithm was altered to spread the notifications over the course of the day
22/07/2015	Added new logo for splash screen and tile/badge
16/07/2015	Fixed error - reminders still being sent when disabled
16/07/2015	Fixed timing errors - mobile App using British Summer Time and server using GMT

There were found to be a number of errors in the software, which were investigated and resolved by the engineer. An important change made by the software engineers was the migration of the App from the Windows 8.1 operating system to Windows 10 mobile. Other changes in the software were mainly in relation to ensuring the notification system was working correctly, and the screen size and timings were correct. Furthermore, based on the feedback from the service user representatives a more user-friendly process of logging in using visual feedback was implemented.

6.7.4 Improvements to the Research Procedure

The first factor, which was reviewed in conjunction with the service user representatives and through the qualitative work with health professionals and service users, was factors relating to the consent procedure and participant information resources. Feedback from the service user representatives suggested an easy to understand user guide would be of benefit to service users in understanding how to use the App. It was recommended that images in a storyboard format would be a feasible means of developing the user manual for the App. I worked with the service user representatives to develop a simple easy to use manual. The images are cartoon characters, which provided a walkthrough of the App. The use of images was found to be a beneficial medium of providing

descriptive information of how to use the TechCare App for the participants (see Appendix 10).

In addition, a practical issue that I encountered in the delivery of the intervention was ensuring the participants would have credit on the mobile device. It transpired that participants would run out of internet connectivity and further allowances had to be made for participant TC4, who used all the data for internet connectivity in the first week. The initial allocation of £15 provided 5 GB of data and unlimited text. It was also noted that for some participants completing the assessment questionnaires, the time taken was deemed acceptable. However, some participants required extra time as they may have started to lose concentration. In remediating this, I was mindful of ensuring that the participants had enough time and were given breaks as not to burden them.

6.7.5 Initial Development of the TechCare App

The present section highlights the considerations in the initial development of the TechCare intervention. Factors such as security of device and stigma were highlighted by both the service users and health professionals. The area of mHealth is a relatively novel field with a paucity of research investigating the application of techniques such as Experiential Sampling Methodology (ESM) technology within the conceptual framework of iRTT. I have outlined a number of key factors below, which were examined as part of Strand 2 of the study.

Firstly, viewing data on mobile devices highlighted a number of safety and ethical implications. Portability is a key factor in mHealth due to the rapid access to health data; however, security of data is important as outlined by the Data Protection Act (1998). Perera (2012) described a number of safeguards, which can be used to ensure data security on mobile devices. For example, they should be accessible via a PIN, and it is recommended that rather than a four digit pin an alphanumeric passcode be used. In addition, functionality whereby data is wiped from the device after 10 failed passcode attempts further protects data (Perera, 2012). Furthermore, the encryption of mobile devices, enabling remote wiping of data held on the device and also storing data in the cloud rather than on the mobile device, were key strategies employed in ensuring data security.

Another factor, which needed to be considered, was the number of notifications and alerts which were programmed into the App. The notification iconography needed to be discreet as not to cause any distress to participants in the case of someone accidentally

viewing the icon, as this may have inferred that the individual was undergoing therapy and was deemed as stigmatising. The App initially displayed the NHS logo, however based on feedback from the service user representatives a new logo was designed (see Figure 6.1 below).



Figure 6.1: TechCare App Logo

It was also important that participants felt no pressure in replying to notifications. A study by Palmier-Claus et al., (2012) found that out of the total population of participants in their study, one participant withdrew from the study due to distress as a result of continual rumination of symptoms. It was recommended by the service user representatives and participants in Strand 2, that participants should be given control in the use of the mobile device, and it should not be seen as an intrusion into their daily life, with participants not being required to respond to notifications. The TechCare App was thus designed to allow participants to ignore notifications, if the participant did not want to respond to the TechCare App notifications at any time point in the study.

It was important to ensure that participants in the study had a point of contact for any technical difficulties that they faced. If the mobile device is faulty or experiencing a technical fault, it could have detracted from the overall effectiveness of the intervention. This is more of a significant concern when dealing with individuals who may be in mental health crisis and need to alert the EIS. A study by Spaniel et al., (2012) used a text message based questionnaire to score early warning signs in participants. High scores on early warning signs would initiate an alert to the clinician in the form of an email with the clinician initiating a pharmacological intervention. It was therefore imperative that the mobile devices were in full working order to ensure the safety of service users when there was a need for alerts to be sent and received. To overcome this, I had planned to discuss difficulties with the device during the weekly assessment visits.

Mobile technology can be seen as a potentially beneficial platform for delivering health interventions in the real-life experiences of people with psychiatric disorders such as psychosis. However, it was vital when developing the research study that considerations

were made to the safety and security of the device to allow participants to be free from harm. A significant consideration was the personal and sensitive nature of the questions posed on the TechCare App. The App questions were thus developed with the service user representatives. I informed participants exactly what was involved, allowed for as many breaks as needed and handled the assessments sensitively. Participant's details were entered anonymously onto the database with raw data stored in a locked cabinet in a secure room.

The information held on the smartphone device was only accessible via a PIN number ensuring confidentiality. All information collected, as part of this study, written or digital was kept strictly confidential and conformed to the Data Protection Act (1988) with respect to data storage, collection, and destruction. This was to ensure the confidentiality of any information that was obtained from the participants' NHS Records. All participants were given a unique code which I used to identify their research data. The research data itself was stored on computers in scrambled (encrypted) format and could only be read with a 'key' (password). With the participants' permission, the GP as well as their care coordinator and psychiatrist were notified of their participation in the study.

6.7.6 Further Refinement of the TechCare App

After the initial development of the TechCare App, in conjunction with the service user representatives, further refinements to the App were made based on recommendations by the health professionals and service user participants in the test-run. Firstly, based on feedback from the participants it was highlighted that the App should be accessible via a PIN. I also gained feedback on the notifications iconography and also how many notifications the service user would like to receive in the test-run strand. The preliminary results suggested three notifications per day would be feasible and acceptable for participants. One of the key changes that was suggested by the participants in the test-run was the layout of the App. There was also factors such as the connectivity of the device when participants used the App at home. Although the majority of participants in the test-run we're able to connect to their Wi-Fi, one participant required further top-up to continue on the study. Changes to improve the App were also made based upon the views of the health professionals. Advancement in mobile technology can be seen as a potentially beneficial platform for delivering health interventions in the context of real life experiences of people with psychiatric disorders such as psychosis.

Another factor which was identified in this phase was concerns over potential adverse effects the intervention could have in relation to an exacerbation of symptoms. Through

consultation with the care coordinators, maintaining participant safety during the study was of utmost importance. The primary area of concern was whether the system would be able to detect exacerbations in symptoms and prompt health professional support in a timely manner. However, as the test-run was only 2 weeks long with stable and low risk participants taking part, no side effects were reported during the weekly visits. Building on this, I felt a means to better ensure safety for participants would be to discuss this with participants and care coordinators in the weekly assessment visits. I then planned to review safety with the care coordinators at each weekly assessment visit, in the feasibility study. This would also involve having a discussion with the service user to ensure if they had experienced any side effects whilst using the TechCare App.

6.8 Summary and conclusion of Test-run Findings Section

The results of the pre-intervention qualitative work was collated alongside the results of the test-run. This led to the further development and refinement of the TechCare App, alongside involvement with the PPI members. It was important to conduct preliminary testing and qualitative work before roll-out of the research in the Strand 3 feasibility study. In addition, not only was the App further developed and refined based on the suggestion of the participants and PPI members, I also looked at the processes and procedures relating to the delivery of the App. There were a number of important technical factors relating to the software which were logged and resolved by the software engineers. This strand of the research was important as I was able to work with the service user representative to develop the participant resources such as the user manual and participant information leaflet.

6.9 Chapter 6: Summary & Conclusion

This chapter has presented, in two consecutive sections, findings from qualitative inquiry with stakeholders, comprising preliminary/pre-intervention focus groups with health professionals, and preliminary one-one interviews with service users and a test-run of the App with service users. Taken together, the results of Strand 1 (pre-intervention qualitative work) and 2 (Test-run) were used to further develop and refine the TechCare App, along with PPI involvement. Other important considerations which were made related to the stigma faced by the service users, and concerns about confidentiality. The qualitative component of the research pre-intervention was conducted to examine the views and perspectives of the health professionals. This was an important component of the research as it provided insights from health professionals who work with the target population in clinical practice within the context of the EIS. Findings of this strand

of the research were found to contribute to the research aim of determining feasibility but at the same design of the intervention. The key changes made at this stage are summarised in Table 6.5 below. Although it was my aim to include all the suggestions made by participants, I was restricted to only those changes which would not necessitate any increase to the development budget. Although many changes were made as part of this stage of the intervention, there were some changes which would need to be considered as part of any future scale up work.

Taking all of the project groundwork together, from the immersion in context and background, use of the HIAT, the systematic review, and inquiry informing the development and refinement of the App and decisions about overall study design, a logical development process is apparent. We can see the results of the HIAT working with service users determined the differing aspects that would need to be considered relating to health inequalities. I then conducted an evidence synthesis to determine what research had been conducted in this area. Finally, through the Strand 1 and 2 pre-intervention qualitative work and test-run, I was able to establish key factors related to the refinement and development of the App. These stages of the research ultimately provided the groundwork for the Strand 3 feasibility study.

Table 6.6: Strand 1 Feedback and the TechCare App Development/Refinement

Feedback from Strand 1 & 2	Refinement and Development of the TechCare App
Feedback from the health professionals	
(1) The health professionals felt that the App would benefit service users if they were able to incorporate meditation and relaxation techniques	The App was programmed to be able to incorporate YouTube links on meditation and relaxation
(2) Medication management was a prominent theme which came out of the qualitative work with health professionals	As part of the personalisability, messages could be included in the TechCare App system for service users to take their medication
(3) It was suggested that the inclusion of a helpful links sections consisting of useful websites could be potentially beneficial to participants	Links to internet resources such as Rethink.org and MIND could be accessed on the App
(4) The health professionals noted that the participants tended to lose their crisis plan and that incorporating this on to the App would be beneficial	Personalised Care Plan could be embedded into the TechCare system with incorporation of the service users Crisis Plan
Feedback from service user participants & PPI members	
(1) Inclusion of a crisis support helpline (Samaritans) and useful websites	Changes were made to the App, whereby participants could access useful links on the App home screen
(2) Helpful Information on psychosis was noted as being a useful addition to the App	Helpful Information on psychosis was included on the homepage and consisted of psychoeducation developed by Kingdon and Turkington (2005)
(3) Multimedia and other social media links	Multimedia, such as humorous comedy clips could be included via incorporation of links to YouTube
(4) Participants raised the concern that including the NHS logo on the App may increase stigma.	The App logo was changed from the NHS logo to a more discreet logo in consultation with the PPI members
(5) Access to EIS useful contacts	Helpful numbers to contact, such as the Duty/Crisis team were included and could be edited based on service user preference

CHAPTER 7: FINDINGS OF STRAND 3 (FEASIBILITY STUDY) & STRAND 1 (POST-INTERVENTION INTERVIEWS)

This chapter outlines the analysis of the quantitative and post-intervention qualitative data gathered during the Strand 3 feasibility study. The quantitative data was analysed to obtain data on feasibility and acceptability. The objectives of this strand of the research were to determine the feasibility and acceptability of the intervention, compile follow-up data and to examine recruitment and retention rates to the feasibility trial. I interpreted the results of the study, as an in-depth analysis of the data within the context of the feasibility study. On completion of the Strand 3 feasibility study, service users provided their views and perspectives of their experience of using the TechCare App

7.1 Sample demographics

The study sample comprised of a total of 16 participants (n=4) in the test-run and feasibility study (n=12), all participants were aged between 25 and 40 years and with a mean age of 24.83, with all participants under the care of the EIS. In addition, the sample consisted of 8 males and 4 females, who consented to take part in the study, 9 were unemployed and 7 were single, with 12 having access to the internet. All but one had access to a smartphone phone (see Table 7.1 below).

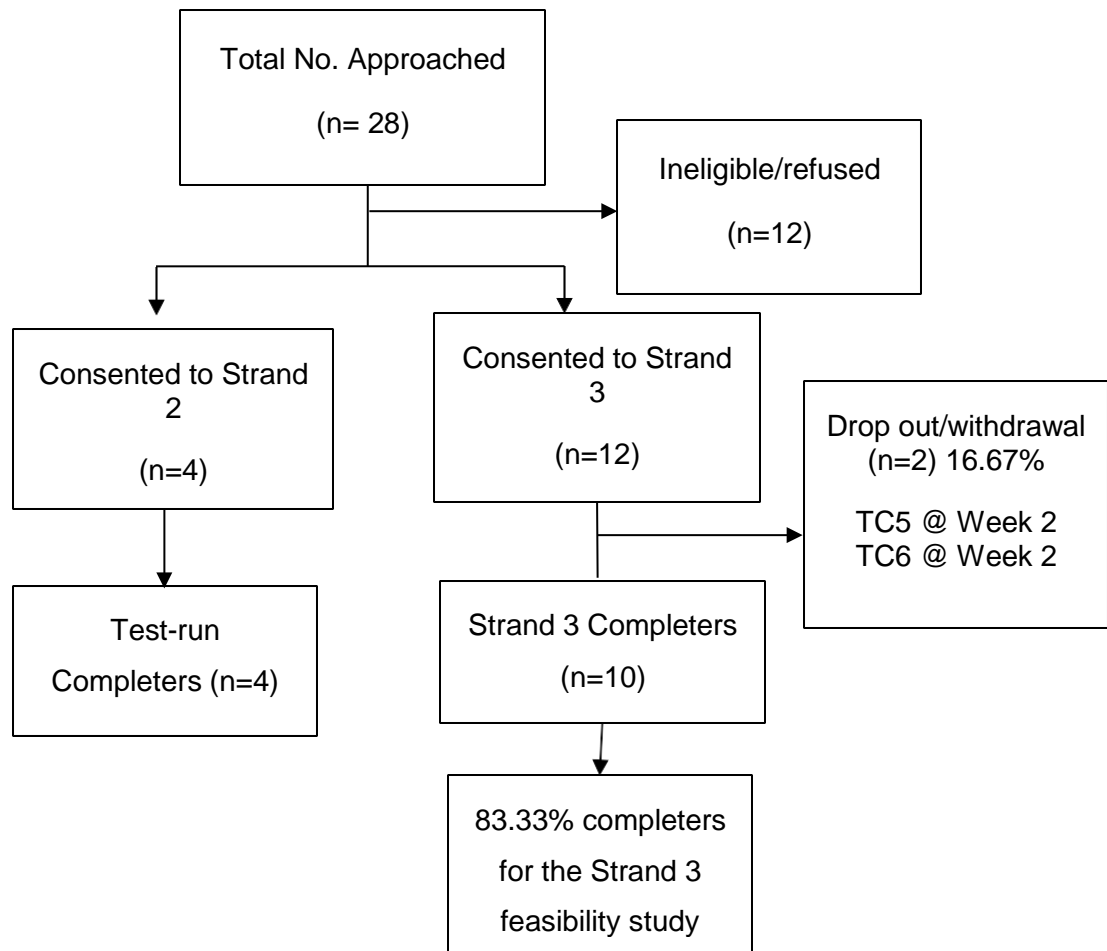
Table 7.1: Demographic for Participants in Strand 3

Strand 3 Feasibility Study		Total
Gender	Male	8
	Female	4
Age	Mean Age	24.83
	Range	19-35
Ethnicity	British - White	8
	British - Indian	2
	British - Pakistani	2
Work	Self-employed	0
	Part-time employment	1
	Unemployed	9
	Student	2
Living situation	Living with family	10
	Lives on own	1
	Lives in shared accommodation	1
Marital Status	Single	7
	Partner/Married	4
	Separated/Divorced	1
Diagnosis	Psychosis	12

7.2 Recruitment and retention

A total of n=12 participants were recruited to this strand however, a total of n=2 participants dropped out. TC5 was unable to continue on the study at week 2 due to not being concordant with their medication. TC6 decided to drop out at week 2 due to not wanting to proceed. No explanation was given as to the reasons behind the latter drop-out. Overall, the percentage of completers who took part in the 6 week intervention period was 83.33%. Figure 7.1 below shows the number of participants completing both Strand 2 & 3.

Figure 7.1: Flow diagram to show Recruitment and Retention



7.3 Strand 3: Feasibility Study PANSS and PSYRATS Scores

Data gathered in Strand 3 was analysed using SPSS statistical software to provide descriptive summary statistics. The mean scores on both measures was calculated at baseline ((PANSS Positive Scale ($M=18.33$, $SD=3.81$; 95% CI , 16.41 to 21.25), PANSS Negative Scale ($M=18.00$, $SD= 7.45$; 95% CI , 13.27 to 22.73), PANSS General Psychopathology ($M=34.58$, $SD=4.91$; 95% CI , 31.47 to 37.70), PSYRATS Voices ($M=12.75$, $SD= 12.48$; 95% CI , 4.82 to 20.68) and PSYRATS Delusions ($M=9.17$, $SD= 11.43$; 95% CI , 12.76 to 16.91)) and at week 6 (end of intervention) ((PANSS Positive Scale ($M=12.50$, $SD=7.06$; 95% CI , 8.01 to 16.99), PANSS Negative Scale ($M=11.67$, $SD= 7.97$; 95% CI , 6.60 to 16.73), PANSS General Psychopathology ($M=22.75$, $SD=12.85$; 95% CI , 14.59 to 30.91), PSYRATS Voices ($M=14.83$, $SD= 3.27$; 95% CI ,

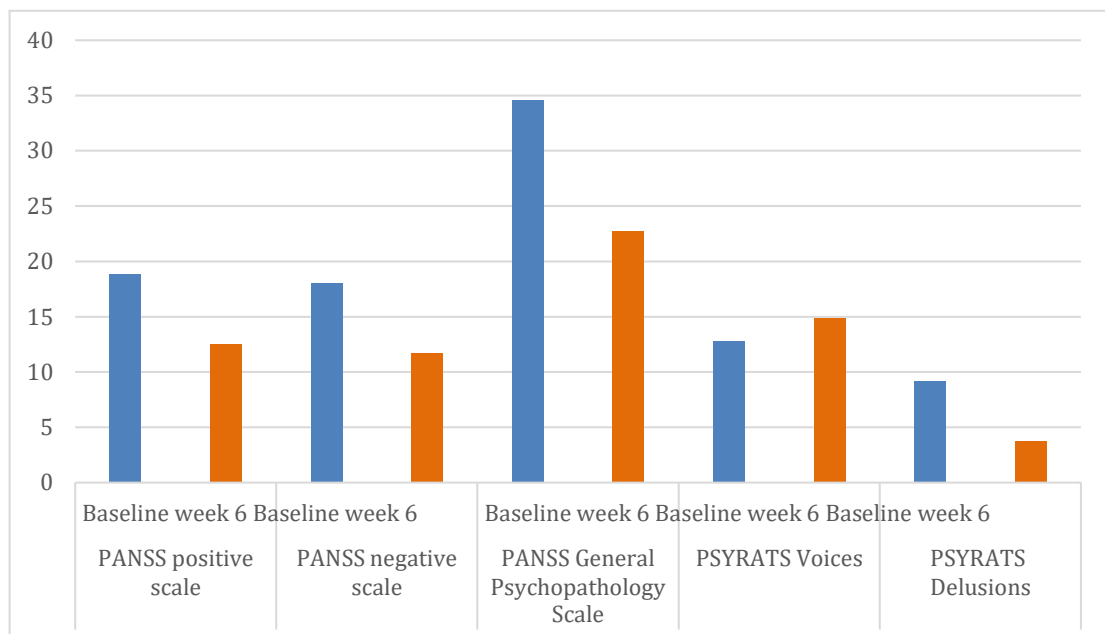
1.90 to 16.43) and PSYRATS Delusions ($M=3.75$, $SD= 7.11$; 95% CI , -0.77 to 8.27)) (see Table 7.2 below).

Table 7.2: Table to show mean and standard deviations for the PANSS and PSYRATS at baseline and week 6 (End of intervention)

Strand 3: Feasibility Study		Mean	Std. Deviation
PANSS positive scale	Baseline	18.83	3.81
	week 6	12.5	7.06
PANSS negative scale	Baseline	18	7.45
	week 6	11.67	7.97
PANSS General Psychopathology Scale	Baseline	34.58	4.91
	week 6	22.75	12.85
PSYRATS Voices	Baseline	12.75	12.48
	week 6	14.83	3.27
PSYRATS Delusions	Baseline	9.17	11.43
	week 6	3.75	7.11

From analysis of the means and standard deviations, I plotted a bar graph to examine the difference in means on both measures at baseline and week 6 (end of intervention).

Figure 7.2: Graph to Show Mean Scores on the PANSS and PSYRATS at Baseline and Week 6 end of Intervention



The graph above (Figure 7.2) shows that there was a reduction in means from baseline to week 6 for the PANSS and the PSYRATS Delusions subscale. However, scores on

the PSYRATS Voices subscale seemed to increase from baseline to week 6. To examine this further I conducted parametric and non-parametric testing to examine whether there was a significant difference in scores on both the PANSS and PSYRATS. I would like to note that with the feasibility context, significance testing is not carried out in feasibility studies, as the main aim is to determine feasibility. However, within the context of the PhD project I conducted significance testing as it allowed me to examine whether the pre-outcome measures were at least no lower than then the post-outcome measures. From this, I would thus be able to infer a preliminary indication of whether the intervention exacerbated symptoms indicating safety implications which I would have to consider when evaluating feasibility.

As the PANSS scores was a continuous variable, I applied parametric testing in the form of a paired samples t-test. The results showed that there was a significant difference in mean scores on the PANSS Positive Scale ($t(11)=2.95$, $p<0.05$), PANSS General Psychopathology Scale ($t(11)=3.13$, $p<0.05$), and PANSS Negative Scale ($t(11)=2.23$, $p<0.05$) suggesting that the scores on the PANSS differed significantly at baseline and week 6 (end of intervention). In addition, as the PSYRATS mean scores were not normally distributed, I applied non-parametric testing on the PSYRATS variable. The results of the Mann-Whitney U test showed that there was no significant difference in scores on the PSYRAT Voices subscale ($U=60.50$, $p=0.478$), however a significant difference was found on the PSYRATS Delusions subscale ($U=21.00$, $p<0.05$). This suggested that symptoms of psychosis reduced over the study period on the PANSS and the PSYRATS Delusions subscale. However, this was not the case for PSYRATS Voices.

7.4 Strand 3: analysis of weekly assessment data

In addition to the pre- and post-intervention measures, I also undertook weekly assessments with the participants. The weekly measures which were used in the study are outlined in chapter 5. The mean and standard deviation for each of the weekly measures are shown in Table 7.3 below.

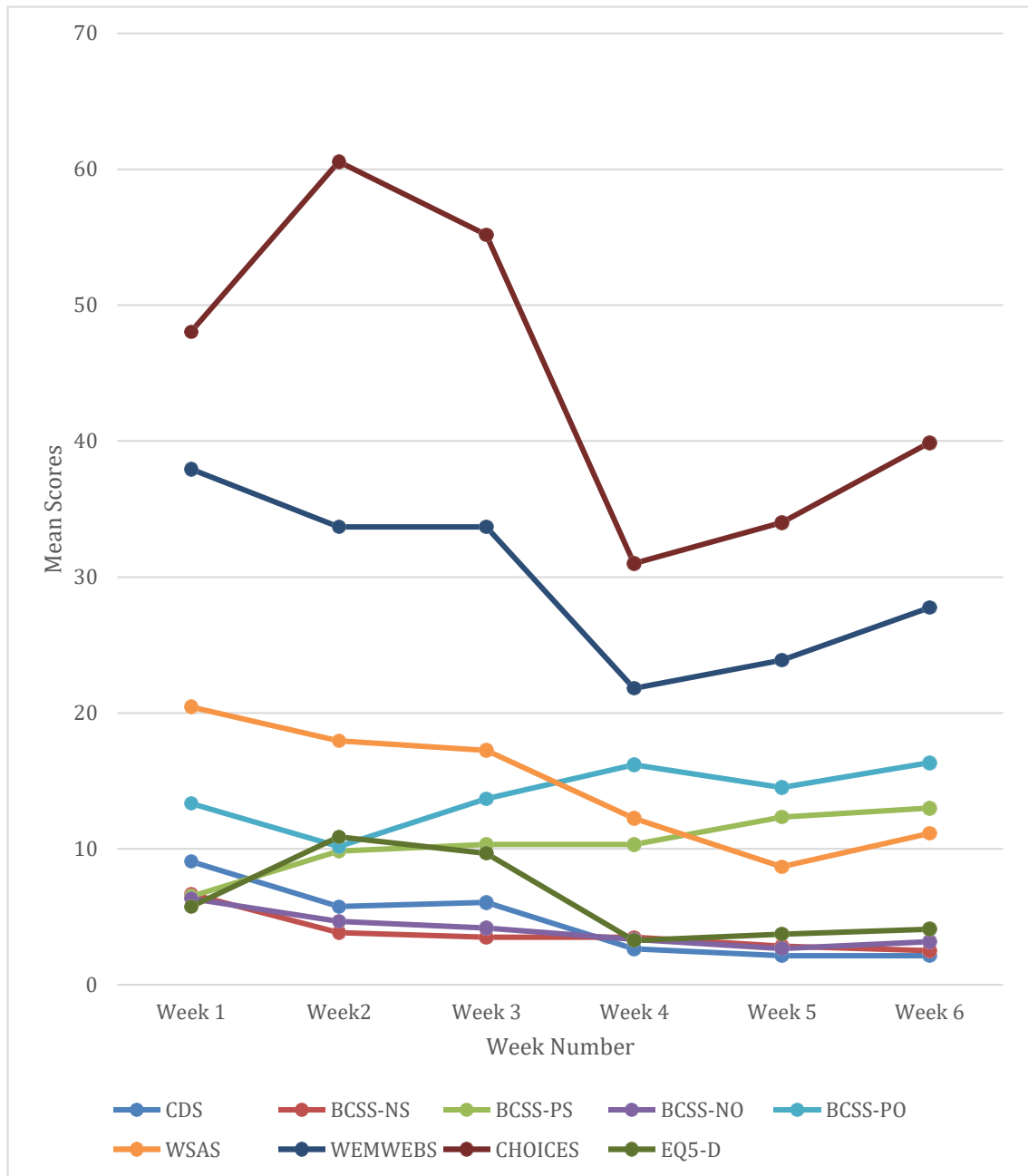
Table 7.3: Table to show Mean and Standard Deviations for the Weekly Assessment Measures

		<i>Calgary Depression Scale</i>	<i>Brief Core Schema Scale Negative Self)</i>	<i>Brief Core Schema Scale (Positive Self)</i>	<i>Brief Core Schema Scale (Negative Self)</i>	<i>Brief Core Schema Scale (Positive Other)</i>	<i>Work and Social Adjustment Scale</i>	<i>Warwick- Edinburgh Mental Wellbeing Scale</i>	<i>Choices</i>	<i>EQ5-D</i>
Week 1 (Baseline)	Mean	9.06	8.00	5.17	9.42	9.42	20.44	37.94	48.06	5.75
	Std. Deviation	5.51	5.58	4.58	7.34	5.59	10.23	10.39	30.02	2.64
Week 2	Mean	5.75	5.40	7.50	8.50	7.50	17.94	33.69	60.56	10.88
	Std. Deviation	5.80	5.32	5.09	7.88	5.77	11.50	16.04	58.62	23.62
Week 3	Mean	6.06	7.00	8.56	9.22	10.00	17.25	33.69	55.19	9.66
	Std. Deviation	5.80	7.91	4.95	8.59	6.12	12.16	20.11	45.66	24.00

Week 4	Mean	2.63	5.44	7.44	6.56	12.33	12.25	21.81	31.00	3.26
	Std. Deviation	4.43	6.56	5.09	7.55	7.28	13.85	21.30	33.33	3.29
Week 5	Mean	2.13	2.88	11.88	5.25	12.71	8.69	23.88	34.00	3.73
	Std. Deviation	3.50	4.05	3.40	6.85	5.70	11.66	25.54	38.90	3.87
Week 6	Mean	2.13	5.80	10.00	7.30	11.70	11.13	27.75	39.88	4.08
	Std. Deviation	3.32	7.31	6.31	7.68	6.90	13.38	24.57	40.45	3.64
Totals	Mean	4.63	5.97	7.78	7.96	9.77	14.61	29.79	44.78	6.22
	Std. Deviation	5.37	5.57	4.70	7.25	5.58	12.59	20.62	42.48	13.97

The weekly outcome measures were collected over the 6 week feasibility study period. Table 7.3 above shows the mean score for each assessment measure for each week, and also the average mean score across the 6 weeks on the Calgary Depression Scale ($M= 4.63$, $SD= 5.37$; 95% CI , 3.63 to 5.71), Brief Core Schema Scale (Negative-Self (NS)) ($M= (5.97$, $SD= 5.57$; 95% CI , 3.62 to 8.33), Brief Core Schema Scale (Positive-Self (PS)) ($M= (7.78$, $SD= 4.70$; 95% CI , 5.79 to 9.76), Brief Core Schema Scale (Negative-Other (NO)) ($M= (7.96$, $SD= 7.25$; 95% CI , 4.90 to 11.02), Brief Core Schema Scale (Positive-Other (PO)) ($M= 9.77$, $SD= 5.58$; 95% CI , 7.41 to 12.13), Work and Social Adjustment Scale ($M= 14.61$, $SD= 12.59$; 95% CI , 12.05 to 17.06), Warwick Edinburgh Mental Wellbeing Scale ($M= 29.79$, $SD= 20.62$; 95% CI , 25.59 to 34.05), and Choices ($M= 44.78$, $SD= 42.48$; 95% CI , 36.59 to 53.61), EQ5-D ($M= 6.22$, $SD= 13.97$; 95% CI , 3.99 to 9.52). To examine the data further, I constructed a line graph to examine trends in the data (see Figure 7.3 below).

Figure 7.3: Graph to show Scores on the Weekly Outcome Measures



I looked for trends in the above graph to determine the change in mean score across the 6 week intervention period. Figure 7.3 shows that there was a reduction in mean scores over the 6 week period on all measures, except for the Brief Core Schema Scale (Positive-Self (PS) and Brief Core Schema Scale (Positive-Other (PO)). However, for some of the measures, for example the CDS, Brief Core Schema Scale (Negative-Other (NO)) and Brief Core Schema Scale (Negative-Self (NS)) there was an early reduction in scores; followed by a plateauing between weeks 4-6. Generally, the levelling out of scoring is difficult to interpret in the context of evaluating such a short data collection

period. However speculatively, this may have been the result of increased interest and engagement with the App during week 1-3 and this diminishing over the latter half of the intervention period (weeks 4-6). Alternatively, the observed plateauing may be due to factors, such as the questions that were asked not being sensitive enough to pick up minor issues such as boredom with the App or lack of perceived benefit over the 6 week period.

Furthermore, it may be said that the rate of symptom reduction or increase, may be due to factors which would need to be examined more closely in future research, with a focus on investigating possible adverse effects. Longitudinal trends would only become apparent with a longer intervention period and longitudinal follow-up. For example, fluctuations in an individual's enthusiasm in using the App and the interaction between this and levels of symptom reduction and recovery. Additionally, as this was a feasibility study I did not conduct any inferential statistical analysis on the weekly assessment scores, as the main purpose of the feasibility study was to determine feasibility and acceptability. The examination of longitudinal trends in a future trial for individual participants would provide further details on how the intervention could be used, to gain a better understanding of the factors associated with recovery and also trends related to experiences, symptoms and adverse effects.

7.5 Analysis of TechCare App derived participant data

In addition to the researcher completed measures, the TechCare system also allowed for the collection of patient derived response data through the TechCare App. The data was scored on a 1-7 likert scale, with 1 being disagree and 7 being agreement with the statement (Questions presented to the participants can be seen in chapter 5), the average weekly score in week 1 for the Depression scale was $M=29.13$ ($SD=18.29$) and for week 6 was $M=17.50$ ($SD=11.92$), which indicates a decrease in depressive symptoms from week 1 to week 6. Furthermore, there was a similar trend on the paranoia scale, with the average score decreasing from week 1 ($M=38.00$, $SD=28.27$) to week 6 ($M=33.92$, $SD=27.88$) (see Table 7.4 below).

Table 7.4: iRTT Depression and Paranoia Average Weekly Scores

Week No.	Depression Scale Questions		Paranoia Scale Questions	
	Mean Score	Std. Dev	Mean Score	Std. Dev
1	29.13	18.98	38	28.27
2	20.14	15.94	31.88	26.72
3	20.41	19.33	38.12	34.63
4	16.06	17.03	34.9	35.25
5	20.88	11.97	20.71	16.67
6	17.5	11.92	33.92	27.88
Total	21.5	16.8	33.43	28.9

On further analysis of the notification data gathered, it was found that out of the daily 3 notifications participants responded on average to 1.9 messages over the 6 week period, with a mean score of 2.66 (SD= 1.90) for the depression scale questions and the 2.71 (1.75) for the paranoia question. These scores are within the range for the iRTT system, as scores of 4 or greater triggering initiation of the iRTT protocol. Table 7.5 below shows the mean scores and standard deviations for the TechCare App questions for the depression and paranoia scale.

Table 7.5: To Show Mean Scores on the TechCare Questions

Question	Total	Mean	Std. Dev
Depression	1021	2.66	1.9
I have felt Sad	256	2.64	1.83
I have not felt Cheerful	254	2.68	1.88
I have not felt motivated to do things	256	2.75	1.99
My mood has affected my appetite or sleep	255	2.59	1.92
Paranoia	1549	2.71	1.75
I am slightly worried when I am at home alone	3	5.33	1.53
I am worried about people stealing my thoughts	5	2.6	1.82
I have been distressed about hearing voices	37	6.11	2.07
I have been distressed about the voices and talking to myself	88	3.31	0.9
I have been distressed about thoughts being inserted into my mind about me being worthless	50	1.26	1.03
I have been suspicious	175	2.73	1.68
I have been worried about my future	5	4.8	1.64
I have felt like someone was trying to read my mind	20	1.65	1.53
I have felt like someone was watching me	119	3.19	1.37
I have felt like something or someone meant me harm	176	2.56	1.65
I have felt like something was watching me at home	3	4.33	2.31
I have felt like there was a conspiracy against me	10	6	1.05
I have felt paranoid	50	1.14	0.86
I have found it difficult being in social situations	2	3	2.83
I have found it difficult to concentrate on other things	228	2.61	1.74
I have worried about saying too much	227	2.4	1.62
This has stopped me from doing things	175	2.81	1.71
This has stopped me from spending time with others	176	2.57	1.58
Total	2570	2.69	1.81

7.6 Analysis of the iRTT data

From the data, it was found that, the interventions screen was shown a total of 82 times across the 6 week period with the most selected intervention being the multimedia intervention. The second most common intervention selected was the behavioural activation intervention. The App was suspended a total of 7 times (8.5%) which could have been as a result of a technical glitch or the participant pressing back (see Table 7.6 below).

Table 7.6: Interventions Selected and Presented to Participants on the App

Intervention Selection and Presentation	Total
Interventions shown	82
Intervention Presented: Media	14
Intervention selected: Media	13
Intervention Presented: Behavioural Activation	11
Intervention selected: Behavioural Activation	11
Interventions page - App suspended (back button pressed)	7
Intervention selected: Social Network	6
Interventions page shown	6
Intervention Presented: Social Network	6
Intervention Media Clicked: Media	6
Intervention Presented: Unhelpful Thinking	5
Intervention selected: Unhelpful Thinking	5
Intervention Presented: CBT	4
Intervention selected: CBT	4
Intervention Presented: Goal Setting	3
Intervention selected: Goal Setting	3
Intervention selected: Problem Solving	1
Intervention Presented: Problem Solving	1
Total	188

Data collected from the online server provided insight into the day-to-day usage of the App by each of the participants. There were a number of key variables that were analysed to provide a descriptive account of the App usage across the feasibility study period. Overall the analysis found that out of the 12 participants the App was registered and loaded a total of 947 times with participants using the App on average 1.88 times per day. Just to note these figures take into account Participant TC5 and TC6 who dropped out at assessment point week 2.

In addition, on analysis of the notification system data, it can be seen that over the 6 week period participants clicked on the notifications a total of 521 times with adherence to the iRTT protocol being closely aligned to the presentation of interventions. One interesting finding from the results is that none of the participants reached the threshold for the crisis intervention. Table 7.7 below shows the iRTT system data.

Table 7.7: iRTT System Data

iRTT Protocol	Total
TechCare Notification clicked	521
Checking IRTT Protocol	476
Notification Complete for Cluster 1	255
Notification Complete for Cluster 2	228
OK after Notification Session, Cluster 1	199
OK after Notification Session, Cluster 2	190
Threshold reached for Cluster 1	54
Threshold reached for Cluster 2	31
Total	1954

Furthermore, the general utilisation of the App was also recorded, with the average number of times the App was loaded by participants being 5.63 times per day (Range: 0-25), with participants clicking notifications on average 2.95 time per day (Range: 0-11). These findings from the analysis suggest engagement with the App and feasibility of the system.

