

# Outcome feedback in physiotherapy: What works for whom in which circumstances?

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School of Health Sciences

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# STUDENT DECLARATION FORM

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## **Abstract**

The application of Patient Reported Outcome Measures (PROMs) and their operative use is a pertinent issue debated amongst policy makers, researchers and clinicians alike. This study was designed to explore the impact of PROMs, and the processes which occur when PROMs information is fed back to patients.

The overarching study research question comprised 'Outcome feedback in physiotherapy: What works for whom, in which circumstances?' The scoping literature review included eight studies exploring feedback of information (PROMs and other objective markers) to patients in a physical health setting. The literature review identified a paucity of qualitative research and mixed responses to feedback of information. Realist evaluation was identified as an approach to support a mixed methods study, aiming to unpack the underlying processes occurring in the feedback of PROMs. The Contextualised Feedback Intervention Theory (CFIT) was selected as a middle-range theory to drive research methods and to test the data.

The two-phase study in total recruited 27 patient participants. There were two drop outs, with 25 remaining participants who consented to be interviewed.

The study began with a pilot, designed to explore acceptance, relevancy and utility of feedback to patients in a physiotherapy setting using a disease-specific PROM (QuickDASH) throughout the treatment period. The 10 pilot study interviews identified eight of 10 participants to accept the PROM feedback as relevant and useful. The phase II main study expanded the study scope, to explore more specific elements of feedback using a realist evaluation approach. A further 17 patient participants were recruited, with two drop-outs and three physiotherapists providing the feedback were also interviewed.

Using descriptive statistics, matrix analyses and realist evaluation, Context, Mechanism and Outcome configurations (CMOC) were constructed from the data. The CMOCs described and mapped

the singular processes into an overall shape, producing a cumulative CMOc map which was compared with the existing CFIT.

The thesis details what works for whom in which circumstances in relation to feedback of PROMs information. This study concludes that feedback works in the way it is intended for patients when they feel the PROM tracks progress accurately, there is consonance with the feedback process and there is a positive rapport with their therapist, producing an impact which is larger when both the patient and therapist are working together to manage the patient's condition. The PROM as a tool enhances patient experience, but does not appear to measure experience, only clinical change. This study proposes PROMs to be used as such: to measure clinical change as a validated tool, but also to enhance patient management and experience via feedback, encouraging patients to be centred at the heart of quality, individualised care.

This study contributes to feedback theory by modifying the original CFIT, originally utilised for clinician feedback, to include three additional elements, adapting the CFIT for use with a patient population. The three additional elements in the 'modified CFIT' comprise 'tracking progress and closeness to goal', 'collective impact' (where the collective efforts of both patient and therapist produce a better outcome) and 'consonance or dissonance' with the feedback process. This modified CFIT can now be used as a 'reusable conceptual platform', to be tested with alternative patient populations and thus further modified.

## Table of contents

Abstract .....	3
Table of contents .....	5
List of tables.....	12
List of figures .....	13
Acknowledgements .....	15
Glossary of abbreviations .....	16
Chapter 1 - Thesis introduction.....	18
1.1 Researcher background .....	18
1.2 Research purpose.....	20
1.3 Key issues in practice .....	20
1.3.1 The use of outcome research in practice .....	20
1.3.2 The impact of PROMs.....	23
1.3.3 Evidence Based Practice (EBP) movement .....	25
1.3.4 Patient Reported Experience Measures (PREMs).....	26
1.3.5 Measuring quality .....	27
1.3.6 Public Involvement (PI) in PROMs .....	28
1.3.7 Outcome measures and physiotherapy .....	30
1.4 Developing the research idea.....	31
1.5 Theories underpinning behaviour change.....	32
1.5.1 Chronicle of behaviour change theories.....	32
1.5.2 Changing health behaviour .....	35
1.5.3 Which theory is suitable to predict health related behaviours?.....	36
1.6 What is feedback? .....	39
1.6.1 Definitions of feedback .....	39
1.6.2 Use of information feedback in healthcare .....	40
1.6.3 Contextual conditions for feedback effectiveness .....	43
1.7 Theories underpinning feedback as an intervention: How does feedback work? .....	44
1.7.1 Control Theory .....	44
1.7.2 Contextualised Feedback Intervention Theory (CFIT) (Riemer & Bickman, 2011) .....	46
1.8 Selected middle range theory .....	48
Chapter 2 - A review of the literature surrounding information feedback of outcome data in healthcare settings .....	49
2.1 Introduction .....	49

2.2	The literature review.....	50
2.2.1	Inclusion and exclusion criteria: Setting the scope of the study.....	50
2.2.2	Overview of inclusion and exclusion criteria for the literature review.....	53
2.3	Search strategy .....	53
2.3.1	Breakdown of literature search results .....	59
2.4	Included studies.....	61
2.4.1	Quality of reporting.....	61
2.4.2	Quality of study.....	61
2.4.3	Characteristics of included studies.....	64
2.4.4	Types of interventions including feedback.....	64
2.4.5	Evidence supporting use of feedback.....	65
2.4.6	Feedback not working in the way it is intended.....	68
2.4.7	How feedback programmes might work.....	68
2.5	Summary of the literature search .....	69
2.5.1	Limitations.....	69
2.5.2	What is known?.....	70
2.5.3	What is not known? .....	70
2.5.4	Contributions .....	70
2.6	Development of a research question .....	72
Chapter 3 – Research methods and philosophical underpinnings .....		74
3.1	Introduction .....	74
3.2	Philosophical underpinnings .....	74
3.2.1	Ontology and epistemology .....	74
3.3	Qualitative research .....	76
3.3.1	Previous research overview in relation to qualitative approaches.....	76
3.4	Mixed methods .....	77
3.4.1	Quantitative indicators.....	79
3.5	Options for research methods .....	79
3.6	Realist research: approach chosen for the phase I pilot study and phase II main study .....	81
3.6.1	Branches of realism.....	82
3.6.2	Study placing in realism.....	83
3.6.3	Realist synthesis and realist evaluation as methods .....	84
3.6.4	Programme theory and middle range theory.....	84
3.7	Definition of terms .....	85

3.7.1	Context.....	85
3.7.2	Mechanism.....	85
3.7.3	Outcome .....	86
3.7.4	Intervention .....	87
3.8	Research methods and philosophical underpinnings conclusion.....	87
Chapter 4:	Phase I Pilot study methods .....	88
4.1	Introduction .....	88
4.2	Shoulder Impingement Syndrome (SIS) .....	89
4.3	Choice of PROM: Disease specific QuickDASH .....	92
4.4	Recruitment in the phase I pilot study .....	92
4.5	Interviews .....	94
4.6	Analysis .....	95
4.7	Rigour.....	99
4.8	Ethics.....	101
4.9	Phase I pilot study preliminary findings informing the phase II main study.....	101
Chapter 5:	Findings phase I pilot.....	103
5.1	Introduction .....	103
5.2	Participant summaries .....	103
5.3	Overview of analysis .....	103
5.4	Question 1: Are patients accepting of the feedback process and is it feasible?.....	104
5.4.1	Accuracy.....	104
5.4.2	Relevancy .....	106
5.5	Question 2: What do patients think about the usefulness of outcome feedback? .....	108
5.6	Anomalies .....	109
5.7	Realist presentation of conclusions from the pilot phase I study.....	110
5.8	Additional findings to the pilot study questions .....	114
5.9	Reflections on using a realist lens .....	115
Chapter 6:	Phase II Main study methods .....	116
6.1	Aims and objectives: How the research question will be addressed.....	116
6.2	Focused aim .....	117
6.3	Ethics.....	117
6.4	Method of sampling.....	117
6.4.1	Physiotherapist participants providing patient feedback.....	118
6.4.2	Patient participants.....	119

6.5	PROMs feedback .....	120
6.6	Data collection of the QuickDASH PROM .....	121
6.7	Interviewing style and schedule .....	122
6.8	Overview of analysis .....	124
6.9	Transcription and computer assisted qualitative data analysis software .....	128
6.10	Coding methods .....	129
6.11	Theme development .....	131
6.12	Progression of analysis: Context – Mechanism – Outcome configurations (CMOCs) .....	133
6.13	Testing of CMOCs as programme theories .....	135
6.14	Testing combined CMOCs.....	136
6.14.1	Data saturation .....	137
6.15	Limitations .....	138
Chapter 7: Cumulative findings phase I pilot and phase II main study.....		140
7.1	Number of participants in the study population .....	140
7.2	Descriptive statistics .....	142
7.2.1	Demographics .....	142
7.2.2	Age .....	143
7.2.3	Gender .....	144
7.2.4	Employment.....	144
7.2.5	Severity of starting QuickDASH scores .....	145
7.2.6	QuickDASH change of score during information feedback.....	147
7.3	Matrix analysis .....	147
7.4	Qualitative analysis .....	150
7.4.1	Conclusion of themes.....	150
7.4.2	Themes, CMO configurations and the CFIT .....	155
7.5	CMOC 1: Goal choice .....	158
7.5.1	Overview .....	158
7.5.2	Outcome .....	161
7.5.3	Mechanisms .....	163
7.5.4	Context.....	164
7.6	CMOC 2: Tracking changes and closeness to goal via feedback .....	166
7.6.1	Overview .....	166
7.6.2	Outcome .....	167
7.6.3	Mechanism.....	169