Table 7.8: Participant Usage of Helpful Links and Psychoeducation

Home Screen Resources	Total
Other links clicked	76
Thought interference and reference clicked	51
Cognitive Therapy of Psychosis clicked	38
Research about thought interference and reference clicked	25
Mind website launched	7
Paranoia website launched	7
Samaritans website launched	2
Hearing website launched	2
Saneline website launched	2
Total	210

Furthermore, it was found that the participants used the self-help material a total of 114 times, this was the psychoeducational information tab located on the home screen. Other resources which were selected can be seen in Table 7.8 above, which shows participants went on the helpful websites section a total of 20 times.

7.7 Compliance to the iRTT intervention

A breakdown of participant usage over the 6 week period showed that the participant that engaged with the system the greatest number of times was TC14 and the participant

who engaged with the system the least was TC8. Previous research as part of the ClinTouch study (Ainsworth et al., 2011), calculated compliance as; 33% of the available notification/questions completed. The system notified the participants 3 times per day (A minimum of 126 over the 6 week period). Compliance was based on engagement with the App, at least, a total of 42 times over the study period (33%). It was found that the out of 12 participants 66.67% of the participants achieved compliance, however this figure takes in to account TC5 and TC6 who dropped out after week 1. On removing TC5 and TC6, the 10 completers achieved 70% compliance, related to answering the TechCare App questions. In contrast based on the total number of times the participants engaged with the App, it was found that out of the 12 participants a total of 91.7%, engaged with the App over the compliance threshold of 42 times across the study period (see Table 7.9 below).

Table 7.9: No. of Questions Answered and Engagement with App

Participant	Total No. of Questions Answered	No. of times engaged with the Application
TC5	36	44
TC6	16	28
TC7	440	423
TC8	29	47
TC9	34	44
TC10	244	209
TC11	73	169
TC12	108	124
TC13	440	306
TC14	1073	926
TC15	34	74
TC16	43	47
Totals	3085	2908

7.8 Chapter 7: Summary & Conclusion

The main findings of Strand 3 suggest that the TechCare App was a feasible and acceptable intervention for service users experiencing distress associated with psychotic symptomatology. These results support previous research in mHealth for psychosis (Pamier-Claus et al., 2013; Ben-Zeev et al., 2014). However, with the added feasibility testing of the novel iRTT concept, which provided a means of delivering interventions in real-time based on the software algorithm. The iRTT concept was evaluated through the TechCare mobile App platform and provided novel insights into the real world working of

the intervention within the clinical context of the NHS. However, the results can only be examined on the basis of feasibility and acceptability, as the clinical efficacy of the iRTT system was not investigated, as this would be explored in the proposed future trial. From the results I can surmise that the clinical effectiveness of the iRTT concept should be tested in a larger scale effectiveness trial. Based on the results from this strand, the following recommendations are made:

- The TechCare App research procedures were found to be feasible and acceptable to participants and thus could be scaled up in a larger study
- The data system was found to be robust and was able to detect and record changes in symptoms experienced by the participants
- There was an 83.33% retention rate
- Only one participant lost their phone, out of the total 16 participants in the study

7.9 Findings of the Post- Intervention Qualitative Interviews with Service Users

On completion of Strand 2 (test-run) and Strand 3 (feasibility study), I conducted follow-up one-to-one interviews with the participants post-intervention. The interviews were conducted to gain an understanding of the participant's experience of undertaking the TechCare App intervention. As part of this strand of the study; in addition to the 2 participants who had dropped out, I was unable to make contact with TC2. Therefore I was not able to conduct a post-intervention qualitative interview with participant TC2. Overall, a total of n=13 participants took part in the post-intervention qualitative work.

The data collected in the interviews was collated and analysed, with the primary findings indicating the acceptability and feasibility of the TechCare App intervention. A framework of the themes (see Table 7.10) was developed and provided a structure for the coding of the participant data. The main themes, which were highlighted; in addition to the acceptability and feasibility of the TechCare intervention were; the usability and user experience considerations, suggestions for improving the TechCare App Intervention and insights into the iRTT system.

Table 7.10: Coding Framework for Post-Intervention Interviews with Service User Participants

	Themes	Sub themes
		Post-intervention
Coding Framework	1. <i>Acceptable for me: Acceptability and Feasibility</i>	a) Overall acceptability b) Research related procedures and processes
	2. <i>Very easy, very simple: Usability and User Experience</i>	a) TechCare App content & comprehension b) TechCare App Navigation considerations c) Interactivity of the App d) Usability of different target groups
	3. <i>I don't think I would cope without my phone: Accessing and engaging with support through the App</i>	a) Importance of face to face contact b) Overcoming Stigma c) Barriers to accessing support
	4. <i>It's good yeah, but: Suggestions for improving the TechCare App Intervention</i>	a) Novel ideas for improvement b) Use of multimedia
	5. <i>Care coordinator in my pocket: Insights into the iRTT system</i>	a) Self-management of symptoms b) Real-time intervention

I will now present each theme and describe the data, with reference to participant quotes.

1) Acceptable for me: Acceptability and Feasibility

The participants provided their views relating to their experience of using the App, and that it was an acceptable form of receiving psychosocial interventions. The main theme, which emerged from the data, was the acceptability and feasibility of the TechCare App, with subthemes relating to the research related procedures and processes. The research related procedures such as the length of time taken to complete assessments and the recruitment procedures, were deemed acceptable to the participants. Participants provided feedback on the overall acceptability of taking part in the TechCare research study, with the experience being enjoyable and empowering.

1a) Overall acceptability

Participants held the view that the TechCare App was an acceptable form of treatment, with TC12 highlighting that the App was a 'new way of doing things' and could work alongside other treatments such as medication within the context of the EIS:

"TC9: Yeah it was acceptable for me. Umm and I think most of the people would find it acceptable as well. I don't think it was inappropriate or anything "

"TC12: Overall, I think the App was a really good idea, it's a new way of doing treatments and it works alongside your medication"

Further support of the acceptability of the intervention, came from TC10 who advised using the App had been an enjoyable experience for them. Moreover, it was found that the familiarity of mobile technology was an integral part of the service users' day-to-day life, with it having a potentially positive impact on mental health:

"TC10: Umm, no, it seemed really good to be honest. I really enjoyed using it"

"TC16: Well I believe that since smartphones are so much a ubiquitous part of people daily lives to the most part, at least in the UK. It does only make sense to incorporate some form of health treatment into people's phones or an App and in this case mental health. I believe it can actually have a positive effect in some way or another"

1b) Research related procedures and processes

Furthermore, individuals found the research process and procedure to be acceptable in their opinion further indicating feasibility. Factors such as providing the participant with time to decide whether to take part, and the assessment measures not being too intense to complete, were viewed as acceptable as part of the process of carrying out the research:

"TC9: Umm I am very selective, and it is not very intense. I didn't think so. Umm I mean, they aren't short. Umm I don't think they were too long at the same time"

Furthermore, at the recruitment stage of the research, participants reported that the research was explained to them clearly and they had been given suitable time to make a decision on taking part. Moreover, on discussing the most appropriate means of approaching potential participants in the future trial. Participant TC10 suggested that

using feedback quotes of individuals who had undergone the intervention would be an acceptable means of recruiting participants:

"TC10: Yeah, I'd say definitely try it because it helped me a lot really so if it can help one person why can't it help loads of people..."

"TC11: No, I think it was all described as it should be, understandable quite easily"

Participation in the study was also seen as an empowering experience by TC15 who reported that in their view the App provided a means to engage with the service, and enhanced feelings of being supported:

"TC15: The process of the using the TechCare App was empowering and was an achievement as I normally struggle to come out.... motivated me to come out more and come to the service.... felt supported"

From the above quotes, it can be inferred that the TechCare App research procedures were acceptable to the participants.

2) *Very easy, very simple: Usability and User Experience*

The usability of the device in terms of its day-to-day usage was found to be easy to manage with particular reference to the easy navigation of the App. This was suggested to be an important factor in the Apps usage, with participants describing the App as easy to understand. It was also highlighted that the psychoeducational links were a useful tool in helping to understand specific information on psychosis. Although one participant did find the information long, they did state the content was easy to understand suggesting the importance of the App content and comprehension. Moreover, it was suggested by the participants that having the App on their own personal device rather than the study device would enhance the day-to-day usability. Further considerations relating to the App layout, interactivity and usability for different target groups were key subthemes found.

2a) *TechCare App content & comprehension*

The participants were of the view that the App content was easy to understand and there was no concerns around the comprehension of the information held on the TechCare App. However, further simplification of the information was deemed an important factor in the further development of the App. TC12 reported that being concise and delivering the information in bullet points would make the information easier to understand. This

was further emphasised by TC9, who advised that the quantity of the information was large with a need for the information to be broken down into its simplest form in the future trial.

"TC16: It was quite easy to understand... Yeah, I found it easy to understand. I don't have any complaints with it"

"TC12: It was very easy to use, very easy, very simple, there wasn't any obstacles using it or anything, think it was made very simple, which is a good thing....bullet points keep it concise straight to the point"

"TC9: I didn't, Umm If I remember correctly there was a lot of information to learn. I think I am not sure if it was broken down to the simplest form but that might be it...something to look into"

2b) TechCare App Navigation considerations

Navigation of the App was a subtheme that emerged from the data, in the context of coordinating the App menu and layout. It was noted by TC9 that the App was quick to get through, supporting the notion of the ease of use of the App. However, in contrast, two participants shared their experience of not being able to navigate the App to the multimedia section, suggesting the need to take layout and navigation factors into consideration when designing a future trial:

"TC9: Umm I liked how quick it was to umm get through the app. Umm... Yeah like the time taken to complete the questions.... I liked how quick it was"

"TC16: I found it a little bit difficult to get to the multimedia things... and to this day I'm still not hundred percent sure how you access it, so I found that a bit complicated to get to..."

2c) Interactivity of the App

In context of the usability there were a number of factors which were seen as inhibiting or limiting the usage of the App which related to the interactivity and functionality of the App. As I described above the usability and user experience of using such technologies is an important consideration in the development of interventions. Participants voiced the importance of including colour and a more interactive user interface:

"TC4: Bland, black and white needs to be more colourful however it did not take away from the experience layout and design bit more interesting and colourful"

"TC9: Yeah I would go for colourful modern... Yeah I had expected it to be easy to use. Umm....Umm the layout was okay actually"

Adding more colour was the major recommendation made by the participants, with the suggestion that there was a need for a more engaging user environment.

2d) Usability for different target groups

Another usability consideration which emerged from the data was the notion that some people may not be able to use the App, as they may be less tech savvy than a younger audience. In particular, the participants believed that older people may not be able to use the technologies and these considerations should be taken into account when designing a future trial:

"TC4: Older people will not be able to use"

"TC10: People probably that aren't up to date with technology I think, you know people who don't really have smartphones"

"TC12: Generally, for everyone, because the age range there's a difference, like some people might be able to use the App, but say somebody who's older might not know how to function the App properly..."

3) I don't think I would cope without my phone: Accessing and engaging with support

From the data, it was identified in the view of participants, the ability to have easy access to information and useful contact details provided an avenue for participants to seek help. Even the availability of help was seen as a prompt for service users to seek help and access services. Participants found that accessing the App was based on their own preference. One of the key suggestions was engagement with health professionals and face-to-face contact, also being an important part of the treatment process. Engagement of the App for some participants was based on their experiences of distress, indicating that the App was used at times when participants experienced distress associated with their illness, thus providing greater autonomy and patient choice. Further subthemes found which related to this theme were; the importance of face-to-face contact, overcoming stigma and barriers to access.

3a) Importance of face-to-face contact

Furthermore, access to mobile devices was suggested to be an important means of starting conversations and providing an alternative way of communicating with health professionals. Although the App was seen as an important tool in accessing support in real-time, the participants were of the view that face-to face contact was an integral part of the care they received from the EIS service.

"TC11: Understanding the thoughts, helps start conversations and stuff just for the fact that I ended up with a new phone just to use for the time being, just started conversations with that so yeah"

"TC10: Just that the App focuses on your mood, where as having a face to face interview can explore different things like why you are actually feeling down and stuff"

3a) Overcoming Stigma

Stigma was an important subtheme, which was emphasised by many participants, in particular as the TechCare App provided a means to access support in a confidential manner, in cases where communicating distress face-to-face was difficult for service users.

"TC9: Umm I think it would help people understand it more.....Um and that matters with stigma"

The use of technology was also found to be a beneficial means of communicating and sharing experiences of psychosis via the mobile phone, rather than in person thus taking away the stigmatising effect of face-to-face communication. These findings related to tackling stigma and were a beneficial means of understanding the impact of stigma within the EIS.

"TC12: It makes it easier with technology because it's confidential, sometimes you don't want to share it with another human being, you just want to get things out of your chest without having human intervention"

"TC10: Just that the App focuses on your mood, where as having a face to face interview can explore different things like why you are actually feeling down and stuff"

3b) Barriers to accessing support

It was stated that connectivity to the internet was also an important factor, particularly relating to the inequality of access to those who may live in areas where there is limited or no internet connection. Challenges faced by the participants in the study related to access to the Internet. One important example was TC15 who lived in a rural area. Although TC15 had broadband, difficulties in mobile phone communication such as text messaging which was problematic due to the lack of signal. This was an important example of a diminished means of contact with services. TC15 nonetheless did have use of an alternative messaging App such as Facebook messenger and suggested that a possible means of overcoming this difficulty would be to provide the App in an off-line mode, with a data cache which could sync data once an Internet connection was available.

"TC11: Yeah, I don't think I'd be able to cope without my phone and stuff like that, had the internet cut off for a day the other day and I felt lost, I didn't know what to do when the internet was gone because that meant I couldn't go on my Xbox, I couldn't watch my TV, couldn't go on my phones or anything like, just that happening, you realise how much you take it for granted don't you"

"TC16: Yeah, it's more difficult for them because they've got a greater distance to travel... So, it is vitally important that options are available for when they can't access the other services. Which I think is where the App can come into play because it provides one of those. And even like... as I say if they can upload the data when it gets an internet connection it's still provides full functionality on a bit of a delayed basis"

4) Its good yeah, but: Suggestions for improving the TechCare App Intervention

Through discussions with the participants a number of suggestions to improve the TechCare App were provided by the participants. These improvements and areas of refinement were a crucial means of gaining an insight into further developments for the future definitive trial. The improvements related mainly to the App content, such as incorporating a news feed, calendar and progress tracking. It was highlighted that mobile technology was part of the future, in providing support for individuals with mental health difficulties, but it was not the whole picture. In addition, participants who had differing mobile device platforms would struggle if the App was limited to only one platform.

Instead, a cross platform system would increase access to the intervention. Further subthemes related novel ideas for improving the App and the use of multimedia.

4a) Novel ideas for improvement

The areas of improvement included, novel Ideas such as inclusion of news feed where people with similar experiences could comment on strategies they had used and benefitted from:

"TC4: News feed so other people can respond to it like when I'm feeling down I do this"

The TechCare App would record the participants score over the study period, with this being reviewed in conjunction with the participants health professional. It was suggested that Inclusion of a calendar diary system, where service users could write their feelings directly onto the App would be a beneficial means of understanding their experiences. This was an important recommendation, as it would allow participants to note down their experiences of distress in their own language, providing greater insights into experiences of psychosis.

"TC12: Yeah like a diary, calendar diary where you can write all your feelings down, how you're feeling"

"TC15: Weekly progress monitoring can be useful end of the day specify good bad or anxious and give a summary"

Another improvement of the system was the inclusion of additional functionality which would give service users more options in the Apps usage. One example of this was the inclusion of reminders and more interactivity in providing feedback on the service users experience of distress:

"TC15: The functionality, asking questions tracking the feedback....have reminders early in the day"

"TC11: When it says, you seem to be feeling distressed, you prefer to put some input in and then get another response back maybe"

4b) Use of multimedia

Another key area of App usage was the multimedia component; however, an improvement on the system was proposed as being the inclusion of a playlist of songs.

In addition, social media and images could also be incorporated into the App, as many people engaged with these forms of technology.

"TC11: Oh yeah, if there was like a playlist of songs or something... if it was just like the UK top 40 and it just, if it just refreshed itself every week, or just linked to YouTube because it has the UK top 40 all the time.....yeah that would be quite good [Photos] that's what Facebook does, just shows you pictures from last year, it says one year ago....I think most people are constantly on Facebook anyway aren't they, so I don't think people need encouraging to go on Facebook because it's like everyone's on it"

Furthermore, it was noted by TC4 that multimedia in the form of music was an important means of increasing mood. This was a commonly used strategy for the participant, who would engage in listening to music on a regular basis, suggesting the impact of multimedia on mood:

"TC4: Using music and internet was helpful to increase my mood, I normally have the music channel on..."

5) Care coordinator in my pocket: Insights into the iRTT system

As the research had been conducted to gain an understanding of the feasibility and acceptability of the TechCare intervention. The key area of focus was on the testing of the iRTT concept. In the view of participants, some of the more popular interventions used were multimedia, problem solving and the use of links to support websites and psychoeducation. The participants held a consensus view that the iRTT system had allowed them to gain insight into their experiences and allowed them to manage their symptoms. Key subthemes related to self-management of symptoms and experience of real-time intervention.

5a) Self-management of symptoms

Furthermore, in gaining an insight into the iRTT concept in action, a good example of this is the views reported by TC12 who advised that the App had been an important means of gaining support, as he had been dependent on his care coordinator a lot. However, the TechCare App had given him a new perspective on the management of his symptoms and as a result he was managing his symptoms better and was able to receive self-help in real-time through the App.

"TC12: Before I was depending a lot on [Care coordinator] all the time, whenever something went wrong, but since I got the app, it's been like [Care coordinator] in my pocket, so it felt like there was a mental health professional in my pocket, so whenever I have like a problem I just go on...and score and it would give me solutions which I don't think about at the time...yeah, because now I don't rely on the App as much, because I've kind of programmed it in my mind, how to, like if I'm facing adversity how to step by step break the problem down"

"TC10: Yeah it has really because its helped me quite a lot because I've learnt that when using the App, when I'm feeling down and stuff, I can now use that when I'm feeling down and think well I did this differently, I did that differently"

This had a beneficial impact on TC12, who even when not using the App was still able to employ the CBT based self-help strategies which he had learnt during the time he had used the App. This was an important finding as it provided grounding that real-time interventions were an acceptable treatment approach, with the potential for continued recovery.

"TC13: Helped organise my thoughts.... Helped me to understand...What I was going through"

"TC10: Yeah I used to use that as a good tool and then like if I was distressed and then it said go on Facebook, have a look on Facebook. Just anything that took my mind of things really, yeah [social media]"

5b) Real-time intervention

It emerged from the data that the interventions used, provided a means for participants to take their 'mind off things'. This was an important means of reducing symptoms of distress experienced by the service users, and also provided a 'unique way' of dealing with problems. In addition, in the view of TC11, access to helpful links included on the App, provided information on other services, which service users could use to access support:

"TC10: It was just there and able to take my mind off things and sort of like, it would say if there was anything interesting look on Facebook and id use that and would have a look and keep looking and it would just take my mind off anything that was worrying me or bothering me"

"TC12: I think it's a good way of like, it's a different unique way of dealing with your problems"

"TC11: I think I went on all of them [links, saneline, mind]....they were quite handy to have, because there was some things I've never even heard of before, so it was good know they were one of the extra services"

7.10 Post-intervention qualitative work: Summary and conclusion

Overall, it is important to note that there was a considerable and significant view held by the participants that the TechCare App intervention was an acceptable and feasible intervention and that the research procedures and processes were acceptable. Based on this strand of the research, I can infer the feasibility of scaling up this work and investigate the TechCare App in a larger clinical trial, including evaluation of clinical-effectiveness. More importantly, the suggestions given by the participants provided a valuable means of improving the TechCare intervention with insights into novel areas of development.

In concluding this chapter, it can be seen that understanding symptoms in the real-time had a beneficial impact on participants who took part in the study. The participants gave examples of how the App had assisted in their personal recovery journey. However, it may be noted that as this project involved weekly assessments there was opportunity for greater levels of engagement with participants, thus a greater chance of concordance with the routine treatment approach provided by the EIS. The comment that the App is like having a 'care coordinator in my pocket' is a heartening affirmation of the perceived value of the intervention and supports a service emphasis upon encouraging self-management together with continued professional engagement.

Although the results of the qualitative work were promising, I would have to present these with caution given the multiple factors associated with the routine treatment. Taking this into account, the definitive effectiveness of certain interventions can only be understood more robustly through clinical testing using controlled designs. However, this feasibility work has provided insight through the qualitative data presented above as the foundation for future research in this area.

CHAPTER 8: DISCUSSION OF THE TECHCARE PHD PROJECT

The final chapter of the PhD thesis will present a discussion of the overall findings of the project with reference to previous research in the area. In addition, the strengths and weaknesses of the PhD project will be highlighted and discussed with the chapter concluding with the novel aspects of the trial, and future recommendations for scaling up the research. The study provided insights into the development of mHealth interventions for psychosis which used the iRTT conceptual model. I will highlight the key findings from the study in relation to the research objective. Overall, the key finding was the demonstration of the acceptability and feasibility of the TechCare App Intervention, study design and methods for evaluation. In addition, with regard to the former, service users and professional staff were both enthusiastic about the value and utility of the App. In the latter regard, the main objectives of the study, which related to the recruitment, assessment measures and drop-out rates of participants were also achieved, with the findings suggesting feasibility.

The feasibility project, aimed to examine the feasibility and acceptability of the TechCare intervention, and closely followed the guidance by the National Institute of Health Research (NIHR, 2015), in designing feasibility studies to test the vital parameters which would inform the design of a larger definitive trial. The study was designed with a focus on implementation from the outset. I thus took a pragmatic approach to conducting the research and engaged with the target audience in each step of developing the intervention. The service user representatives were involved in developing the protocol, obtaining ethics for the study and also assisted in the development of the layout and overall design of the intervention. The aim of the PhD project was to develop, and feasibility test the TechCare App, with a view to conducting a future larger scale effectiveness trial. The main objectives of the study were to explore the views and perspectives of both health professionals and service users on the TechCare App, and to conduct feasibility testing of the TechCare App with service users in the EIS. The study was able to demonstrate feasibility and acceptability of the intervention within the context of an Early Intervention Service for psychosis in the North West. The findings support previous research in the area of mHealth for psychosis, by Palmier-Claus et al., (2012) and Ben-Zeev et al., (2014), who also reported acceptability and feasibility of mHealth interventions for individuals with psychosis.

With regard to the App, within the clinical context, Rees and Stone (2004) found that clinical psychologists rated therapeutic alliance lower in a videoconferencing therapy

condition compared to face-to-face intervention. This shows that therapeutic alliance may be lesser developed within mHealth interventions than face-to-face interventions, which could have a negative impact on treatment (and this was certainly an initial concern expressed by some staff and service users in this study). However, Cook and Doyle (2000) found that clients reported feeling satisfied with the therapeutic alliance within an online therapy intervention. Moreover, the TechCare intervention demonstrated the ability to potentially overcome some of these criticisms as it intertwined mHealth with existing therapeutic relationships (client's relationships with their care team), potentially enhancing rather than limiting the therapeutic capacity of the relationship.

The availability of the intervention in real-time, in contrast to limited time with the therapist and the flexibility in the use of the intervention, could be seen as a potential advantage. However, a significant proportion of the participants held the view that face-to-face contact was equally important. Further support comes from a study by Lester et al., (2014) showing the importance of technology in engagement within EIS. This is important in drawing emphasis on how mHealth functions could provide continued support, but also give service users greater autonomy. Indeed, future research may fruitfully concern itself with addressing the value of mHealth for different groups of service users, distinguishing between cooperative engagers and more self-reliant refusers of services for example. It may be that mobile technologies offer different forms of value to both groups, with the former responding similarly to participants in this study and the latter, rather, utilising technologies to maximise autonomous independence from services. Both scenarios raise interesting questions for exploring the nature and experience of self-management in the context of services operating within the current neoliberal polity.

Furthermore, an interesting finding of the study was the data collected in real-time, provided an insight into the day-to-day experiences of the participants, with the system providing a tailor-made self-help intervention, if low mood or paranoia was detected. Participants were able to use this data retrospectively to recollect events in the past week, providing the service user participants greater insight into their experience of their illness. Current services require service users to retrospectively recollect experiences throughout the week. However due to the distress experienced by service users, difficulties in recollection of experiences can occur. This coupled with the difficulties in communicating distress, have been found to be confounding factors when undertaking therapeutic work in psychosis (Byrne & Morrison, 2010; Palmier-Claus et al., 2012). The TechCare App provided an alternative means to record the participant's experiences and allowed health professionals to view any changes in the symptomatology of the service

users, thus overcoming difficulties in recollection of experiences. The results of the study support previous research (see Oorschot et al., 2009; Myen-Germeys, 2008), with Ecological Sampling Methodologies (ESM) being used as an important means of gaining understanding of the real-world socio-environmental factors related to psychotic symptoms.

I thoroughly engaged with service users throughout the process of conducting the research. The engagement of service users in the development of the App, formed an integral part of early aspects of the process. Providing service users with the voice and choice in how technology can be used to support them is of great importance and is congruent with ideals and policy recommendations for user involvement in research (Brett et al., 2014; Shipee et al., 2015) and the valuing of a coproduction ethos in services and research (Gillard et al., 2010; Slay & Stephens, 2013; Thornicroft & Tansella, 2005). Similarly, this valuing of involvement practices has been urged by service users themselves and movement allies, and advocated as a means itself for tackling health inequalities (Beresford, 2007; Wallcraft, Schrank, & Amering, 2009). The means by which participants were engaged, was through providing feedback and consulting on the study. Previous research within this area has also reported the positive impact research has on service users particularly in regards to empowerment and service user autonomy (Boote, Baird and Beecroft, 2010; Hanley, 2005).

8.1 mHealth for medication management

One of the findings of the study was that participants highlighted a need for support with managing medications and side-effects. This was suggested as being related to accessing information on medication and its side-effects and also reminders to take medication. Research has suggested medication side-effects are predictors of medication non-adherence in psychiatric patients (Di Bonaventura et al., 2012). Management of side-effects is therefore a key factor in ensuring improved treatment outcomes. Psychiatric medication such as antipsychotic medications have been found to be associated with a number of adverse side effects such as; 1) weight gain and obesity; 2) diabetes; 3) hyperlipidemia; 4) prolongation of the QT interval on the ECG; 5) prolactin elevation and related sexual side effects; 6) extrapyramidal side effects, akathisia, and tardive dyskinesia; 7) cataracts; and 8) myocarditis (Marder et al., 2014).

In the UK the Medicines and Healthcare Products Regulatory Agency (MHRA) has developed a good pharmacovigilance practice guide which outlines the standards required for the monitoring and safety of medicines for use by the public in the European

Union (MHRA, 2014). The MHRA also have an online system called the Yellow Card Scheme (yellowcard.mhra.gov.uk) which is a tool to report the side effects or adverse drug reactions experienced by service users. However, recent research in the US, has suggested that there is a delay in the signal detection of adverse drug reactions with a significant time lag to detect the signals of unknown adverse drug reactions (Hashiguchi et al., 2015). The study concluded that there is a need for health professionals and service users to rapidly and proactively report medication side effects even when the relationship of the drug and adverse drug reactions is not yet established (Hashiguchi et al., 2015). The use of mHealth technologies may hold the key to improving real-time reporting of medication management and side-effects, which may be a better indicator of drug efficacy, ideally enabling the optimum dose prescribing, with fewer side effects and maximum efficacy by capturing data on treatment effects in real-time. Furthermore, the results of the systematic review conducted highlighted the strongest evidence for mHealth for had been in medication adherence, this coupled with the importance of medication management and side-effect information for service user participants in the present study provides a case for improving medication adherence and safety using the iRTT conceptual framework.

8.2 Access to digital technologies

Another finding of the study was that participants reported service users with psychotic disorders have access to mobile devices, further supporting the feasibility of the delivery of psychosocial intervention on an accessible platform. Firth et al., (2016) conducted a systematic review of mobile ownership and endorsement of mHealth for individuals with psychosis, of the 15 included studies it was found that 88.4% had access to a mobile phone between 2014 to 2016. Furthermore, there was a general consensus view by the health professionals, that most people had access to mobile phones, this finding is also in line with research by Torous et al., (2014), who found that the 97% of individuals in an outpatient psychiatric department reported having access to a mobile phone with 72% having access to a smartphone. Considering the rapid increase in the development of mobile technology and the increasing affordability of smartphone devices, it can be seen that mobile phones may well be a viable means of increasing access to support for those with mental health difficulties.

Furthermore, on direct examination of the impact of health inequalities on service users' access to both services and digital technologies. The research design used did not necessitate the users paying for their mobile or the App. Despite some initial staff

misgivings, only one phone was lost, showing that this group of service users can actually be trusted to look after a valued device. In any event, insurance policies can potentially cover for losses. A future trial could include cost benefit analysis in relation to service usage. One possibility is that the App improves patient outcomes and reduces service usage, with cost savings more than defraying the resources invested in mobile devices and technology development. The extension of helpful digital access to this client group, including the wider functionality of these phones beyond the TechCare App, could represent a substantial impact in opening up digital inclusion and ameliorating some of the other social and health inequities that afflict people with psychosis. Further research could also investigate the impact on social isolation, with the potential for digital apps, wider digital inclusion and mobile phones to actually contribute to expansion of social networks and improving connectedness within established networks – amongst family, friends, peers and with care teams for example.

Out of the 16 participants, all the participants owned a mobile phone. Although it was stated that there was an ease of access to mobile devices, participants held mixed views on the cost implications, with these possible implications related to these exclusionary factors. Research has reported that digital exclusion can have an important impact on the social determinants of health. Technology is increasing at an exponential rate with digital technologies providing a key platform for the delivery of improved health outcomes. The findings of the research provide grounding in relation to equitable care through the use of digital technology, but only preliminary inferences can be made due to the exploratory nature of the study. One of the most dramatic developments in the use of the Internet in recent years is the exponential increase in usage of social media sites, which have been suggested to be of benefit to individuals with SMI's. For instance, with a positive impact upon social capital and inclusion, and perhaps employability – with job applications and interaction with welfare agencies mediated online. However, a recent study by Chen & Lee (2013) highlighted there is a potential for increased interaction with the social media site 'Facebook' resulting in communication overload and reduced self-esteem. In addition, it should also be highlighted that increased use of the Internet may increase people's vulnerability to cyberbullying particularly for individuals with severe mental health problems (Chen & Lee, 2013).

However, the lack of a presence or inadequate participation in this virtual community means that mental health service users may be missing out on an opportunity to help facilitate social inclusion and fight the stigma of mental illness. Most importantly, organisations such as the American Psychiatric Association, the Royal College of

Psychiatrists (UK) and other mental health organisations need to adopt digital inclusion as an important element of the social inclusion agenda. Research focused on developing insights into digital interaction and the effects on mental wellbeing could be of benefits to service users within EIS. The use of digital technology would offer numerous benefits if it became part of clinical discourse, such as enhancing patient engagement and ease of access to accurate information regarding health conditions.

Furthermore, availability of a suitable infrastructure for disadvantaged groups is a major problem, which would need to be addressed for these changes to be implemented. User interfaces will require adaptation for people with learning disabilities, older people and those with cognitive impairment. Initiatives to promote uptake might involve subsidising access to broadband for patients and mental health services. In view of the large IT infrastructure which already exists within healthcare services and mental health care providers, such as healthcare trusts and is already available in some hospitals in the North West. This may not be expensive and would be at least cost neutral if anticipated benefits accrue.

The nature, degree and extent of digital exclusion in my view, still needs to be defined clearly for those suffering from mental illness to accurately assess the size of the problem. Digital inclusion, like social inclusion, is a multidimensional concept. It is unlikely that all dimensions of the concept will impact mental health significantly and further investigations would guide where interventions would be best focused. Studies examining patient preferences would clearly be of benefit, as it is unclear if lack of interaction is due to motivation, skills or interest. This will help to provide guidance on policy, training and resources.

The considerable variation in ICT access and use within lower income and disadvantaged groups should be acknowledged and accommodated by health initiatives and services when delivering digitally mediated interactions, online health information, or online self-management of health conditions. Increasingly, services require patients to participate in digitally mediated communications. It is, therefore, the responsibility of the health professionals and the institutions serving patients that they provide support, skills and technology in order to avoid exacerbating health inequities and promote the benefits of digital inclusion on mental health.

8.3 mHealth Apps: The concept of usability and user experience

Another significant finding was related to the usability and the user experience of the TechCare App, with participants strongly recommending a more interactive user interface. There has been a global increase in the use of mobile technology for healthcare (Tran et al., 2010; Alvarez-Jiminez et al., 2012; Piette et al., 2012; Ainsworth et al., 2011, Granholm et al., 2011). In recent years, these technological advances particularly broadband expansion and integration of multiple types of data have made remote medical assessment and treatment delivery significantly more feasible (Yellowlees, 2003). Estimates suggest the global penetration of mobile phone subscriptions was 6.9 Billion in 2014 (WHO, 2014), with over 20 000 health Apps available on the Apple App store and over 3000 available on the Google Android Store. The majority of research has reported that mobile technologies have provided a key platform in the delivery and accessibility of health information and services in the real-world environment. As we can see from the findings of the study, mHealth has the potential to provide greater access to psychosocial interventions and has been suggested to be a key platform to overcoming the social detriments of health. Increasingly, many health and social services require digitally mediated input from service users. It is, therefore, the responsibility of the health professionals and the organisations serving patients that they provide support, skills and technology in order to enhance user experience and to increase engagement with mHealth Apps.

More importantly, when developing mHealth interventions for those with mental health problems, care should be taken in regard to the adverse effects and safety profile of mHealth Apps to ensure the safety of service users. This is an important factor, especially for those with severe mental illnesses (SMIs). The mobile interface design and content should be tailored to meet the needs of individuals suffering from SMIs specifically those with paranoid ideation or antisocial personality disorder and social anxiety, with user-friendly functionality allowing for support in the case of crisis.

Alvarez-Jimenez et al., (2014) has suggested that computerised technology has advanced rapidly over the past 20 years, especially through the advent of mobile technology and mobile phones. It is argued, that availability of mobile technology has transformed the way people communicate with each other in the wider community and that the Internet has become a powerful source of information. Smartphone access to the Internet has provided the rapid access to health information. One of the key factors associated with testing mHealth Apps that deliver psychosocial interventions, is the user

experience or the usability of these forms of intervention. The very notion of 'psychosocial' takes on interesting potential characteristics and opportunities when the 'social' is expanded to include virtual/digital interactions.

Furthermore, in the context of usability, the availability of suitable infrastructure for disadvantaged groups is a major problem, which needs to be addressed with changes to enhance user experience of mHealth Apps needing to be implemented. These may be in relation to user interfaces that may require adaptation for people with learning disabilities, older people and those with cognitive impairments. Luxton et al., (2010) suggested that mHealth Apps could be versioned, enabling them to meet the needs of various audiences, and to improve accessibility for persons with disabilities. In addition, Ben-Zeev et al., (2013) also reported usability factors such as having a mix of genders, ethnicities and ages when displaying images of people. This highlights the need to be sensitive to different user groups when developing mHealth Apps. It is also important to ensure that technological devices that deliver mHealth Apps are fit for purpose. Gong & Tarasewich (2004) reported that the key barriers to improved usability were factors such as the small screens on some mobile devices, problematic onscreen touch functionality and the difficult use of onscreen keyboards, which are used for text input. In addition to these factors, it is also important to note that screen brightness, clarity and quantity of text displayed on devices are key factors, which need to be considered in developing device platforms for mHealth App delivery.

Usability considerations for mHealth App design

The effectiveness of mHealth Apps is very much grounded in the usability of such technologies. Individuals who experience mental health difficulties can experience a range of symptoms such as anxiety, hallucinations, paranoia, depression and elation (Coyle et al., 2007). These symptoms can have an impact on an individual's ability to process thoughts, perceptions, emotions, poor concentration and organisational skills (Coyle et al., 2007). Therefore, it is important to take these considerations into account when developing mHealth Apps for mental illnesses, and imperative that novel approaches to mHealth design and development are informed by the usability testing of mHealth Apps such as TechCare.

Device Navigation

It has been suggested by Nilsen et al., (2012), that the rapid increase of mobile technology interventions has been developed without scientific enquiry into the design,

layout and evaluation of such technologies. An important aspect of the user experience in mHealth App development is the ease of navigation. Research by Carson (1999) reported that user interface designs such as Internet web browsers, allow individuals to navigate through the systems via links, which direct individuals to areas where further information can be accessed. Research in this area for severe mental illnesses has suggested that individuals with schizophrenia had difficulty navigating Internet sites geared to the general public (Brunette et al., 2012). In addition, research by Ben Zeev et al., (2013) in the development of the FOCUS mobile App for the self-management of schizophrenia, used design features, which had been previously used in the development of eResources for individuals with schizophrenia. These were found to be user-friendly and usable to those with mental-illness related impairments (Rotondi et al., 2007). Carson (1999) advised navigation links, which were presented in colour, are easier to engage with, with poor presentation of navigation links or buttons impeding user navigation. Buttons or links on the App should be clear and concise and provide a logical pathway to access primary and secondary content. Furthermore, there is also a need for the App to be uniform, with a consistent design throughout; this would hopefully ensure ease of navigation for those using mHealth Apps.

Engagement with mHealth Apps

Furthermore, in the context of mHealth Apps for mental health disorders Ben-Zeev et al., (2013) highlighted that individuals with severe mental illnesses may display characteristics such as cognitive impairment, salient symptoms and limited literacy which may impede engagement with digital clinical technologies such as mHealth Apps. A good starting point may be research already conducted in the area of Computer Human Interactions. Doherty et al., (2004), suggest that any mobile/web interface providing a therapeutic link between the service user and mental health professionals must be designed with ease of use and minimal technical support requirement. This is a relatively novel area of research and it is hard to stipulate whether the key stakeholders and users of mHealth interventions are computer/mobile phone competent. Furthermore, it has been highlighted that ensuring end-user customisation could be a useful tool in enhancing engagement with mHealth Apps. Luxton et al., (2010) suggested that the visual appearance or selection of male or female voice narration could potentially be some examples of this customisation. This is a hugely important factor to be considered as many individuals that suffer from severe mental illnesses experience perceptual disturbances such as voices or hallucinations, ensuring an ability to customise user preferences may be important in increasing engagement.

The recent and rapid increase use of mobile devices has been remarkable; however, there is very little research on the usability and user experience of mHealth Apps, which are currently in use, or the preferences of key stakeholders in the development of future mHealth technologies for mental health difficulties. Health care researchers may benefit from exploration of insights of the user experience of using digital clinical technologies that provide psychosocial interventions and the effects on mental wellbeing. Increasing the evidence base for the usability of mHealth may provide increased uptake, engagement and adoption of mHealth apps. Furthermore, ensuring the usability of mHealth Apps for underserved populations such as those with mental illness and those from diverse cultures, has the potential of reducing the inequality of access to mental health services due to barriers such as stigma. The use of digital technologies has already become a part of the daily lives of large number of service users and may potentially have numerous benefits, if it becomes part of clinical discourse. Such as enhancing patient engagement and ease of access to accurate information regarding health conditions.

8.4 Risk and Benefits of mHealth

In the project, one of the findings was that there were no occurrences of adverse events during the study period and some initial professional concerns proved to be unfounded in this small-scale study. This could have been due to the safety considerations made in conjunction with participant's care coordinator when developing the project, vindicating efforts to also thoroughly involve professionals in the study. However, although the study reported that no adverse events were experienced by the participants in the study, it is important to note that due to the developing nature of the field and relatively limited evidence base, the adverse events may not have been apparent or due to the short follow-up duration were not detected.

Furthermore, the health professionals provided unique perspectives on the current services and how the TechCare intervention could be integrated within the EIS. The finding was that health professionals initially reported concerns, that there was a greater chance of participants losing or stealing the study phone. However, these failed to materialise and it was actually found that only one participant lost the phone in the course of the study. It may be noted that prolonged usage or excessive usage may be the cause of adverse effects. In this regard, future research would require closer monitoring of adverse effects. In particular it would thus be imprudent to state that there were no incidences of adverse events within the trial, with this being ascertained by the

longitudinal analysis of controlled data and safety monitoring as a core part of any future work.

Recent developments in mobile devices and faster Internet connectivity on these devices, has led to the start of a new era in health technology. Smartphones and tablet devices are thus becoming increasingly popular for accessing information and a wide range of services, including healthcare services. Modern mobile phones offer stable and versatile platforms that allow delivery of a variety of services. Mobile Apps for smartphones are being developed at a significant pace, and can support a variety of routine medical tasks, ranging from education and assistance to clinicians to help and support the patients. Mobile phone Apps have also been found to benefit patients in a scope of interventions, across numerous medical specialties and treatment modalities. Medical Apps offer clinicians the power to access medical knowledge and patient data at the level of care with unprecedented comfort. However, this is an emerging area, and in spite of the potential advantages and immense possibilities there is a need to ensure that patient safety is not compromised before this field matures.

As with many interventions, the decision to use a mobile App in a particular clinical situation should be dependent on clinicians perceived risk benefit ratio. These judgments require health care professionals to understand the intended benefits, limitations, and risks associated with medical Apps in order to make an informed App usage decision. Research has suggested that providing accurate information in easy to understand language about development and initial testing should be an essential part of mHealth Apps. This information will help both patients and clinicians in making informed decisions. It is important that the person using these Apps, is fully aware of the safety profile and potential side effects of these Apps.

Security and privacy are probably the most obvious concerns in this regard. Insecure mobile Apps can cause serious information security and data privacy breaches and can have severe repercussions on users and organisations alike. The proliferation of mobile devices equipped with position sensors has made Location-Based services (LBS) increasingly popular. These mobile devices send users actual location information to third party location servers, which compile and in some cases, share information with other service providers. As a result, users aware of the privacy implications can feel continuously tracked. This might have serious implications for those with paranoia who are using an App that uses location based services.

In relation to security, Perera (2012) described a number of safeguards, which can be used to ensure data security on mobile devices. To ensure protection mobile devices should be accessible via a PIN. It is recommended that rather than a four-digit PIN, an alphanumeric passcode be used. In addition, functionality whereby data is wiped from the device after 10 failed passcode attempts would further protect data of a clinical sort (Perera, 2012). Furthermore, encryption of mobile devices, enabling remote wiping of data held on the device and also storing data in the cloud rather than on the mobile device are key strategies in ensuring data security (Perera, 2012). Notifications and alerts which are programmed into mHealth Apps also warrant consideration. Firstly, the notification iconography may need to be discreet/private as not to cause any distress to participants or show any inference that the individual is undergoing therapy. Individuals should be given control in the use of the mobile device and it should not be seen as an intrusion into their home daily life. These risk factors can be broken down into internal and external risk factors. While the internal risk factors may be reduced through appropriate regulation, external risk factors may require a formal education program to raise awareness among App users.

8.5 Adverse effects of mHealth and Internet use

One of the key adverse effects of the digital technologies within the context of mental health is Internet addiction. Kuss et al., (2013) reported that out of 2257 university students in the UK 3.2% were addicted to the Internet. There are also possible adverse effects of using the Internet for increased periods, which can contribute to increased levels of inactivity and sedentary behaviours which have been reported to increase the risk of obesity (Vandelanotte et al., 2009). More specific to the area of Apps, mobile devices that run mHealth Apps produce electromagnetic fields, which have been suggested as being carcinogenic by the World Health Organisation (2014). Furthermore, it has also been found that another possible side effect of Apps is high frequency usage. A study by Thomee et al., (2011) found an increased risk factor for mental health outcomes in young adults with high frequency use associated with stress, sleep disturbances and symptoms of depression at one-year follow-up. In addition, research suggests an increased risk of ocular problems, with viewing mobile phone screens causing eyestrain. Other complications have also been found in relation to viewing mobile device screens. For example, Wood et al., (2013) reported that exposure to self-luminous screens on mobile devices have the potential to increase the likelihood of sleep disorders due to factors such as melatonin suppression, particularly in the blue light spectrum.

Other possible side effects associated with the utilisation of mobile Apps is the increased chance of bacterial accumulation on devices, which can have the potential to spread infection. It is also important that individuals feel no pressure in replying on the mHealth App notifications and alerts, as there may be a risk of increasing paranoia and anxiety. A study by Ainsworth et al., (2013) found that out of the total population of participants one participant withdrew from the study due to distress, as a result of rumination of symptoms. It is difficult to say at this stage, how these side effects might start or worsen in those who use mHealth interventions. However, it is important to establish the side effect profiles of mHealth Apps and the Internet, including the conduct of qualitative studies to examine the experiences of those who use mHealth Apps.

8.6 Strengths and limitations of the research

The main strength of the study was the feasibility testing of a novel intervention for psychosis, which used the iRTT conceptual model (Kelly et al., 2011). iRTT has not been evaluated before and as such, the study provided novel insights into the development of mHealth interventions. Furthermore, another strength of the study was the engagement of the service users, across the study period with only two participants dropping out. In addition, as I chose a pragmatic philosophical worldview, the research was conducted within the NHS context, allowing the TechCare App to provide a workable solution to increasing access to psychological therapies, and allowing for potential generalisability to other EIS's in the country. Moreover, there was a low level of missed follow-ups, with participants meeting 88% of all follow-up data points. In addition, the study was conducted in line with guidance on feasibility study design by the NIHR (2014). This was important as it followed the MRC guidance for the evaluation of complex interventions (MRC, 2000). The proposed future trial would thus be able to be, evaluated in a phase III effectiveness trial.

On examination of the limitations of the study, it was found that the major limitation of the study was the relatively small sample size for the feasibility study. Across the study period I recruited a total sample of n=16. Previous research in the area of feasibility studies have used a range of sample sizes, as described by Billingham et al., (2013) who reported a sample size range for feasibility studies of between 10 to 300 participants (median = 36, range = 10 to 300 participants). Despite being within this range, the study would have benefitted from a larger sample size allowing for a more representative sample of participants. In addition, a further limitation of the study was the lack of a Randomised Controlled Trial (RCT) design, the addition of a control and interventional

arm would have provided beneficial insights into the scalability of the study in relation to allocation and randomisation procedures. However, as I have noted I had limited resources to conduct an RCT of the TechCare study and had to be realistic in the work conducted for the purposes of a PhD.

In addition, with regards to the methodology, the key limitation of qualitative research is the lack of a clear guidance which provides a uniform methodological approach in feasibility work (Attride-sterling 2001). This is further highlighted by Braun and Clarke (2006), in that difficulties may arise due to the lack of flexibility in the approach to analysis which can be restrictive in necessitating analysis. Furthermore, Furber (2010) highlighted the need for transparency in the coding and analysis of qualitative data as it ensures that there is a clear audit trail of the derived findings ensuring accountability and integrity of the research. Moreover, the study used a mixed method approach to examine the feasibility of the TechCare App. This approach was selected as it allowed me to both objectively and subjectively evaluate the intervention. The key strength of the mixed method approach is the ability for both the qualitative and quantitative methods to complement each other drawing on both to formulate results. This is particularly important in the case of mental health research, as there is a greater need to not only examine objective measures such as the usage of the intervention, but also the experience of participants using the App.

In addition, mixed methods are also beneficial in ensuring that data collected is in fact congruent across the two approaches. To put this in to context, the quantitative data of the study could be checked against the qualitative data to examine any errors in measurement and whether the study outcome measures provided a valid representation of the results. In contrast research within health care has also included process evaluations to determine discrepancies in the procedural aspects of the study. One of the key strengths of this approach is to safeguard against errors or bias, which can invalidate the results, ensuring a robust means of evaluating a novel intervention in a large scale RCT.

Despite the feasibility study providing useful data on the feasibility of the TechCare App, it is imperative that any future research examines the practicality of trial related processes and procedures. As part of this feasibility study, participants were assessed on a weekly basis, with only a short follow-up period. As I mentioned in the results a short period of time for follow-up was chosen as a pragmatic means of assessing feasibility, with only a small number of participants across 6 weeks. As we saw on page 165

(Section 7.4) of the thesis, the short data collection period raised some complexities for interpreting the longitudinal trends related to the scoring on the outcome measures. A future trial would need to examine the duration and number of follow-up points, with the inclusion of a longer-term follow-up of 6 months to determine treatment effects in the longer term. These are similar recommendations made by Ainsworth et al., (2011) as part of the ClinTouch study.

Furthermore, although the assessments were conducted weekly, in routine clinical practice the App would be monitored remotely, with the TechCare App supplementing face-to-face care coordinator input with the service users. Under the current NHS resource pressures, implementing such a therapeutic intervention into the existing EIS care pathway may be an important factor to consider and evaluate as part of future research, due to the potential for the TechCare App to improve patient outcome using a cost-effective approach. However, this work would need to be investigated as part of future research work.

In addition, the inclusion of family members and carers in qualitative work may also shed light on important design features and functionality, which may include adaptations to the TechCare App to support family members or carers of individuals with psychosis. Not only is this important in terms of a participatory approach to research but considerable research has amassed pertaining to the development of family member/carer interventions. For example, the Relatives Education And Coping Toolkit (REACT) which was conducted in a similar context, within the EIS in the North West Coast (Lobban et al., 2013). Further developments in the TechCare App could provide novel approaches, allowing for the inclusion of family interventions, which have been recommended by NICE in the treatment of Schizophrenia (NICE, 2014).

As can be seen, there were a number of confounding factors, which may have impacted the validity of the research. Future scale-up work would necessitate conducting a suitably powered RCT with an increased sample size and economic evaluation. This would provide robust clinical- and cost-effectiveness data on the TechCare App intervention, with implications for future research being further discussed in the following section.

8.7 Implications for future research

mHealth can play a huge role in the low resourced settings especially in areas where there is limited funds and resources to spend on healthcare. Therefore analysis of data can be of huge benefit in identifying where resources are being spent and those, which

target and channel the resources/funding accordingly. Decisions made based on this evidence will provide better outcomes for patients and improve efficiency. This will also encourage service improvement that may reflect in better patient care that is both high quality and cost-effective. mHealth can also set a standard of performance, known as benchmarking. This standard can be measured against other health centres/hospitals, which will help in determining the quality of care that is being provided and also help with identifying any deficiencies.

Measuring trends and analysing data will also allow for better forecasting and ensure measures can be put in place to improve clinical practice and reduce wastage of resources. This research was a feasibility project, with the aim of examining the feasibility and acceptability establishing further research in this area. Following this feasibility study, relevant alterations can be made with the aim of submitting a grant proposal for a larger scale RCT. Overall, the results of this project can aid the adaptation and development of the TechCare App intervention, with future research in this area being very much needed, to build upon existing understanding (Barak et al., 2008) and in addressing health inequalities.

8.8 Conclusions

Research conducted within the area of SMI's has played an important role in providing a deeper understanding in the development and refinement of mental health service provision in the UK. Most importantly, research conducted through the CLAHRC NWC has been primarily focused on health inequality, with the overall aim being to tackle mental health inequality within the North West Coast, to better meet the needs of individuals. Individuals in the North West coast live in areas of high deprivation and suffer the greatest levels of morbidity and mortality (ONS, 2014). However, the question remains to what extent can we utilise the findings of the present study in helping address this health inequality, thus providing a rationale for future research.

Recent and rapid increase in the use of mobile devices has been remarkable. The study investigated a new concept iRTT, which had not been evaluated previously. The project was able to demonstrate the feasibility and acceptability of the TechCare App intervention. The research was helpful in providing grounding for the development of mHealth interventions, which may help reduce the demand on mental health services. In addition, it can be concluded that the TechCare App, provided insights into overcoming mental health inequalities by increasing access to mental health services and reducing stigma. As has been vastly reported stigma plays a major role in confounding service

users with mental illness, but as found in the project discrete mediums, which allow for engagement with services have the potential to overcome stigma related barriers. Feasibility testing of the TechCare App provided important feedback on the further refinement and development of the intervention.

Innovative digital clinical technologies such as the TechCare App may have the potential to increase service access, reduce health inequality, and promote self-management with real-time intervention, through enabling access to mental health resources in a stigma-free, evidence-based, location and time-independent manner. Integration with community shared care strategies can support medication adherence and appointment attendance, in addition to hastening self and EIS identification of mental health deterioration.

Moreover, I examined matters relevant to the experience or impact of health inequalities on service user's access to both services and digital technologies. Out of the 16 participants, all the participants owned a mobile phone. Although it was stated that access to mobile devices was easy, participants held mixed views on the cost implications, and research has reported that digital exclusion can have an important impact on the social determinants of health. Technology development is increasing at an exponential rate with digital technologies providing a key platform for the delivery of improved health outcomes. The feasibility project had aimed to examine the feasibility and acceptability of the TechCare intervention, and closely followed the guidance by the National Institute of Health Research (NIHR, 2014) for designing feasibility studies to test the vital parameters which would inform the design of a larger definitive trial.

The notions of self-management and self-help are interesting, in that they appear to chime in with a valuing of independence and individual autonomy that fits well with a recovery ethos within services. Critics, however, point out the simultaneous compatibility of a self-help impulse with a neoliberal polity that is driving disinvestment in services and the wider welfare state. This creates dilemmas for critical service users and allied progressive professionals who may care to promote self-management within a culture of recovery and positive rights at the same time as decrying the cuts to services attendant on austerity policies. Perhaps the resolution of these dilemmas, at least in part, is within the findings of this study that suggest staff and service users emphasise a balance between the positive aspects of self-reliance, a more collective, network based psychosocial support system, and a continued valuation of face to face therapeutic relations with skilled professionals. Interestingly, the most critical service user/survivor

groups may subvert a perceived neoliberal sponsorship of mobile technologies to refuse mainstream services altogether, picking and choosing helpful digital support offerings in an ultimate act of self-reliance and autonomy.

mHealth innovations are important as they have the potential to bridge the 'therapy-practice gap', going beyond the confines of the therapy setting and bringing real-time treatment into an individual's day-to-day life and within their lived environment. The potential benefits of digital technologies in providing a new way to connect with health services and to potentially improve health outcomes, are limited by a number of barriers in their use. Hollis et al., (2015) summarised these barriers as the insufficient evidence base, limited uptake and outcomes being anecdotal and unpublished. Hollis et al., (2015) further stated that for the potential of digital technologies to be fully realised, service user requirements need to be at the centre of developing interventions, and that there is a need for a rapid increase in the efforts to develop the evidence base for the clinical-effectiveness of mHealth.

References

- Addington, D., Addington, J., & Schissel, B. (1990). A depression rating scale for Schizophrenia. *Schizophrenia research*, 3(4), 247-251.
- Ainsworth, J., Palmier-Claus, J. E., Machin, M., Barrowclough, C., Dunn, G., Rogers, A., ... & Hopkins, R. S. (2013). A comparison of two delivery modalities of a mobile phone-based assessment for serious mental illness: native smartphone application vs text-messaging only implementations. *Journal of Medical Internet Research*, 15(4).
- Allen, J., Balfour, R., Bell, R. and Marmot, M., (2014). Social determinants of mental health. *International Review of Psychiatry*, 26(4), pp.392-407.
- Alvarez-Jimenez M, Parker AG, Hetrick SE, McGorry PD,.(2011) Gleeson JF. Preventing the second episode: a systematic review and meta-analysis of psychosocial and pharmacological trials in first-episode psychosis. *Schizophrenia Bulletin*, (3):619-30. PubMed PMID: 19900962. Pubmed Central PMCID: 3080698.
- Andrew, S. & Halcomb, E.J., (2007). Mixed methods research is an effective method of enquiry for community health research. *Contemporary Nurse*, 23(2), pp.145-153.
- Antoine, P., Antoine, C., & Nandrino, J. (2008). Development and validation of the Cognitive Inventory of subjective distress. *International Journal of Geriatric Psychiatry*, 23(11), 1175-1181. doi:10.1002/gps.2051
- Archie, S., Akhtar-Danesh, N., Norman, R., Malla, A., Roy, P., & Zipursky, R. B. (2010). Ethnic diversity and pathways to care for a first episode of psychosis in Ontario. *Schizophrenia bulletin*, 36(4), 688-701.
- Arjadi, R., Nauta, M. H., Chowdhary, N., & Bockting, C. L. (2015). A systematic review of online interventions for mental health in low and middle income countries: a neglected field. *Global Mental Health*, 2. doi:10.1017/gmh.2015.10
- Årsand, E., Tatara, N., & Hartvigsen, G. (2010). Mobile phone-based self-management tools for type 2 diabetes: the few touch Application. *Journal of diabetes science and technology*, 4(2), 328-336.
- Atkinson, N. L., Saperstein, S. L., & Pleis, J. (2009). Using the internet for health-related activities: findings from a national probability sample. *Journal of medical Internet research*, 11(1).

- August KJ, Nguyen H, Ngo-Metzger Q et al. (2011) Language concordance and patient-physician communication regarding mental health needs, *J Am Geriatr Soc.*, 59(12):2356-62.
- Ayers, S. L., & Kronenfeld, J. J. (2007). Chronic illness and health-seeking information on the Internet. *Health.*, 11(3), 327-347.).
- Ayers, S., & De Visser, R. (2010). *Psychology for medicine*. Sage.
- Balls P (2009) Phenomenology in nursing research: methodology, interviewing and transcribing. *Nursing Times* 105,30–33.
- Barak, A., Hen, L., Boniel-Nissim, M. & Shapira, N. (2008). A Comprehensive Review and a Meta-Analysis of the Effectiveness of Internet-Based Psychotherapeutic Interventions. *Journal of Technology in Human Services*, 26(2/4), 109-160
- Baum F, Newman L, Biedrzycki K. (2012). Vicious cycles: digital technologies and determinants of health in Australia. *Health Promotion International*.
- Bennett L, Baikie K. The client as educator: learning about mental illness through the eyes of the expert. *Nurse Education Today*. 2003;23(2):104-11.
- Bentall, R. (2003). *Madness Explained*. London: Allen Lane.
- Bentall, R. P. and Morrison, A. P. (2002). More harm than good: the case against using antipsychotic drugs to prevent severe mental illness. *Journal of Mental Health*, 11, 351-365.
- Ben-Zeev D , McHugo G J, Xie H, Dobbins K, Young M A (2012). Comparing retrospective reports to real-time/real-place mobile assessments in individuals with schizophrenia and a nonclinical comparison group. *Schizophrenia bulletin*, 38(3), 396-404.
- Ben-Zeev, D., Brenner, C. J., Begale, M., Duffecy, J., Mohr, D. C., & Mueser, K. T. (2014). Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. *Schizophrenia bulletin*, 40(6), 1244-1253.
- Ben-Zeev, D., Kaiser, S. M., Brenner, C. J., Begale, M., Duffecy, J., & Mohr, D. C. (2013). Development and usability testing of FOCUS: A smartphone system for self-management of schizophrenia. *Psychiatric rehabilitation journal*, 36(4), 289.

- Beresford, P., (2007). User involvement, research and health inequalities: developing new directions. *Health & Social Care in the Community*, 15(4), pp.306-312.
- Berry, K., & Haddock, G. (2008). The implementation of the NICE guidelines for schizophrenia: Barriers to the implementation of psychological interventions and recommendations for the future. *Psychology and Psychotherapy: Theory, Research and Practice*, 81, 419–436. doi:10.1348/147608308X329540
- Bettencourt LA, Ostrom AL, Brown SW and Roundtree RI (2002). 'Client coproduction in knowledge-intensive business services'. *California Management Review*, vol 44, pp100–128.
- Bhavsar, V., Boydell, J., Murray, R., & Power, P. (2014). Identifying aspects of neighbourhood deprivation associated with increased incidence of schizophrenia. *Schizophrenia research*, 156(1), 115-121.
- Bhugra D. (2010) No health without public mental health: the case for action (Position statement PS4/2010). Royal College of Psychiatrists, Retrieved from: [http://www.rcpsych.ac.uk/pdf/ Position%20Statement%204%20website.pdf](http://www.rcpsych.ac.uk/pdf/Position%20Statement%204%20website.pdf)
- Bhui, K., Stansfeld, S., Hull, S., Priebe, S., Mole, F., & Feder, G. (2003). Ethnic variations in pathways to and use of specialist mental health services in the UK Systematic review. *The British Journal of Psychiatry*, 182(2), 105-116.
- Billingham, S. A., Whitehead, A. L., & Julious, S. A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC medical research methodology*, 13(1), 104.
- Birchwood M, McGorry P, Jackson H. Early intervention in schizophrenia. *Br J Psychiatry* 1997; 170: 2–5.
- Birchwood, M., & Fiorillo, A. (2000). The critical period for early intervention. *Psychiatric Rehabilitation Skills*, 4(2), 182-198.
- Birchwood, M., Todd, P., & Jackson, C. (1998). Early intervention in psychosis: the critical-period hypothesis. *International Clinical Psychopharmacology*, 13, S31-S40.
- Bird, V., Premkumar, P., Kendall, T., Whittington, C., Mitchell, J., & Kuipers, E. (2010). Early intervention services, cognitive–behavioural therapy and family intervention in early psychosis: systematic review. *The British Journal of Psychiatry*, 197(5), 350-356.

Boote J, Baird W, Beecroft C. Public involvement at the design stage of primary health research: A narrative review of case examples. *Health Policy*, 2010; 95: 10–23.

Booth, A., Clarke, M., Dooley, G., Ghera, D., Moher, D., Petticrew, M., & Stewart, L. (2012). The nuts and bolts of PROSPERO: an international prospective register of systematic reviews. *Systematic reviews*, 1(1), 2.

Borzekowski DLG, Leith J, Medoff D, et al. (2009). Use of the Internet and Other Media for Health Information Among Clinic Outpatients With Serious Mental Illness. *Psychiatric Services*. 60(9):1265-8.

Bottlender R, Sato T, Jager M. (2009). The impact of the duration of untreated psychosis prior to first psychiatric admission on the 15-year outcome in schizophrenia. *Schizophr Res*, 62: 37–44.

Boulos, M. N. K., Wheeler, S., Tavares, C., & Jones, R. (2011). How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. *Biomedical engineering online*, 10(1), 24.

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., ... & Fernandez, M. (2009). How we design feasibility studies. *American journal of preventive medicine*, 36(5), 452-457.

Bower, P., Wilson, S., & Mathers, N. (2007). how often do UK primary care trials face recruitment delays?. *Family Practice*, 24(6), 601-603.

Bowes, P., Stevenson, F., Ahluwalia, S., & Murray, E. (2012). 'I need her to be a doctor': patients' experiences of presenting health information from the internet in GP consultations. *Br J Gen Pract*, 62(604), e732-e738.

Boydell KM, Stasiulis E, Volpe T, Gladstone B. A descriptive review of qualitative studies in first episode psychosis. *Early intervention in psychiatry*. 2010 Feb;4(1):7-24. PubMed PMID: 20199476.

Boydell, K. M., Volpe, T., Gladstone, B. M., Stasiulis, E., & Addington, J. (2013). Youth at ultra high risk for psychosis: using the revised network episode model to examine pathways to mental health care. *Early intervention in psychiatry*, 7(2), 170-186.

- Bracken, P., Thomas, P., Timimi, S., Asen, E., Behr, G., Beuster, C., ... & Downer, S. (2012). Psychiatry beyond the current paradigm. *The British journal of psychiatry*, 201(6), 430-434.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), 77-101.
- Braveman, P., & Gottlieb, L. (2014). The social determinants of health: it's time to consider the causes of the causes. *Public Health Reports*, 129(1_suppl2), 19-31.
- Brett, J., Staniszewska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C., & Suleman, R. (2014). MAPPING the impact of patient and public involvement on health and social care research: a systematic review. *Health Expectations*, 17(5), 637-650.
- Brunette MF, Ferron JC, Devitt T, Geiger P, Martin WM, Pratt S, McHugo GJ. Do smoking cessation websites meet the needs of smokers with severe mental illnesses? *Health Education Research*.2012;27:183–190. doi: 10.1093/her/cyr092.
- Bryman, A. 2012. *Social Research Methods. 4th edn. Oxford: Oxford University Press*
- Bucci S, Barrowclough C, Ainsworth J, Morris R, Berry K, Machin M, Emsley R, Lewis S, Edge D, Buchan I, Haddock G (2015). Using mobile technology to deliver a cognitive behaviour therapy-informed intervention in early psychosis (Actissist): study protocol for a randomised controlled trial. *Trials*, 16(1), p.1.
- Buchy L, Brodeur MB, Lepage M. (2012). The Beck Cognitive Insight Scale: psychometric properties in a Canadian community sample. *Schizophrenia research*, 137(1-3):254-5. PubMed PMID: 22446141.
- Bunyan, S., & Collins, A. (2013). Digital exclusion despite digital accessibility: empirical evidence from an English City. *Tijdschrift voor economische en sociale geografie*, 104(5), 588-603.
- Byrne, P. (2000). Stigma of mental illness and ways of diminishing it. *Advances in Psychiatric treatment*, 6(1), 65-72.
- Byrne, R., & Morrison, A. P. (2010). Young people at risk of psychosis: a user-led exploration of interpersonal relationships and communication of psychological difficulties. *Early Intervention in Psychiatry*, 4(2), 162-168.

Cahn E (2000). No more throw away people: the co-production imperative. *Washington: Essential Books*.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ: British Medical Journal*, 321(7262), 694.

Campion, J., Bhugra, D., Bailey, S., & Marmot, M. (2013). Inequality and mental disorders: opportunities for action. *Lancet*, 382(9888), 183–184.

Casey, D. A., Rodriguez, M., Northcott, C., Vickar, G., & Shihabuddin, L. (2011). Schizophrenia: medical illness, mortality, and aging. *The International Journal of Psychiatry in Medicine*, 41(3), 245-251.

Cayton H (2004). Patient-engagement and patient decision-making in England. *Paper*

Chaudhry, I. B., Hallak, J., Husain, N., Minhas, F., Stirling, J., Richardson, P., ... & Deakin, B. (2012). Minocycline benefits negative symptoms in early schizophrenia: a randomised double-blind placebo-controlled clinical trial in patients on standard treatment. *Journal of psychopharmacology*, 26(9), 1185-1193.

Chen, W., & Lee, K. H. (2013). Sharing, liking, commenting, and distressed? The pathway between Facebook interaction and psychological distress. *Cyberpsychology, Behavior, and Social Networking*, 16(10), 728-734.

Clark, D. M. (2011). Implementing NICE guidelines for the psychological treatment of depression and anxiety disorders: the IAPT experience. *International review of psychiatry*, 23(4), 318-327.

Clayton, S., Borzekowski, D., Himelhoch, S., Dixon, L., Potts, W., Medoff, D., ... & Balis, D. (2009). Media and internet ownership and use among mental health outpatients with serious mental illness. *The American journal of drug and alcohol abuse*, 35(5), 364-367.

Clement, S., Schauman, O., Graham, T., Maggioni, F., Evans-Lacko, S., Bezborodovs, N., ... & Thornicroft, G. (2015). What is the impact of mental health-related stigma on help-seeking? A systematic review of quantitative and qualitative studies. *Psychological medicine*, 45(1), 11-27.

Collins, P. Y., Patel, V., Joestl, S. S., March, D., Insel, T. R., Daar, A. S., ... & Glass, R. I. (2011). Grand challenges in global mental health. *Nature*, 475(7354), 27-30.

- Cook, J.E. & Doyle, C. (2004). Working Alliance in Online Therapy as Compared to Face-to-Face Therapy: Preliminary Results. *CyberPsychology & Behavior*, 5(2), 95-105
- Corrigan, P. (2004). How stigma interferes with mental health care. *American Psychologist*, 59(7), 614.
- Covington, M. A., He, C., Brown, C., Naçi, L., McClain, J. T., Fjordbak, B. S., ... & Brown, J. (2005). Schizophrenia and the structure of language: the linguist's view. *Schizophrenia research*, 77(1), 85-98.
- Creswell, J. W. (2007). *Qualitative inquiry & research design: Choosing among five approaches* (2nd ed.). Thousand Oaks, CA: Sage.
- Creswell, J. W. (2014). *A concise introduction to mixed methods research*. Sage Publications.
- Creswell, J. W., & Miller, D. L. (2000). Determining validity in qualitative inquiry. *Theory into practice*, 39(3), 124-130.
- Crotty, M. (1998). *The foundations of social research: Meaning and perspective in the research process*. Sage.
- Dang J, Zhang J, Guo Z, Lu W, Cai J, Shi Z, Zhang C (2014). A pilot study of iPad-assisted cognitive training for schizophrenia. *Archives of psychiatric nursing*, 28(3), pp.197-199.
- Das-Munshi, J., Bécares, L., Boydell, J. E., Dewey, M. E., Morgan, C., Stansfeld, S. A., & Prince, M. J. (2012). Ethnic density as a buffer for psychotic experiences: findings from a national survey (EMPIRIC). *The British Journal of Psychiatry*, bjp-bp.
- Data Protection: Parliament, B. (1998). *Data protection act of 1998*.
- Department of Health (2007). *Best Practice in Managing Risk*. London. DoH.
- Department of Health (2012). *Digital Strategy: Leading the Culture Change in Health and Care*. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213222/final-report1.pdf
- Depp, C.A., Mausbach, B., Granholm, E., Cardenas, V., Ben-Zeev, Dror., Patterson, T.L., Lebowitz. B.D. & Jeste, D.V. (2010). *Mobile Interventions for Severe Mental Illness*.

Design and Preliminary Data From Three Approaches. *The Journal of Nervous and Mental Disease*, 198(10), 715-721

DiBonaventura, M., Gabriel, S., Dupclay, L., Gupta, S., & Kim, E. (2012). A patient perspective of the impact of medication side effects on adherence: results of a cross-sectional nationwide survey of patients with schizophrenia. *BMC psychiatry*, 12(1), 20.

Dilks S, Tasker F, Wren B. Managing the impact of psychosis: A grounded theory exploration of recovery processes in psychosis. *The British journal of clinical psychology / the British Psychological Society*. 2010 Mar;49(Pt 1):87-107. PubMed PMID: 19426583.

Doherty, G., Coyle, D., & Matthews, M. (2010). Design and evaluation guidelines for mental health technologies. *Interacting with computers*, 22(4), 243-252.

Domecq, J. P., Prutsky, G., Elraiyah, T., Wang, Z., Nabhan, M., Shippee, N., ... & Erwin, P. (2014). Patient engagement in research: a systematic review. *BMC health services research*, 14(1), 89.

Doze, S., Simpson, J., Hailey, D. & Jacobs, P. (1999). Evaluation of a telepsychiatry pilot project. *Journal of Telemedicine and Telecare*, 5(1), 38-46

Duncan P (2010) *Ethics* Sage

Dutton WH, Blank G. (2011). Next Generation Users: The Internet in Britain Oxford Internet Survey 2011. *Oxford: Oxford Internet Institute*.

Eisner E, Drake R, Barrowclough C. Assessing early signs of relapse in psychosis: Review and future directions. *Clinical Psychology Review*. 2013;33(5):637-53.

Ennis L, Rose D, Denis M, et al. (2012). Can't surf, won't surf: The digital divide in mental health. *Journal of Mental Health*. 21(4):395-403.

Ennis, L., & Wykes, T. (2013). Impact of patient involvement in mental health research: longitudinal study. *The British Journal of Psychiatry*, 203(5), 381-386

Eysenck, H. J. (1952). The effects of psychotherapy: an evaluation. *Journal of consulting psychology*, 16(5), 319.

Fazey, I., Bunse, L., Msika, J., Pinke, M., Preedy, K., Evely, A. C., ... & Reed, M. S. (2014). Evaluating knowledge exchange in interdisciplinary and multi-stakeholder research. *Global Environmental Change*, 25, 204-220.

- File T. (2013). Computer and Internet Use in the United States, Current Population Survey Reports. *Washington, DC: U.S. Census Bureau*, Report No.
- Firth, J., Cotter, J., Torous, J., Bucci, S., Firth, J. A., & Yung, A. R. (2015). Mobile phone ownership and endorsement of “mHealth” among people with psychosis: a meta-analysis of cross-sectional studies. *Schizophrenia bulletin*, 42(2), 448-455. Chicago
- Foss C and Ellefsen B (2002) The value of combining qualitative and quantitative Approaches in nursing research by means of method triangulation, *Journal of Advanced*
- Fowler, D., Freeman, D., Smith, B., Kuipers, E., Bebbington, P., Bashforth, H., . . . Garety, P. (2006). The Brief Core Schema Scales (BCSS): Psychometric properties and associations with paranoia and grandiosity in non-clinical and psychosis samples. *Psychological Medicine*, 36(6), 749-759.
- Fox, S., & Duggan, M. (2013). Health online 2013. Washington, DC: Pew Internet & American Life Project.
- Frowe, I. (2001). Language and educational research. *Journal of philosophy of education*, 35(2), 175-186.
- Fryers, T., Melzer, D., Jenkins, R., & Brugha, T. (2005). The distribution of the common mental disorders: social inequalities in Europe. *Clinical Practice and Epidemiology in Mental Health*, 1(1), 14.
- Furber, C. (2010). Framework analysis: a method for analysing qualitative data. *African Journal of Midwifery & Women's Health*, 4(2).
- Galizzi, M. M., Miraldo, M., Stavropoulou, C., Desai, M., Jayatunga, W., Joshi, M., & Parikh, S. (2012). Who is more likely to use doctor-rating websites, and why? A cross-sectional study in London. *BMJ open*, 2(6), e001493.
- Garety, P. A., Kuipers, E., Fowler, D., Freeman, D., & Bebbington, P. E. (2001). A cognitive model of the positive symptoms of psychosis. *Psychological medicine*, 31(2), 189-195.
- Geddes, J. R., & Lawrie, S. M. (1995). Obstetric complications and schizophrenia: a meta-analysis. *The British journal of psychiatry*, 167(6), 786-793.

Gillard, S., Turner, K., Lovell, K., Norton, K., Clarke, T., Addicott, R., McGivern, G. and Ferlie, E., 2010. "Staying native": coproduction in mental health services research. *International Journal of Public Sector Management*, 23(6), pp.567-577.

Godin, K., Stapleton, J., Kirkpatrick, S. I., Hanning, R. M., & Leatherdale, S. T. (2015). Applying systematic review search methods to the grey literature: a case study examining guidelines for school-based breakfast programs in Canada. *Systematic reviews*, 4(1), 138.

Goffman, E. (1963). *Stigma: Notes on the management of spoiled identity*. Harmondsworth, *Middlesex: Penguin Books*

Goffman, E. (1968) *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*. Harmondsworth: Penguin.

Gong, J., & Tarasewich, P. (2004, November). Guidelines for handheld mobile device interface design. *In Proceedings of DSI 2004 Annual Meeting* (pp. 3751-3756).