7.6.4	Context.....	170
7.7	CMOc 3: Low impact or high impact of feedback.....	171
7.7.1	Overview .....	171
7.7.2	Outcome .....	172
7.7.3	Mechanism.....	175
7.7.4	Context.....	175
7.8	CMOc 4: Collective impact of feedback CMO.....	177
7.8.1	Overview .....	177
7.8.2	Outcome .....	179
7.8.3	Mechanism.....	181
7.8.4	Context.....	184
7.9	CMOc 5: Dissonance or consonance .....	187
7.9.1	Overview .....	187
7.9.2	Outcome .....	188
7.9.3	Mechanism.....	189
7.9.4	Context.....	190
7.10	CMOc 6: Causal attribution .....	192
7.10.1	Overview .....	192
7.10.2	Outcome .....	193
7.10.3	Mechanism.....	194
7.10.4	Context.....	195
Chapter 8: Integration of findings: relationship of CMOcs and modification to theoretical framework .....		198
8.1	Combined CMOcs: Ripple effects and relationships.....	198
8.1.1	Chronologically ordered CMOcs .....	198
8.1.2	Positive and negative impact status .....	199
8.1.3	Summary example: Combined CMOcs with a positive impact (no improvement on the QuickDASH).....	201
8.1.4	Summary example: Combined CMOcs with a positive impact (improvement on the QuickDASH).....	205
8.1.5	Summary example: Combined CMOcs without a positive impact.....	208
8.2	Combined ripple effect: The cumulative CMOc .....	213
8.2.1	The overall shape of the six CMOcs: a non-linear process .....	213
8.2.2	The overall context of the feedback process.....	214
8.2.3	The overall mechanisms occurring within the feedback process .....	214

8.2.4	Overall outcome and the cumulative CMOc .....	215
8.3	Research question revisited .....	216
8.4	Modification to theory .....	218
Chapter 9:	Discussion.....	220
9.1	Summary of findings .....	220
9.2	Discussion introduction.....	220
9.3	Comparison with empirical studies in the literature review .....	223
9.3.1	Differences in findings.....	223
9.3.2	Common findings .....	225
9.4	Common experiences.....	225
9.4.1	Contextual conditions for a positive or negative outcome of feedback .....	226
9.5	The patient-therapist relationship .....	227
9.5.1	The patient therapist relationship as a stratified reality .....	228
9.5.2	Communication and relationships.....	229
9.5.3	Importance of the feedback source .....	230
9.6	The use of PROMs .....	230
9.7	Quality measures .....	233
9.8	What is the desired outcome of PROMs feedback? .....	234
9.8.1	PROMs and feedback as a quality indicator .....	235
9.9	The holistic use of PROMs feedback in clinical practice .....	236
9.9.1	Supporting patient-centred care .....	236
9.9.2	Holistic approach to quality .....	237
9.10	Answering the research questions .....	238
9.11	Feedback .....	241
9.12	CFIT modification .....	242
9.12.2	Modified CFIT as a middle range theory.....	245
9.12.3	Contribution to feedback theory.....	247
9.13	Generalisation and the use of re-useable conceptual platforms .....	247
9.14	Contribution to realism: The cumulative CMOc .....	248
9.15	The use of outcome research in practice and within physiotherapy.....	249
9.16	Dissemination and reflection .....	251
9.17	Limitations of the study .....	253
9.17.1	Literature review type.....	253
9.17.2	Realist evaluation as an approach.....	254

9.17.3	The practitioner role .....	255
9.18	Research reflection .....	256
9.19	Recommendations .....	257
9.19.1	Education .....	257
9.19.2	Recommendations for practice .....	257
9.19.3	PROMs use .....	258
9.19.4	Patient experience and management .....	258
9.19.5	Opportunities for further research.....	259
Chapter 10:	Conclusion.....	262
Appendices	.....	265
Appendix A:	Data extraction form .....	265
Appendix B:	Pilot study phase I successful ethics approval LREC.....	274
Appendix C:	Pilot study phase I NHS R&D letter of approval .....	279
Appendix D:	Pilot study phase I UCLan ethics approval letter .....	281
Appendix E:	Main study phase II successful ethics approval LREC .....	282
Appendix F:	Main study phase II NHS R&D letter of approval.....	288
Appendix G:	Main study phase II UCLan ethics approval letter .....	291
Appendix H:	The QuickDASH PROM.....	292
Appendix I:	Pilot study phase I patient information sheet and consent form.....	295
Appendix J:	Main study phase II patient information sheet and consent form.....	302
Appendix K:	QuickDASH completed example graph (participant 17).....	309
Appendix L:	Pilot study interview schedule with written notes .....	310
Appendix M:	Interview summary example sent to participant for comment .....	311
Appendix N:	Two examples of combined participant storyboard analysis.....	312
Appendix O:	Matrix analysis examples participants 01-08.....	314
Appendix P:	Combined storyboard analysis.....	318
Appendix Q:	Main phase II patient and physiotherapist interview schedules .....	319
Appendix R:	Mapping participant data against the CFIT participant 15 .....	324
Appendix S:	Mapping orders of processes with participant data by hand .....	325
Appendix T:	Analysis notes for identifying elements of CMOcs .....	326
Appendix U:	Poster for CARES October 2016.....	327
Appendix V:	Starting QuickDASH score for each patient participant and category of severity .....	328
Appendix W:	Examples of individual CMOcs.....	329
References	.....	346

## List of tables

Table 1 - The Quality Assurance Standards of the Chartered Society of Physiotherapy .....	23
Table 2: The five types of PROMs .....	24
Table 3: Medline and Embase via OVID focused search (2 pages) .....	55
Table 4: Backwards referencing .....	57
Table 5: PSYCHinfo search .....	57
Table 6: Wide search OVID: Medline and EMBASE .....	57
Table 7: CINAHL search .....	58
Table 8: Additional search codes and descriptions of use .....	59
Table 9: Traditional grading of studies .....	62
Table 10: Included study characteristics .....	63
Table 11: Study characteristics of feedback spacing, number of feedback repetitions and duration of the study over which feedback was provided .....	66
Table 12: Ontological, epistemological, methodological and data analysis distinctions between quantitative and qualitative approaches .....	78
Table 13: Mild, moderate and severe ratings .....	121
Table 14: Combined demographics showing age, gender, location of data collection and employment status for all participants .....	143
Table 15: Fan et al. (2008) study synopsis .....	145
Table 16: Mean score changes on the QuickDASH for improvement categorisation and calculated score range .....	147
Table 17: Number of participants exhibiting different combinations of starting severity and change status .....	148

## List of figures

Figure 1: Definitions of quality .....	28
Figure 2: General model of the attribution field .....	33
Figure 3: Theory of Planned Behaviour .....	34
Figure 4: The Behaviour Change Wheel .....	38
Figure 5: Control Theory .....	45
Figure 6: The Contextualised Feedback Intervention Theory.....	47
Figure 7: Flowchart of included studies for literature review .....	60
Figure 8: Diagram depicting rotator cuff tendinopathy .....	90
Figure 9: The iterative steps of data analysis for the phase I pilot study .....	97
Figure 10: Example matrix analysis flowchart.....	99
Figure 11: Generalised CMOc describing a positively conducive feedback process.....	110
Figure 12: CMOc describing a positively conducive feedback process with quotes from participant 05 .....	111
Figure 13: An example of a positive outcome CMOc using quotes from participant 07 .....	112
Figure 14: CMOc describing a negative outcome from the feedback process .....	113
Figure 15: CMOc describing a negative feedback process with quotes from participant 04.....	114
Figure 16: The iterative steps of data analysis Phase II main study .....	127
Figure 17: Example of adult node split into multiple child nodes .....	131
Figure 18: A visual representation, which has been used to explain CMOcs .....	134
Figure 19: Example of visual depiction of CMOc with quotes .....	135
Figure 20: Diagram to show recruitment through both study phases and recruitment of participants from individual physiotherapists .....	141
Figure 21: Open coding listing from patient participant interviews.....	150
Figure 22: Expanded QuickDASH open code.....	151
Figure 23: The five themes and the open coding categories developed to generate the themes ....	153
Figure 24: The five themes with example quotes from raw interview data which were allocated to each theme .....	154
Figure 25: CMO configurations categorised under each broad theme heading.....	156
Figure 26: CFIT with CMOcs projected onto the framework.....	157
Figure 27: CMOc to give an overview of how participants chose goals .....	161
Figure 28: The five different classifications of goals with relevant quotes from participants to demonstrate each classification .....	162
Figure 29: CMOc to explain how participants track changes and closeness to their goal .....	167
Figure 30: CMOc to show differing outcomes from low impact and high impact of a participant's shoulder impingement.....	172
Figure 31: Cyclical process to inform high or low impact.....	173
Figure 32: CMOc to explore the collective impact of the physiotherapist and participant in the feedback process .....	179
Figure 33: CMOc to explore the two outcomes arising from dissonance or concordance of new information via the feedback process.....	188
Figure 34: CMOc to outline causal attribution for a patient with a shoulder problem engaging with treatment.....	193
Figure 35: Chronological CMOc progression through the feedback process .....	199