Gradinger, F., Britten, N., Wyatt, K., Froggatt, K., Gibson, A., Jacoby, A., ... & Popay, J. (2015). Values associated with public involvement in health and social care research: a narrative review. *Health Expectations*, 18(5), 661-675.

Granholm, E., Ben-Zeev, D., Link, P. C., Bradshaw, K. R., & Holden, J. L. (2011). Mobile Assessment and Treatment for Schizophrenia (MATS): a pilot trial of an interactive text-messaging intervention for medication adherence, socialization, and auditory hallucinations. *Schizophrenia bulletin*, sbr155.

Granholm, E., Loh, C., & Swendsen, J. (2008). Feasibility and validity of computerized ecological momentary assessment in schizophrenia. *Schizophrenia bulletin*, 34(3), 507-514.

Greenwood, K. E., Sweeney, A., Williams, S., Garety, P., Kuipers, E., Scott, J., & Peters, E. (2010). CHOICE of Outcome In Cbt for psychosEs (CHOICE): The Development of a New Service user-Led Outcome Measure of CBT for Psychosis. *Schizophrenia Bulletin*, 36(1), 126-135.

Griffiths KM, Christensen H. (2000). Quality of web based information on treatment of depression: cross sectional survey. *BMJ*. 321(7275):1511-5.

Guba, E. G. (Ed.). (1990). *The paradigm dialog*. Sage publications.

Gumley, A., White, C. A., & Power, K. (1999). An interacting cognitive subsystems model of relapse and the course of psychosis. *Clinical Psychology & Psychotherapy*, 6(4), 261-278.

Gurillo, P., Jauhar, S., Murray, R. M., & MacCabe, J. H. (2015). Does tobacco use cause psychosis? Systematic review and meta-analysis. *The Lancet Psychiatry*, 2(8), 718-725.

H M Government. (2013a) Universal credit personal planner: find out what will change for you. *London: Department for Work and Pensions* [cited 2013 25th April 2013]; Available from: <https://secureonline.dwp.gov.uk/universal-credit-preparation/>.

H M Government (2013b). Universal credit: what you need to do. *London: H M Government*, 2013 [cited 2013 25th April 2013]; Available from: <https://www.gov.uk/universal-credit/what-you-need-to-do>.

Haddock, G., McCarron, J., Tarrier, N., & Faragher, E. B. (1999). Scales to measure dimensions of hallucinations and delusions: the psychotic symptom rating scales (PSYRATS). *Psychological Medicine*, 29(4), 879-889.

Hagen, R., Turkington, D., & Berge, T. (Eds.). (2010). CBT for psychosis: A symptom-based approach. *Routledge*.

Hamine, S., Gerth-Guyette, E., Faulx, D., Green, B. B., & Ginsburg, A. S. (2015). Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. *Journal of medical Internet research*, 17(2).

Hanley B. Research as Empowerment. (2005). Report of a Series of Seminars Organised by the Toronto Group. *York: Joseph Rowntree Foundation*. www.jrf.org.uk/sites/files/jrf/1859353185.pdf, p. accessed 02 December 2011.

Hardy KV, Dickson JM, Morrison AP. Journey into and through an early detection of psychosis service: the subjective experience of persons at risk of developing psychosis. *Early intervention in psychiatry*. 2009 Feb;3(1):52-7. PubMed PMID: 21352175.

Harrigan S, McGorry P, Krstev H. Does treatment delay in first-episode psychosis really matter? *Psychol Med* 2003; 33: 97–110.

Harrison G, Hopper K, Craig T, Laska E, Siegel C, Wanderling J, et al. Recovery from psychotic illness: a 15- and 25-year international follow-up study. *Br J Psychiatry* 2001; 178: 506–17.

- Hashiguchi, M., Imai, S., Uehara, K., Maruyama, J., Shimizu, M., & Mochizuki, M. (2015). Factors Affecting the Timing of Signal Detection of Adverse Drug Reactions. *PLoS one*, 10(12), e0144263
- Hatfield D, McCullough L, Frantz SH, Krieger K. (2010). Do we know when our clients get worse? an investigation of therapists' ability to detect negative client change. *Clinical psychology & psychotherapy*, (1):25-32. PubMed PMID: 19916162.
- Hatzenbuehler, M. L., Phelan, J. C., & Link, B. G. (2013). Stigma as a fundamental cause of population health inequalities. *American journal of public health*, 103(5), 813-821.
- Haynes, R. B., Ackloo, E., Sahota, N., McDonald, H. P., & Yao, X. (2008). Interventions for enhancing medication adherence. *The Cochrane Library*.
- Hebert, M. A., Korabek, B., & Scott, R. E. (2006). Moving research into practice: a decision framework for integrating home telehealth into chronic illness care. *International journal of medical informatics*, 75(12), 786-794.
- Helsper EJ. (2008). Digital Inclusion: An Analysis of Social Disadvantage and the Information Society. *London: Oxford Internet Institute*
- Henderson, C., Evans-Lacko, S., & Thornicroft, G. (2013). Mental illness stigma, help seeking, and public health programs. *American journal of public health*, 103(5), 777-780.
- Higgins, J. P., Altman, D. G., Gøtzsche, P. C., Jüni, P., Moher, D., Oxman, A. D., ... & Sterne, J. A. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *Bmj*, 343.)
- Hinchcliff, R., Greenfield, D., & Braithwaite, J. (2014). Is it worth engaging in multi-stakeholder health services research collaborations? Reflections on key benefits, challenges and enabling mechanisms. *International journal for quality in health care*, 26(2), 124-128.
- HM_Government. (2008). Delivering digital inclusion: an action plan for consultation. *London: Communities and local government*.
- Hollis, Chris, Richard Morriss, Jennifer Martin, Sarah Amani, Rebecca Cotton, Mike Denis, and Shôn Lewis. "Technological innovations in mental healthcare: harnessing the digital revolution." *The British Journal of Psychiatry* 206, no. 4 (2015): 263-265.

Howes, O. D., & Murray, R. M. (2014). Schizophrenia: an integrated sociodevelopmental-cognitive model. *The Lancet*, 383(9929), 1677-1687.

Husain, N., Cruickshank, K., Husain, M., Khan, S., Tomenson, B., & Rahman, A. (2012). Social stress and depression during pregnancy and in the postnatal period in British Pakistani mothers: A cohort study. *Journal of affective disorders*, 140(3), 268-276.

Husain, N., Qureshi, M., Warburton, J., Gire, N., Ayub, M., & Chaudhry, I. (2012). Ethnicity and referrals to an early intervention service for psychosis in north-west England; An ecological study. *Early Intervention in Psychiatry*, 6, 72.

IMS Institute for Healthcare Informatics (2015) Retrieved from <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/patient-adoption-of-mhealth.pdf?la=en&hash=01603C9DB399D3C96EA306056C06966C573123C9>

Ince, P., Haddock, G., & Tai, S. (2016). A systematic review of the implementation of recommended psychological interventions for schizophrenia: rates, barriers, and improvement strategies. *Psychology and Psychotherapy: Theory, Research and Practice*, 89(3), 324-350.

International Telecommunication Union (ITU) (2014). ICT Facts and Figures. <http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2014-e.pdf>. (Accessed 27 June 2016).

Internet World Stats (2015). Internet usage statistics - The Internet big picture. <http://www.Internetworldstats.com/stats.htm> (Accessed 27 June 2016).

Ivankova, N. V., Creswell, J. W., & Stick, S. L. (2006). Using mixed-methods sequential explanatory design: From theory to practice. *Field methods*, 18(1), 3-20.

Jackson T. (2013), Patient powered health. *BMJ*. 346.

Johns, L. C., & Van Os, J. (2001). The continuity of psychotic experiences in the general population. *Clinical psychology review*, 21(8), 1125-1141.

Johnson BR and Onwuegbuzie AJ (2004) Mixed methods research: A research paradigm whose time has come, *Educational Researcher* 33(7): 14–26.

Jones, D. J., Anton, M., Gonzalez, M., Honeycutt, A., Khavjou, O., Forehand, R., & Parent, J. (2015). Incorporating mobile phone technologies to expand evidence-based care. *Cognitive and behavioural practice*, 22(3), 281-290.

- Kasckow J, Felmet K, Appelt C, Thompson R, Rotondi A, Haas G (2013). Telepsychiatry in the assessment and treatment of schizophrenia. *Clinical schizophrenia & related psychoses*, 8(1), 21-27A.
- Kauppi, K., Kannisto, K. A., Hätönen, H., Anttila, M., Löyttyniemi, E., Adams, C. E., & Välimäki, M. (2015). Mobile phone text message reminders: Measuring preferences of people with antipsychotic medication. *Schizophrenia research*, 168(1), 514-522.
- Kay M, Santos J, Takane M (2011). mHealth: New horizons for health through mobile technologies. *World Health Organization*, 64(7), pp.66-71.
- Kay, S. R., Fiszbein, A., & Opfer, L. A. (1987). The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophrenia bulletin*, 13(2), 261.
- Kelly, J., Gooding, P., Pratt, D., Ainsworth, J., Welford, M., & Tarrier, N. (2012). Intelligent real-time therapy: harnessing the power of machine learning to optimise the delivery of momentary cognitive-behavioural interventions. *Journal of Mental Health*, 21(4), 404-414.
- Kennerley, H., Kirk, J., & Westbrook, D. (2016). An introduction to cognitive behaviour therapy: Skills and applications. Sage.
- Keshavan, M.S., DeLisi, L.E. & Seidman, L.J. (2011). Early and broadly defined psychosis risk mental states. *Schizophrenia Research*, 126(1-3), 1–10
- Killackey E. Psychosocial and psychological interventions in early psychosis: essential elements for recovery. *Early intervention in psychiatry*. 2009 Sep;3 Suppl 1:S17-21. PubMed PMID: 21352192.
- Kingdon, D. G., & Turkington, D. (1994). Cognitive-behavioral therapy of schizophrenia. *Guilford Press*.
- Kingdon, D. G., & Turkington, D. (2005). Cognitive therapy of schizophrenia. *Guilford Press*
- Kraepelin, E. (1990). Psychiatry: A Textbook for Students and Physicians. Vol. 2, Clinical Psychiatry. Amerind Publishing.
- Kraepelin, E., & Diefendorf, A. R. (1915). Clinical psychiatry: a text-book for students and physicians. Macmillan.

- Kuss, D. J., Griffiths, M. D., & Binder, J. F. (2013). Internet addiction in students: Prevalence and risk factors. *Computers in Human Behavior*, 29(3), 959-966.
- Lambert, T. J., & Chapman, L. H. (2004). Diabetes, psychotic disorders and antipsychotic therapy: a consensus statement. *Medical Journal of Australia*, 181(10), 544.
- Lancaster, G. A. (2015). Pilot and feasibility studies come of age! *Pilot and Feasibility Studies*, 1(1), 1.
- Leech, N.L. and Onwuegbuzie, A.J., 2009. A typology of mixed methods research designs. *Quality & quantity*, 43(2), pp.265-275
- Lester H, Khan N, Jones P, Marshall M, Fowler D, Amos T, et al. Service users' views of moving on from early intervention services for psychosis: a longitudinal qualitative study in primary care. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2012 Mar;62(596):e183-90. PubMed PMID: 22429435. Pubmed Central PMCID: 3289824.
- Lester, H., & Gask, L. (2006). Delivering medical care for patients with serious mental illness or promoting a collaborative model of recovery?. 401-402.
- Lester, H., Marshall, M., Jones, P., Fowler, D., Amos, T., Khan, N. & Birchwood, M. (2011). Views of Young People in Early Intervention Services for First-Episode Psychosis in England. *Psychiatric Services*, 62(8), 882-887
- Lewis, T., Synowiec, C., Lagomarsino, G., & Schweitzer, J. (2012). E-health in low-and middle-income countries: findings from the Center for Health Market Innovations. *Bulletin of the World Health Organization*, 90(5), 332-340.
- Lieberman, J. A., Dixon, L. B., & Goldman, H. H. (2013). Early detection and intervention in schizophrenia: a new therapeutic model. *Jama*, 310(7), 689-690.
- Lincoln, Y. S., Lynham, S. A., & Guba, E. G. (2011). Paradigmatic controversies, contradictions, and emerging confluences, revisited. *The Sage handbook of qualitative research*, 4, 97-128.
- Linszen D, Dingemans P, Lenoir M. Early intervention and a five-year follow- up in young adults with a short duration of untreated psychosis: ethical implications. *Schizophr Res* 2001; 51: 55–61.

Lisiecka, D. M., Suckling, J., Barnes, T. R., Chaudhry, I. B., Dazzan, P., Husain, N., ... & Deakin, B. (2015). The benefit of minocycline on negative symptoms in early-phase psychosis in addition to standard care-extent and mechanism (BeneMin): study protocol for a randomised controlled trial. *Trials*, 16(1), 71.

Liu, C., Zhu, Q., Holroyd, K. A., & Seng, E. K. (2011). Status and trends of mobile-health applications for iOS devices: A developer's perspective. *Journal of Systems and Software*, 84(11), 2022-2033.

Lloyd M, Carson AM. (2012) Critical conversations: developing a methodology for Service user involvement in mental health nursing. *Nurse Educ Today*, 32(2):151-5. PubMed PMID: 22093883

Lobban, F., Glentworth, D., Chapman, L., Wainwright, L., Postlethwaite, A., Dunn, G., ... & Haddock, G. (2013). Feasibility of a supported self-management intervention for relatives of people with recent-onset psychosis: REACT study. *The British Journal of Psychiatry*, 203(5), 366-372.

Lu, W., Zhang, C., Yi, Z., Li, Z., Wu, Z., & Fang, Y. (2012). Association between BDNF Val66Met polymorphism and cognitive performance in antipsychotic-naïve patients with schizophrenia. *Journal of Molecular Neuroscience*, 47(3), 505-510.

Luborsky, M. R., & Rubinstein, R. L. (1995). Sampling in qualitative research: Rationale, issues, and methods. *Research on aging*, 17(1), 89-113.

Luxton, D. D., McCann, R. A., Bush, N. E., Mishkind, M. C., & Reger, G. M. (2011). mHealth for mental health: Integrating smartphone technology in behavioral healthcare. *Professional Psychology: Research and Practice*, 42(6), 505.

Mallen, M. J., Day, S. X. & Green, M. A. (2003). Online versus face-to-face conversations: An examination of relational and discourse variables. *Psychotherapy: Theory, Research, Practice, Training*, 40(1-2), 155-163.

Marmot, M. (2005). Social determinants of health inequalities. *The Lancet*, 365(9464), 1099-1104.

Marmot, M. G., Allen, J., Goldblatt, P., Boyce, T., McNeish, D., Grady, M., & Geddes, I. (2010). Fair society, healthy lives: Strategic review of health inequalities in England post-2010.

- Marmot, M., & Allen, J. J. (2014). *Social determinants of health equity*. S517-S519.
- Marmot, M., & Bell, R. (2012). Fair society, healthy lives. *Public health*, 126, S4-S10
- Marshall, M., Barrowclough, C., Drake, R., Husain, N., Lobban, F., Lovell, K., ... & Pedley, R. (2015). The HELPER programme: HEalthy Living and Prevention of Early Relapse—three exploratory randomised controlled trials of phase-specific interventions in first-episode psychosis.
- Martínez, T. D., Blanqué, J. M., Codina, J., Montoro, M., Mauri, L., & Barrantes-Vidal, N. (2011). Rationale and state of the art in early detection and intervention in psychosis. *Salud Mental*, 34(4), 341-350.
- McAuley C, McCurry N, Knapp M, Beecham J and Slead M (2006) Young families under stress: Assessing maternal and child well-being using a mixed-methods Approach, *Child and Family Social Work* 11: 43–54.
- McCrone, P., Craig, T.K.J., Power, P. & Garety, P.A. (2010). Cost-effectiveness of an early intervention service for people with psychosis. *The British Journal of Psychiatry*, 196, 377–382
- McCrone, P., Singh, S. P., Knapp, M., Smith, J., Clark, M., Shiers, D., & Tiffin, P. A. (2013). The economic impact of early intervention in psychosis services for children and adolescents. *Early intervention in psychiatry*, 7(4), 368-373.
- McGorry, P. (2013). Prevention, innovation and implementation science in mental health: the next wave of reform. s3-s4.
- McGorry, P. D., Killackey, E., & Yung, A. (2008). Early intervention in psychosis: concepts, evidence and future directions. *World Psychiatry*, 7(3), 148-156.
- McGorry, P., Bates, T., & Birchwood, M. (2013). Designing youth mental health services for the 21st century: examples from Australia, Ireland and the UK. *The British Journal of Psychiatry*, 202(s54), s30-s35.
- Medical Research Council (2016) Retrieved from: www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/index.htm
- Medical Research Council (2017) Retrieved from: <https://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/good-research-practice/>

Medical Research Council. (2000). A framework for the development and evaluation of RCTs for complex interventions to improve health. *London: MRC*

MHRA GPvP Inspection Metrics: April 2013 – March 2014
[https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/418323/Pharmacovigilance_Inspection_Metrics_Report_2013-2014.pdf]

MIND (2014) Retrived from <http://www.mind.org.uk/information-support/types-of-mental-health-problems/statistics-and-facts-about-mental-health/how-common-are-mental-health-problems/>

MIND (2017) Retrived from https://www.mind.org.uk/media/494424/we-still-need-to-talk_report.pdf

Moncrieff J (2015) Antipsychotic maintenance treatment: time to rethink? *PLoS Med*; 12:e1001861

Montes J M, Medina E, Gomez-Beneyto M, Maurino J (2012). A short message service (SMS)-based strategy for enhancing adherence to antipsychotic medication in schizophrenia. *Psychiatry research*, 200(2), 89-95.

Morgan C, Burns T, Fitzpatrick R, et al. (2007). Social exclusion and mental health: Conceptual and methodological review. *The British Journal of Psychiatry*. 191(6):477-83.

Morris A. (2007). E-literacy and the grey digital divide: a review with recommendations. *Journal of Information Literacy*. 1(3):pp. 13-28.

Morrison, A. P. (2001). The interpretation of intrusions in psychosis: an integrative cognitive approach to hallucinations and delusions. *Behavioural and Cognitive Psychotherapy*, 29(3), 257-276.

Morrison, A. P., Byrne, R., & Bentall, R. P. (2010). DSM-5 and the 'Psychosis Risk Syndrome': Whose best interests would it serve?. *Psychosis*, 2(2), 96-99.

Morrison, A., Renton, J., Dunn, H., Williams, S., & Bentall, R. (2004). Cognitive therapy for psychosis: A formulation-based approach. *Routledge*.

Morse J M (2003) Principles of mixed methods and multimethod research design, in: Handbook of Mixed Methods in Social and Behavioral Research, A. Tashakkori and C. Teddlie (eds.), pp. 189–208. Thousand Oaks CA: Sage Publications.

MQ. UK mental health research funding. MQ landscape analysis. *London*; 2015.

MRC Guidelines on Good Research Practice <http://www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/>

Mundt, J. C., Marks, I. M., Shear, M. K., & Greist, J. M. (2002). The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *The British Journal of Psychiatry*, 180(5), 461-464.

Myin-Germeys, I., Oorschot, M., Collip, D., Lataster, J., Delespaul, P., & van Os, J. (2009). Experience sampling research in psychopathology: opening the black box of daily life. *Psychological medicine*, 39(9), 1533-1547.

Myin-Germeys, I., Peeters, F. P. M. L., Havermans, R., Nicolson, N. A., DeVries, M. W., Delespaul, P. A. E. G., & Van Os, J. (2003). Emotional reactivity to daily life stress in psychosis and affective disorder: an experience sampling study. *Acta Psychiatrica Scandinavica*, 107(2), 124-131.

Naeem, F., Gire, N., Xiang, S., Yang, M., Syed, Y., Shokraneh, F., ... & Farooq, S. (2016). Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: an update. *World journal of psychiatry*, 6(2), 187.

National Institute for Clinical Excellence (2002). Schizophrenia: Core interventions in the treatment of schizophrenia in primary and secondary care. *London, UK: Author*.

National Institute for Clinical Excellence (2014). Psychosis and schizophrenia in adults: Treatment and management (CG178). *London, UK*

National Institute for Health and Care Excellence (2014) Psychosis and schizophrenia in adults Quality standard [QS80] Published date: February 2015 <https://www.nice.org.uk/guidance/qs80>

National Institute for Health and Care Excellence (2016) Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance Version number: 1 First published: April 2016 Prepared by: NHS England, the National Collaborating Centre for Mental Health and the National Institute for Health and Care Excellence Classification: OFFICIAL NHS England Publications Gateway Reference 04294

National Institute of Health Research (NIHR) (2014) Retrieved from http://www.nihr.ac.uk/CCF/RfPB/FAQs/Feasibility_and_pilot_studies.pdf

National Institute of Health Research CLAHRC (2012) Incidence and Prevalence of Psychotic Disorders in England: A Systematic Review Briefing Paper (October 2012)

Needham C and Carr S (2009). SCIE Research briefing 31: co-production: an emerging evidence base for adult social care transformation. London: Social Care Institute for Excellence. Available from: www.scie.org.uk

NHS Health Research Authority (2014) Retrieved from <https://www.hra.nhs.uk/>

Nickelson, D. W. (1998). Telehealth and the evolving health care system: Strategic opportunities for professional psychology. *Professional Psychology: Research and Practice*, 29(6), 527-535

Norris P. (2001). Digital Divide: Civic Engagement, Information Poverty, and the Internet Worldwide. *Cambridge: Cambridge University Press*.

Nuevo, R., Chatterji, S., Fraguas, D., Verdes, E., Naidoo, N., Arango, C., & Ayuso-Mateos, J. L. (2011). Increased risk of diabetes mellitus among persons with psychotic symptoms: results from the WHO World Health Survey. *The Journal of clinical psychiatry*, 72(12), 1592-1599.

Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J., & RIPPLE Study Team. (2006). Health services research: process evaluation in randomised controlled trials of complex interventions. *BMJ: British Medical Journal*, 332(7538), 413

Office for National Statistics (2013) Statistical bulletin: internet access quarterly update, Q4 2012. London: 2013 20th February 2013. Report No.

Office for National Statistics (2014) Inequality in Healthy Life Expectancy at Birth by National Deciles of Area Deprivation: England, 2009-11: Statistical Bulletin p 1-24 London

Office for National Statistics (2015) Retrieved from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/465791/English_Indices_of_Deprivation_2015_-_Statistical_Release.pdf

The Office of Communications (OFCOM) (2014)
<http://stakeholders.ofcom.org.uk/market-data-research/market-data/communications-market-reports/cmr13/uk/> (Accessed on 01/04/2014)

Oh H, Rizo C, Enkin M, Jadad A (2005). What Is eHealth (3): A Systematic Review of Published Definitions J Med Internet Res 2005;v7(1):e1 URL: <http://www.jmir.org/2005/1/e1/> doi: 10.2196/jmir.7.1.e1 PMID: 15829471

Oorschot, M., Kwapil, T., Delespaul, P., & Myin-Germeys, I. (2009). Momentary assessment research in psychosis. *Psychological assessment*, 21(4), 498.

Palmier-Claus, J. E., Ainsworth, J., Machin, M., Barrowclough, C., Dunn, G., Barkus, E., ... & Lewis, S. W. (2012). The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. *BMC psychiatry*, 12(1), 172.

Palmier-Claus, J., Taylor, P., Ainsworth, J., & Lewis, S. (2015). Advances in the Real-time Documentation of Psychosis and Suicidal Ideation. *European Psychiatry*, 30, 120.

Paluck EL. 2010. The promising integration of qualitative methods and field experiments. *Ann. Am. Acad. Polit. Soc. Sci.* 628:59–71

Pappas, C., & Williams, I. (2011). Grey literature: its emerging importance. *Journal of Hospital Librarianship*, 11(3), 228-234.

Patton, M. Q. (1990). *Qualitative evaluation and research methods*. SAGE Publications, inc

Pelosi, A. J., & Birchwood, M. (2003). Is early intervention for psychosis a waste of valuable resources?. *The British Journal of Psychiatry*, 182(3), 196-198.

Perera C., (2012) Principles of Security for the use of Mobile Technology in Medicine *Journal MTM* 1:2:5-7

Piette J D, Datwani H, Gaudio S, Foster S M, Westphal J, Perry W, Rodríguez-Saldaña J, Mendoza-Avelares M O and Marinec N (2012). Hypertension management using mobile technology and home blood pressure monitoring: results of a randomized trial in two low/middle-income countries. *Telemedicine and e-Health*, 18(8), pp.613-620.

Pijnenborg G H M, Withaar F K, Evans J J, Van Den Bosch R J, Brouwer W H (2007). SMS text messages as a prosthetic aid in the cognitive rehabilitation of schizophrenia. *Rehabilitation Psychology*, 52(2), p.236.

Pijnenborg GHM, Withaar FK, Brouwer WH, Timmerman ME, van den Bosch RJ (2010). The efficacy of SMS text messages to compensate for the effects of cognitive impairments in schizophrenia. *British Journal of Clinical Psychology* 49: 259–274.

Pinnock, H., Slack, R., Pagliari, C., Price, D., & Sheikh, A. (2007). Understanding the potential role of mobile phone-based monitoring on asthma self-management: qualitative study. *Clinical & Experimental Allergy*, 37(5), 794-802.

Pitt L, Kilbride M, Nothard S, Welford M, Morrison AP. Researching recovery from psychosis: a user-led project. *Psychiatric Bulletin*. 2007;31(2):55-60.

Pope, C., & Mays, N. Qualitative research in health care. 2006. BMJ Book, Blackwell Publishing, London.

Popper, K. (1959). *The Logic of Scientific Discovery*. Basic Books, New York presented at the Improving Quality of Health Care in the United States and the United Kingdom: Strategies for Change and Action.

Realpe, A., & Wallace, L. M. (2010). What is co-production. *London: The Health Foundation*, 1-11.

Rector, N. A., & Beck, A. T. (2001). Cognitive-behavioral therapy for schizophrenia: An empirical review. *Journal of Nervous and Mental Disease*, 189, 278 – 287

Reed SI. (2008). First-episode psychosis: a literature review. *International journal of mental health nursing*, 17(2):85-91. PubMed PMID: 18307596.

Rees, C.S. & Stone, S. (2005). Therapeutic Alliance in Face-to-Face Versus Videoconferenced Psychotherapy. *Professional Psychology: Research and Practice*, 36(6), 649-653

Reger, M. A., & Gahm, G. A. (2009). A meta-analysis of the effects of Internet- and computer-based cognitive-behavioral treatments for anxiety. *Journal of Clinical Psychology*, 65, 53–75. doi:10. 1002/jclp.20536.

Rethink (2014) Retrieved from <http://www.rethink.org/>

Ritchie, J., Lewis, J., & Elam, R. G. (2013). Selecting samples. *Qualitative research practice: A guide for social science students and researchers*, 111.

- Ritchie, J., Spencer, L., Bryman, A., & Burgess, R. G. (1994). *Analysing qualitative data*. London: Routledge, 3.
- Rotondi AJ, Sinkule J, Haas GL, et al. Designing websites for persons with cognitive deficits: design and usability of a psychoeducational intervention for persons with severe mental illness. *Psychol Serv*. 2007;4:202–224.
- Royal College of Nursing (2012) *Health inequalities and the social detriments of health. Policy & International Department Policy Briefing #01/12* London
- Ruhrmann, S., Schultze-Lutter, F., Salokangas, R. K., Heinimaa, M., Linszen, D., Dingemans, P., ... & Morrison, A. (2010). Prediction of psychosis in adolescents and young adults at high risk: results from the prospective European prediction of psychosis study. *Archives of general psychiatry*, 67(3), 241-251.
- Santos, A. P., & Teixeira, J. A. (2016). Psychosocial interventions for schizophrenia. *European Psychiatry*, (33), S725.
- Schizophrenia Commission. (2012). *The abandoned illness: a report from the Schizophrenia Commission*. London: *Rethink Mental Illness*.
- Schmidt H, McFarland J, Ahmed M, McDonald C, Elliott MA.c(2011). Low-level temporal coding impairments in psychosis: preliminary findings and recommendations for further studies. *Journal of abnormal psychology*, 120(2):476-82. PubMed PMID: 21553943.
- Scotland, J. (2012). Exploring the philosophical underpinnings of research: Relating ontology and epistemology to the methodology and methods of the scientific, interpretive, and critical research paradigms. *English Language Teaching*, 5(9), 9.
- Sentell T. Shumway M. Snowden L. (2007). Access to mental health treatment by English language proficiency and race/ethnicity. *J Gen Intern Med.*, 22 Suppl 2:289-93.
- Shippee, N.D., Domecq Garces, J.P., Prutsky Lopez, G.J., Wang, Z., Elraiyah, T.A., Nabhan, M., Brito, J.P., Boehmer, K., Hasan, R., Firwana, B. and Erwin, P.J., (2015). Patient and service user engagement in research: a systematic review and synthesized framework. *Health Expectations*, 18(5), pp.1151-1166.
- Silverman, D. (2011). *Interpreting qualitative data: A guide to the principles of qualitative research*. SAGE Publications Limited.

Simons JS, Gaher RM. (2005) The Distress Tolerance Scale: Development and Validation of a Self-Report Measure. *Motivation and Emotion*, 29(2):83-102.

Singh MBaSP. (2013). Mental health services for young people: matching the service to the need. *The British Journal of Psychiatry*, (202):1-2.

Slade, M., & Hayward, M. (2007). Recovery, psychosis and psychiatry: research is better than rhetoric. *Acta Psychiatrica Scandinavica*, 116(2), 81-83.

Slay, J. and Stephens, L., (2013). Co-production in mental health: A literature review. London: new economics foundation.

Small, M. L. (2011). How to conduct a mixed methods study: Recent trends in a rapidly growing literature. *Annual Review of Sociology*, 37.

Smith RB. 2008. Cumulative Social Inquiry: Transforming Novelty into Innovation. *New York: Guilford*

Sobocki, P., Ekman, M., Ågren, H., Krakau, I., Runeson, B., Mårtensson, B., & Jönsson, B. (2007). Health-related quality of life measured with EQ-5D in patients treated for depression in primary care. *Value in Health*, 10(2), 153-160.

Španiel, F., Hrdlicka, J., Novák, T., KOŽENÝ, J., Hoeschl, C., Mohr, P., & Motlova, L. B. (2012). Effectiveness of the information technology-aided program of relapse prevention in schizophrenia (ITAREPS): a randomized, controlled, double-blind study. *Journal of Psychiatric Practice*, 18(4), 269-280.

Španiel, F., Vohlídka, P., Hrdlička, J., Kožený, J., Novák, T., Motlová, L., ... & Höschl, C. (2008). ITAREPS: information technology aided relapse prevention programme in schizophrenia. *Schizophrenia Research*, 98(1), 312-317.

Srivastava, A., & Thomson, S. B. (2009). Framework analysis: a qualitative methodology for applied policy research.

Stafford, M. R., Jackson, H., Mayo-Wilson, E., Morrison, A. P., & Kendall, T. (2013). Early interventions to prevent psychosis: systematic review and meta-analysis. *Bmj*, 346, f185.

Stewart KD. (2013). Factors Contributing to Engagement During the Initial Stages of Treatment for *Psychosis Qual Health Res*, 23:336-48.

Strauss, A., & Corbin, J. (1998). Basics of qualitative research techniques. *Sage publications*.

Strauss, J. S., Hafez, H., Lieberman, P., & Harding, C. M. (1985). The course of psychiatric disorder: III. Longitudinal principles. *The American journal of psychiatry*.

Tashakkori, A., & Teddie, C. (2003). Mixed Methods research, Alternative approaches and Unresolved Issues in Conceptualization and Design of Mixed Methods.

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., ... & Stewart-Brown, S. (2007). The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health and Quality of Life Outcomes*, 5(1), 63.

The Deputy Prime Minister (2005). Inclusion through innovation- tackling social exclusion through new technologies. *London: Office of the Deputy Prime Minister*.

Thomé, S., Härenstam, A., & Hagberg, M. (2011). Mobile phone use and stress, sleep disturbances, and symptoms of depression among young adults-a prospective cohort study. *BMC public health*, 11(1), 66.

Thornicroft, G. and Tansella, M., (2005). Growing recognition of the importance of service user involvement in mental health service planning and evaluation. *Epidemiology and Psychiatric Sciences*, 14(1), pp.1-3.

Thornicroft, G., Rose, D., & Kassam, A. (2007). Discrimination in health care against people with mental illness. *International review of psychiatry*, 19(2), 113-122.

Tickle-Degnen, L. (2013). Nuts and bolts of conducting feasibility studies. *American Journal of Occupational Therapy*, 67(2), 171-176.

Torous, J., Friedman, R. and Keshavan, M., 2014. Smartphone ownership and interest in mobile Applications to monitor symptoms of mental health conditions. *JMIR mHealth and uHealth*, 2(1).

Tran K, Ayad M, Weinberg J, Cherng A, Chowdhury M, Monir S, El Hariri M, Kovarik C (2011). Mobile teledermatology in the developing world: implications of a feasibility study on 30 Egyptian patients with common skin diseases. *Journal of the American Academy of Dermatology*, 64(2), pp.302-309.

Trevena LJ, Davey HM, Barratt A, Butow P, Caldwell P. (2006). A systematic review on communicating with patients about evidence. *Journal of evaluation in clinical practice*, 12(1):13-23. PubMed PMID: 16422776.

- Trower, P., Birchwood, M., Meaden, A., Byrne, S., Nelson, A., & Ross, K. (2004). Cognitive therapy for command hallucinations: randomised controlled trial. *The British Journal of Psychiatry*, 184(4), 312-320.
- Truog RD: Patients and doctors. (2012). The evolution of a relationship. *N Engl J Med*, 366: 581-585. 10.1056/NEJMp1110848.
- Turkington, D., Kingdon, D., Rathod, S., Hammond, K., Pelton, J., & Mehta, R. (2006). Outcomes of an effectiveness trial of cognitive-behavioural intervention by mental health nurses in schizophrenia. *The British Journal of Psychiatry*, 189(1), 36-40.
- UK Clinical Research Collaboration. UK health research analysis 2014. *London; 2015*.
- US Department of Commerce Administration. (2010). Exploring the digital nation: home broadband Internet adoption in the united states. *Washington DC: US Department of Commerce*.
- Van Meijel, B., Van Der Gaag, M., Kahn, R. S., & Grypdonck, M. (2002). The practice of early recognition and early intervention to prevent psychotic relapse in patients with schizophrenia: an exploratory study. Part 2. *Journal of Psychiatric and Mental Health Nursing*, 9(3), 357-363.
- Van Os, J., & Kapur, S. (2010). Psychosis: from diagnosis to syndrome. *Nederlands tijdschrift voor geneeskunde*, 154, A1874.
- Van Os, J., Linscott, R. J., Myin-Germeys, I., Delespaul, P., & Krabbendam, L. (2009). A systematic review and meta-analysis of the psychosis continuum: evidence for a psychosis proneness–persistence–impairment model of psychotic disorder. *Psychological medicine*, 39(2), 179-195.
- Vandelanotte, C., Sugiyama, T., Gardiner, P., & Owen, N. (2009). Associations of leisure-time internet and computer use with overweight and obesity, physical activity and sedentary behaviors: cross-sectional study. *Journal of medical Internet research*, 11(3).
- Vanderplasschen, W., Rapp, R. C., Pearce, S., Vandavelde, S., & Broekaert, E. (2013). Mental health, recovery, and the community. *The scientific world journal*,.
- Walker BM, Harper J, Lloyd C, et al. (2003). Methodologies for the exploration of computer and technology transference. *Computers in Human Behavior*. 19(5):523-35.

- Walker, E. R., McGee, R. E., & Druss, B. G. (2015). Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA psychiatry*, 72(4), 334-341.
- Wallcraft, J., Schrank, B. and Amering, M., (2009). Handbook of service user involvement in mental health research (Vol. 6). John Wiley & Sons.
- Weerasekera, P. (1996). Multiperspective case formulation. A step toward treatment integration. Malabar, Florida: Krieger Publishing Company, pp. 276–277
- Whelan, P., Machin, M., Lewis, S., Buchan, I., Sanders, C., Applegate, E., ... & Roberts, C. (2015). Mobile early detection and connected intervention to coproduce better care in severe mental illness. *Studies in health technology and informatics*, 216, 123.
- Whiteford, H.A., Degenhardt, L., Rehm, J., Baxter, A., Ferrari, A., Erskine, H., ... Vos, T. (2013). Global burden of disease attributable to mental and substance use disorders: Findings from the Global Burden of Disease Study 2010. *Lancet*, 382(9904), 1575–1586
- Whitehead MC, Bambra C, Barr B, Bowles J, Caulfield R, Doran T, et al. (2014). *Due North: Report of the Inquiry on Health Equity for the North. Liverpool and Manchester: University of Liverpool and Centre for Local Economic Strategies.*
- Whitehead, M., & Dahlgren, G. (2006). Concepts and Principles for Tackling Social Inequities in Health: Levelling Up Part 1. *Copenhagen: World Health Organization.*
- Wiersma D, Wanderling J, Dragomirecka E, Ganev K, Harrison G, an der HW, et al. (2000). Social disability in schizophrenia: its development and prediction over 15 years in incidence cohorts in six European centres. *Psychol Med*, 30(5):1155–67. pmid:12027051
- Wolpe J. Behaviour Therapy Techniques. *The British Journal of Psychiatry*. 1967;113(495):239-
- Wood, B., Rea, M. S., Plitnick, B., & Figueiro, M. G. (2013). Light level and duration of exposure determine the impact of self-luminous tablets on melatonin suppression. *Applied ergonomics*, 44(2), 237-240.
- Wood, L., Burke, E., Byrne, R., Pyle, M., Chapman, N., & Morrison, A. (2015). Stigma in psychosis: A thematic synthesis of current qualitative evidence. *Psychosis*, 7(2), 152-165

World Health Organization (2011) mHealth New horizons for health through mobile technologies Based on the findings of the second global survey on eHealth Global Observatory for eHealth series - Volume 3

World Health Organization (1993) The International Classification of Diseases (10th edition, ICD-10) Geneva, Switzerland World Health Organization

World Health Organization. (1995). The World health report: 1995: bridging the gaps.