Figure 36: Three participants' quotes exhibiting positive outcomes from feedback without significant improvement on the QuickDASH .....	201
Figure 37: Linear CMOcs with quotes to show timeline for combined CMOcs with a positive impact with no improvement on the QuickDASH (07).....	204
Figure 38: Linear CMOcs with quotes to show timeline for combined CMOcs with a positive impact with improvement on the QuickDASH .....	207
Figure 39: Linear CMOcs with quotes to show timeline for combined CMOcs without a positive impact, without improvement on the QuickDASH.....	210
Figure 40: CMOc processes occurring with negative impact of feedback .....	211
Figure 41: CMOc processes occurring with positive impact of feedback .....	212
Figure 42: Combined CMOcs to create a combined ripple effect 'cumulative CMOc' .....	215
Figure 43: CFIT with CMOcs projected onto the framework.....	217
Figure 44: Modified CFIT with three CMOcs added to the framework .....	219
Figure 45: The five elements required for collective impact and the demonstration of how each element is met within this study.....	229
Figure 46: The cumulative CMOc developed from participant data .....	238
Figure 47: The CFIT and projection of CMOcs on the theoretical framework .....	244
Figure 48: The modified CFIT, inclusive of the three 'critical' points found within this study .....	246

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## Glossary of abbreviations

<b>Abbreviation</b>	<b>Complete explanation</b>
CAQDAS	Computed Aided Qualitative Data Analysis Software
CASP	Critical Appraisal Skills Programme
CERQual	Confidence in the Evidence from Reviews of Qualitative research
CFIT	Contextualised Feedback Intervention Theory
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CMOc	Context Mechanism Outcome configuration
CONSORT	Consolidated Standards Of Reporting Trials
COREQ	Consolidated criteria for Reporting Qualitative research
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation
CSP	Chartered Society of Physiotherapy
DARE	Database of Abstracts and Review of Effect
EBCD	Experience Based Co Design
EBP	Evidence Based Practice
EMBASE	Excerpta Medica dataBASE
EQ-5D	EuroQol Five Dimensions
IRT	Item Response Theory
LREC	Local Research Ethics Council
MCID	Minimal Clinical Important Difference
MYMOP	Measure Yourself Medical Outcome Questionnaire
NeLH	National Electronic Library for Health
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PICOT	People/Population Intervention Comparison Outcome Time
PI	Public Involvement
PPI	Patient and Public Involvement
PROM	Patient Reported Outcome Measure
PROMIS	Patient Reported Outcome Measure Information System
QuickDASH	Quick Disability of the Arm Shoulder and Hand
RCT	Randomised Controlled Trial
ROM	Routine Outcome Monitoring
SET	Supervised Exercise Therapy
SFSS	Symptom and Functioning Severity Scale
SF12	Short Form 12
SIS	Shoulder Impingement Syndrome
STEMH	Science Technology Engineering Medicine and Health
TAU	Treatment As Usual
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
VICTORE	Volitions, Implementation, Contexts, Time, Outcomes, Rivalry and Emergence
VO2 MAX	Maximum rate oxygen consumption
WA	Walking Advice
YABOQ	Young Adult Burn Outcome Questionnaire

## **Summary of sections: Chapters 1 and 2**

The thesis introduction (Chapter 1) commences by presenting the researcher background as a reflexive account. Written in the first person, it aims to provide context of the researcher's role and previous experience in relation to the initial conception of the study aims and objectives. The purpose of the research is disclosed, to give an overall basis for the direction of the thesis.

Chapter 1 provides a background of the key issues in clinical practice in relation to outcome research. It explores the use of outcome measures, with a specific focus on Patient Reported Outcome Measures (PROMs). The underlying culture of evidence based practice is outlined alongside the importance of patient experience and quality improvement. With outcome measures aiming to increase standards in healthcare, the definition of quality is debated. Engaging the public in healthcare is a key concept for putting patients at the heart of care and the potential for enhancing individual treatment by use of PROMs is considered. In direct relation to this study, the use of outcome measures within physiotherapy is discussed, giving rise to the development of the research questions underpinning this study.

Feedback of this outcome data to patients is put into context in this chapter by introducing theories of behaviour change and more specifically those aiming to change health behaviour. Theories of behaviour change which include feedback loops are described alongside current evidence available in the theoretical domain for feedback effectiveness. Chapter 1 concludes with the selection of one middle range theory to explore and test with participant data.

The literature review (Chapter 2) then follows on to consider what types of feedback have been researched in practice, concluding with an integrated review of the research studies to establish the current knowledge base regarding use of feedback of outcome data to patients in a health setting.

# Chapter 1 - Thesis introduction

## 1.1 Researcher background

The researcher background only will be written in the first person, presenting as a personal narrative to give context to the thesis and the background behind the research idea and subsequent study.

The remainder of the thesis will be written in the third person, as a personal preference, to emphasise and showcase participants' points of view and experiences without the views or voice of the researcher (Sandelowski, 1998).

Since graduating in 2000, I have worked as a musculoskeletal physiotherapist. Within my workload over the years I have always enjoyed the practical elements of assessment and treatment, although the evidence base behind the tests and techniques used (or lack of it) interested me. I have always been aware and interested in research, with the view that it can improve practice if we know what works and for whom. I had previously enjoyed participating in research whilst working for the National Health Service (NHS), by recruiting participants and gathering data for external researchers. I had also previously been recruited as a participant for an MSc study which involved taking part in a semi-structured interview, which I found to be an interesting but a rather daunting experience.

As my physiotherapy career progressed I became more involved in auditing the department, leading an audit within one North West trust for two years, selecting appropriate Patient Reported Outcome Measures (PROMs) to collect and collate. The audit I completed on the NHS trust PROMs sparked my interest in this area of research as I noticed some patients exhibited interest in their own scores although others were disinterested.

Since specialising in musculoskeletal physiotherapy in 2006, I developed a special interest in shoulder conditions, initially working on secondment as an Extended Scope Physiotherapist and growing networks across the North West within the upper limb musculoskeletal and orthopaedic communities. Whilst refining my speciality, I was also undertaking a Post-Graduate Certificate in

Professional Practice (Research and Development) at the University of Central Lancashire. This commenced with one stand-alone module studying the use of evidence based practice. My interest grew and I expanded to take on further modules, concluding with a writing module, from which an article was written on best practice exercises for Shoulder Impingement Syndrome, which was accepted and later published (Dewhurst, 2010). I started to enjoy combining research and physiotherapy, so when the opportunity arose for a funded PhD I was excited to apply and develop my skill set further.

I realised quickly that research and practice should exist in harmony, to complement each other. In the process of this PhD I have grappled with combining the two, aiming to influence and create knowledge for clinical practice and academic research. I feel, because of this process, that I have grown to enjoy clinical and academic work alike, with a realisation that as a physiotherapist, working with academic supervision I was able to develop into a researcher, creating a study idea that could contribute original knowledge which could then be translated back into practice.

With my physiotherapy background, I previously had a bias towards quantitative research techniques, purely because it was an approach I was familiar with, and which in practice was used often to answer questions of what worked, and for whom. The original approach used for the literature review was a scoping review. After this generalised review, I realised my study would require a more specialised and precise direction to address the research gap. There was a specific requirement to understand the underlying mechanisms occurring behind the intervention comprising the feedback of PROMs to a patient population. I was drawn to realist evaluation (Pawson & Tilley, 1997) as a way of further understanding and explaining 'what worked and for whom?', extending to 'in which circumstances, why and how?' Realist Evaluation promised to aid explanation of processes where multiple factors influenced decision making, presenting as an approach to help me as a researcher to explore participant experiences of the intervention of PROMs feedback. The pilot study was a preliminary realist evaluation, trialling the Context,

Mechanism, Outcome process of configuring the findings. In this initial analysis, realist evaluation was fully embraced, but with basic Context, Mechanism, Outcome configurations (CMOCs).

Progressing to the phase II main study, I developed skills in understanding realist evaluation to be able to configure more complex CMOCs, develop relationships between CMOCs and compare the processes as an overall shape back to the chosen middle range theory. In summary, realist evaluation was established as an elemental part of the study after the literature review, developing as an integral component into the main phase II study.

I faced two challenges when choosing this PhD and subsequent research question: the transition to academic research from a practice background, combining the two as a part-time PhD student and part-time physiotherapist and secondly, embracing the realist evaluation approach from a previously quantitative bias. I have enjoyed the journey, learning valuable skills moving forward as a clinical academic and now find myself respecting and embracing both qualitative and quantitative methods, each for their specific lens, which illuminate differing elements of knowledge. Translating research into clinically relevant findings within this study aimed to enhance the proficiency of physiotherapists' clinical practice (Scurlock-Evans, Upton, & Upton, 2014) and allow the direction of interventions to those for whom it will be successful in delivering maximum patient benefit.

## **1.2 Research purpose**

The aim of this study was to explore patient responses to information feedback via outcome measures (PROMs) with a view to gaining further insight on what worked for whom in which circumstances.

## **1.3 Key issues in practice**

### **1.3.1 The use of outcome research in practice**

Outcomes research emerged as an important method for documenting the effectiveness of healthcare services in the 1980s and 1990s (Duckworth, 1999; Grove, Burns, & Gray, 2015).

Outcomes measurement in clinical practice can function as a means of facilitating communication, uncovering patients' problems, monitoring response to treatment (Greenhalgh, Long, & Flynn, 2005), promote efficient treatment planning, demonstrate service impact and efficiency (Duncan & Murray, 2012), and increase patient attention to symptoms, thereby supporting self-management (Trillingsgaard, Nielsen, Hjøllund, & Lomborg, 2016).

For clinicians to use outcomes in practice to achieve these gains they must maintain their current knowledge surrounding outcomes research and be prepared to use these tools in practice (Rose & Beznak, 2009). Historically, clinicians have reported barriers which have slowed the transition to widespread use of outcome measures with patients, including time required to keep up to date, access to easily understandable summaries of evidence, limited journal access to facilitate knowledge and lack of personal skills in searching and evaluating research evidence (Rose & Beznak, 2009; Turner & Whitfield, 1997). More recently, a systematic review was carried out by Duncan and Murray (2012) to further explore the key factors affecting allied health professionals' (Physiotherapy, Occupational Therapy, and Speech and Language Therapy) use of routine outcome measurement. Duncan and Murray (2012) found the status of outcome measure use to be largely unchanged: within the 15 included studies dating between 1997 and 2010, they concluded there was a recognition of the importance of routinely measuring outcomes within the allied health professions, but it has largely been undelivered. Specific barriers that influence clinicians' ability and desire to undertake routine outcome measurement have been posited as: professionals' level of knowledge and confidence about using outcome measures, and the degree of organisational and peer-support professionals received with a view to promoting their work in practice (Duncan & Murray, 2012).

Outcomes can be measured in a variety of ways including the use of Routine Outcome Monitoring (ROM) (regular use of validated outcome measures in practice), and in a more patient-centred

context with Patient Reported Outcome Measures (PROMs) (an outcome tool which is completed by the patient themselves).

Encouragement has been required to evoke increased use of outcome measures, which has initiated government-led strategies such as the Commissioning for Quality and Innovation (CQUIN) framework, introduced in April 2009 as a national framework to develop quality improvement schemes (Department of Health, 2010c). Although there is no UK health policy directly mandating routine outcome monitoring data use with patients, PROMs were identified as a useful outcome tool for quality reporting. Following release of the CQUIN framework, many NHS trusts began to collate outcome measures for quality reporting (Department of Health, 2010c), aiming to demonstrate outcomes with objective evidence. Initially the requirement by the Department of Health to collect PROMs data was applied to just four surgical procedures: hernia repair, hip and knee replacement, and varicose vein surgery (Devlin & Appleby, 2010). It has been noted that PROMs use is broadening in the NHS to encompass a wide variety of health care areas, with the physiotherapy domain being an area where increased use is anticipated (Kyte et al., 2015).

The Quality Assurance Standards of the Chartered Society of Physiotherapy (CSP) (Chartered Society of Physiotherapy, 2013) comprises 10 standards which can be observed in Table 1, demonstrating at this higher organisational level, physiotherapists are encouraged to demonstrate evaluation of care and provision of effective services (standards 2 and 4) which can involve the use of PROMs.

**Table 1 - The Quality Assurance Standards of the Chartered Society of Physiotherapy**

(Source: Chartered Society of Physiotherapy, 2013)

Standard number	Standard definition
1.	Autonomy and accountability
2.	Delivering a safe and effective service
3.	Learning and development
4.	Working in partnership
5.	Consent
6.	Record keeping and information governance
7.	Communication
8.	Physiotherapy management and treatment
9.	Evaluation of clinical care and services
10.	Promoting, marketing and advertising physiotherapy services and products

### **1.3.2 The impact of PROMs**

PROMs are categorised into five types of measures: generic, disease specific, utility based, item response theory (IRT) and individualised. Table 2 explains each specific type of measure, its potential uses and an example of each type. The type of PROM chosen depends on what the purpose of the PROM is and what is it aiming to measure.

**Table 2: The five types of PROMs**

(adapted from Greenhalgh et al. (2017))

PROM type	Description of what each measure aims to capture	Example
Generic	PROM to measure health and functioning in the general population, relevant to people both with and without illness, and to people with any condition	Short Form 36 (SF-36)
Disease specific	To capture the specific ways in which a condition or its treatment impacts on patients' health and functioning.	Quick Disability of the Arm, Shoulder and hand (QuickDASH)
Utility based	To combine quality and quantity of life into a single score of between 0 and 1 for use in health economic evaluations comparing different treatments	EuroQol 5D (EQ-5D)
IRT	To test the relationship between individuals' performances on a test item and the test takers' levels of performance on an overall measure of the ability that item was designed to measure	Patient-Reported Outcomes Measurement Information System (PROMIS)
Individualised	Individualised measures enable patients to select issues that are of greatest importance to them, to rate how they feel about those issues and, in some cases, to determine the weighting that should be given to those issues	Measure Yourself Medical Outcome Questionnaire (MYMOP)

Clinical use of PROMs coupled with collection and aggregation of data allows assessment and comparison of provider performance (Black, 2013), aiming to drive changes in healthcare organisation and delivery. A recent systematic review completed by Boyce, Browne, and Greenhalgh (2014) confirmed PROMs are recognised as a research and audit tool although some professionals found that the measures were not of clinical value as the results provided them with no new information. This suggests the impact of PROMs is varied, with Boyce et al. (2014) identifying some negative effects on patients, including the intrusive nature of collection affecting doctor-patient interaction, the capacity to narrow the focus of a consultation, and the perceived reduced benefit in comparison with other more important aspects of care which could have been promoted (opportunity cost). Positive indirect effects of collecting PROMs were also identified by Boyce et al. (2014) which included the ability to build patient confidence in the competence of the professional, to manage patient expectations and to assist in handing responsibility of care back to the patient.

### **1.3.3 Evidence Based Practice (EBP) movement**

Devlin and Appleby (2010) in their publication for the King's fund discuss PROMs use as an approach to measure and compare changes in health, concluding that PROMs collection has potentially important implications for enlarging the base of EBP.

EBP is about finding, appraising and applying scientific evidence to the treatment and management of healthcare (Hamer & Collinson, 2014). The evidence-based approach to providing health care has been recognised by health professionals and clinicians worldwide, and has increased the expectation that healthcare practice is based on up-to-date, high-quality evidence (Aasekjær, Waehle, Ciliska, Nordtvedt, & Hjälmhult, 2016). EBP as an umbrella term includes real-world evidence on clinical effectiveness and cost effectiveness that could potentially influence institutions such as the National Institute for Health and Care Excellence (NICE) when producing guidance to the NHS.

Aasekjær et al. (2016) describe the principles of EBP to involve the following seven steps:

1. Ignite a spirit of inquiry and EBP culture
2. Formulate an answerable question in PICOT format (People/Population, Intervention, Comparison, Outcome, Time)
3. Search for the best evidence
4. Critically appraise that evidence in terms of its validity, reliability, and clinical applicability
5. Integrate the evidence with clinical expertise and the patient's values and circumstances
6. Evaluate the outcomes of the EBP change
7. Disseminate the outcomes

Step six is of particular importance in relation to this study as evaluating the outcomes of EBP change can be exhibited by collecting PROMs data in clinical practice (Kyte et al., 2015). Evaluation of outcomes does not just apply to effectiveness alone which is the traditional stance of EBP, but can concern improving any aspect of quality care provision.