World Health Organization. (2014). Social determinants of mental health. World Health Organization.

World Medical Association. (2001). World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. *Bulletin of the World Health Organization*, 79(4), 373.

Wykes, T., Steel, C., Everitt, B., & Tarrier, N. (2008). Cognitive behavior therapy for schizophrenia: effect sizes, clinical models, and methodological rigor. *Schizophrenia Bulletin*, 34(3), 523-537. doi: 10.1093/schbul/sbm114

Yur'yev A, Värnik P, Sisask M, et al. (2013). Some aspects of social exclusion: Do they influence suicide mortality? *International Journal of Social Psychiatry*. 59(3):232-8.

Zimmermann, G., Favrod, J., Trieu, V. H., & Pomini, V. (2005). The effect of cognitive behavioral treatment on the positive symptoms of schizophrenia spectrum disorders: a meta-analysis. *Schizophrenia research*, 77(1), 1-9.

Zubin, J., & Spring, B. (1977). Vulnerability: A new view of schizophrenia. *Journal of abnormal psychology*, 86(2), 103.

Appendices

Appendix 1: Digital Inclusion: The Concept and Strategies for People with Mental Health Difficulties.

Reference:

Farooq, S., Taylor, C. D., Gire, N., Riley, M., Caton, N., & Husain, N. (2015). Digital inclusion: The concept and strategies for people with mental health difficulties. *Australian and New Zealand Journal of Psychiatry*, 0004867415591827.

Digital inclusion: The concept and strategies for people with mental health difficulties

Saeed Farooq^{1,2}, Christopher DJ Taylor³, Nadeem Gire⁴, Myfanwy Riley⁵, Neil Caton⁶ and Nusrat Husain⁷

Australian & New Zealand Journal of Psychiatry
2015, Vol. 49(9) 772–773
DOI: 10.1177/0004867415591827

© The Royal Australian and
New Zealand College of Psychiatrists 2015
Reprints and permissions:
sagepub.co.uk/journalsPermissions.nav
anp.sagepub.com



Within five years, digital exclusion will rival all other social and economic determinants, and may become the major social justice challenge of our time.

Perlgut (2011)

Widespread use of mobile and wireless technologies has the potential to transform health care. Increasingly, digital technologies such as smart phones, the Internet and digital TV are becoming an important way to gain access to the social determinants of health including employment, education and social networks. The use of smart phones has rocketed, with over 11 million Smartphone users in Australia in 2013, up 29% compared to 2012 (Australian Communication and Media Authority, 2013). However, the quantity and quality of access to these technologies and the possible effects of this on people from socially disadvantaged groups especially for those experiencing mental health problems have rarely been considered. Perlgut (2011) has put it succinctly in the context of digital inclusion in Australia as ‘the concept of—digital divide has slipped from the public radar in recent years under the onslaught of smart phones, iPads, other—tablets and the bewildering and growing collection of digital devices ...’

The concepts of digital divide and digital inclusion are used interchangeably to describe the access or lack of access to the digital technology for the population. While the digital inclusion is hotly debated in social and information technology (IT) sectors, there is almost complete lack of debate about the digital inclusion in mental health. We will argue that digital inclusion will become the

most important determinant of social inclusion and wellbeing, and will suggest measures to enhance digital inclusion for those suffering from mental illness.

Digital inclusion is the ability of individuals and groups to access and use information and communication technologies (ICTs). This includes access to the Internet, suitable hardware and software and training for the digital literacy skills (Perlgut, 2011). Better access to these technologies results in wider choice and empowerment, with better integration in society. Much of social inclusion is now created and nurtured online. Lack of access to or the knowledge of how to use ICT results in digital exclusion which is considered as an important indicator of economic inequity (Norris, 2001).

Socially disadvantaged people not only lack in access to digital technologies, they are also falling further behind the rest of society who use technology to their advantage. This increases both width and depth of the digital exclusion. Digitally excluded people are increasingly at risk of becoming ‘invisible’, as the key platforms for discussion and social participation (e.g. e-petitions) are also digitally driven. This leads to a vicious cycle in which those excluded from the digital advantage suffer from higher costs of living and often restriction to access from services. Disability groups and patients remain key groups who experience digital exclusion. In Australia, 28% of those suffering from a disability have broadband access compared to 48% of people who do not need assistance (Perlgut, 2011). As a result, those who lack digital access and are unable to use the technology effectively are likely to suffer from increasing health inequities.

Most importantly, perhaps in future, large number of interventions will be based on digital platforms (see, for example, www.marketwired.com/press-release/wellframe-expands-partnership-with-mclean-hospital-deliver-pioneering-support-model-1955815.htm). Therefore, digital exclusion may limit potential treatment options for patients with mental illness in the future.

Although the effects of digital exclusion on mental health are not studied, the social exclusion and its relationship with poor mental health is well known. For example, a recent study based on a large dataset from 26 European countries found that both ‘economic/employment’ and ‘social/welfare’ dimensions of social exclusion significantly influenced suicide mortality among male patients (Yur’ev et al., 2013). Existing literature on the use of Internet and mobile technologies in the assessment and treatment of psychiatric disorders is limited to cross-sectional surveys based on convenience samples from outpatient populations without comparison groups. A relatively larger

¹Black Country NHS Foundation Trust, West Midlands, UK

²Staffordshire University, Staffordshire, UK

³Lancashire Care NHS Foundation Trust, Accrington, UK

⁴Research and Development, Lancashire Care NHS Foundation Trust, Preston, UK

⁵Lancashire Care NHS Foundation Trust, Blackpool, UK

⁶Lancashire Care NHS Foundation Trust, UK

⁷Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK

Corresponding author:

Saeed Farooq, Penn Hospital, Penn Road, Wolverhampton WV14 4HN, UK.
Email: sfarooqlrh@yahoo.com

US study found that only one-third of those with serious mental health difficulties reported having used the Internet and less than one-third of Internet users had ever searched for health information. This was in stark contrast to the Internet use by chronic condition groups, where half went online regularly, and the majority were avid consumers of online health information (Borzekowski et al., 2009).

The acceptability, motivation and attitudes toward the use of digital devices by people suffering from mental health difficulties are also poorly understood. The distressing experiences of unusual beliefs and delusions associated with psychotic disorders, possible interference with patient–clinician communication and anxiety associated with using digital devices can result in distorted perceptions and suspiciousness regarding computers and mobile phones.

The interventions to enhance the digital inclusion should focus on individual, institutional and professional levels. Most programs to help service users have focused on providing IT training and computer literacy. Anecdotally, these do not seem to work and instead can create more anxiety and skepticism around technology. Predictors of what encourages people to become online users can be very personal. It is important to assess the individual interests of people and demonstrate how ‘going online’ could further enhance areas they already enjoy. Such a personalized approach can help individuals to train in ICT. Different incentives could be provided to encourage patients to visit health websites with reliable and up-to-date information.

Digital exclusion should also be considered at institutional and professional levels. Increasingly, services require patients to participate in digitally mediated communications. It is, therefore, the responsibility of the health professionals and the institutions serving patients that they provide support, skills and technology in order to avoid exacerbating health inequities and promote the benefits for health of digital inclusion. Clinicians would benefit from developing insights into digital interaction and the effects on mental

wellbeing, and this must become part of routine clinical discourse.

At institutional level, lack of a presence or inadequate participation in the virtual community means that mental health professionals are missing out on an opportunity to help facilitate social inclusion and fight the stigma of mental health difficulties. The organizations such as the Royal College of Psychiatrists need to develop policies and advocate for the digital inclusion. Availability of a suitable infrastructure for disadvantaged groups is a major obstacle that needs to be addressed. User interfaces will require adaptation for people with learning disabilities, older people and those with cognitive impairment. Initiatives to promote uptake might involve subsidizing access to broadband for patients and mental health services. Mental health centers could be benchmarked and rated for their access to broadband and whether these are ICT friendly, in an effort for this to become adopted by services.

Digital inclusion cannot be considered separately from economic and social inclusion. As digital technologies rapidly evolve and have much greater impact on our lives, it is likely that socially disadvantaged and mentally ill people will lag much behind the rest of the population, if digital inclusion is not addressed as a priority issue. There is need for concerted efforts by all stake holders, especially the clinicians and institutions involved in mental health care. Studies examining the nature and degree of digital inclusion are urgently required to inform the policy and clinical practice in this rapidly changing area.

Acknowledgements

S.F. has been convener for the Clinical Research Group (CRG) of the Mental Health Research Network (MHRN), UK, on the use of mobile technology in mental health. C.T. gratefully acknowledges the support of a National Institute for Health Research (NIHR) Personal Fellowship award (DRF-2012-05-211). N.G. gratefully acknowledges the support of the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast and Lancashire Care

National Health Service (NHS) Foundation Trust. N.H. is a member of The Clinical Research Group on the use of mobile technology in mental health, a UK initiative and has received funding from Lancashire Care NHS Foundation Trust, UK, to develop an intervention for early psychosis using mobile technology.

Declaration of interest

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. The authors have no financial conflicts of interest to declare. All authors contributed to the writing of the manuscript. The first author is guarantor of the article and corresponding author.

Funding

National Institute for Health Research, (Grant/Award Number: ‘DRF-2012-05-211 awarded to C.T.’) Department for Health—National Institute for Health Research—Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast, (Grant/Award Number: ‘Research Training Award to N.G.’) Department for Health—National Institute for Health Research Clinical Research Network (CRN) formerly Mental Health Research Network (MHRN), (Grant/Award Number: ‘CRG Mobile Technology in Mental Health—to S.F.’) Department for Health—Lancashire Care NHS Foundation Trust, (Grant/Award Number: ‘TECHCARE grant—awarded to N.H.’).

References

- Australian Communication and Media Authority. (2013). Communication report 2012-2013. Available at: <http://www.acma.gov.au/theACMA/Library/Corporate-library/Corporate-publications/communications-report-2012-13> (accessed 11 June 2015).
- Borzekowski DLG, Leith J, Medoff D, et al. (2009) Use of the Internet and other media for health information among clinic outpatients with serious mental illness. *Psychiatric Services* 60: 1265–1268.
- Norris P (2001) *Digital Divide: Civic Engagement, Information Poverty, and the Internet Worldwide*. Cambridge: Cambridge University Press.
- Perlgut D (2011) Digital inclusion in the broadband world: Challenges for Australia. Available at: www.intelligentcommunity.org/clientuploads/PDFs/Digital-Inclusion-Australia-Nov2011_Perlgut.pdf (accessed 29 January 2015).
- Yur'yev A, Värnik P, Sisask M, et al. (2013) Some aspects of social exclusion: Do they influence suicide mortality? *International Journal of Social Psychiatry* 59: 232–238.

Appendix 2: mHealth Based Interventions for The Assessment and Treatment of Psychotic Disorders: A Systematic Review

Reference:

Gire, N., Farooq, S., Naeem, F., Duxbury, J., McKeown, M., Kundi, P. S., ... & Husain, N. (2017). mHealth based interventions for the assessment and treatment of psychotic disorders: a systematic review. *mHealth*, 3.

mHealth based interventions for the assessment and treatment of psychotic disorders: a systematic review

Nadeem Gire¹, Saeed Farooq², Farooq Naeem³, Joy Duxbury¹, Mick McKeown¹, Pardeep Singh Kundi⁴, Imran Bashir Chaudhry⁵, Nusrat Husain⁵

¹The University of Central Lancashire, Preston, PR1 2HE, UK; ²Keele University, Keele, Staffordshire ST5 5BG, UK; ³Queens University, Kingston, ON K7L 3N6, Canada; ⁴Vancouver General Hospital, Vancouver, BC V5Z 1M9, Canada; ⁵The University of Manchester, Manchester, M13 9PL, UK

Contributions: (I) Conception and design: N Husain, I B Chaudhry; (II) Administrative support: N Gire, PS Kundi; (III) Provision of study materials or patients: None; (IV) Collection and assembly of data: N Gire, PS Kundi; (V) Data analysis and interpretation: S Farooq, N Husain, J Duxbury, F Naeem, M McKeown, N Gire; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Professor Nusrat Husain. The Institute of Brain Behaviour and Mental Health, Jean Macfarlane Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK. Email: nusrat.husain@manchester.ac.uk.

Abstract: The relative burden of mental health disorders is increasing globally, in terms of prevalence and disability. There is limited data available to guide treatment choices for clinicians in low resourced settings, with mHealth technologies being a potentially beneficial avenue to bridging the large mental health treatment gap globally. The aim of the review was to search the literature systematically for studies of mHealth interventions for psychosis globally, and to examine whether mHealth for psychosis has been investigated. A systematic literature search was completed in Embase, Medline, PsychINFO and Evidence Based Medicine Reviews databases from inception to May 2016. Only studies with a randomised controlled trial design that investigated an mHealth intervention for psychosis were included. A total of 5690 records were identified with 7 studies meeting the inclusion criteria. The majority of included studies, were conducted across Europe and the United States with one being conducted in China. The 7 included studies examined different parameters, such as Experiential Sampling Methodology (ESM), medication adherence, cognitive impairment, social functioning and suicidal ideation in veterans with schizophrenia. Considering the increasing access to mobile devices globally, mHealth may potentially increase access to appropriate mental health care. The results of this review show promise in bridging the global mental health treatment gap, by enabling individuals to receive treatment via their mobile phones, particularly for those individuals who live in remote or rural areas, areas of high deprivation and for those from low resourced settings.

Keywords: mHealth; mental health gap; psychosis; global mental health

Received: 19 May 2017; Accepted: 11 July 2017; Published: 14 August 2017.

doi: 10.21037/mhealth.2017.07.03

View this article at: <http://dx.doi.org/10.21037/mhealth.2017.07.03>

Introduction

Globally, the relative burden of mental health disorders is on the rise in terms of prevalence, disability and mortality (1), with limited controlled data available to guide treatment choices for clinicians worldwide. Since the 1990s, electronic service delivery within healthcare has expanded significantly (2). This mode of service delivery initially received a number

of titles such as ‘Telemedicine’, ‘Telehealth’ and ‘Telecare’. However, with the merging of different technologies, the whole area is becoming more encompassing and the term ‘eHealth’ has emerged.

One particular form of eHealth is mHealth (mobile Health), the Global Observatory for eHealth (GOe) defines mHealth or mobile health as ‘*medical and public health practice supported by mobile devices, such as mobile phones,*

patient monitoring devices, personal digital assistants (PDAs), and other wireless devices' (3). mHealth technologies utilise components and functionalities of mobile devices such as Short Messaging Service (SMS), General Packet Radio Service (GPRS), Bluetooth, Global Positioning Systems (GPS) and mobile connectivity (3 and 4 g) and smartphone applications more commonly known as mobile Apps. mHealth has been successfully used in delivering treatment modalities in a variety of settings, predominantly in High Income Countries (HICs). In recent years, there have been studies on the successful use of a variety of mHealth interventions for Severe Mental Illness (SMI). More recently, a number of apps for psychosis have been launched e.g.; TechCare, Actisist and ClinTouch (4-6).

Mental, Neurological, Substance use (MNS) disorders constitute 14% of the global burden of disease (7). Low resourced countries face greater challenges to overcoming this burden due to lack of resources and limited availability and access to mental health care (8). The treatment gap for MNS disorders is estimated to be over 75% in many LMICs, due to the inequitable and insufficient usage of resources (1). mHealth technologies may be a potentially beneficial avenue to bridging this large treatment gap, through improved access to self-management and self-help interventions utilising digital clinical technologies, which may also significantly assist in recovery from SMI such as psychosis.

Individuals with a diagnosis of psychosis may experience a number of symptoms, such as auditory hallucinations and delusional ideation (9). Research has suggested the prevalence of psychosis to be roughly 1% globally (10). Psychotic illnesses are usually preceded by a prodrome which can last anywhere from one to three years (11), with individuals experiencing a wide range of non-specific behavioural and psychological symptoms, and a deterioration in functioning (12). Interventions that prevent or delay transition to psychosis from the prodromal phase, may be clinically and economically important (13).

mHealth interventions have been used in the assessment and treatment of psychosis. A recent review by Alvarez-Jimenez *et al.* (14) highlighted a number of mobile interventions for psychosis. However the focus of the paper was in relation to web based and social media interventions and did not take into account mobile devices as defined above. Another review conducted by Kasckow *et al.* (15) also reported the feasibility of telephone, the internet and videoconferencing interventions. However, these reviews focused more on eHealth interventions which are in most

cases dependant on an internet connection. Globally only 34.3% (16) of the global population have access to the internet whereas the International Telecommunication Union (ITU) estimates roughly 7 billion mobile phone subscriptions being held worldwide, with an estimated penetration of 96% of individuals having access to mobile phones globally (17). It can therefore be seen that mobile devices could be a potentially effective modality in providing health interventions, by bridging the gap for those individuals who do not have access to the internet in low resourced settings.

The aim of this review is to search the literature systematically for studies utilising different mHealth interventions for psychosis; to assess what kind of interventions have been used globally. We believe a synthesis of available information could lead to a better understanding of the feasibility and effectiveness of these techniques in the treatment and assessment of psychotic illnesses. The results may help develop similar approaches for use in other mental illnesses, to reduce the burden of mental health disorders globally.

Methods

Inclusion and exclusion criteria

We followed the Cochrane collaboration guidelines on conducting systematic reviews (18). The inclusion criteria for studies was based on the following criteria: (I) described the use of a mobile device intervention in patients who were suffering from psychosis (II) at least one outcome measure was the assessment and treatment of psychosis (III) was a controlled trial (randomised or quasi-randomised). Studies were excluded if they used internet or other technologies without utilising mobile devices such as smartphones and tablets.

Literature search

We searched the following databases; Embase, Medline, PsychINFO and Evidence Based Medicine Reviews. A number of keywords were searched in each of the databases from inception to May 2016; the search criteria was initially configured and deployed in Medline and the same search criteria was then extrapolated to other databases. The key words that were searched included; 'mHealth' 'Mobile Health' or 'SMI' or 'Schizophrenia' or 'Schizo-Affective Disorder' or 'Intervention' or 'Assessment' or 'Treatment'.

(Please see Supplementary for full search strategy). We also searched for relevant systematic reviews in the Cochrane Database of Systematic Reviews and the Cochrane Database of Abstracts of Reviews of Effects (DARE) and randomised controlled trials were searched in the Cochrane Central Trials Register (CENTRAL).

Assessment of methodological quality

The methodological quality of the included randomised controlled trials and clinical controlled trials were assessed using the list from the Cochrane Risk of Bias Tool (19), which included 4 domains comprising of 11 criteria which assess internal validity of the selected studies. The 4 domains that were examined and the criteria used are as follows: (I) selection bias; this domain looked at whether an adequate randomisation procedure was used, similarity in baseline data on the primary indicator and whether treatment allocation was concealed; (II) performance bias; this included blinding of patients to the intervention, whether intervention compliance was adequate, and whether health professionals/therapists were blinded to intervention groups (IG); (III) attrition bias; this domain looked at whether the study included an intention to treat analysis and whether the study had an acceptable level of dropout rate at baseline; (IV) detection bias this domain examined whether the study used similar or the same outcome measures across the study groups, and whether the outcome assessor was blinded to the study groups. Overall, the studies were scored independently by two of the researchers (NG & PSK) across each of the 4 domains, the studies were scored either with a 'Yes', 'No' or 'Unclear'. Studies which scored more than 6 across each of the 4 domains were classed as high quality otherwise the remaining studies were classed as low quality. Any disagreements were discussed with senior researchers (SF, NH & JD) until a consensus was reached.

Data synthesis

The data was extracted from the databases and all abstracts were read by two of the research associates (NG & PSK). Those studies which met the inclusion criteria were then extracted by the reviewers using a standardised data extraction sheet. The following variables were extracted from the included studies; mobile Intervention used, type of study, outcome measures, duration, diagnostic criteria and results. Any disagreements were resolved through discussion with two investigators, (SF & NH) until consensus was

gained. We had plans to conduct a meta-analysis, but in view of the nature of studies (see below), no meta-analysis was conducted.

Results

Characteristics of the included studies

We found a total of 5,690 titles across the databases we searched, using our search strategy, from these, 43 studies were selected based on the title and abstract for further scrutiny. We selected 23 studies which were read full text, with sixteen studies being excluded (see *Figure 1*). Out of the excluded studies, four studies were excluded as they did not include a randomised controlled design, these included a study by Pijnenborg *et al.* (20) which investigated an SMS text message intervention for cognitive rehabilitation in schizophrenia. A study by Depp *et al.* (21) which looked at the mobile assessment of psychotic symptoms coupled with a low intensity intervention and Ben-Zeev *et al.* (22) who looked at retrospective multiple real-time/real-place assessments using a dual methods design, in individuals with schizophrenia and a non-clinical group. Another excluded study by Palmier-Claus *et al.* (5) investigated ambulatory assessment of psychotic symptoms. Other reasons for excluded studies are given in *Figure 1*.

The 7 included studies examined different parameters, one of the studies used an Experiential Sampling Methodology (ESM) which looked at monitoring symptoms real-time, one looked at medication adherence, two looked at cognitive impairments, one looked at social functioning, one looked at suicidal ideation in veterans with schizophrenia, one looked at mobile phone text message reminders and one examined relapse prevention and early warning signs. In view of the widely different interventions and outcome measures it was not possible to conduct a meta-analysis. Therefore we decided to give a descriptive account of the results.

Main findings

The characteristics of included studies are given in *Table 1*. The majority of studies were conducted across Europe and the United States with one in China; one was conducted in the UK, two in Spain, one in Finland, one in the Netherlands, one in China and one in the United States. Four of the studies were conducted in outpatient psychiatric settings, and three studies in an inpatient psychiatric unit.

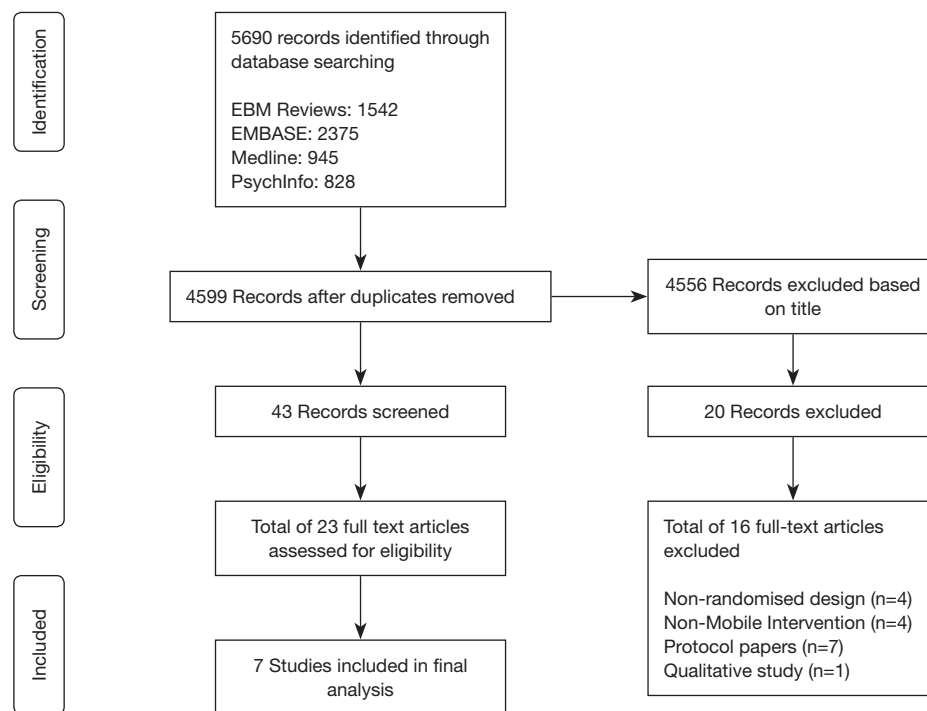


Figure 1 Consort diagram to show search results.

The total population across all studies was 1,105 (Mean =158, SD =197.20), with 637 males (Mean =91, SD =92.58) and 468 females (Mean =67, SD =107.27), the mean age of participants was 35.35 (SD =8.73). Five studies used a randomised controlled trial design, one used a prospective randomised open-label controlled trial and one was quasi-randomised. (Please see *Table 1* for the main findings of the included studies).

mHealth interventions

The included studies used a number of differing delivery platforms. Ainsworth *et al.* (23) aimed to compare two differing mediums of receiving assessment notifications on a mobile phone device. The smartphone was loaded with a software application which provided questions to assess symptoms of psychosis. The system either utilised SMS text messages or smartphone based application to deliver the assessment questions. The study used a repeated measures crossover design which assigned the 24 study participants to either undergo the SMS condition first and then the smartphone application condition or vice versa. Both conditions used the same assessment questions which were based on the Positive and Negative Syndrome Scale

(PANSS).

Another included study conducted by Dang *et al.* (24) examined the effects of an iPad assisted cognitive training programme on working memory in a group of male first-episode (FEP) schizophrenia patients. The training programme included user-friendly iPad games such as “Shanghai Mahjong”, “Little Ace and the Ten Commandments”, “Math vs. Brains” and “Brain Teaser Extreme. Participants engaged in the cognitive training for 60 minutes a day, 5 days a week. Assessments of working memory was conducted at baseline and follow up (week 4) through the N-Back task.

In addition, a total of four studies used a SMS based system as a delivery platform for the intervention (25-28). Pijnenborg *et al.* (25) investigated the efficacy of SMS messages to provide prompts to participants to achieve goals in their daily lives. These goals included, medication adherence, appointments, activities, attending training sessions and inhibition of undesired behaviours. Achievement of goals was based on an observer filling in a score sheet which indicated whether the goal had been achieved or not. The information technology aided relapse prevention in schizophrenia (ITAREPS) (26) used a multicentre randomised controlled trial design to examine

Table 1 Main findings of the included studies

Author	Year	Population	mHealth delivery method	Outcome measures used	Main findings
Ainsworth <i>et al.</i>	2013	N=24	Smartphone application and mobile phone	Purpose-designed Quantitative Feedback Questionnaire to assess the acceptability and feasibility of these methods was used. Positive and Negative Symptom Scale (PANSS)	Participants in the smartphone application condition took significantly less time to complete the assessment questions (Mean =68.4 seconds, SD =39.5) compared to the SMS only condition (Mean =325.5 seconds, SD =145.6) ($\beta=0.78$, SE =0.09, $P<0.001$). There was also a significant difference in data points completed in the smartphone app group compared to the SMS only group ($\beta=-0.25$, SE =0.11, $P=0.02$). There was no significant difference in PANSS score across the domains Hallucinations Anxiety Grandiosity Delusions Paranoia, Hopelessness
Dang <i>et al.</i>	2014	iPad assisted cognitive training group: N=8; Control group: N=9	Tablet device	N-Back performance was recorded as an accuracy rate, composed of the percent of correct responses (%) and reaction time for each response (ms)	Participants in the experimental group significantly improved in accuracy rate at 2-back ($Z=-3.27$, $P_{corrected} < 0.01$), and reaction time in 0, 1 and 2-back ($Z=-2.89$, $P_{corrected} =0.012$; $Z=-2.60$, $P_{corrected} =0.048$; $Z=-2.98$, $P_{corrected} =0.012$, respectively) from baseline to week 4, compared to the control group
Kasckow <i>et al.</i>	2016	Telehealth (Health Buddy) group: N=25; Control group: N=26	Handheld mobile device	Questionnaire items assessing participants positive or negative views on the telehealth intervention and the Beck Scale for Suicidal Ideation (BSS), 17 item Hamilton depression scales, Calgary depression rating scale, Mini mental status exam, Scale for assessment of positive symptoms, Scale for assessment of negative symptoms	Monthly adherence to the Health Buddy system was 83% (n=20), 92% (n=19) and 89% (n=15) for month 1, month 2, and month 3 respectively. Both groups exhibited improvement in suicidal ideation. The health buddy group BSS score reduced from 9.8 (SD =6.15) at baseline to 2.44 (SD =5.52) at endpoint, whilst the control group score reduced from 10.7 (SD =8.24) at baseline to 2.88 (SD =6.71) at endpoint. For the subgroup of participants who had a life time history of suicide attempt, a trend for a higher rate of remission at the 3-month period was found for those in the Health Buddy condition (16/18) compared to the ICM condition (14/19; log rank=2.82; df=1; $P=0.093$)
Kauppi <i>et al.</i>	2015	N=562	Mobile phone	Demographic data and readmission to psychiatric services measured by no. of healthy days	Overall a total of 2,112 text messages were sent to participants, the mean no. of messages selected by participants was 10 per month (SD 4.0; range, 2–25). There was a significant difference found in gender and age, with older females and younger males preferring greater number of messages. The most popular day to receive messages was found to be Monday and the least popular timing for messages was the weekend
Montes <i>et al.</i>	2012	Total 254 patients. SMS Group N=100; Control group N=154	Mobile phone	Morisky Green Adherence Questionnaire (MAQ)	Mean change in MAQ Score in IG was -1.0 (95% CI, -1.02, -0.98) while in the CG the change was -0.7 (95% CI, -0.72, -0.68) ($P=0.02$). Improvement was also noted in negative and cognitive symptoms and attitude towards medication

Table 1 (continued)

Table 1 (continued)

Author	Year	Population	mHealth delivery method	Outcome measures used	Main findings
Pijnenborg <i>et al.</i>	2010	N=62		Client Motivations for Therapy Scale, several scales to measure the cognitive functioning, PANSS, Social Functioning Scale and Rosenberg Self-Esteem Questionnaire	Overall the mean success percentage was 47% across all the goal categories during baseline (SD 27.9), this increased to 62% during the intervention (SD 20.1), and reduced to 40% at follow-up (SD 31.7). Participants who responded to the alerts and achieved their goals had significantly lower positive symptoms compared to the non-responders ($t=2:11$, $P=0.4$)
Spaniel <i>et al.</i>	2012	Active group: N=75; Control group: N=71	Mobile phone	Clinical Global Impression Severity and Improvement Scales (CGI-S and CGI-I), Hayward 7-item Medication Compliance Rating Scale and GAF Scale	Overall, the return rate for the Early Warning Signs Questionnaire (EWSQ) was 80% (active =79.8%, controls =81.3%), it was reported that the individuals who did not receive an increase in antipsychotic medication following a Pharmacological Intervention Requiring Event (PIRE) had an increased risk of hospitalisation (HR =10.8; 95% CI, 1.4–80.0; $P=0.002$)

ICM, intensive case monitoring; IG, intervention groups; HR, hazard ratio; CI, confidence interval.

the detection of early warning signs, through the use of SMS based alerts delivered using a mobile phone. The clinicians were provided alerts to increase pharmacological intervention if there was an increase in scores on the early warning signs questionnaire (EWSQ).

Kauppi *et al.* (27) utilised SMS based user defined prompts, relating to medication, follow up appointments and daily issues such as hygiene, physical exercise, symptom management and other supporting messages during discharge from a psychiatric inpatient setting. The frequency and timing of the SMS prompts were also defined by the user. A total of 562 participants enrolled in the study with participants' receiving a mean total of 10 messages a month (SD 4.0; range, 2–25) over the 12-month study period. Montes *et al.* (28) used an SMS based mHealth delivery modality for medication adherence, a total of 254 participants took part in the study. Similarly, Montes *et al.* (28) used an SMS based mHealth delivery modality for medication adherence. In this study participant in the IG condition received daily reminders to take their medication.

In contrast, Kasckow *et al.* (29) assessed the feasibility of a telehealth monitoring intervention known as 'Health Buddy' for suicidal behaviour in a population of recently admitted inpatient US veterans aged 18 to 64, diagnosed with schizophrenia or schizoaffective disorder and recent suicidal ideation. The Health Buddy was a daily use system that facilitated symptom assessment and patient-staff

communication during weekly visits for veterans following an intensive case monitoring (ICM) program. The study assessed, whether augmentation of ICM with the Health Buddy system would result in a significant reduction in suicidal ideation comparative to an ICM only group. This was reviewed using the beck scale for suicidal ideation (BSS).

Medication adherence

A total of 4 studies looked at medication adherence, with a combined sample size of $n=921$ participants, although the study by Kasckow *et al.* (29) investigated suicidal ideation in veterans with schizophrenia using the Health Buddy system. The daily monitoring of participants using the Health Buddy system included queries about medication adherence, which was described by participants as being effective in improving their medication adherence. In addition, the study by Pijnenborg *et al.* (25), reported that participants who responded to the alerts and achieved their goals had significantly lower positive symptoms compared to the non-responders ($t=2.11$, $P=0.04$). It was found that participants showed an increase in leisure activities and keeping to appointments with their health professionals. However, this was not the case for medication adherence and attendance at training sessions. These results differed from the study by Kauppi *et al.* (27), Kasckow *et al.* (29) and Montes *et al.* (28), who found improvements in medication adherence.

Kauppi *et al.* (27) utilised SMS based user defined prompts, relating to medication, follow up appointments and daily issues such as hygiene, physical exercise, symptom management and other supporting messages during discharge from a psychiatric inpatient setting. The frequency and timing of the SMS prompts were also defined by the user. A total of 562 participants enrolled in the study with participants receiving a mean total of 10 messages a month (SD 4.0; range, 2–25) over the 12-month study period. The results showed that the most preferable timing for the selected messages was at the beginning of the week, with participants less likely to prefer receiving messages on a weekend. The most selected messages related to medication (175 participants), follow up appointments (149 participants) and physical exercise (82 participants). Furthermore, in the Montes *et al.* (28) study participants who were in the IG condition significantly improved in medication adherence compared to those in the control group (CG) Mean change in score in IG was -1.0 (95% CI: $-1.02, -0.98$) while in the CG the change was -0.7 (95% CI: $-0.72, -0.68$) ($P=0.02$). In addition, the Montes *et al.* (28) reported that participants in the intervention group held more positive views about medications.

ESM

Only one of the studies utilised an ESM based methodology (23). The system would use randomly selected data points to obtain participant's symptoms through either; smartphone notifications or SMS. This in effect constructed a daily record of the participant's symptoms, enabling them to produce a day-to-day symptom profile. Participants in the smartphone application condition took significantly less time to complete the assessment questions (Mean =68.4 seconds, SD =39.5) compared to the SMS condition (Mean =325.5 seconds, SD =145.6) ($\beta=0.78, SE =0.09, P<0.001$). It was also reported that individuals completed significantly more notifications in the smartphone condition compared to the SMS only condition. There was also a significant difference ($\beta=-0.25, SE =0.11, P=0.02$) in data points completed in the smartphone application condition compared to the SMS group with smartphone application group completing 69% of entries, (mean =16.5), compared to the SMS condition (56% of entries, mean =13.5). There was no significant difference in PANSS scores across the domains, hallucinations anxiety, grandiosity, delusions, paranoia and hopelessness.

Cognitive functioning

The study by Dang *et al.* (24) examined cognitive functioning and used the N-Back task to assess cognitive functioning. In addition, the Wechsler Memory Scale-Revised (WMS-R) and full versions of the Wechsler Adult Intelligence Scale-Revised (WAIS-R) were used to assess participants at baseline. The results suggested that participants in the experimental group significantly improved in accuracy rate at 2-back ($Z =-3.27, P_{corrected} b 0.01$), and reaction time in 0, 1 and 2-back ($Z =-2.89, P_{corrected} =0.012; Z =-2.60, P_{corrected} =0.048; Z =-2.98, P_{corrected} =0.012$, respectively) from baseline to week 4, compared to those in the CG. In addition, Montes *et al.* (28) also looked at cognitive functioning and reported improvements in negative symptoms (Baseline =3.3 *vs.* 3 months =3.5) and cognitive symptoms (Baseline=3.3 *vs.* 3 months =3.5) $P<0.05$, in the IG compared to the CG group on the Severity of illness subscale of the Clinical Global Impression-Schizophrenia Scale (CGI-SCH-SI).

In contrast, the study by Pijnenborg *et al.* (25) looked at the efficacy of SMS based prompts to compensate for cognitive impairments in schizophrenia. This was done through SMS based prompts aimed at improving their everyday functioning through setting goals. Pijnenborg *et al.* (25) reported that the mean success percentage was 47% across all the goal categories during baseline (SD 27.9), this increased to 62% during the intervention (SD 20.1), and reduced to 40% at follow-up (SD 31.7).

Engagement with mHealth technology

The Kasekow *et al.* (29) study looked at monthly adherence to the Health Buddy system which was reported to be 83% ($n=20$), 92% ($n=19$) and 89% ($n=15$) for month 1, month 2, and month 3 respectively. Monthly adherence rates were calculated, by adding the number of days participants completed the questions divided by the number of days the participants were in the study that month. Both groups were reported to have shown improvement in suicidal ideation. The health buddy group BSS score reduced from 9.8 (SD =6.15) at baseline to 2.44 (SD =5.52) at endpoint, whilst the CG score reduced from 10.7 (SD =8.24) at baseline to 2.88 (SD =6.71) at endpoint. No difference in groups was found when examining duration to remission (defined as having a BSS score =0), however for the subgroup of participants with a life time history of suicide attempt, a trend for a higher rate of remission at 3 months was reported for those

in the Health Buddy condition (16/18), compared to those in the ICM condition (14/19; log rank=2.82; df=1; P=0.093). No significant differences were detected between groups in scores on Calgary Depression Rating Scale, Hamilton Depression Rating Scale and Scale for Positive Symptoms and Scale for Negative Symptoms were included. However, in contrast Spaniel *et al.* (26) reported, that despite the fact that over the study period 17,082 SMS messages were sent by participants, it was reported that the study was largely unsuccessful, due to poor adherence by investigators to the protocol. They reported that only 39% of participants received an increase in antipsychotic medication in response to increased scores of the EWSQ.

Feasibility and acceptability

One of the main results of the included studies was the feasibility and acceptability of the mHealth interventions. Montes *et al.* (28) concluded that due to the ease of implementation, using mobile phones to prompt medication was feasible and acceptable. In addition, the Ainsworth *et al.* (23) study reported that mobile phones and smartphones were acceptable forms of technology. However there was shown to be a greater preference by participants to a smartphone application compared to a mobile phone. It was reported that participants took longer to complete each entry in the SMS condition (325.5 seconds, SD 145.6) compared to the smartphone application condition (68.4 seconds, SD 39.5). Overall 67% of participants preferred using the smartphone application compared to 13% who preferred SMS, 21% of individuals had no preference on the delivery method. Furthermore, it was reported that 71% of participants found using the smartphone application easier than the SMS delivery modality, 17% found the SMS condition to be easier and 13% had no preference (23).

The studies that used mobile phones were primarily used for the sending and receiving of SMS messages, these mobile devices had basic functionality such as voice calling, gaming, alarm, SMS and vibrate alerts (25,26,28). These studies also reported positive evaluations of using mobile phone based interventions. Pijnenborg *et al.* (25), found that the 70% of participants viewed the SMS intervention as positive, 20% were neutral and 10% held negative views. In addition, Pijnenborg *et al.* (25) reported that 41% of the participants found the intervention effective, 33% were neutral and 26% evaluated the intervention as ineffective. However, in contrast, Spaniel *et al.* (26) reported that feasibility could only be gauged once there had been

acceptance of computerised methods and a change in clinical thinking.

In addition, feasibility of the Health Buddy system was examined over a 3-month period, with 20 of the 25 participants able to set up the Health Buddy system. Kasckow *et al.* (29). Of the 25 participants, it was reported that 4 individuals required some assistance to help with setting up the health buddy system. A number of reasons were reported for the 5 participants who did not set up the device, such as permission from landlord, substance misuse, cognitive impairment, phone company debt and transportation problems. In addition, Kauppi *et al.* (27) reported that participants preferred messages at the beginning of the week. It was suggested that individuals preferred messages early in the morning and in accordance to a working week format, running through Monday to Friday.

Risk of bias assessment

We used the Cochrane collaboration risk of bias instrument (19) to measure the risk of bias in the assessment of quality of trial reports, which is shown in *Figure 2*. Only one study had low risk of bias (26). All studies included were randomised trials however one was a quasi-randomised trial (25). Three of the studies described an appropriate method to generate the sequence of randomisation or gave the details, however the method used in the Pijnenborg *et al.* (25) was scored as high risk. All studies gave the details of withdrawal and drop outs. Ainsworth *et al.* (23) did not report the PANSS outcome measures highlighting a risk of bias when reporting data on outcomes used in their trial. The study by Dang *et al.* (24) indicated that the methods of the study were described in an earlier paper Lu *et al.* (30), however it was unclear as to what methods of randomisation and allocation to treatment arm were employed highlighting a risk of bias.

Discussion

The present systematic review is the first to look at mobile device interventions for the treatment and assessment of psychosis, with a focus on how future research can inform the use of mHealth technologies to increase access to treatments for SMI such as psychosis globally. Previous reviews have focused on telehealth, web based and internet interventions (14,15). However, these reviews investigated an array of differing delivery modalities such as the internet and telephone based land lines. Considering the increasing

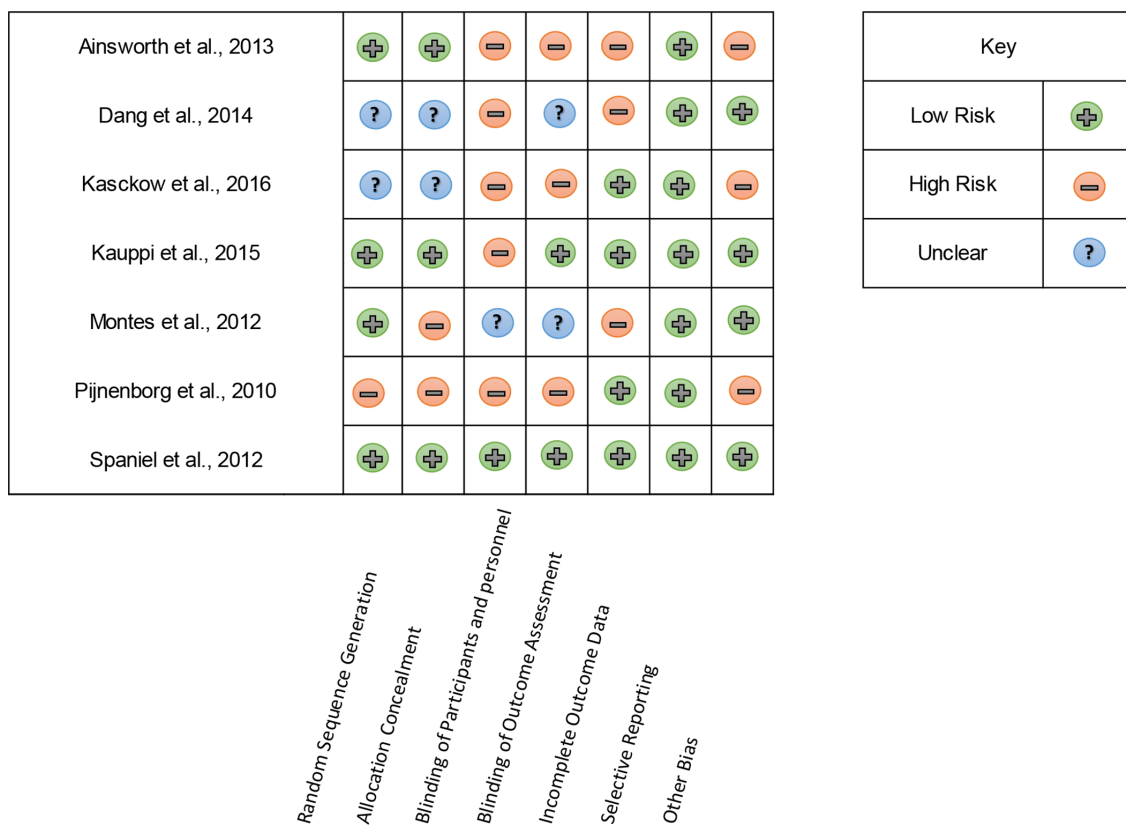


Figure 2 Risk of bias assessment diagram.

access to mobile devices globally, mHealth may potentially increase access to appropriate mental health care.

In view of the limited literature on the subject, the findings of this review can only help to comment on feasibility and acceptability of the mHealth interventions. Most studies found that mobile based interventions were feasible. Overall, it appears that the strongest evidence found, was related to mHealth technologies for medication adherence. Kauppi *et al.* (27) and Montes *et al.* (28) found that using mobile phones to prompt medication was feasible and acceptable. Similarly, Kasckow *et al.* (29) reported no significant difference in the clinical measures between the groups, however qualitative analysis of end-point surveys revealed a mainly positive response from participants in the Health Buddy condition with participants describing the program as effective in relation to improvement in medication adherence, and reduction in symptoms of anxiety and depression

The included studies reported a variety of outcomes. These included treatment adherence (28), social functioning (25), mobile text message preferences for people

on antipsychotics (27), experiential sampling (23), cognitive impairment (24) relapse prevention (26) and suicidal ideation (29). This combined with limited literature on the subject means that it is not possible to have any definitive findings on the effectiveness of mHealth based interventions in improving these outcomes. There was an increase in medication adherence; Montes *et al.* (28) and Pijnenborg *et al.* (25) reported improvement in social functioning. This is consistent with literature in other branches of medicine (31), where mobile devices have successfully been used to improve adherence.

The mobile phones were primarily used for the sending and receiving of SMS messages. (25,26,28). These studies also reported positive evaluations of using mobile phone based interventions. Pijnenborg *et al.* (25), found that the 70% of participants viewed the SMS intervention as positive and only 10% held negative views Pijnenborg *et al.* (25). These findings are important and demonstrate that even the simple mobile devices can be used for interventions using functions such as SMS alerts, voice calling or alarms. This is relevant for low resourced settings, where large populations

may have access to mobile devices with basic functionality.

However, it must be noted that, delivery of assessment questions in the Ainsworth *et al.* (23) study utilised either a mobile App or SMS text messages. It was reported that participants took longer to complete each entry in the SMS condition compared to the smartphone application condition. Overall 67% of participants preferred using the smartphone application compared to 13% who preferred SMS. This may suggest factors such as usability and user experience may be key factors in ensuring a user-friendly medium to deliver mHealth intervention, which goes beyond basic SMS messaging.

An innovative use of mHealth is the real-time assessment psychosis using an ESM methodology which was conducted by Ainsworth *et al.* (23). The study was based on the mHealth interventions engaging with participants in real-time. Research, in the real-time assessment of psychosis has been conducted by Myin-Germeys *et al.* (32) who described the method as ESM. The method looks at the differing moods, thoughts and psychotic symptoms of individuals which occur in their day to day lives. The method is used to construct an understanding of individual's psychotic symptoms with a view to understanding the aetiological underpinnings of psychosis in the real-world context (33). Methods such as experiential sampling provide greater insight into SMI's, constructing a picture of individual's experiences of psychosis in day-to-day life. These uses, however, need to be evaluated in larger well-designed studies.

Limitations

The major limitation of the present review is that we were only able to identify 7 studies with relatively smaller sample sizes. It is unlikely that we missed any studies as we used a comprehensive search strategy. However, the limited literature shows that it is possible to design and conduct studies using mHealth interventions for improving treatment adherence, monitoring symptoms, and social functioning. Although this data is useful in providing evidence for the proof of concept of the potential benefits and applicability of mHealth for psychosis, this has not been properly evaluated. Furthermore, we were unable to find studies which looked at both the assessment and treatment of psychosis, using a randomised controlled trial design. This is important as interventions which can provide assessment and treatment for psychosis in real time such as the Depp *et al.* (21) study can be hugely beneficial to

individuals with SMI particularly in low resourced settings.

Implications

The utility of mHealth has been shown in a number of Non-Communicable disorders globally. For example, Piette *et al.* (34) reported that mobile technologies can be used effectively in self-management of hypertensive patients to improve outcomes. Tran *et al.* (35), investigated teleconsultation with a software-enabled mobile telephone for common skin diseases by a dermatologist, it was found that mobile technology enabled greater access to dermatological expertise where access is limited. It may be possible to employ these methodologies for providing teleconsultations with mental health professionals, in areas where there is limited access to specialist mental health care. This potentially may be of huge benefit to those individuals who live in remote or rural areas and areas of high deprivation. Similarly, it may be possible to employ the cheap and widespread use of SMS messages for public health interventions such as reducing stigma associated with psychosis.

Acknowledgements

The authors wish to thank Miv Riley and Yaseen Edros, for their support in preparing the manuscript. NG gratefully acknowledges the support and funding of his PhD Studentship with the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West Coast, UK.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

References

1. Whiteford HA, Degenhardt L, Rehm J, et al. Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. *Lancet* 2013;382:1575-86.
2. Oh H, Rizo C, Enkin M, et al. What Is eHealth (3): A Systematic Review of Published Definitions *J Med Internet Res* 2005;7:e1
3. Kay M, Santos J, Takane M. mHealth: New horizons for health through mobile technologies. *World Health*

- Organization 2011;64:7:66-71.
4. Gire N, Chaudhry I B, Naeem F, et al. TechCare: mobile-assessment and therapy for psychosis: An intervention for clients within the early intervention service. *SAGE Open Med* 2016;4:2050312116669613.
 5. Palmier-Claus JE, Ainsworth J, Machin M, et al. The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. *BMC Psychiatry* 2012;12:172.
 6. Bucci S, Barrowclough C, Ainsworth J, et al. Using mobile technology to deliver a cognitive behaviour therapy-informed intervention in early psychosis (Actissist): study protocol for a randomised controlled trial. *Trials* 2015;16:404.
 7. Collins PY, Patel V, Joestl SS, et al. Grand challenges in global mental health. *Nature* 2011;475:27-30.
 8. Arjadi R, Nauta MH, Chowdhary N, et al. A systematic review of online interventions for mental health in low and middle income countries: a neglected field. *Glob Ment Health (Camb)* 2015;2:e12.
 9. van Os J, Linscott RJ, Myin-Germeys I, et al. A systematic review and meta-analysis of the psychosis continuum: evidence for a psychosis proneness-persistence-impairment model of psychotic disorder. *Psychol Med* 2009;39:179-95.
 10. Walker ER, McGee RE, Druss BG. Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA Psychiatry* 2015;72:334-41.
 11. McGlashan TH. Commentary: Progress, issues, and implications of prodromal research: an inside view. *Schizophr Bull* 2003;29:851-8.
 12. Ruhrmann S, Schultze-Lutter F, Salokangas RK, et al. Prediction of psychosis in adolescents and young adults at high risk: results from the prospective European prediction of psychosis study. *Arch Gen Psychiatr* 2010;67:241-51
 13. Stafford MR, Jackson H, Mayo-Wilson E, et al. Early interventions to prevent psychosis: systematic review and meta-analysis. *BMJ* 2013;346:f185
 14. Alvarez-Jimenez M, Alcazar-Corcoles MA, Gonzalez-Blanch C, et al. Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. *Schizophr Res* 2014;156:96-106.
 15. Kasckow J, Felmet K, Appelt C, et al. Telepsychiatry in the assessment and treatment of schizophrenia. *Clin Schizophr Relat Psychoses* 2013;8:21-27A.
 16. Internet World Stats. Internet usage statistics - The internet big picture 2015, Available online: <http://www.internetworldstats.com/stats.htm>. Accessed on 8th July, 2017.
 17. International Telecommunication Union (ITU) (2014). ICT Facts and Figures 2014, Available online: <http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2014-e.pdf>. Accessed on 8th July, 2017.
 18. Higgins JP, Green S, editors. *Cochrane handbook for systematic reviews of interventions*. John Wiley & Sons; 2011.
 19. Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;18;343:d5928.
 20. Pijnenborg GH, Withaar FK, Evans JJ, et al. SMS text messages as a prosthetic aid in the cognitive rehabilitation of schizophrenia. *Rehabil Psychol* 2007;52:236-40.
 21. Depp CA, Mausbach B, Granholm E, et al. Mobile interventions for severe mental illness: design and preliminary data from three approaches. *J Nerv Ment Dis* 2010;198:10:715-21.
 22. Ben-Zeev D, McHugo GJ, Xie H, et al. Comparing retrospective reports to real-time/real-place mobile assessments in individuals with schizophrenia and a nonclinical comparison group. *Schizophr Bull* 2012;38:3:396-404.
 23. Ainsworth J, Palmier-Claus JE, Machin M, et al. A comparison of two delivery modalities of a mobile phone-based assessment for serious mental illness: native smartphone application vs text-messaging only implementations. *J Med Internet Res* 2013;15:e60.
 24. Dang J, Zhang J, Guo Z, et al. A pilot study of iPad-assisted cognitive training for schizophrenia. *Arch Psychiatr Nurs* 2014;28:197-9.
 25. Pijnenborg GH, Withaar FK, Brouwer WH, et al. The efficacy of SMS text messages to compensate for the effects of cognitive impairments in schizophrenia. *Br J Clin Psychol* 2010;49:259-74.
 26. Španiel F, Vohlídka P, Hrdlička J, et al. ITAREPS: information technology aided relapse prevention programme in schizophrenia. *Schizophr Res* 2008;98:312-7.
 27. Kauppi K, Kannisto KA, Hätönen H, et al. Mobile phone text message reminders: measuring preferences of people with antipsychotic medication. *Schizophr Res* 2015 31;168:514-22
 28. Montes JM, Medina E, Gomez-Beneyto M, et al. A short message service (SMS)-based strategy for enhancing adherence to antipsychotic medication in schizophrenia. *Psychiatry Res* 2012;200:89-95.
 29. Kasckow J, Zickmund S, Gurklis J, et al. Using telehealth to augment an intensive case monitoring program in

- veterans with schizophrenia and suicidal ideation: A pilot trial. *Psychiatry Res* 2016;30;111-6.
30. Lu W, Zhang C, Yi Z, et al. Association between BDNF Val66Met polymorphism and cognitive performance in antipsychotic-naive patients with schizophrenia. *J Mol Neurosci* 2012;47:505-10.
 31. Yellowlees P. Trends in e-Health—Technological Advances that will Impact on Diagnosis and Treatment. *Business Briefing: Global Healthcare*, 2003;1-4.
 32. Myin-Germeys I, Oorschot M, Collip D, et al. Experience sampling research in psychopathology: opening the black box of daily life. *Psychol Med* 2009;39:1533-47.
 33. Myin-Germeys I, Peeters F, Havermans R, et al. Emotional reactivity to daily life stress in psychosis and affective disorder: an experience sampling study. *Acta Psychiatr Scand* 2003;107:124-31.
 34. Piette JD, Datwani H, Gaudio S, et al. Hypertension management using mobile technology and home blood pressure monitoring: results of a randomized trial in two low/middle-income countries. *Telemed J E Health* 2012;18:613-20.
 35. Tran K, Ayad M, Weinberg J, et al. Mobile teledermatology in the developing world: implications of a feasibility study on 30 Egyptian patients with common skin diseases. *J Am Acad Dermatol* 2011;64:302-9.

doi: 10.21037/mhealth.2017.07.03

Cite this article as: Gire N, Farooq S, Naeem F, Duxbury J, McKeown M, Kundi PS, Chaudhry IB, Husain N. mHealth based interventions for the assessment and treatment of psychotic disorders: a systematic review. *mHealth* 2017;3:33.

Search strategy

- (I) random\$ or control or controlled or trial or condition or assigned or groups
- (II) exp schizophrenia/ or exp psychosis/ (psychotic or schizo\$ or psychos\$ or psychoses) or ((chronic\$ or sever\$) adj5 mental\$ adj5 (ill\$ or disorder\$)) or exp psychiatric treatment/ or exp therapy/ or exp therapy/ or exp sociotherapy/ or exp clinical study/
- (III) (intervention or psychotherapy or rehabilitation or training or therapy) or ((psychological or psychosocial or psychiat\$ or clinical) adj5 (intervention or therap\$ or rehabilitation or remediat\$ or training or clinical or care)) or ((cognitive or behav\$ or family or focused or psycho\$ or social\$ or education\$ or skill\$) adj5 (intervention or therap\$ or rehabilitation or remediat\$ or training))
- (IV) smartphone\$ OR smart phone\$ OR (window? adj3 phone) OR (window? adj3 mobile) OR nokia OR palm OS OR symbian OR iphone OR ipad OR iPod touch\$ OR m health OR mhealth OR PDA OR personal digital assistant? OR android OR blackberr\$ cellular phone [MeSH] OR phone\$ OR telephone\$ app OR apps OR application? OR software OR twitter OR facebook OR telemedicine OR telemedicine OR telehealth OR tele health OR ehealth OR computerised intervention\$ OR computerized intervention\$ OR e health OR e mail\$ OR email\$ OR Electronic mail OR health technolog\$ OR intranet?

Appendix 3: TechCare: Mobile Assessment and Therapy For Psychosis–An Intervention For Clients In The Early Intervention Service: A feasibility study protocol.

Reference:

Husain, N., Gire, N., Kelly, J., Duxbury, J., McKeown, M., Riley, M., ... & Caton, N. (2016). TechCare: mobile assessment and therapy for psychosis–an intervention for clients in the Early Intervention Service: A feasibility study protocol. *SAGE open medicine*, 4, 2050312116669613.

TechCare: mobile assessment and therapy for psychosis – an intervention for clients in the Early Intervention Service: A feasibility study protocol

SAGE Open Medicine
Volume 4: 1–9
© The Author(s) 2016
Reprints and permissions:
sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/2050312116669613
smo.sagepub.com


Nusrat Husain^{1,2}, Nadeem Gire^{2,3}, James Kelly², Joy Duxbury³, Mick McKeown³, Miv Riley², Christopher DJ Taylor², Peter J Taylor^{1,4}, Richard Emsley¹, Saeed Farooq⁴, Neil Caton², Farooq Naeem⁵, David Kingdon⁶ and Imran Chaudhry¹

Abstract

Objectives: Technological advances in healthcare have shown promise when delivering interventions for mental health problems such as psychosis. The aim of this project is to develop a mobile phone intervention for people with psychosis and to conduct a feasibility study of the TechCare App.

Methods: The TechCare App will assess participant's symptoms and respond with a personalised guided self-help-based psychological intervention with the aim of exploring feasibility and acceptability. The project will recruit 16 service users and 8–10 health professionals from the Lancashire Care NHS Foundation Trust Early Intervention Service.

Results: In strand 1 of the study, we will invite people to discuss their experience of psychosis and give their opinions on the existing evidence-based treatment (cognitive behavioural therapy) and how the mobile app can be developed. In strand 2, we will complete a test run with a small number of participants ($n=4$) to refine the mobile intervention (TechCare). Finally, in strand 3 of the study, the TechCare App will be examined in a feasibility study with 12 participants.

Conclusion: It has been suggested that there is a need for a rapid increase in the efforts to develop the evidence base for the clinical effectiveness of digital technologies, considering mHealth research can potentially be helpful in addressing the demand on mental health services globally.

Keywords

Early intervention in psychosis, mHealth, cognitive behavioural therapy, intelligent real-time therapy

Date received: 25 February 2016; accepted: 4 August 2016

Background

Mental illness is a major source of disease burden in the United Kingdom, costing in the region of £105 billion pounds.¹ Psychosis is a severe form of mental illness that has huge social, economic and personal costs.² The disorder has the highest prevalence in the young population between 15 and 35 years of age.³ Individuals who experience psychosis may encounter a number of symptoms such as perceptual phenomena, including auditory hallucinations and delusional ideation or other disturbances in thinking.⁴ At later stages of the disorder, there may be a marked deterioration in an individual's functioning.⁵

The UK National Health Service (NHS England) Improving Access to Psychological Therapies for Severe Mental Illness

(IAPT-SMI) initiative aims to increase the availability of psychological interventions.⁶ Despite such initiatives, access to psychological treatments is low, with individuals experiencing a psychotic illness being less likely to be offered psychological

¹The University of Manchester, Manchester, UK

²Lancashire Care NHS Foundation Trust, Preston, UK

³University of Central Lancashire, Preston, UK

⁴Keele University, Keele, UK

⁵Queen's University, Kingston, ON, Canada

⁶University of Southampton, Southampton, UK

Corresponding author:

Nusrat Husain, The University of Manchester, Manchester M13 9PL, UK.

Email: nusrat.husain@manchester.ac.uk



interventions.⁷ One way of tackling this poor access to treatment is through the use of mobile and wireless technologies, which have the potential to transform mental healthcare. Globally, estimates suggest close to 5 billion mobile phone subscriptions worldwide,⁸ with over 85% of the world's population being covered by a commercial wireless signal.⁸ In the United Kingdom, it is estimated that 93% of adults own/use a mobile phone, with 66% owning a smartphone.⁹

The emergence and continual development of technology in this era cannot be ignored, both socially, professionally, and personally technology encroaches upon all of our daily lives. Telehealth and mobile health (mHealth) are emerging fields in providing treatment and care globally.^{10–13} It involves the use of telecommunications to provide healthcare, support and interventions from a distance.^{14–16} Telehealth has been implemented into the treatment of chronic physical illnesses including diabetes, congestive heart failure and asthma.^{16,17} Barak et al.¹⁸ found Internet-based interventions to be more successful for the treatment of psychological problems than for physical or medical problems. Using technology to advance psychological treatment is 'a developing professional reality'.¹⁸

A study by Lester et al.¹⁹ showed the importance of technology in engagement within Early Intervention Services (EIS). This is important in drawing emphasis on how mHealth functions could provide continued support, but also give clients greater autonomy. Rotondi et al.²⁰ found that for many clients, just having the access to support at their fingertips when needed was sufficient reassurance for them.

However, due to the current and developing nature of digital health technologies, these have faced criticism, such as the lack of interpersonal closeness when compared to face-to-face intervention delivery. It has been reported that clients using a face-to-face intervention compared with an online chat overall felt more satisfied, a better sense of closeness and more comfortable in disclosing their difficulties.^{21,22} These criticisms are important to address, as each of these factors play key roles in contributing to a therapeutic relationship,²³ which has been highlighted as important in delivering efficacious treatment and encouraging engagement.¹⁹ However, in contrast, a meta-analysis of research on Internet-based psychotherapeutic interventions found it to be as efficacious as face-to-face therapy in the treatment of certain mental health difficulties such as depression, anxiety and post-traumatic stress disorder.¹⁸ This shows that in many cases, the effectiveness of the therapy is not diminished. Barak et al.¹⁸ found cognitive behavioural therapy (CBT) a much more effective therapy than others for online treatment of psychological difficulties. Furthermore, a systematic review by Alvarez-Jimenez et al.²⁴ found that mobile- and Internet-based interventions for psychosis were feasible and acceptable and have the potential to improve health outcomes.

A number of studies have shown support for the use of mHealth in severe mental illness.^{10,11,13,25} Palmier-Claus et al.¹¹ reported that overall, 67% of participants preferred using a smartphone app compared to 13% who preferred Short

Message Service (SMS) and 21% who had no preference on the delivery method. Furthermore, Granholm et al.¹⁰ reported that participants increased their level of socialisation, and there was also a reduction in severity of hallucinatory behaviour when using a low-level SMS-based intervention. The key findings of these studies were the feasibility and acceptability of mHealth Apps for Severe Mental Illnesses (SMIs) and the ability of mHealth technology to overcome barriers to accessing mental health treatment through the use of a non-stigmatising approach. Moreover, mHealth interventions as reported by Palmier-Claus et al.,¹¹ Granholm et al.,¹⁰ and Ben-Zeev et al.¹³ are acceptable forms of intervention and thus provide a unique and beneficial platform for engagement.

mHealth innovations are important as they have the potential to bridge the 'therapy-practice gap',²⁶ going beyond the confines of the therapy setting and bringing real-time treatment in individual's day-to-day lives and within their lived environments. The potential benefits of digital technologies in providing a new way to connect with health services and to potentially improve health outcomes are limited by a number of barriers in their use. Hollis et al.²⁷ summarised these barriers as the insufficient evidence base, limited uptake and outcomes being anecdotal and unpublished. Hollis et al.²⁷ further stated that for the potential of digital technologies to be fully realised, patients' requirements need to be at the centre of developing interventions, and that there is a need for a rapid increase in the efforts to develop the evidence base for the clinical effectiveness of digital technologies.²⁷

This project aims to integrate a momentary sampling assessment approach that is matched with a psychological intervention in real time to address low mood and paranoia. This proposal describes a feasibility project 'Mobile Assessment and Therapy for Psychosis' which is an integrated mobile application which is provisionally titled 'TechCare'. Guidance regarding the development of new complex interventions suggests that it is appropriate to conduct a phase II or feasibility study.²⁸ This study will follow guidance by the National Institute of Health Research²⁹ on feasibility study design. Feasibility studies are conducted prior to conducting large studies in order to assess whether the study can be done. Vital parameters are examined that are needed to design the main study. The results of this feasibility study will inform the design of subsequent trials regarding expected treatment effects, identification of appropriate outcome measures and follow-up periods, estimates of recruitment and feasibility of the intervention.

Aims and objectives

The proposed study aims to address the following questions:

1. Can appropriate individuals be identified and recruited to a trial for the evaluation of TechCare for psychosis?

2. Will TechCare be an acceptable intervention for individuals with psychosis? Will they be able to engage in setting goals and reporting outcomes with care coordinators and work towards these with the TechCare App?
3. What would be the most appropriate primary outcome measure for a future randomised controlled trial (RCT) of the TechCare intervention?

Methods

Design

We will use a mixed-methods design, which will consist of both qualitative and quantitative components. The study will be run across three strands as follows: (1) qualitative work, (2) test run and intervention refinement and (3) feasibility trial.

Inclusion criteria

The following inclusion criteria will be used:

- The service user is receiving care from the Lancashire EIS.
- The service users between 18 and 35 years of age.
- There has been no change in the medication for at least 2 months prior to entry into the study.
- Clients must be currently stable; Lancashire Early Intervention Team uses a traffic light system to indicate current symptomatology and risks of each client. Therefore, the clients who are considered to be stable according to this system will be eligible.
- A score of 3 or more on any of the positive symptoms on the Positive and Negative Syndrome Scale (PANSS) (e.g. delusions, hallucination).
- Minimum score of 1 on the Calgary Depression Scale.

Exclusion criteria

We will exclude patients meeting the following criteria:

- Drug induced psychosis as determined by the individual's care team.
- An acquired brain injury or learning disability as determined by participant's care team.
- Clients who are undergoing assessment, not formally diagnosed and accepted into the service.
- Lacking capacity for informed consent determined by the participant's care team.

Recruitment

The research team will contact potential referrers (care coordinators, clinical psychologists and psychiatrists) at the

Lancashire EIS service. They will be provided with information about the study and will be asked to share this with potential participants. In addition, information sessions will be offered by the research teams at the recruitment sites. If participants are interested and wish to be approached to receive further information about the research, a risk assessment will be carried out with the care coordinator. This assessment will then inform the best way to approach participants.

We will also recruit health professionals such as care coordinators, clinical psychologists and EIS doctors from the Lancashire Care EIS and will adopt a purposive sampling strategy seeking to maximise the range of views accessed. We will leave participant information sheets with the clinical teams, so that potential participants can contact the research team directly.

A total of 16 qualitative interviews will be conducted with service users who will take part in strand 2 (test run) and strand 3 (feasibility trial). In addition, we will also carry out two focus groups with 8–10 health professionals (e.g. nurses, psychologists, psychiatrists and social workers). Interviews and focus groups will explore feasibility, acceptability and further development of the TechCare intervention.

Equipment

The TechCare software is being developed for use on a touchscreen mobile phone. The service users who have compatible smartphones will be able to upload the application to their phone. The team will lend a preloaded phone to those who wish to participate but do not have a smartphone. If participants encounter any technical problems with their device, they will be advised to directly contact the research assistant (RA) or the principal investigator (PI).

Defining the intervention

EISs were introduced into the NHS in the early 1990s, for people with a first episode of psychosis.¹⁹ Recent research shows that these services are cost-effective in reducing relapse and thus leading to reduction in hospital admissions.^{30,31} CBT is commonly used for the treatment of early psychosis³² and is a recommended treatment for first episode psychosis (National Institute of Health and Care Excellence (NICE)³³). In the Lancashire Care NHS Foundation Trust (LCFT) EIS tier 1 CBT is delivered by all care coordinators who have undertaken the 3-day psychosocial intervention (PSI) training and is at the level of guided self-help interventions. These consist of understanding principles of recovery and hope, basic CBT thought–feeling–behaviour relationship, stress models, techniques for managing mood, goal setting, SMART goals and relapse prevention. The intervention will be informed by the work of Kingdon and Turkington³⁴ on CBT for psychosis. The TechCare intervention will be an add-on to treatment-as-usual (TAU), with the EIS team continuing the routine care of each

participant, which involves case management, medical treatment and crisis planning. In addition, the RA will visit the participant on a weekly basis.

Experiential sampling methodology

Experiential sampling methodology (ESM) is a structured methodology, with the capacity to examine the context and natural flow of daily occurrences in people's lives. This is achieved by the real-time assessments of thoughts, feelings and events which are prompted at regular intervals within a day, typically via an electronic device (e.g. smartphone app). ESM has been used in psychosis with the aim of constructing an understanding of individual's psychotic symptoms and the aetiological underpinnings of psychosis.³⁵ ESM for psychosis has also been validated by Palmier-Claus et al.,¹¹ which resulted in the development of the ClinTouch smartphone application. The ClinTouch system developed by Palmier-Claus et al.¹¹ is a novel mobile assessment application, which uses ESM technology to assess individual's symptoms of psychosis. Based on this feasibility work, which reported that the ClinTouch system was safe, feasible and acceptable for individuals with psychosis, the ClinTouch team have furthered this work through the development of 'CareLoop' which is a digital clinical system looking at long-term symptom monitoring of SMIs and is guided by qualitative input from service users and health professionals.³⁶ The system prompts service users to respond to a number of structured questions about their symptoms. The key advantage of the system is that the data gathered is recorded in real time on a database, which is useful in monitoring symptoms and potentially allowing for warning signs to be highlighted to the team without delay.

Intelligent real-time therapy

There is a relatively large amount of research which suggests the efficacy of the use of mobile technologies to collect the longitudinal data on individual's symptoms and views of their illness.³⁷ However, there is little research suggesting the use of mobile devices to deliver psychological interventions.³⁸ One such concept which can be considered is called intelligent real-time therapy (iRTT). This conceptual model outlines the use of mobile technologies to deliver interventions for mental health problems. This system goes beyond the momentary assessment of symptoms, by also providing service users with a remotely delivered psychological intervention such as CBT to help reduce the distress being experienced due to their symptoms.²⁶

The proposed TechCare App will use a combination of ESM and iRTT. The system will also use differing iRTT media formats to convey user-preferred video messages, recordings, text messages, poems and images, providing an interactive interface for service users to engage with and possibly provide better engagement with health professionals.

Strand 1: qualitative component

1. *In-depth interviews.* A total of 16 service users who consent to take part in the study will be asked to take part in semi-structured interviews, in order to obtain insight into the experience of the TechCare intervention. The semi-structured interviews with the participants will be digitally recorded and will be transcribed verbatim.
2. *Focus group.* We will conduct two focus groups with 8–10 health professionals (e.g. nurses, psychologists, psychiatrists and social workers) who work with service users who experience psychosis. The focus groups will also be digitally recorded and transcribed verbatim. We will look to explore the health professional's views on the intervention and possible areas which may need to be refined in preparation for strands 2 and 3.

Strand 2: test run and intervention refinement

In this phase, we will conduct a test run of the TechCare intervention which will last for duration of 2 weeks, with a small group of four participants who will be recruited from Lancashire Care EIS. This will allow us to preliminarily test the intervention. We will gather feedback from the participating individuals, therapists and the clinical staff (psychiatrist/care coordinators) on the relevance and acceptability of the TechCare approach. This will inform the further refinement of the intervention to the local context and how best to run the TechCare intervention in the feasibility trial. We will undertake semi-structured, one-to-one interviews with all participants in the test run to obtain their opinions on the intervention, its feasibility, acceptability, impact on their lives and their thoughts about the role of the intervention in reducing symptoms of psychosis. All interviews and focus groups will be carried out by one member of the research team (N.G.); these interviews will be digitally recorded and subsequently transcribed.

The interview schedule will include pre-determined questions (based on findings from strand 1) but will also include open-ended questions to facilitate emergence of new themes. We will investigate the acceptability of the treatment through addressing themes such as participant's expectations of the intervention, factors associated with therapeutic alliance, its relevance to their psychotic symptoms, problems and social circumstances, their experience of the delivery method, what they found helpful or less helpful and potential changes that could be made to improve their overall experience of the TechCare intervention.

Refinement. The team will collate the quantitative data and qualitative data from this strand and work with the software development team to refine the intervention and delivery of the TechCare intervention.

Strand 3: feasibility trial

A total of 12 service users will be recruited from the Lancashire EIS for the feasibility trial. Each client's care coordinator will play a key role in the development of individualised tier 1 psychological interventions.

Outcome measures

PANSS (for schizophrenia).³⁹ This is a clinician administered 30-item semi-structured interview which provides balanced representation of positive symptoms and negative symptoms over a 2-week period and gauges their relationship to one another and to global/general psychopathology. The use of PANSS in mHealth interventions has been validated by Palmier-Claus et al.¹¹ through the ClinTouch application.

The Psychotic Symptom Rating Scales (PSYRATS).⁴⁰ The PSYRATS is a semi-structured interview, measuring dimensions of delusions and hallucinations. The instrument has been validated against the PANSS by Drake et al.⁴¹

CHOICE of Outcome In Cbt for psychosEs (CHOICE).⁴² This is an outcome measure which reflects the aims of CBT for psychosis and the priorities of service users. It was developed with service users, and this shortened version is being utilised in the National IAPT for psychosis programme. Lancashire Care EIS is one of two national demonstration sites for the programme in the United Kingdom.

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS).⁴³ The WEMWBS is a measure of mental well-being, which focuses entirely on positive aspects of mental health. It consists of 14 items on one page, is quick to administer and is psychometrically robust.⁴⁴ It is also a core measure with the IAPT for psychosis project and will measure improvements in positive aspects of mental health, as a result of the TechCare mobile application.