#### **1.3.4 Patient Reported Experience Measures (PREMs)**

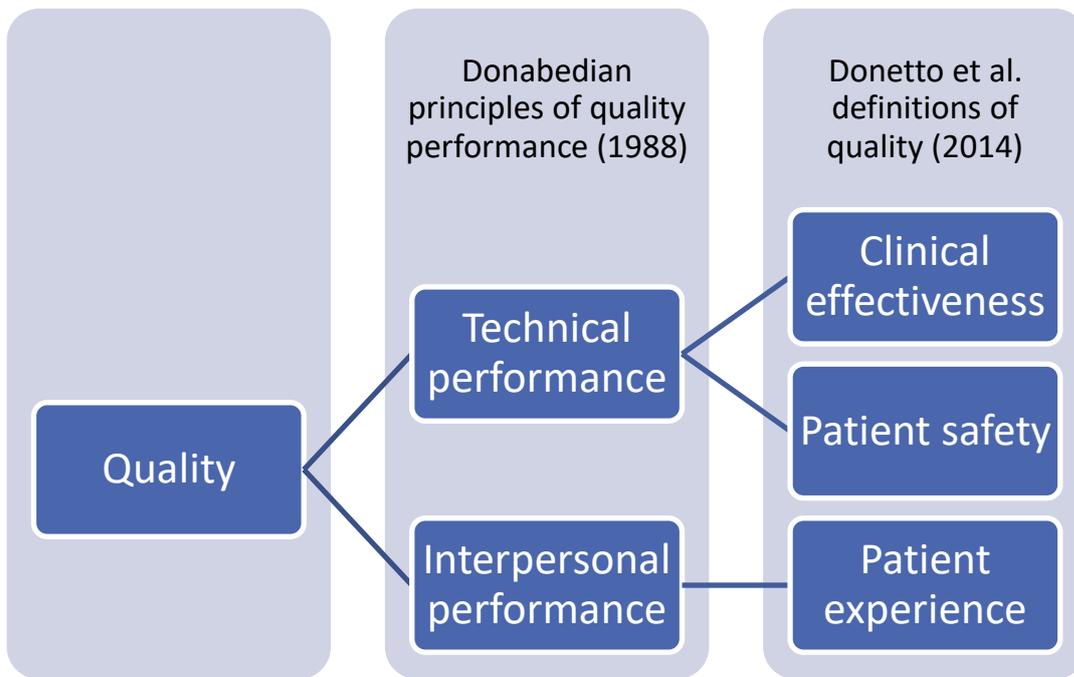
PREMs are used in practice to collect different data in comparison with PROMs. PREMs are similar to PROMs as they are patient reported measures, but the main focus is to identify patient views, perspectives of experience and opinions on the quality of care. This is currently taking place in the United Kingdom with widespread use of the 'Friends and Family test' across the NHS since its introduction in 2013 (OECD, 2017) as a standardised form asking the public if they would recommend the services they have used, aiming to highlight both good and poor patient experience. PREMs can also be developed for disease-specific use, and have been used in practice for conditions such as stroke and diabetes (OECD, 2017) and inflammatory arthritis (El Miedany, El Gaafary, Youssef, Ahmed, & Palmer, 2013). PREMs consistently include questions regarding patient experiences and views upon the processes of care, elements which, if positive, contribute to a quality service.

### 1.3.5 Measuring quality

When PROMs are used to compare providers' performances to stimulate improvements in services, they aim to improve quality of care (Black, 2013). Quality, however, is difficult to quantify. On a practical level, previous studies have used measures such as hospital readmission rates (Benbassat & Taragin, 2000), emergency hospital admissions and mortality rates (Downing et al., 2007) to determine quality. Many papers have discussed quality improvement by implementing best practice changes (Boyce & Browne, 2015; Ferlie & Shortell, 2001; Grol & Grimshaw, 2003), but there is no unanimous opinion as to what constitutes 'quality', and who defines it.

Donetto, Tsianakas, and Robert (2014) completed the final report on the Experience-based Co-design (EBCD) study which encompassed 80 studies over 10 years. Their approach suggested clinical effectiveness, patient safety and patient experience as measures of quality. An alternative viewpoint is proposed by Donabedian (2005), describing in a more ambiguous statement that quality can be: *"anything anyone wishes it to be, although it is, ordinarily, a reflection of values and goals current in the medical care system and in the larger society of which it is a part"* (page 692).

Donabedian (1988) describes two elements comprising the quality of practitioner performance: one technical and the other interpersonal. The Donetto et al. (2014) definitions of quality can be placed under each category of technical and interpersonal performance, which can be viewed in Figure 1 (page 28). Clinical effectiveness and patient safety can be included under the banner of technical performance, whereas patient experience can be included under interpersonal performance.



**Figure 1: Definitions of quality**

(Donabedian, 1988; Donetto et al., 2014)

In combining the quality elements of Donabedian (1988) and Donetto et al. (2014), common ground is found to present a view of what patients may feel constitutes a quality service.

Despite claims that PROMs aim to improve quality (Black, 2013), a recent NIHR funded realist synthesis by Greenhalgh et al. (2017) uncovered the tension between PROMs as a quality improvement strategy versus their use in the care of individual patients. Specifically, Greenhalgh et al. (2017) concluded that the PROMs which clinicians find useful in assessing patients, such as individualised measures, are not useful as indicators of service quality.

### **1.3.6 Public Involvement (PI) in PROMs**

Repeated calls have been made to engage and involve patients and the public, and to place them at the centre of treatment plans (Ocloo & Matthews, 2016). Quality centres the patient at the heart of care, with agreement from health care experts that truly safe and effective care can only be achieved when patients are present, powerful and involved at all levels (Berwick, 2013). Patients being 'involved' includes research being carried out 'with' or 'by' members of the public as patients,

potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services, and does not include research being done 'to', 'about' or 'for' the public (INVOLVE, 2012). 'Public involvement', as a phrase, is a new concept and was previously referred to as 'Patient and Public Involvement' (PPI) (National Research Ethics Service & INVOLVE, 2009) but is now more inclusive of the wider community by developing to 'PI'.

PI encompasses 'involvement' only, where members of the public are actively involved in research projects and in research organisations. Other phrases which are commonly used which should not be confused with 'involvement' include: 'participation', where people take part in a research study and 'engagement', where information and knowledge about research is provided and disseminated (INVOLVE, 2012).

Examples of PI programmes include the National Institute for Health Research funded programme 'INVOLVE' (INVOLVE, 2012) and the Health Research Authority (INVOLVE and the Health Research Authority, 2016). Public engagement is supported by the Department of Health. The white paper 'Equity and Excellence: Liberating the NHS' (Department of Health, 2010a) set out the Government's vision of an NHS that puts patients and the public first. Further papers have followed, with 'No decision about me, without me' championing PI as the norm (Department of Health, 2012, 2013a). Members of the public as patients, carers and potential patients can play an important role in shaping the way in which care is offered and delivered. Specifically, increasing involvement of the public as patients and carers can help to diagnose and treat minor, self-limiting conditions; prevent occurrence or recurrence of disease or harm; help to select the most appropriate form of treatment in partnership with health professionals for more serious illness; and actively managing long term conditions in a more effective way (Coulter & Ellins, 2006).

PROMs therefore have great potential for PI in development, evaluation and application, with members of the public as active members of the research team, to enhance the quality, relevance, and acceptability of PROMS (Staniszewska, Haywood, Brett, & Tutton, 2012). It is beneficial, and

essential to collaborate with the public intimately in all stages of PROM development as measures need to be understandable and relevant to the patient group (Nicklin, Cramp, Kirwan, Urban, & Hewlett, 2010).

PI in most PROMs studies occurs at the level of patient 'involvement' in the study and 'participation' in completing the PROMs for a study or testing and developing PROMs (Ikiugu, 2014). Most routinely recorded PROMs were originally designed for assessing treatment effectiveness in the context of clinical trials. Although PROMs are now used more widely to assess patient perspectives of care outcomes, the results of these measures are mainly used to assess services 'to', 'about' and 'for' the public (INVOLVE, 2012). Specifically, PROMs are primarily used to measure the impact of healthcare interventions in practice, assist with guiding resource allocation, evaluating the effects of changes to services, and providing feedback to health care services to assist clinical governance (Dawson, Doll, Fitzpatrick, Jenkinson, & Carr, 2010).

### **1.3.7 Outcome measures and physiotherapy**

Following the CQUIN framework release the Chartered Society of Physiotherapy (CSP) collated suggestions for outcome measures (Chartered Society of Physiotherapy, 2013; Department of Health, 2010c). The CSP developed quality assurance standards (Chartered Society of Physiotherapy, 2016a) to mandate use of standardised, validated outcome measures in clinical practice. The researcher, working in a physiotherapy department at one North West NHS Trust, observed introduction of separate outcome measures for each body area assessed by physiotherapists. These measures included: Quick Disabilities of the Arm Shoulder and Hand (QuickDASH) for the upper limb (Institute of Work and Health Canada, 2013), Neck Disability Index for the cervical spine (Vernon & Mior, 1991), Roland Morris Disability Questionnaire (Roland & Morris, 1983) for lumbar spine dysfunction, Linton and Hallden questionnaires for prediction of outcome in the lumbar spine (Linton & Halldén, 1998); and the Lower Extremity Functional Scale for the lower limb (Binkley, Stratford, Lott, & Riddle, 1999).

The researcher, working in the aforementioned North-West trust at the time of the introduction of compulsory outcome measure collection, noticed some patients enjoyed filling in their questionnaires, asking what the scores meant, asking how it differed from other people's and some were interested to know their scores on finishing their course of treatment. Some patients found the questionnaires time consuming and were indifferent to their results. The collated outcome measures for this North-West trust were used to demonstrate clinical effectiveness and quality outcomes for commissioners and were collated in preparation for Care Quality Commission (CQC) assessment. The increase in use of outcomes in daily practice was discussed frequently within the physiotherapy team and on an anecdotal level appeared to change the patients' experiences by initiating increased involvement and engagement in physiotherapy for some patients, but not for all. For those who presented as having a higher level of engagement, it was not clear what specific behaviour it influenced or if they did in fact have more advanced interactions with their therapist. The data collected via the PROMs for the North-West Trust only demonstrated quantitative outcomes of effectiveness of treatment and were unable to provide further insight into the processes potentially occurring due to outcome measure introduction in practice.

#### **1.4 Developing the research idea**

The research idea was conceived from this experience in practice, where the researcher developed a deeper understanding and insight into the use of monitoring with patients, mainly surrounding the specific context of Patient Reported Outcome Measures (PROMs). Data use was observed by the researcher, noticing audits took place to prepare information for commissioners or for service assessment. Clinicians were routinely 'involved' in finding out the PROMs outcomes, lacking interaction 'with' patients and exploration of the PROMs 'by' patients (INVOLVE, 2012). PROMs are validated prior to use to ensure they are effective in identifying change in status for the condition they are designed to assess. Concurrent with their design purpose, the use of PROMs in practice appeared to confirm change in clinical status, but they presented as influencing patient behaviour further when patients were informed of their PROMs scores.

The research idea therefore grew from a standpoint of finding out what mechanisms were occurring with patients when PROMs were used, specifically in circumstances where patients had access to this information via feedback. The PROMs feedback to patients was therefore classed as the 'intervention' within this study.

## **1.5 Theories underpinning behaviour change**

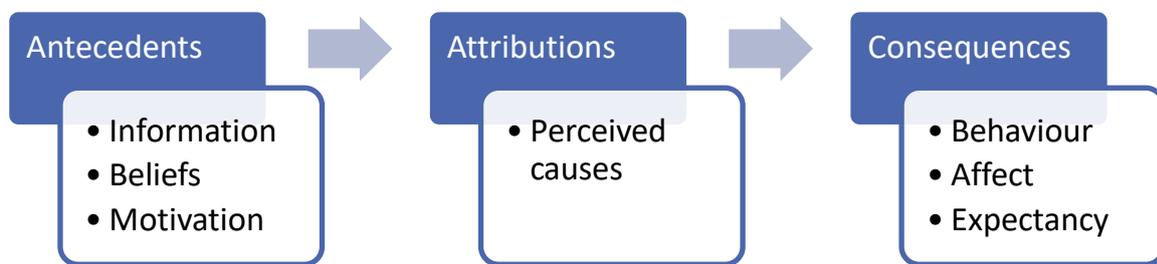
Behaviour change theories can give insight into underlying mechanisms which occur in social programs (Kaplan, Spittel, & David, 2015) and can serve as "*summaries of hypothesised causal processes*" (Gardner, Whittington, McAteer, Eccles, & Michie, 2010) (page 1618) offering systematic and standardised frameworks for evaluating interventions. Behaviour change theory therefore aims to provide explanations for observed effects, to then be able to generate future practice recommendations (Michie & Abraham, 2004).

### **1.5.1 Chronicle of behaviour change theories**

Behaviour has been widely researched in social psychology over the last 50 years (Ajzen, 1985, 1991, 2002; Bandura, 1986; Bickman, Riemer, Breda, & Kelley, 2006; Festinger, 1962; Heider, 1958; Kluger & DeNisi, 1996; Michie, van Stralen, & West, 2011), with theories proposing hypotheses to predict or modify behaviour. Taylor (2007) identifies that many behaviour change theories "*share identical or overlapping characteristics, and have evolved from common roots as a result of an evolutionary process of development*" (page 6). In this section about theories of behaviour change, this stance is supported, chronologically discussing the progression of widely-used theories, starting with 'Attribution theory', conceptualised in the 1950's (Heider, 1958), exploring refinement over time to the Theory of Reasoned Action (Fishbein, 1979; Fishbein & Ajzen, 1975, 2011) and subsequent development to arrive at the Theory of Planned Behaviour (TPB) (Ajzen, 1985, 1991, 2015). The TPB, as the most recently developed theory in this line of advancement, will be critiqued.

### 1.5.1.1 Attribution theory

A theoretical proposal was established by Heider (1958), named 'Attribution theory.' This theory considers how a person uses information to arrive at causal explanations for events, examining what information is gathered and how it is combined to form a causal judgement (Fiske & Taylor, 2017). It was thought that the causes of behaviour were linked to either one of two influences: internal or external, although it was argued that the distinction between the two required more definition (Buss, 1978). Kelley and Michela (1980) therefore developed a more detailed 'Attribution field' theory involving antecedents, attributions and consequences which can be viewed below in Figure 2, where researchers interested in cognitive processes primarily focused on the antecedents-attributions link and those interested in the dynamics of behaviour, on the attributions-consequences link.

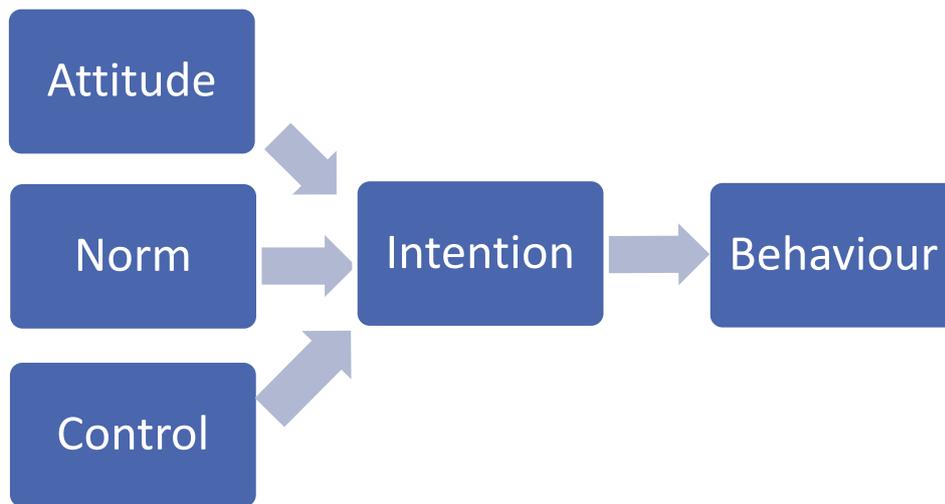


**Figure 2: General model of the attribution field**

(Kelley & Michela, 1980)

### 1.5.1.2 Theory of Reasoned Action and Theory of Planned Behaviour

The Theory of Reasoned Action (TRA) (Fishbein & Ajzen, 1975) was also developed at a similar time to attribution theory development, with the TRA originating from the field of social psychology as a conceptual framework to show how attitude impacted behaviour, developed explicitly to deal with purely volitional behaviours (Ajzen, 1988), where actions are underpinned by conscious choice, decision, and intention. TRA evolved into the more complex Theory of Planned Behaviour (TPB) (Ajzen, 1985) by adding perceived behavioural control, allowing TPB to emerge as an influential and popular conceptual framework for the study of human action (Ajzen, 2002) (Figure 3).



**Figure 3: Theory of Planned Behaviour**

Ajzen (1991) noted the central factor in both the TRA and the TPB as the element of *intention*. As the principal predictor of behaviour, intention is regarded as the motivation necessary to engage in a particular behaviour: the more one intends to engage in a behaviour, the more likely should be its performance (Armitage & Conner, 1999).