Brief Core Schema Scales (BCSS).⁴⁵ This is a 24-item measure of core beliefs regarding self and others. Four scores are obtained; negative self, positive self, negative others and positive others. Fowler et al.⁴⁵ found the BCSS to have good psychometric properties.

Calgary Depression Scale (CDS).⁴⁶ The CDS was developed to measure the level of depression in schizophrenia. It is a 9-item scale which allows for the quantitative and subjective dimensions of depression in schizophrenia; items are scored on a scale of 0–4 with a minimum score of 0 and maximum score of 27 for an assessment. The CDS is psychometrically robust and has been validated against the Hamilton Depression Scale.⁴⁷

The Work and Social Adjustment Scale (WSAS).⁴⁸ This is a 5-item measure of perceived impairment in five areas:

work, home management, social life, private leisure and relationships. Each item is scored from 0 (no impairment) to 8 (very severe impairment) with a total score of 40.

EuroQoL-5 Dimensions (EQ5-D). Health-related quality of life will be measured using the EuroQoL-5 Dimensions (EQ-5D);⁴⁹ the measure is a standardised instrument looking at quality of life across five health domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The measure has been widely used in psychosis research.

TechCare application assessment questions

A range of unusual or paranoid beliefs are reported by individuals with psychosis. The TechCare App will be equipped with a 'delusions' and 'mood' menu in the setup section (adapted from Palmier-Claus et al.¹¹), where the researcher or case manager can personalise which delusions the participant is currently experiencing based on the initial PANSS interview and other self-report questionnaires. This delusional belief will be the basis for TechCare questions asked and scored for level of preoccupation, distress and impact on behaviour. Up to two personalised delusions can be entered for each person. For those with more, the delusions with greatest conviction and distress rating will be utilised. We will also include items from the Calgary Depression Scale to assess mood. Depending on the threshold of response, the assessment question will trigger the intervention screen for that specific difficulty. The intervention screen will display a list of personalised self-help interventions such as thought–feeling–behaviour relationships, stress models, techniques for managing mood and goal setting, which will be informed by the work of Kingdon and Turkington³⁴ on CBT for psychosis and participant tailored iRTT media (music, images and video clips) (see Figure 1). In this feasibility study, the personalised self-help interventions will be available to participants at all times in response to the symptoms reported. The TechCare self-help intervention is designed only to test the intervention to address symptoms of low mood and paranoia, with all responses made by the participant being recorded in real time through the App. The participants will also be able to access some materials on psychoeducation³⁴ and also some other helpful links, along with the routine EIS treatment which includes a crisis plan.

The TechCare App ESM and iRTT system will utilise intelligence at two levels:

1. Intelligently increasing the frequency of assessment notifications if low mood/paranoia is detected. This will be done through feedback loops which monitor symptoms over time, with the deployment of a personalised crisis plan, if prolonged duration of low mood/paranoia is detected (≈ 4 h).

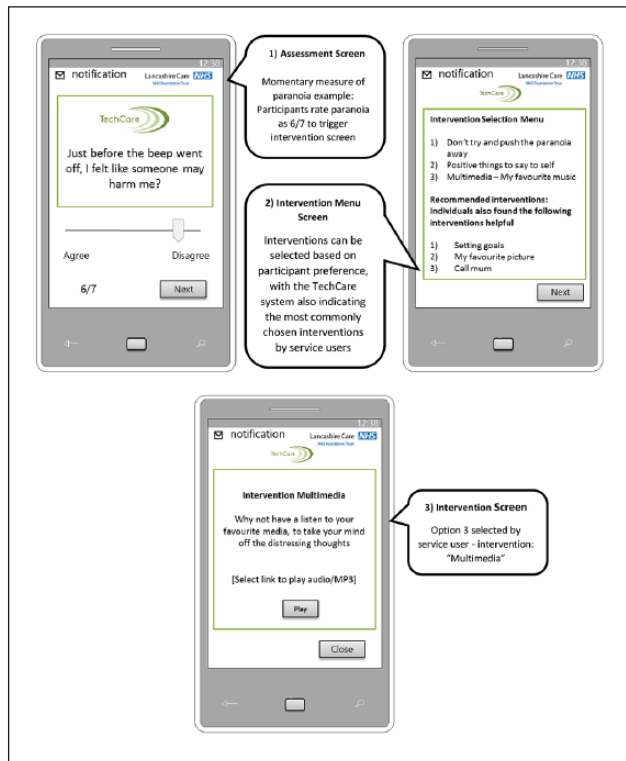


Figure 1. An example of ESM and iRTT in the TechCare App.

2. An intelligent machine learning algorithm which provides interventions in real time based on breach of assessment thresholds and also provides recommendations on the most popular interventions. Recommendations will be based on most selected interventions by the cohort of participants on the study, with the most popular listed interventions in rank order.

A total of three notifications will be sent between 10 a.m. and 10 p.m. If low mood/paranoia is detected by the App, it will re-notify the participant every 60 min to assess symptoms in real time with personalised interventions being displayed to participants. The system will re-notify participants a total of three times with an agreed crisis response being displayed on the App if low mood/paranoia is detected for a prolonged duration of time (a period of ≈ 4 h). Crisis planning is a routine part of EIS treatment with all service users working with their health professionals to agree a plan of action which they can follow if they are in crisis. The crisis plan will also be displayed via the TechCare App. The crisis response will consist of an agreed plan of action in the case participants are in distress due to their symptoms and will also prompt the participant to contact the EIS service or an agreed designated contact. In the feasibility context, we will examine response rates to questions and notifications and also the participant's selection of the intervention. The researcher and case manager will be able to view participant

responses and selection of interventions by the participant over the intervention period; this data will hold important insights into the feasibility of the intervention.

Adverse event reporting

The research team will adhere to principles of Good Clinical Practice in reporting adverse events.⁵⁰ The adverse events in digital interventions are generally not well reported, as we have described previously.⁵¹ Monitoring of any serious adverse events (SAEs) will be carried out throughout the study. The PI N.H. will be directly notified of all adverse events, with all SAEs being reported to the NHS Research Ethics Committee (REC). In the light of the limited literature on adverse events in digital technology,^{51,52} we will explore these further through the strand 1 qualitative interviews and the data on the side effects such as worsening of symptoms and/or mood which will be assessed at the weekly review assessment and will be reported to the case manager.

Results

The trial is currently ongoing, and we have completed two focus groups with health professionals and some qualitative interviews with participants, who are participating in the strand 2: test run and intervention refinement component.

Proposed analysis strategy

Quantitative data analysis. All analyses will be conducted using SPSS v20, with preliminary analysis, being conducted where appropriate. We will compare baseline and post-intervention scores on the primary and secondary outcome measures. In the feasibility context, we aim to test our hypothesis that TechCare does not lead to poorer outcomes, that is, that the post-intervention scores are at least no worse than at pre-test.

Qualitative data analysis. Once the interviews and focus groups have been completed, these will be fully transcribed in order to be analysed. We will look for themes emerging in areas of feasibility, acceptability and further development. All of these aspects will provide insight to develop the intervention further and test in a future RCT. The qualitative data will be analysed using a framework analysis.⁵³ We will analyse each individual transcript by identifying and highlighting portions or sections of the data relating to important or emerging themes. We will then compare and contrast these themes from across transcripts to find common ones and then combine similar themes into more general themes and sub-themes taking into account data from the whole data set. The data in its original textual context will then be placed under the headings and subheadings of the themes and sub-themes and will be used to form a conceptual framework. The process of framework analysis will be ongoing throughout the data

collection period. Any discrepancies will be resolved through discussion within the research team, with the final themes and findings being read for congruence and reliability.⁵⁴

Discussion/conclusion

Technology is increasing at an exponential rate with digital technologies providing a key platform for the delivery of improved health outcomes. The proposed research is a feasibility project, which aims to examine the feasibility and acceptability of the TechCare intervention. The intervention is based on sound theory derived from earlier research.^{10,25,26} We have also closely followed the guidance by the National Institute of Health Research²⁹ in designing feasibility studies to test the vital parameters which will inform the design of a definitive trial.

Rees and Stone⁵⁵ found that clinical psychologists rated therapeutic alliance lower in the videoconferencing condition than the face-to-face intervention. This shows that therapeutic alliance may be lesser developed within mHealth interventions than face-to-face intervention, which could have a negative impact on treatment. However, Cook and Doyle²¹ found that clients reported feeling satisfied with the therapeutic alliance within an online therapy intervention. Moreover, the TechCare intervention has the potential to overcome some of these criticisms as it intertwines mHealth with existing therapeutic relationships (client's relationships with their care team), potentially enhancing rather than limiting the therapeutic capacity of the relationship. The mHealth intervention will have other advantages which can offset the disadvantage due to lack of face-to-face contact. The availability of the intervention at all times in contrast to limited time with the therapist and the flexibility in the use of the intervention are potential advantages. Furthermore, a study by Lester et al.¹⁹ showed the importance of technology in engagement within EIS. This is important in drawing emphasis on how mHealth functions could provide continued support, but also give clients greater autonomy.

The study has been designed with a focus on implementation from the outset and has engaged with the target audience in each step of developing the intervention. The service users were involved in developing the protocol, obtaining ethics for the study and also assisted in the development of the layout and overall design of the intervention.

Acknowledgements

The team is grateful for the help and support of Ian Cheung of Lancashire Care NHS Foundation Trust and Andrew Holland of Maywoods Ltd. All authors contributed to the writing of the manuscript. The first author (N.H.) is guarantor of the article and corresponding author. Trial registration: ClinicalTrials.gov. Identifier: NCT02439619.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Ethical approval

The project has obtained ethical approval from the NRES Committee North West – Preston, REC reference: 14/NW/1192.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: N.H. and I.C. are members of The Clinical Research Group on the use of mobile technology in mental health and have received funding from Lancashire Care NHS Foundation Trust, UK, to develop an intervention for early psychosis using mobile technology. N.G. gratefully acknowledges the support and funding of his PhD Studentship with the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC), North West Coast, UK. C.D.J.T. gratefully acknowledges the support of the National Institute of Health Research (NIHR), Research Fellowship Award (DRF-2012-05-211). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Informed consent

Written informed consent will be obtained from all subjects before participation in the study.

References

1. Bhugra D. *No health without public mental health: the case for action* (Position statement PS4/2010). Royal College of Psychiatrists, 2010, <http://www.rcpsych.ac.uk/pdf/Position%20Statement%204%20website.pdf>
2. McCrone P. *Paying the price: the cost of mental health care in England to 2026*, 2008, http://www.kingsfund.org.uk/sites/files/kf/Paying-the-Price-the-cost-of-mental-health-care-England-2026-McCrone-Dhanasiri-Patel-Knapp-Lawton-Smith-Kings-Fund-May-2008_0.pdf
3. Kessler RC, Amminger GP, Aguilar-Gaxiola S, et al. Age of onset of mental disorders: a review of recent literature. *Curr Opin Psychiatry* 2007; 20(4): 359–364.
4. Van Os J, Linscott RJ, Myin-Germeys I, et al. A systematic review and meta-analysis of the psychosis continuum: evidence for a psychosis proneness-persistence-impairment model of psychotic disorder. *Psychol Med* 2009; 39(2): 179–195.
5. Keshavan MS, DeLisi LE and Seidman LJ. Early and broadly defined psychosis risk mental states. *Schizophr Res* 2011; 126(1–3): 1–10.
6. Jolley S, Garety P, Peters E, et al. Opportunities and challenges in Improving Access to Psychological Therapies for people with Severe Mental Illness (IAPT-SMI): evaluating the first operational year of the South London and Maudsley (SLaM) demonstration site for psychosis. *Behav Res Ther* 2015; 64: 24–30.
7. Kuipers E. Cognitive behavioural therapy and family intervention for psychosis – evidence-based but unavailable? The next steps. *Psychoanal Psychother* 2011; 25(1): 69–74.
8. Kay M, Santos J and Takane M. *mHealth: new horizons for health through mobile technologies*. Geneva: World Health Organization, 2011, pp. 66–71.
9. The Office of Communication UK. Facts & figures, <http://media.ofcom.org.uk/facts/> (accessed 24 May 2016).

10. Granholm E, Ben-Zeev D, Link PC, et al. Mobile Assessment and Treatment for Schizophrenia (MATS): a pilot trial of an interactive text-messaging intervention for medication adherence, socialization, and auditory hallucinations. *Schizophr Bull* 2012; 38: 414–425.
11. Palmier-Claus J, Ainsworth J, Machin M, et al. The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. *BMC Psychiatr* 2012; 12(1): 172.
12. Bucci S, Barrowclough C, Ainsworth J, et al. Using mobile technology to deliver a cognitive behaviour therapy-informed intervention in early psychosis (Actissist): study protocol for a randomised controlled trial. *Trials* 2015; 16(1): 404.
13. Ben-Zeev D, Brenner CJ, Begale M, et al. Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. *Schizophr Bull*. Epub ahead of print 8 March 2014. DOI: 10.1093/schbul/sbu033.
14. Nickelson DW. Telehealth and the evolving health care system: strategic opportunities for professional psychology. *Prof Psychol: Res Pr* 1998; 29(6): 527–535.
15. Weinstein RS, Lopez AM, Joseph BA, et al. Telemedicine, telehealth, and mobile health applications that work: opportunities and barriers. *Am J Med* 2014; 127(3): 183–187.
16. Henderson C, Knapp M, Fernández JL, et al. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. *BMJ* 2013; 346: f1035.
17. Hebert MA, Korabek B and Scott RE. Moving research into practice: a decision framework for integrating home telehealth into chronic illness care. *Int J Med Inform* 2006; 75(12): 786–794.
18. Barak A, Hen L, Boniel-Nissim M, et al. A comprehensive review and a meta-analysis of the effectiveness of Internet-based psychotherapeutic interventions. *J Tech Hum Serv* 2008; 26(2–4): 109–160.
19. Lester H, Marshall M, Jones P, et al. Views of young people in early intervention services for first-episode psychosis in England. *Psychiatr Serv* 2010; 62(8): 882–887.
20. Rotondi AJ, Haas GL, Anderson CM, et al. A clinical trial to test the feasibility of a telehealth psychoeducational intervention for person with schizophrenia and their families: intervention and 3-month findings. *Rehabil Psychol* 2005; 50(4): 325–336.
21. Cook JE and Doyle C. Working alliance in online therapy as compared to face-to-face therapy: preliminary results. *Cyberpsychol Behav* 2002; 5(2): 95–105.
22. Mallen MJ, Day SX and Green MA. Online versus face-to-face conversations: an examination of relational and discourse variables. *Psychother: Theor Res* 2003; 40(1–2): 155–163.
23. Horvath AO, Del Re AC, Flückiger C, et al. Alliance in individual psychotherapy. *Psychotherapy* 2011; 48(1): 9.
24. Alvarez-Jimenez M, Alcazar-Corcoles MA, Gonzalez-Blanch C, et al. Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. *Schizophr Res* 2014; 156(1): 96–106.
25. Depp CA, Mausbach B, Granholm E, et al. Mobile interventions for severe mental illness: design and preliminary data from three approaches. *J Nerv Ment Dis* 2010; 198(10): 715–772.
26. Kelly J, Gooding P, Pratt D, et al. Intelligent real-time therapy: harnessing the power of machine learning to optimise the delivery of momentary cognitive-behavioural interventions. *J Ment Health* 2012; 21(4): 404–414.
27. Hollis C, Morris R, Martin J, et al. Technological innovations in mental healthcare: harnessing the digital revolution. *Br J Psychiatry* 2015; 206(4): 263–265.
28. Medical Research Council (MRC). *A framework for the development and evaluation of RCTs for complex interventions to improve health*. London: MRC, 2000.
29. NETSCC definition of pilot and feasibility studies, <http://www.netscc.ac.uk/glossary/> (accessed 24 May 2016).
30. McCrone P, Craig TKJ, Power P, et al. Cost-effectiveness of an early intervention service for people with psychosis. *Br J Psychiatry* 2010; 196: 377–382.
31. Craig TKJ, Garety P, Power P, et al. The Lambeth Early Onset (LEO) Team: randomised controlled trial of the effectiveness of specialised care for early psychosis. *BMJ* 2004; 329: 1067.
32. Wykes T, Steel C, Everitt B, et al. Cognitive behavior therapy for schizophrenia: effect sizes, clinical models, and methodological rigor. *Schizophr Bull* 2008; 34(3): 523–537.
33. Kuipers E, Yesufu-Udechuku A, Taylor C, et al. Management of psychosis and schizophrenia in adults: summary of updated NICE guidance. *BMJ* 2014; 348: g1173.
34. Kingdon DG and Turkington D. *Cognitive-behavioral therapy of schizophrenia*. New York: Guilford Press, 1994.
35. Myin-Germeys I, Peeters FPML, Havermans R, et al. Emotional reactivity to daily life stress in psychosis and affective disorder: an experience sampling study. *Acta Psychiatr Scand* 2003; 107(2): 124–131.
36. Centre for Health Informatics, The University of Manchester. CareLoop, <http://www.population-health.manchester.ac.uk/healthinformatics/research/Careloop> (accessed 24 May 2016).
37. Granholm E, Loh C and Swendsen J. Feasibility and validity of computerized ecological momentary assessment in schizophrenia. *Schizophr Bull* 2008; 34(3): 507–514.
38. Španiel F, Vohlídka P, Hrdlička J, et al. ITAREPS: information technology aided relapse prevention programme in schizophrenia. *Schizophr Res* 2008; 98(1): 312–317.
39. Kay SR, Fiszbein A, Opler LA, et al. The Positive and Negative Syndrome Scale (PANSS) for schizophrenia. *Schizophr Bull* 1987; 13(2): 261–276.
40. Haddock G, McCarron J, Tarrier N, et al. Scales to measure dimensions of hallucinations and delusions: the psychotic symptom rating scales (PSYRATS). *Psychol Med* 1999; 29(4): 879–889.
41. Drake R, Haddock G, Tarrier N, et al. The Psychotic Symptom Rating Scales (PSYRATS): their usefulness and properties in first episode psychosis. *Schizophr Res* 2007; 89(1): 119–122.
42. Greenwood KE, Sweeney A, Williams S, et al. CHOICE of Outcome In Cbt for psychoses (CHOICE): the development of a new service user-led outcome measure of CBT for psychosis. *Schizophr Bull* 2010; 36(1): 126–135.
43. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007; 5(1): 63.
44. Stewart-Brown S, Tennant A, Tennant R, et al. Internal construct validity of the Warwick-Edinburgh mental well-being scale (WEMWBS): a Rasch analysis using data from the

- Scottish health education population survey. *Health Qual Life Outcomes* 2009; 7(1): 15–22.
45. Fowler D, Freeman D, Smith B, et al. The Brief Core Schema Scales (BCSS): psychometric properties and associations with paranoia and grandiosity in non-clinical and psychosis samples. *Psychol Med* 2006; 36(6): 749–759.
 46. Addington D, Addington J and Schissel B. A depression rating scale for schizophrenics. *Schizophr Res* 1990; 3(4): 247–251.
 47. Schennach R, Obermeier M, Seemüller F, et al. Evaluating depressive symptoms in schizophrenia: a psychometric comparison of the Calgary Depression Scale for Schizophrenia and the Hamilton Depression Rating Scale. *Psychopathology* 2012; 45(5): 276–285.
 48. Mundt JC, Marks IM, Shear MK, et al. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002; 180(5): 461–464.
 49. Sobocki P, Ekman M, Ågren H, et al. Health-related quality of life measured with EQ-5D in patients treated for depression in primary care. *Value Health* 2007; 10(2): 153–160.
 50. National Institute of Health Research. *Good Clinical Practice (GCP) pocket guide*, <https://drive.google.com/file/d/0B-EwP8Oxl7jdM005QS0wMIRJZ3c/view> (2014, accessed 13 July 2015).
 51. Naeem F, Gire N, Xiang S, et al. Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: an update. *World J Psychiatry* 2016; 6(2): 187–191.
 52. Marley J and Farooq S. Mobile telephone apps in mental health practice: uses, opportunities and challenges. *BJPsych Bull* 2015; 39(6): 288–290.
 53. Ritchie J, Spencer L, Bryman A, et al. *Analysing qualitative data*, vol. 3. London: Routledge, 1994.
 54. Srivastava A and Thomson SB. Framework analysis: a qualitative methodology for applied policy research. *J Publ Admin Govern* 2009; 4(2): 72–79.
 55. Rees CS and Stone S. Therapeutic alliance in face-to-face versus videoconferenced psychotherapy. *Prof Psychol: Res Pr* 2005; 36(6): 649–653.

Appendix 4: Reporting and understanding the safety and adverse effect profile of mobile Apps for psychosocial interventions: an update

Reference:

Naeem, F., Gire, N., Xiang, S., Yang, M., Syed, Y., Shokrane, F., ... & Farooq, S. (2016). Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: an update. *World journal of psychiatry*, 6(2), 187.

Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: An update

Farooq Naeem, Nadeem Gire, Shuo Xiang, Megan Yang, Yumeen Syed, Farhad Shokraneh, Clive Adams, Saeed Farooq

Farooq Naeem, Shuo Xiang, Megan Yang, Department of Psychiatry, Queens University, Kingston, ON K7L 3N6, Canada

Farooq Naeem, Addiction and Mental Health Services - Kingston, Frontenac, Lennox and Addington, Kingston, ON K7L 1B9, Canada

Nadeem Gire, School of Psychology, University of Central Lancashire, Preston, Lancashire PR1 2HE, United Kingdom

Yumeen Syed, Trenlogic, Toronto, ON M2N 6S6, Canada

Farhad Shokraneh, Clive Adams, Cochrane Schizophrenia Group, Nottingham University, Nottingham NG7 2QL, United Kingdom

Saeed Farooq, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire ST5 5BG, United Kingdom

Author contributions: Naeem F conceived the idea; Gire N helped with literature search on side effects of therapy and manuscript; Xiang S and Yang M helped with search of literature on side effects of internet and app use; Syed Y helped with security issues; Shokraneh F helped with the overall script; Adams C and Farooq S provided overall support and organized multiple discussions that lead to this paper.

Conflict-of-interest statement: The authors have no conflict of interest to declare.

Open-Access: This article is an open-access article which was selected by an in-house editor and fully peer-reviewed by external reviewers. It is distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

Manuscript source: Invited manuscript

Correspondence to: Farooq Naeem, Professor, Addiction and Mental Health Services - Kingston, Frontenac, Lennox and Addington, 385 Princess Street, Kingston, ON K7L 1B9, Canada. farooqnaeem@yahoo.com
Telephone: +1-613-5441356
Fax: +1-613-5442346

Received: February 3, 2016

Peer-review started: February 14, 2016

First decision: March 25, 2016

Revised: May 10, 2016

Accepted: May 31, 2016

Article in press: June 2, 2016

Published online: June 22, 2016

Abstract

Recent years have seen a rapidly increasing trend towards the delivery of health technology through mobile devices. Smartphones and tablet devices are thus becoming increasingly popular for accessing information and a wide range of services, including health care services. Modern mobile apps can be used for a variety of reasons, ranging from education for the patients and assistance to clinicians to delivery of interventions. Mobile phone apps have also been established to benefit patients in a scope of interventions across numerous medical specialties and treatment modalities. Medical apps have their advantages and disadvantages. It is important that clinicians have access to knowledge to make decisions regarding the use of medical apps on the basis of risk-benefit ratio. Mobile apps that deliver psycho social interventions offer unique challenges and opportunities. A number of reviews have highlighted the potential use of such apps. There is a need to

describe, report and study their side effects too. The adverse effects associated with these apps can broadly be divided into: (1) those resulting from the security and safety concerns; (2) those arising from the use of a particular psycho social intervention; and (3) those due to the interaction with digital technology. There is a need to refine and reconsider the safety and adverse effects in this area. The safety profile of a mobile PSI app should describe its safety profile in: (1) privacy and security; (2) adverse effects of psychotherapy; and (3) adverse effects unique to the use of apps and the internet. This is, however, a very new area and further research and reporting is required to inform clinical decision making.

Key words: Mobile; Psycho social; Side effects; Health; Media; Security; Privacy

© **The Author(s) 2016.** Published by Baishideng Publishing Group Inc. All rights reserved.

Core tip: Mobile apps offer unique opportunities and risks when used for delivering psychosocial interventions. While there is some evidence to inform clinicians and patients of the efficacy of these apps, only limited information is available on their risk profiles. The side effects of mobile psychosocial apps might be due to the privacy and security issues, side effects of a particular therapy that is being delivered or due to the use of excessive use of internet or the apps. There is a need for clinicians and patients to report the side effects in these areas.

Naeem F, Gire N, Xiang S, Yang M, Syed Y, Shokrane F, Adams C, Farooq S. Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: An update. *World J Psychiatr* 2016; 6(2): 187-191 Available from: URL: <http://www.wjgnet.com/2220-3206/full/v6/i2/187.htm> DOI: <http://dx.doi.org/10.5498/wjp.v6.i2.187>

INTRODUCTION

Recent advances in mobile devices and faster Internet connectivity of these devices has led to a new era in health technology. Smartphones and tablet devices are thus becoming increasingly popular for accessing information and a wide range of services, including health care services. Modern mobile phones offer stable and versatile platforms that allow delivery of a variety of services. Mobile apps can support a variety of routine medical tasks, ranging from education and assistance to clinicians to helping and supporting the patients. These apps have also been established to benefit patients by providing a range of interventions across most medical specialties. Medical apps are used by clinicians to access medical knowledge. All these mobile apps have their advantages and disadvantages. In this article, we will only focus on the mobile apps that are

used for delivering psychosocial interventions. A mobile psychosocial intervention (mPSI) app means a software used on a mobile platform to deliver a psychosocial intervention. These will include apps such as Breathe and Relax, PTSD Coach and the Big White Wall.

As with many interventions, the decision to use a mobile app in a particular clinical situation should be dependent on clinician perceived risk-benefit ratio. These decisions require health care professionals to have a good understanding of the intended benefits, limitations and risks of the medical apps in order to make an informed app usage decision. We have recently argued that providing accurate information in easy to understand language about development and initial testing should be an essential part of the mPSI app^[1]. This information will help both patients and clinicians in making informed decisions. We have also suggested that the risks and adverse effects of psychosocial interventions are an important part of a description of the maps^[1]. It is important that the person using these apps is fully aware of the safety profile and adverse effects of these apps. This is especially important within persons suffering from mental illness, as they may be more vulnerable to the adverse effects from these apps compared to the general population. The adverse effects associated with these apps can broadly be divided into: (1) those resulting from the security and safety concerns; (2) those arising from the use of a particular psychosocial intervention; and (3) those due to the interaction with digital technology. Most writers in this area have focused on security and privacy, an understandable concern^[2-4]. We will briefly describe these here. Other adverse effects such as those resulting from the interaction with these devices have received little attention and will be described in more details^[5].

SECURITY AND PRIVACY ISSUES

When conducting any form of health research, it is imperative for researchers to follow the principles set out by the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects^[6]. These guidelines ensure the safety of participants, the right by participants to withdraw from the study, recruitment of participant's security, privacy and confidentiality.

Mobile applications with a low level of security or privacy can cause serious issues, and can have severe implications for users and organizations alike. But can the mobile environment ever be considered secure? Past security incidents including vulnerabilities found in well-known mobile apps and malware attacks on mobile platforms suggest that the mobile environment is far from secure despite advances in security measures in cyberspace^[4]. Rapid growth of mobile devices with position sensors has made Location-based Services readily accessible. These mobile devices send user's

location information to the third party location servers, which can be accessed by other service providers. Those aware of this, might feel continuously tracked^[3]. This might have serious implications for most persons suffering from any psychiatric disorders with increased anxiety and paranoia.

Perera^[7] described a number of safeguards which can be used to ensure data security on mobile devices. To ensure protection mobile devices should be accessible *via* a pin; it is recommended that rather than a four digit pin an alphanumeric passcode is used. In addition, functionality, whereby data is wiped from the device after 10 failed passcode attempts would further protect data^[7]. Furthermore, encryption of mobile devices, enabling remote wiping of data held on the device and storing data in the cloud instead of the mobile device are key strategies in ensuring data security^[7].

Another factor which needs considering is the number of notifications and alerts which are programmed into mPSI apps. Firstly, the notification iconography may need to be discreet/private as not to cause any distress to participants in the case of someone accidentally viewing the icon; this may infer the individual is undergoing therapy and may be stigmatizing. Individuals should be given control in the use of the mobile device, and it should not be seen as an intrusion into their daily life.

Lewis *et al.*^[2] suggest that these risk factors can be broken down into internal and external risk factors. Although internal risk factors may be reduced through appropriate regulation, external risk factors can only be eliminated through proper training and education. The same authors have also suggested a two-dimensional "app-space" where an app can be located depending on a variety of factors. The authors suggest that based on combined chances of harm and complexity, an app will fall into one of four categories: (1) requiring only local inspection; (2) requiring a more formal risk assessment; (3) requiring professional review of a full profile; and (4) those requiring formal regulation and review by governmental bodies such as the United States Food and Drug Administration Agency due to their high probability of causing harm". In a recent opinion paper^[1], we have reported that the mPSI apps can be divided into three types: (1) type 1, intervention delivered by a human therapist through eMedia (*e.g.*, telephone-delivered problem solving by a therapist, Avatar Therapy); (2) type 2, intervention based on a manualized, well-established therapy delivered through eMedia (*e.g.*, CBT delivered from a website that is based on a manual); and (3) type 3, a new intervention that did not exist before, and is not based on previous theory or on therapeutic principles (*e.g.*, electronic dispensing). These criteria need a further definition that relates to the risks attached.

ADVERSE EFFECTS DUE TO PSYCHOSOCIAL INTERVENTIONS

Since a classic paper of Bergin^[8] on the description of

the possibility of a psychological treatment producing negative effects, clinicians and researchers had low interest in this area^[9]. This is a re-emerging area and research has just started in this area. But it has been estimated that between 3% and 15% of the recipients experience unwanted effects. These rates are similar to those of pharmacotherapy^[10]. There are only a few reported studies comparing the adverse effects of psychosocial interventions, for example, Klingberg *et al.*^[11] reported an RCT, which compared CBT for psychosis with Cognitive Remediation Therapy. Both groups experienced nearly the equal adverse effects. Lambert *et al.*^[12] has suggested that between 5% and 10% of all patients undergoing psychotherapy deteriorate.

Recently, the need for expanded monitoring of negative effects in clinical trials of psychotherapy has been discussed, resulting in different suggestions on how to define and measure the negative effects. Linden^[10] presented a comprehensive checklist dividing negative effects into different categories. These include: (1) deterioration; (2) adverse events; (3) severe adverse events; (4) novel symptoms; (5) dropout; (6) nonresponse; (7) unwanted events; and (8) suicide attempts and deaths by unnatural means.

ADVERSE EFFECTS UNIQUE TO APPS AND INTERNET USE

There are a number of adverse effects that are unique to the use of mobile apps and the internet. These include reduced face to face communication which probably can result in inadequate social skills (however, it can be argued that future generations might not need social skills as we know these). This is particularly important as most psychotherapeutic interventions aim to enhance communication and social skills. The "virtual" interactions may result in reduced problem-solving skills in the real world. There are also possible adverse effects of using the internet for increased periods which can contribute to increased levels of inactivity and sedentary behaviors which have been reported to increase the risk of obesity^[13].

Information overload (or worse still inappropriate information) can lead to cognitive problems. Similarly, insomnia, depression and anxiety are common among heavy net users^[14]. It is important that these factors are highlighted due to the way individuals are using apps and the internet, but also due to the increasing availability of internet on mobile devices.

One of the key adverse effects of the internet is internet addiction, with a study by Boysan *et al.*^[15] in the United Kingdom reporting that out of 2257 university students 3.2% were addicted to the internet. Furthermore, Ko *et al.*^[14] suggested the heightened comorbidity of psychiatric disorders and internet addiction, with more research needed to better understand this phenomenon. Another possible adverse effect of internet usage is the potential for online sexual

grooming and exploitation of children, due to factors such as anonymity which may provide an environment for perpetrators to engage in sexually motivated behaviours^[16].

More specific to the area of apps, mobile devices which run mPSI apps produce electromagnetic fields which have been suggested as being carcinogenic by the World Health Organisation (WHO) with the WHO conducting a formal risk assessment of this potential adverse reaction, due 2016^[17]. Furthermore, it has also been found that another possible adverse effect of apps is high frequency usage. A study by Thomée *et al*^[18] found an increased risk factor for mental health outcomes in young adults with high frequency use associated with stress, sleep disturbances and symptoms of depression at one-year follow up. In addition, there has also been research suggesting increased risk of ocular problems, with viewing mobile phone screens causing eye strain^[19]. Other complications have also been found in relation to viewing mobile device screens, with Wood *et al*^[20] reporting that exposure to self-luminous screens on mobile devices have the potential to increase the likelihood of sleep disorders due to factors such as melatonin suppression, particularly in the blue light spectrum. It is also important that individuals feel no pressure in replying to the mPSI app notifications and alerts, as there may be a risk of increasing paranoia and anxiety.

It is important that these adverse effects are systematically observed, and data are recorded in any psychosocial intervention studies. This will require both qualitative and quantitative studies. The qualitative studies will help us to understand patient experience, which has rarely been studied in psychosocial interventions using mobile apps. Furthermore, adverse effects should be reported to regulatory bodies such as the FDA and MHRA. Naeem *et al*^[1] proposed a framework for understanding that mPSI apps use lessons learned by the pharmaceutical industry to ensure the safety of mPSI apps through rigorous testing and evaluation.

CONCLUSION

There is a need to refine and reconsider the safety and adverse effects in this area. The use of mPSI interventions offers unique opportunities and risks. The safety profile of a mobile PSI app should describe its safety profile in: (1) privacy and security; (2) adverse effects of psychotherapy; and (3) adverse effects unique to the use of apps and the internet.