Attitudes and subjective norms as elements of the TPB can be classed as intentions. Armitage and Conner (1999) conceptualise attitudes as overall positive or negative evaluations of behaviour, which are derived from prominent behavioural beliefs: the perceived likelihood of particular outcomes occurring, multiplied by an evaluation of those outcomes. The second determinant of intention, subjective norms, also part of the TPB, are defined as perception of general social pressure from salient others to perform or not to perform a given behaviour (Armitage & Conner, 1999). Control as the third determinant of intention concerns factors that individuals feel facilitate or hinder their performance. Behaviour can also be affected by other non-motivational factors such as availability of requisite opportunities and resources, for example, time, money, skills and cooperation of others (Ajzen, 1985).

In testing the TPB with empirical research in a health setting, it has been found that intention remains the most important predictor of behaviour change, but perceived behavioural control adds

further predictability in terms of behaviour. Godin and Kok (1996) carried out a systematic review to determine the efficiency of the TPB to explain and predict generalised health related behaviours. They reviewed 56 studies, spanning seven categories of risk behaviour or health behaviour (car safety, addictive, clinical screening, eating, exercise, HIV/AIDS, oral hygiene), finding that in half of the 56 studies, perceived behavioural control significantly added to the prediction. Despite this claim, in a more recent and health focused study reviewing 111 TRA or TPB exercise studies, Downs and Hausenblas (2005) identified the intention–behaviour association was larger in studies that measured intention and behaviour within a 1-month period compared with the studies with a time interval greater than 1 month. The following salient points were concluded by Downs and Hausenblas (2005):

1. Exercise was most strongly associated with intention and perceived behavioural control
2. Intention was most strongly associated with attitude
3. Attitude and perceived behavioural control predicted intention and intention predicted exercise behaviour

Both reviews (Downs & Hausenblas, 2005; Godin & Kok, 1996) confirm that human volition can greatly influence health-related decision making and create differing responses to similar situations, indicating that interventions which can influence attitude, perceived behavioural control and intention elements of the TRA / TPB can influence behavioural changes.

### **1.5.2 Changing health behaviour**

Changing health behaviour has become increasingly important as human behaviour accounts for the largest source of variance in health-related outcomes (Schroeder, 2007). With increased awareness that individuals can make contributions to their own health and well-being through adopting particular health-enhancing behaviours (Conner & Norman, 2005), behaviour change strategies are a high priority, particularly as all individuals make health-related choices on a daily basis (Darnton, 2008). In the United Kingdom, the NHS has published several white papers regarding health

behaviour and change (Department of Health, 2010a, 2010b, 2012, 2013a, 2013b; Michie et al., 2008). 'Choosing Health: making healthy choices easier' (Department of Health, 2004, 2012) outlined that health improvement is dependent upon people's motivation and their willingness to act on it, a view based on the elements of the TPB concerning a decision based on human volition. 'Improving Health: Changing behaviour – NHS health trainer handbook' (Michie et al., 2008) introduces the main techniques that can help people decide whether, and what, they would like to change, and how to change. Techniques discussed include goal setting, self-monitoring, creating action plans and building social support with an over-arching theme of self-monitoring. This presents a more complex system, which recognises that the target behavioural outcome can, in principle, arise from combinations of many components.

### **1.5.3 Which theory is suitable to predict health related behaviours?**

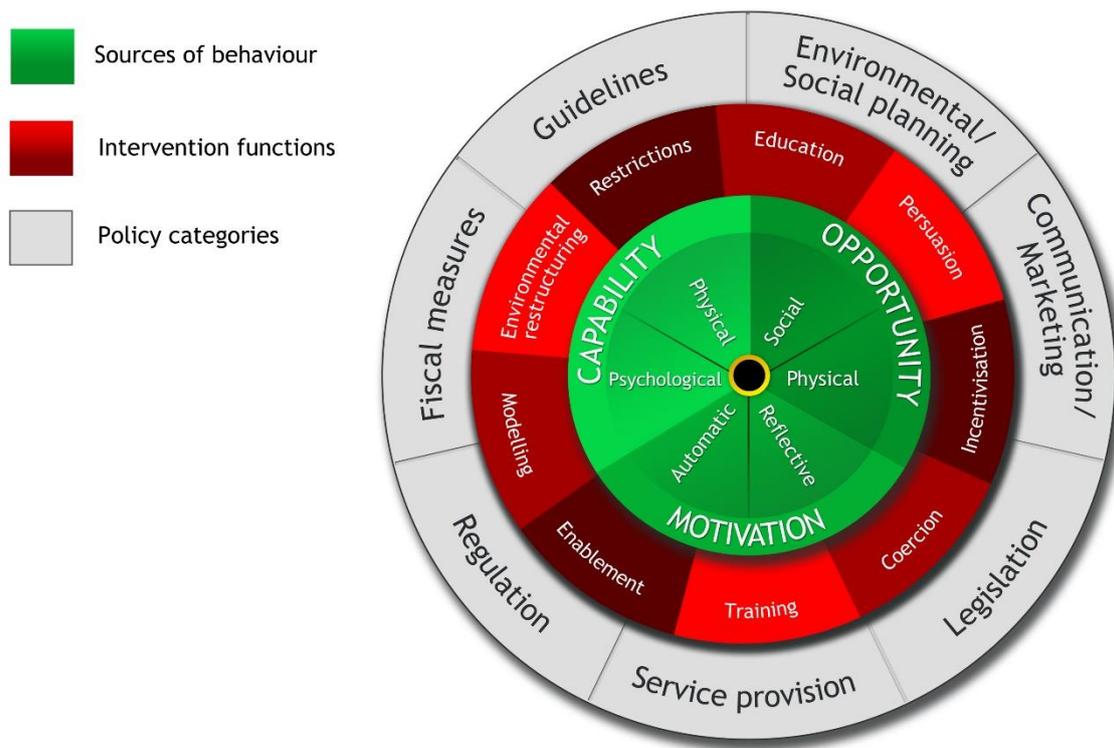
Theories can be developed to predict specific behaviours or global patterns of behaviour, depending on their intended use (Terry, Gallois, & McCamish, 1993) with each exhibiting strengths and weaknesses which require consideration before selecting their use.

The TPB predicts global patterns of behaviour, described by Ogden (2015) as basic, clear and parsimonious but also commenting that human behaviour is more complex than the sum of its basic elements. Conner (2015) presents attitudes and perceived behavioural control to have large effect sizes in predicting intentions in a health domain, a conclusion also confirmed by a meta-analysis (statistical methods to summarise the results of differing studies) carried out by McEachan, Conner, Taylor, and Lawton (2011).

Recent debate has argued the need for 'retirement' of the TPB (Sniehotta, Penseau, & Araújo-Soares, 2014) due to limited validity and utility, calling for a "*better explanation of health behaviour change*" (page 7) as the TPB appears to omit feedback loops from behaviour to cognitions. Ajzen's personal reply to the claim (2015), details a more recently updated version of TPB, which includes the feedback element (Fishbein & Ajzen, 2011), quoting:

*“When a behaviour is carried out, it can result in unanticipated positive or negative consequences, it can elicit favourable or unfavourable reactions from others, and it can reveal unanticipated difficulties or facilitating factors. This feedback is likely to change the person’s behavioural, normative, and control beliefs and thus affect future intentions and actions” (p. 271).*

Simple theories (such as the TRA and TPB) as basic structures are thus built on and refined by theorists and researchers. Behavioural theories have become more complex over time to consider the many other contributing factors and contexts which influence how people behave, to become more specific. One such complex and developed theory is the ‘Behaviour Change Wheel’ in Figure 4 (Michie et al., 2011), which was used reliably to characterise interventions within the English Department of Health’s 2010 tobacco control strategy (Department of Health, 2010b) and the National Institute of Health and Clinical Excellence’s guidance on reducing obesity (National Institute for Clinical Excellence, 2006).



**Figure 4: The Behaviour Change Wheel**

(Michie et al., 2011)

At the centre of the wheel is a 'behaviour system' involving three essential conditions: capability, opportunity, and motivation, around which nine intervention functions are positioned, aimed at addressing deficits in one or more of these conditions. The outer ring, places seven categories of policy that could enable those interventions to occur. It outlines the complexities of behaviour change and the plethora of issues that affect how people change. Theories such as the 'Behaviour Change Wheel' (Michie et al., 2011) are useful due to their specificity and complexity, but often become impossible to operationalise due to their elaborate nature (Ogden, 2015). Theories must therefore be complex enough to explain processes but simple enough to utilise.