REFERENCES

1 Naeem F, Syed Y, Xiang S, Shokraneh F, Munshi T, Yang M, Adams C, Farooq S. Development, Testing and Reporting of Mobile Apps for Psycho-social Interventions: Lessons from the

Pharmaceuticals. *J Med Diagn Methods* 2015; **4**: 4 [DOI: 10.4172/2168-9784.1000.191]

2 Lewis TL, Wyatt JC. mHealth and mobile medical Apps: a framework to assess risk and promote safer use. *J Med Internet Res* 2014; **16**: e210 [PMID: 25223398 DOI: 10.2196/jmir.3133]

3 Patel A, Palomar E. Privacy Preservation in Location-based Mobile Applications: Research Directions. *2014 9th Int Conf Availab Reliab Secur Ares* 2015; 227-233 [DOI: 10.1109/ARES.2014.37]

4 Jain AK, Shanbhag D. Addressing Security and Privacy Risks in Mobile Applications. *IT Professional* 2012; **14**: 28-33 [DOI: 10.1109/MITP.2012.72]

5 Berk M, Parker G. The elephant on the couch: side-effects of psychotherapy. *Aust N Z J Psychiatry* 2009; **43**: 787-794 [PMID: 19670051 DOI: 10.1080/00048670903107559]

6 World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013; **310**: 2191-2194 [PMID: 24141714 DOI: 10.1001/jama.2013.281053]

7 Perera C. Principles of Security for the use of Mobile Technology in Medicine. *J Mob Technology Med* 2012; **1**: 5-7 [DOI: 10.7309/jmtm10]

8 Bergin AE. The empirical emphasis in psychotherapy: A symposium. The effects of psychotherapy: Negative results revisited. *J Couns Psychol* 1963; **10**: 244-250 [DOI: 10.1037/h0043353]

9 Mohr DC. Negative Outcome in Psychotherapy: A Critical Review. *Clin Psychol Sci Pract* 1995; **2**: 1-27 [DOI: 10.1111/j.1468-2850.1995.tb00022.x]

10 Linden M. How to define, find and classify side effects in psychotherapy: from unwanted events to adverse treatment reactions. *Clin Psychol Psychother* 2013; **20**: 286-296 [DOI: 10.1002/cpp.1765]

11 Klingberg S, Herrlich J, Wiedemann G, Wölwer W, Meisner C, Engel C, Jakobi-Malterre UE, Buchkremer G, Wittorf A. Adverse effects of cognitive behavioral therapy and cognitive remediation in schizophrenia: results of the treatment of negative symptoms study. *J Nerv Ment Dis* 2012; **200**: 569-576 [PMID: 22759932 DOI: 10.1097/NMD.0b013e31825bfa1d]

12 Lambert MJ, Harmon C, Slade K, Whipple JL, Hawkins EJ. Providing feedback to psychotherapists on their patients' progress: clinical results and practice suggestions. *J Clin Psychol* 2005; **61**: 165-174 [PMID: 15609358 DOI: 10.1002/jclp.20113]

13 Vandelanotte C, Sugiyama T, Gardiner P, Owen N. Associations of leisure-time internet and computer use with overweight and obesity, physical activity and sedentary behaviors: cross-sectional study. *J Med Internet Res* 2009; **11**: e28 [PMID: 19666455 DOI: 10.2196/jmir.1084]

14 Ko CH, Yen JY, Yen CF, Chen CS, Chen CC. The association between Internet addiction and psychiatric disorder: a review of the literature. *Eur Psychiatry* 2012; **27**: 1-8 [PMID: 22153731 DOI: 10.1016/j.eurpsy.2010.04.011]

15 Boysan M, Kuss DJ, Barut Y, Ayköse N, Güleç M, Özdemir O. Psychometric properties of the Turkish version of the Internet Addiction Test (IAT). *Addict Behav* 2015 Sep 8; Epub ahead of print [PMID: 26421905 DOI: 10.1016/j.addbeh.2015.09.002]

16 Kloess JA, Beech AR, Harkins L. Online child sexual exploitation: prevalence, process, and offender characteristics. *Trauma Violence Abuse* 2014; **15**: 126-139 [PMID: 24608540 DOI: 10.1177/1524838013511543]

17 World Health Organization. Electromagnetic fields and public health: mobile phones. 2014. [accessed 2016 Feb 3]. Available from: URL: <http://www.who.int/mediacentre/factsheets/fs193/en/>

18 Thomée S, Härenstam A, Hagberg M. Mobile phone use and stress, sleep disturbances, and symptoms of depression among young adults--a prospective cohort study. *BMC Public Health* 2011; **11**: 66 [PMID: 21281471 DOI: 10.1186/1471-2458-11-66]

19 Acharya P, Acharya I, Waghrey D. A Study on Some of the Common Health Effects of Cell-Phones amongst College Students. *J Community Med Health Educ* 2013; **3**: 2161-0711 [DOI: 10.4172/2161-0711.1000214]

20 **Wood B**, Rea MS, Plitnick B, Figueiro MG. Light level and duration of exposure determine the impact of self-luminous tablets

on melatonin suppression. *Appl Ergon* 2013; **44**: 237-240 [PMID: 22850476 DOI: 10.1016/j.apergo.2012.07.008]

P- Reviewer: Dumitrascu D, Godoy-Izquierdo D, Roldan-Barraza C
S- Editor: Kong JX **L- Editor:** A **E- Editor:** Wu HL



Appendix 5: Early Intervention Service for Psychosis Care Pathway

Early Intervention Service - Core Offer

	NICE Summary Statement	LCFT Summary Statement
 <p>Assessment within 2 weeks</p>	<p>Early intervention in psychosis services can improve clinical outcomes, such as admission rates, symptoms and relapse, for people with a first episode of psychosis. They do this by providing a full range of evidence-based treatment including pharmacological, psychological, social, occupation and educational interventions. Treatment from these services should be accessed as soon as possible to reduce the duration of untreated psychosis.</p>	<p>We know how important rapid detection of symptoms is to allow the greatest opportunity of future recovery. In order to maximise our assessments, some of our EIS Care Coordinators are specialists in assessment have dedicated time to focus on assessment. Their focus is the first two weeks following referral to EIS, by this point they aim to make a decision whether the person who has been referred:--</p> <ul style="list-style-type: none"> Is suitable for treatment from EIS as they present with a first episode of psychosis Is suitable for support from EIS as they are presenting with an At Risk Mental State Is not suitable for treatment in EIS Has declined treatment in EIS despite being suitable Has a complex presentation so is being offering a prolonged assessment. <p>The standard for EIS is that 50% of individuals who are suitable for treatment are allocated an EIS worker in 2 weeks and provided with NICE concordant care.</p>
 <p>PSI</p>	<p>Psycho-social interventions is critical to the way Early Intervention Services support individuals who are experiencing psychosis or who are at risk of psychosis to a recovery. We use a tiered system for the delivery of CBT informed therapy meaning that the core offer comes from our EIS care coordinators with the clear offer of CBTP or CBT for ARMS from a qualified therapist.</p>	<p>Every individual provided with care by LCFT EIS will have a Master PSI Care plan which will describe the core offer from the service. This will include planned therapeutic psycho-social interventions that have been identified through the process of developing a shared formulation.</p>
 <p>Carer Education</p>	<p>Providing carer-focused education and support reduces carer burden and psychological distress, and may improve the carer's quality of life. As part of the initial process of assessment and engagement, carer-focused education and support programmes can also help carers of adults with psychosis or schizophrenia to be able to identify symptoms of concern.</p>	<p>We know that the family and friends of those who experience psychosis often feel unprepared for the role of carer. The need for a partnership approach to planning care is clear and for information to be provided at the earliest opportunity. Within our pathway, we provide a baseline assessment of carer understanding of psychosis by 4 weeks and offer psycho-education by 12 weeks. We recognise that not everybody will want the details of their illness shared with their family and friends; however this does not stop us providing general information to carers to ensure they still feel confident of how to respond to difficult situation. Providing carer education will help to reduce stress, particularly at times of crisis.</p>
 <p>Family Intervention</p>	<p>Family intervention can improve coping skills and relapse rates of adults with psychosis and schizophrenia. Family intervention should involve the person with psychosis or schizophrenia if practical, and form part of a broad-based approach that combines different treatment options tailored to the needs of individual service users.</p>	<p>We understand that all families can benefit from some time to consider how they interact together to develop their strengths, review their communication strategies and consider how they function as a family. We therefore see family intervention as core to the work of our EIS team. In order to embed FI as core we are working towards all our care coordinators being trained to provide Family Intervention. We offer Family Intervention after providing psycho-education so that families can build on their skills to allow them to support their loved one more effectively.</p>
 <p>Physical Health Assessment</p>	<p>Life expectancy for adults with psychosis or schizophrenia is between 15 and 20 years less than for people in the general population. This may be because people with psychosis or schizophrenia often have physical health problems, including cardiovascular and metabolic disorders, such as type 2 diabetes, that can be exacerbated by the use of antipsychotics. Comprehensively assessing physical health will enable health and social care practitioners to offer physical health interventions if necessary.</p>	<p>We will provide baseline physical health monitoring from the start of the journey with EIS. We will ensure that any changes, particularly weight gain, due to the prescribing of anti-psychotic medication will be proactively managed. We will provide health promotion through completion of the ReThink physical health assessment at 12 weeks and then annually. We will offer a combined healthy diet and physical exercise plan when indicated and always when an individual's BMI is above 30.</p>
 <p>Physical Health Intervention</p>	<p>Rates of obesity and type 2 diabetes in adults with psychosis or schizophrenia are higher than those for the general population. Rates of tobacco smoking are also high in people with psychosis or schizophrenia. These factors contribute to premature mortality. Offering combined healthy eating and physical activity programmes and help to stop smoking can reduce these rates and improve physical and mental health.</p>	
 <p>Medication Management</p>	<p>Adults with schizophrenia that has not responded adequately to treatment with at least 2 antipsychotic drugs are offered clozapine. Clozapine is the only drug with established efficacy in reducing symptoms and the risk of relapse for adults with treatment-resistant schizophrenia. It is licensed only for use in service users whose schizophrenia has not responded to, or who are intolerant of, conventional antipsychotic drugs.</p>	<p>The NICE guidance describes the need for those diagnosed with schizophrenia to receive effective medication and we understand this is critical. We also know that for those experiencing an episode of psychosis or where a diagnosis of schizophrenia is not suitable, all individuals working with EIS need clear, honest information about the benefits and side effects of medication. Our medics will ensure the facts about the medication options available are discussed. Whenever a medication is prescribed, this will be reviewed with one of the medical team and the individual at least every 6 months. We will ensure all service users get clear information to support their decision making. If it becomes clear that clozapine could be helpful, this will be explained and the opportunity to try this medication will be made available.</p>
 <p>CBTP</p>	<p>CBTP in conjunction with antipsychotic medication, or on its own if medication is declined, can improve outcomes such as psychotic symptoms. It should form part of a broad-based approach that combines different treatment options tailored to the needs of individual service users.</p>	<p>We provide a tiered service where our EIS care coordinators provide CBT informed care in the form of therapeutic psycho social interventions. We use this tiered model to help us understand the best time to provide CBTP. All those who are seen by the EIS can access CBTP or CBT for ARMS, the care coordinator from discussion with the service user will decide in the timing and suitability for the CBT offer and make a referral.</p>
 <p>Employment & Education Support</p>	<p>Supported employment programmes can increase employment rates in adults with psychosis or schizophrenia. It is estimated that just 5–15% of people with schizophrenia are in employment and people with severe mental illness (including psychosis and schizophrenia) are 6 to 7 times more likely to be unemployed than the general population. Unemployment can have a negative effect on the mental and physical health of adults with psychosis or schizophrenia.</p>	<p>We understand how important having a fulfilling occupation can be, this can be employment however can also include education, voluntary activities or social inclusion activities which are found valuable. We will promote a culture of positive and hopeful expectations for all who are seen by EIS to promote recovery. We will monitor the occupational status of all service users at each CPA and review the need for support to develop occupation. For all those who are unemployed and seeking work, a care plan will be initiated describing a developed offer for employment or education support. This may include referral to an external service such as Restart or Making spaces in North Lancashire. We also know that if someone is off sick, there is an increased risk of losing their job and we also see this as a critical time for intervention and will plan as above to support the individual to maintain their job.</p>

Appendix 6: TechCare Topic Guide

TechCare -Topic Guide



Introduction

Thank for agreeing to take part in this interview.

Introduce the study and aims of the interview

List some of the terms used to describe psychological/ psychosocial 'therapies' / 'treatments' / 'interventions', and ask participants which they prefer

We have asked you to be here today to help us with a project in which we are trying to design a mobile intervention for people experiencing early psychosis.

Mobile phones

How do individuals with psychosis use mobile phones?

Do they ever use cell phones? What for? Frequency?

Do they ever text messaging (Send/receive)?

Do they ever use the alarm function of your cell phone? Are you currently? For what?

If we were going to develop an application for people living with psychosis using cell phones – what sort of things do you would like to see? e.g., automatic reminders, prevention messages, medication adherence. Any preference of using your own cell phone? or a new one?

Smart phones

We are developing an application for people living with psychosis in England using smartphones (3g mobiles with internet capabilities- a mobile phone that is able to perform many of the functions of a computer, typically having a relatively large screen and an operating system capable of running general-purpose applications. (<http://oxforddictionaries.com/definition/english/smartphone>))

What sort of things should we be sure to include? (What content/information would you like to see on the smart phone? e.g., info on medications.

Which type of technology device do you want to use to discuss your mental health needs with your psychiatrist/care coordinator? Eg. Tablets Why? How about confidentiality?

What sort of things should we include? e.g., media

Internet on mobile devices

How do individuals with psychosis use the Internet on their smart phones?

Do they ever use the Internet? What for?

Do they know about any sites out there for people living with psychosis?

Do they use them?

For what?

Where do they access these?

Do they ever use E-mail? Chat? E-groups? Online support groups? Forums? Blogs?

Advantages/Disadvantages?

Which ones do you prefer?

Social networking using smartphones

How do individuals with psychosis use social networking sites (eg Facebook)?

List some of the terms used to describe psychological/ psychosocial 'therapies' /

'treatments' / 'interventions', and mobile interventions ask participants which they prefer?

The TechCare Application

Emotional support?

Email, skype, phone, CD rom, face-to-face?

How often?

Do you think that individuals with psychosis would be receptive to treatments delivered in these ways? Why do you say that?

What should be the focus of any help be?

Involving the family?

Religious or cultural practices?

Do individuals with psychosis have access to smart phones for people with early psychosis? Or mobile?

Cost?

Time?

Ask about the barriers for obtaining treatment?

For example, permission from the family?

Financial concerns?

Psychological problems?

Time? Duration of intervention? (how many responses per day/week?)

Stigma?

Lack of knowledge about disorder and treatment?

The name of the treatment? Probe on whether the name should be a medical name or a non-medical name? Should it be called treatment or support? Ask about stigma associated with psychological treatments?

Therapy? Advice? Support? Training?

What would be the best way to approach individuals to take part in the study?

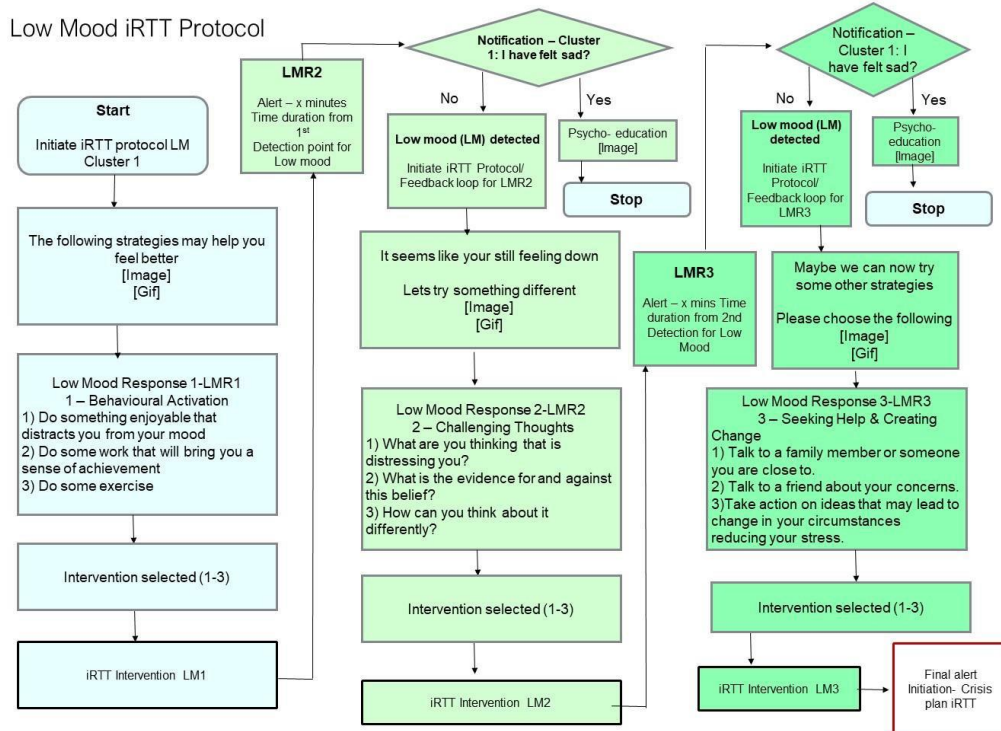
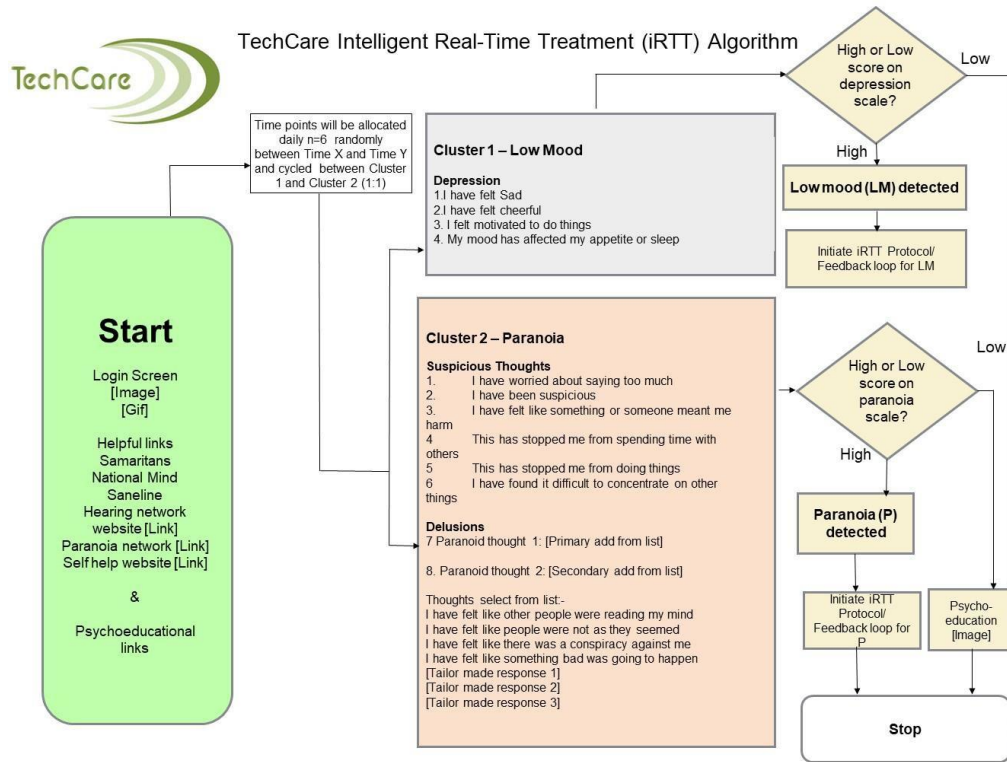
Conclusions/Closing remarks

Duration of intervention?

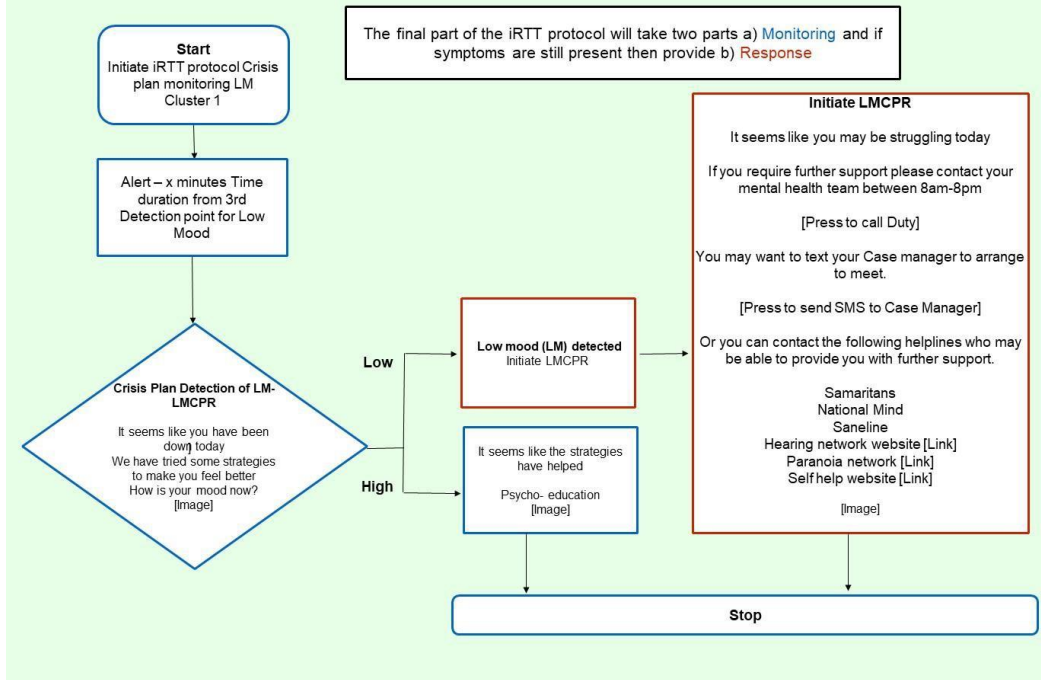
Name?

Is this type of intervention acceptable for individuals with psychosis?

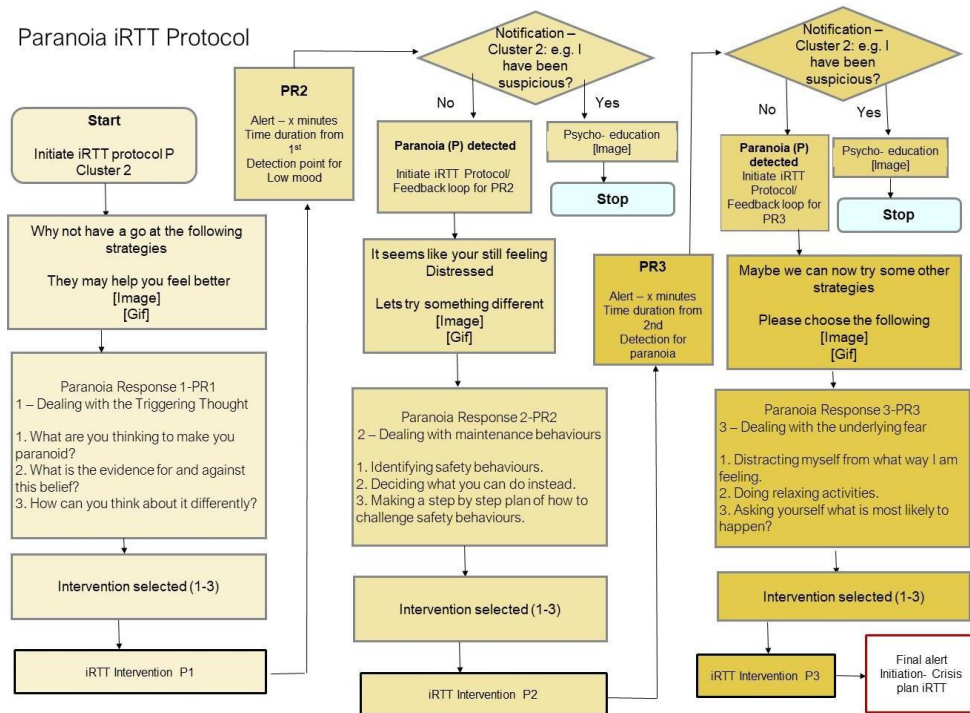
Appendix 7: TechCare App Algorithm



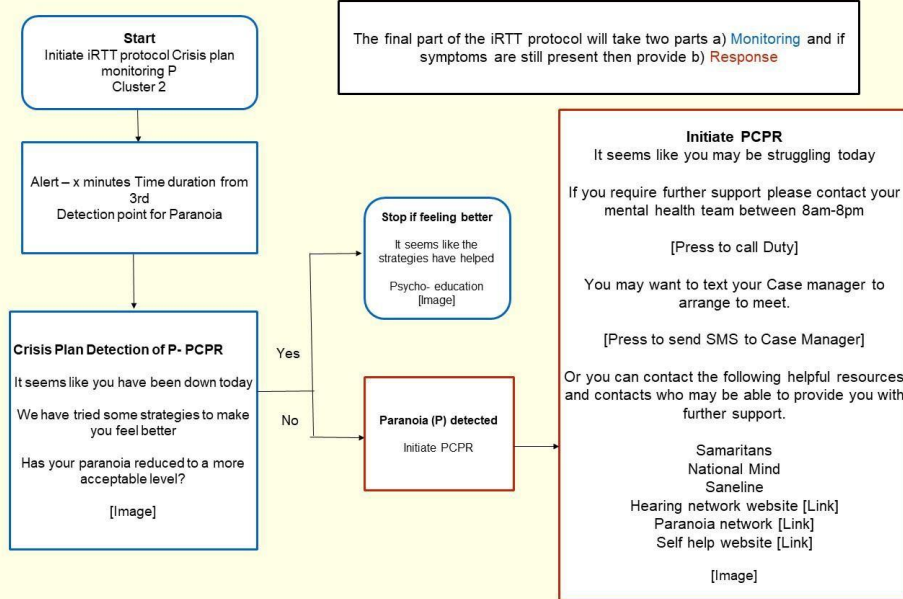
Low Mood Crisis Plan Response - LMCPR



Paranoia iRTT Protocol



Paranoia Crisis Plan Reponse - PCPR



Appendix 8: NHS Health Research Authority Ethics Approval

1



NRES Committee North West - Preston

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Fax: 0161 625 7299

02 September 2014

Dr I B Chaudhry
Consultant
Lancashire Care NHS Trust
The Mount
Whalley Road
Accrington
BB5 5DE

Dear Dr Chaudhry

Study title: TechCare : Mobile-Assessment and Therapy for Psychosis: An intervention for Clients within the Early Intervention Service.
REC reference: 14/NW/1192
Protocol number: N/A
IRAS project ID: 132399

The Research Ethics Committee reviewed the above application at the meeting held on 29 August 2014. The REC thanks the researchers for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mrs Carol Ebenezer, nrescommittee.northwest-preston@nhs.net.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- a. The Committee would like to see the Participant Information Sheet revised to
 - i) Change the heading so that it is all in the same typescript without the capital letters
 - ii) Check the formatting to ensure headings are not at the bottom of the

- page
- iii) Change under "Do I have to take part?" "however, the data you have already provided will be anonymised..." to "however, any data you will have provided by then will be anonymised..."
 - iv) Include at the beginning of part 2 "Four people will be given the mobile app in the first instance for initial testing, and then 12 more will be given the app to test further"
 - v) Include the information that there is a five minute delay button and that they have 15 minutes to respond and then the app moves on
 - vi) Include the information that they will get two calls in the first week and one each week thereafter to check that things are going well and state that this will be in addition to their routine care
 - vii) Omit the words "which you feel may be beneficial to the research" in the first paragraph on page 3 and replace with "to ensure it is correct"
 - viii) Change the wording on waiving confidentiality from "however, unless there is information....." to "however, if you disclose something which puts you or others at serious risk of harm, we will have to disclose this to the relevant party" and put this information as a separate paragraph
 - ix) Include the information that reasonable travel expenses will be paid
 - x) Provide the details, with a telephone number, for the complaints procedure

- b. The Committee would like to see the Consent Form revised to change point 2 to "participation is voluntary" rather than "participation is entirely down to myself"

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

3

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

The Chair welcomed the researchers to the REC and thanked them for attending to discuss the study. The Committee told them that this is a much improved application and appreciated that their comments had been taken on board.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked whether the researchers will know in real time whether the participants are responding. The researchers stated that they will not know this until the end of the week when the information is downloaded. The Committee asked what would happen if they do not respond to the call or do not attend. The researchers pointed out that this intervention is in addition to routine care so they will be getting more than they currently receive. They will still receive routine visits by the care coordinator and the usual crisis plan is in place. Even if the care team is extremely concerned they would get a maximum of two visits, and it would be referred to the crisis team thereafter. If they miss a visit it would trigger a visit from the care coordinator.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee noted that this is an android application and asked how secure the data is. The researchers stated that it is normal care for texts to be sent as reminders for appointments. The data will be as secure as the IT department can make it for this feasibility study but security will be ensured by the time of the bigger study. They are requesting minimal information for this reason and the volunteers to the project will all be aware of this.

Informed consent process and the adequacy and completeness of participant information

The Committee requested changes to the Participant Information Sheet and Consent Form as described in the decision below.

Suitability of supporting information

The Committee pointed out that there is an intention to inform the GP of participation in the study but no GP letter has been provided. Mr Gire stated that this was an error and provided a copy for the Committee which was reviewed by the members and received by the REC Manager.

The researchers confirmed that focus group topic guides had not been provided because the questions will be very open.

The researchers asked whether there is any guidance for the ethics of mobile phone technology. The Committee advised of some work done by Suler and the Association of Internet Research, and the HRA is currently in the process of issuing some guidance on internet research.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [TechCare covering Letter]		24 July 2014
GP/consultant information sheets or letters	1	15 July 2014
Interview schedules or topic guides for participants [TechCare Topic Guide]	V.1	15 July 2014
Other [Panss Scoring System]	V.1	15 July 2014
Other [CHOICES]	V.1	15 July 2014
Other [Brief Core Schema Scale]	V.1	15 July 2014
Other [Pysrats-Voices]	V.1	15 July 2014
Other [Panss Scoresheet]	V.1	15 July 2014
Other [Wemwbs]	V.1	15 July 2014
Other [Sci-Panss]	V.1	15 July 2014
Other [WASAS]	V.1	15 July 2014
Other [EQ-5D]	V.1	15 July 2014
Other [Pysrats- Beliefs]	V.1	15 July 2014
REC Application Form [REC_Form_24072014]		24 July 2014
Research protocol or project proposal [TechCare Research Protocol]	V.1	15 July 2014
Summary CV for Chief Investigator (CI) [Prof I B Chaudry]		
Validated questionnaire [Calgary Depression Scale]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Debbie Foord declared an interest

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/NW/1192	Please quote this number on all correspondence
-------------------	-------------------------------------------------------

With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Patricia Wilkinson
Chair

E-mail: nrescommittee.northwest-preston@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

NRES Committee North West - Preston

Attendance at Committee meeting on 29 August 2014

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr David Abbotts	Lay member	No	
Mr Aidan Cabezas-Hayes	Lay Member	No	
Professor Anoop Chauhan	Consultant Cardiologist	No	
Mr Ken Cook	Acute Care Manager (retired)	No	
Mr John Dalton	Lay Member	Yes	
Mrs Debbie Foord	Service Improvement Manager	Yes	
Professor Carol Haigh	Professor of Nursing	Yes	
Ms Eleanor Jolley	Lay Member	Yes	
Mrs Kate Kilshaw	Radiographer	Yes	
Professor Videsh Raut	Consultant Orthopaedic Surgeon	No	
Mrs Valerie Skinner	Nurse (Retired)	Yes	Co-opted from Lancaster
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Yes	
Dr Patricia Wilkinson	General Practitioner/Chair	Yes	
Dr Hawys Williams	Lay Member	No	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Carol Ebenezer	REC Manager
Maggie O'Connor	REC Assistant

Appendix 9: TechCare Software Changes & Amendment Log

Change ID	Date & Time	Description
211	14/01/2016 14:30	Updated logo and made the intervention detail scrollable
197	28/10/2015 12:38	Moved the Notification processing to the main page and added 'Please Wait' messages to the login and loading of the question page
196	28/10/2015 11:02	Put in logic to ask for a Participant ID except for when notification has been clicked...that is next.
194	21/09/2015 16:34	Fixed logic
192	21/09/2015 15:15	Issue with Cluster ID needs to be read from the notification string as the IRTT protocol requires
191	21/09/2015 15:00	In case the random generator doesn't work in the App use the service random instead
190	21/09/2015 14:40	Clearing up log messages and made the service send the cluster to use as the random cluster generator in the App
189	21/09/2015 12:29	Random timing changes - as sometimes the times would be 1 or 10 minutes apart.
188	17/09/2015 09:43	Added Random notification process. This is a console application (Techcare.Services.dailytasks) that is running in Azure
187	18/08/2015 13:54	Added code to terminate App on suspending
186	18/08/2015 10:50	Bug fixes
183	22/07/2015 15:11	Added new logos for splash screen and tile/badge
180	16/07/2015 15:33	Corrected log message
179	16/07/2015 13:45	Final round of bug fixes
178	16/07/2015 12:35	Recommended interventions tidy up
177	16/07/2015 10:21	Fixed issue where iRTT protocol was getting reminders from disabled broadcast notifications
176	16/07/2015 10:01	Changed operating timings for the jobs due the server timings being non-GMT. Adjusted threshold logic on the App
175	15/07/2015 16:42	Fixed Reminder logic
174	15/07/2015 15:15	Error with calculating total minutes.
173	15/07/2015 11:19	Added exception logging
172	15/07/2015 10:57	Fixing bugs with intervention list and corrected calculating recommended intervention types. Sync'd mobile database
171	14/07/2015 16:35	Added missing file
170	14/07/2015 16:34	Added stored procedure to calculate and populate the Recommended Interventions table
169	14/07/2015 12:33	Added recommended interventions related code
168	14/07/2015 12:13	Completed logic

167	13/07/2015 11:03	Added new recommended Interventions table
166	10/07/2015 12:48	Fix IRTT Protocol
165	10/07/2015 10:22	Added daily routine to reset broadcast notifications
164	09/07/2015 15:48	Change keypad to show numeric by default
163	09/07/2015 15:11	Corrected when retrieving reminders - check in before
162	09/07/2015 15:10	Corrected when retrieving reminders
161	09/07/2015 13:33	Styling of pages
160	09/07/2015 13:08	Included restrictions so jobs run only within certain times
159	09/07/2015 12:56	The notification logic is completed
158	09/07/2015 12:03	Page styling for questions
157	09/07/2015 11:55	Notification logic to process iRTT Protocol
156	08/07/2015 16:17	Change log messages
155	08/07/2015 16:12	Completed setup of scheduled jobs
154	08/07/2015 16:00	Moving notification down a level to ensure proper code reuse
153	08/07/2015 15:39	Added missing files
152	08/07/2015 15:36	Error fix: Back to a working state
151	08/07/2015 09:51	Committing code for deployment to device
150	07/07/2015 14:41	Published the mobile service and made some App changes to support the new notification logic
149	07/07/2015 10:33	Questions page changes
148	06/07/2015 15:14	Completed the top-level code
147	06/07/2015 15:02	Added code to allow numbers to be dialled
146	03/07/2015 16:05	Implemented Autofac and added new table to the mobile database.
145	02/07/2015 09:37	Start of the adjustments to the notification logic
144	01/07/2015 14:52	Added threshold logic
133	04/06/2015 08:49	Cosmetic updates
132	03/06/2015 14:54	Added new API controller to remove the schedule jobs
131	03/06/2015 14:05	Updated views UX changes
130	03/06/2015 10:17	Updated logo
129	02/06/2015 15:59	Increase column sizes to varchar(max) and saving changes to the database
128	02/06/2015 11:50	Updated content page
127	02/06/2015 11:44	Finished draft version of the documentation
126	02/06/2015 11:23	Added first version of documentation
125	02/06/2015 11:20	Fixed logic- sending reminders
124	02/06/2015 09:50	Removed the check for user ID as this is required for the individual push notification

122	01/06/2015 22:57	Added the ability to send a reminder from the admin page.
121	01/06/2015 00:02	UI changes/design cosmetic
120	30/05/2015 20:14	Cleared up code, added new method and corrected logic
119	30/05/2015 19:36	Sorting references and added signal
118	30/05/2015 11:14	Authenticated push notifications related
117	30/05/2015 11:14	Updated database project
116	30/05/2015 11:06	Fixed key creation
115	28/05/2015 16:48	Updated images
113	28/05/2015 16:21	Updated App page to include notification code
111	28/05/2015 16:12	Added all XAML files and model classes from old project into new
110	28/05/2015 14:55	Added profile settings to the project
109	28/05/2015 14:50	Removing duplicate folder
108	28/05/2015 14:48	Updated publish profile again
107	28/05/2015 14:43	Added publish profile for the mobile service
105	28/05/2015 13:10	Trying to fix references and added database clone method
103	28/05/2015 12:39	New projects committed
102	28/05/2015 11:32	Removed projects
101	28/05/2015 10:58	Project file check in
100	28/05/2015 10:49	Added new service project for the new windows phone project
99	28/05/2015 10:49	Added new mobile project with correct Microsoft store credentials
96	28/05/2015 01:24	Added new service project for mobile
95	28/05/2015 01:22	Added new windows phone 8.1 project
94	27/05/2015 16:42	Saving changes
93	27/05/2015 14:20	Added missing file
92	27/05/2015 14:17	Reminder controller - sending notifications.
90	27/05/2015 12:54	Added ID to notification
87	27/05/2015 11:57	Styling changes and App login registration changes
86	27/05/2015 11:40	Project file check-in
85	27/05/2015 08:38	Added notification authentication checks - added new data objects
84	27/05/2015 08:37	Added authentication sign process with Microsoft live account
82	26/05/2015 15:02	Added validation to contact add/edit
81	26/05/2015 14:16	Changes to Interventions list page- added missing filter
80	26/05/2015 12:24	Cleared up the contact functionality and added a dropdown list box for selecting a title.

79	26/05/2015 09:16	Changes to Crisis Plan/tidy up
77	25/05/2015 21:05	Wiring up of Notifications from azure
76	25/05/2015 19:06	Removed PIN with display: none
74	25/05/2015 18:37	Fixed issues around saving and adding a new intervention
71	25/05/2015 12:02	Updated scheduled job and event handling
70	25/05/2015 12:01	Added timer to interventions
69	24/05/2015 21:43	Fixed the contacts to appear on the edit intervention dialog
68	24/05/2015 21:13	Removed database tables which are no longer used
66	24/05/2015 20:16	Updated publish xml file
65	24/05/2015 00:00	Added push notification configs/test sample schedule job
64	23/05/2015 23:58	Added push notification configuration
62	22/05/2015 09:11	Project file check-in
61	21/05/2015 23:35	Mobile Service project check-in
60	21/05/2015 23:34	Mobile project check-in
59	21/05/2015 14:39	Added Mobile EDMX
58	21/05/2015 14:13	Shifted Admin EDMX into Admin namespace
54	20/05/2015 15:40	Able to edit Contacts
52	20/05/2015 11:53	Can save a new Participant now
50	20/05/2015 10:04	Updated Database project
46	18/05/2015 10:28	Solution file checked in
44	15/05/2015 13:02	Mobile solution checked in again
40	15/05/2015 11:32	Restructure to support single repository for mobile and web
39	13/05/2015 16:20	Updating the schema and data script
37	13/05/2015 16:12	Saving work before demo
32	06/05/2015 15:55	Hangfire Integration
30	06/05/2015 14:17	Initial Techcare mobile solution check-in







Appendix 10: TechCare App User Guide



TechCare App User Guide V.1

The TechCare App, is here to help you if you are feeling distressed. The following user guide provides an overview of how to use the TechCare App.

The flowchart is a horizontal sequence of five numbered steps, each in a light green box. Step 1 shows a login screen with a 4-digit PIN field. Step 2 shows a notification icon. Step 3 shows a notification with a document icon. Step 4 shows a question with a sliding scale from 1 to 7. Step 5 shows a character with a speech bubble. Below the steps is a 'Helpful tips' box with two numbered tips, a phone icon, a Wi-Fi icon, and a character with question marks.

- 1** Login to the TechCare App using the 4 digit pin you were provided with


- 2** You will receive a notification on your mobile phone 3 times a day

- 3** Click on the notification to access and answer the questions.

- 4** Each question can be scored, by using the sliding scale from 1-7

- 5** If you are feeling distressed, the TechCare App will display self-help strategies


Helpful tips:

- 1) Remember to charge your phone if you are running out of battery
- 2) If you are experiencing difficulties please call the research team on [Number] or the [Duty team/Crisis team]