In driving forward behavioural change for health improvement, feedback on behaviour has recently become an important factor for informing individuals of their performance to consolidate positive behaviour changes. This trend has mainly been observed in the sector of audit and feedback to

health professionals thus far to improve standards (Flottorp, Jamtvedt, Gibis, & McKee, 2010; Hysong, Best, & Pugh, 2006), and is beginning to be observed in the sector of patient feedback, mainly in the mental health domain (Carlier et al., 2012).

## **1.6 What is feedback?**

Feedback loops are important to include within theoretical frameworks (Ajzen, 2015; Fishbein & Ajzen, 2011; Sniehotta et al., 2014) as they are argued to be a critical component of maintenance of behaviour in addition to the promotion of adaptation and change (DiClemente, Marinilli, Singh, & Bellino, 2001). With feedback presenting an area for debate amongst theorists (Ajzen, 2015; Sniehotta et al., 2014), it is essential to understand the types of feedback which have existed, and to understand the use of feedback as a term in the social sciences and what the feedback element contributes to behaviour change theories in a social context.

### **1.6.1 Definitions of feedback**

Within the social sciences, feedback is difficult to define as it is not a single, precise theoretical concept (Wimsatt, 2007). Rosenblueth, Wiener, and Bigelow (1943) initially explored the term 'feedback' and its application from science to a behavioural context (Van de Ridder, Stokking, McGaghie, & Ten Cate, 2008). Feedback as a general concept in science is considered to be a circular process, denoting that the output energy of something will be returned as input (Rosenblueth et al., 1943). Feedback is therefore an input signal, which gives information in a loop-type process. The feedback of information can be considered as a 'resource', and alone, feedback does not change an output but contributes to the mechanisms which occur to produce change.

The social science definition of feedback is reinforced across numerous disciplines. Feedback in relation to closeness to a goal status can be used to signify that the behaviour of an individual is controlled by the difference between where the individual feels they are placed at a given time with reference to a relatively specific goal (Rosenblueth et al., 1943). This definition is mirrored within the

management sector, where feedback is considered to describe information about the gap between the actual level and the reference level of a system parameter, which is used to alter the gap in some way (Ramaprasad, 1983). Feedback in clinical education is also well defined with a detailed description:

*“Feedback as information has message content as its focus. Central to feedback as a reaction is interaction, a process of information delivery and reception. Feedback as a cycle includes both information and reaction features but also includes a consequence or outcome of the message (e.g. response improvement). In addition, feedback as information is discrete, whereas both the reaction and cycle formulations are processes”* (Van de Ridder et al., 2008) (page 191).

‘Feedback’ as a term within this specific study combines elements from multiple disciplines, and is defined as:

***“An interaction between a health professional and a patient by which information is returned to the patient about their current status. This feedback of information as a resource is then compared with previous information for the patient and health professional to observe whether the patient’s current behaviour needs modifying. Behaviour can then be modified if deemed necessary. This process is then repeated as a feedback cycle.”***

### **1.6.2 Use of information feedback in healthcare**

The use of the word ‘information’ within the feedback definition also requires clarification. Information gathered about an individual can be fed back to the individual it is gathered upon, which in healthcare is usually the patient. It can alternatively be fed back to the clinician treating the patient. Feedback in a healthcare setting can take many forms and has many different definitions. In the context of this study, information feedback will be the focus.

Information feedback in healthcare is prevalent within mental health settings, frequently being used as part of treatment, and this trend has been reflected within research studies (Carlier et al., 2012). The majority of studies using information feedback in mental health have been concerned with providing feedback to health professionals about their clients, with research evident in the following areas: mental health in young people (Bickman, Kelley, Breda, de Andrade, & Riemer, 2011), psychotherapy (Harmon, Hawkins, Lambert, Slade, & Whipple, 2005; Newnham, Hooke, & Page, 2010), and counselling services (Newman & Greenway, 1997). Patient-based measures of health, fed back to clinicians, are commonly used to try to improve patient outcomes by enabling clinicians to detect and treat problems that previously may have been unidentified (Carlier et al., 2012).

The effectiveness of information feedback in mental healthcare has been variable between studies. Knaup, Koesters, Schoefer, Becker, and Puschner (2009) conducted a meta-analysis of studies feeding back outcomes to clinicians and/or clients in mental healthcare and found small, but significant positive short-term effects, (over approximately nine weeks), on the mental health of individuals ( $d=0.10$ ; 95% CI 0.01–0.19). Two longer term studies included within the meta-analysis in which follow-up was conducted at four months (Trudeau, 2000) and six months (Schmidt et al., 2006; Trudeau, 2000), indicated that these effects were not sustained over time. An earlier meta-analysis studying the use of feedback to enhance performance (Kluger & DeNisi, 1996), concluded that feedback has a small to medium effect ( $d=0.41$ ), suggesting approximately two-thirds of individuals given feedback had a similar or better result than people in the control group who were not given feedback (Sapyta, Riemer, & Bickman, 2005).

A systematic review answers a specific research question by collecting and summarising all empirical evidence that meets the review's eligibility criteria. The use of information feedback in a physical health capacity was included in a systematic review by Carlier et al. (2012), where 52 randomised controlled trials (seven physical health focus and 45 mental health focus) tested repeated feedback of information to patients/clients and/or clinicians. The systematic review concluded information

feedback (in this study termed as Routine Outcome Monitoring) was especially effective for the monitoring of patients who are not doing well in mental health therapy. Overall, 63% of the 52 studies found a positive impact of information feedback (using ROM) in the short term, where positive results were classed as the experimental group having significantly fewer complaints than the control group. The smaller numbers of studies researching physical health (seven) versus the larger number in mental health (45) in Carlier's (2012) systematic review was noted as a difference in research trend.

Collectively the results from Kluger and DeNisi (1996), Knaup et al. (2009) and Carlier et al. (2012) suggest that information feedback can be effective within a mental health setting. As the effects only appear to last in the short term and effect sizes are small to moderate (Kluger & DeNisi, 1996; Knaup et al., 2009) the results suggest that there may be certain circumstances which facilitate feedback to have the desired effect.

In the physical health domain, a recently reported feasibility study by Ryan et al. (2016) aimed to determine the viability of using computerised 'real-time' feedback of outcome measurements to recovering patients with burns in a clinical setting. The process of feeding back outcome measurements from the Young Adult Burn Outcome Questionnaire (YABOQ) to communicate progress was mostly well received by the clinicians and patients with burns in the outpatient clinic setting. The results from this study (Ryan et al., 2016) suggest that disease-specific outcome measure feedback is feasible for use in practice, although the authors concluded that further clinical testing was indicated. The qualitative data from the study questionnaire (Ryan et al., 2016) gave some insight into the processes occurring behind the information feedback process, supporting the standpoint provided by multiple literature sources (Duncan & Murray, 2012; Greenhalgh et al., 2017; Trillingsgaard et al., 2016) in which feedback of outcome measures can facilitate communication. Ryan et al. (2016) identified that feedback of YABOQ helped increase communication between patients and clinicians and helped identify clinical issues to address.

### **1.6.3 Contextual conditions for feedback effectiveness**

Theorists and researchers have posited differing ideas on what contextual conditions are conducive to trigger positive use of feedback, resulting in effective outcomes.

Theory suggests that feedback can improve or impair performance and its effects are not always consistent (Kluger & DeNisi, 1996). Giving feedback as an intervention to patients during standard treatment to inform them of their reducing pain levels could be assumed as positive information feedback concerning recovery, although it is suggested that focussing on the 'self' can delay recovery (Kluger & DeNisi, 1996). Kluger and DeNisi (1996) propose that focussing on a task such as a functional ability as an alternative to focussing on the 'self' is more conducive to recovery.

Sapya et al. (2005) suggest an individual is likely to change their behaviour with the feedback intervention only if: they have an important goal to accomplish, they notice a significant discrepancy between the goal and their current status regarding the goal, and they believe they can reduce the discrepancy. Changing behaviour requires self-regulation to control thoughts, feelings and actions in relation to knowledge and action by actively interpreting external feedback in relation to their internal goals (Zimmerman & Schunk, 2001). An individual with a higher level of self-regulation is more likely to be effective in using external feedback to monitor their engagement with activities and tasks, assess progress towards goals and change behaviour accordingly (Nicol & Macfarlane-Dick, 2006; Zimmerman & Schunk, 2001).

The manner in which feedback is presented to an individual can also affect their behavioural response. It is suggested that feedback sources are most effective when the individual feels the source is credible, and the feedback is immediate, frequent, systematic, cognitively simple (such as graphic in nature), unambiguous, and provides individuals with concrete suggestions of how to improve (Norcross, 2011). This partially agrees with a previous study by Hysong et al. (2006), who researched feedback of guideline adherence to clinicians, concurring that feedback must be timely, but in addition must be individualised and non-punitive.

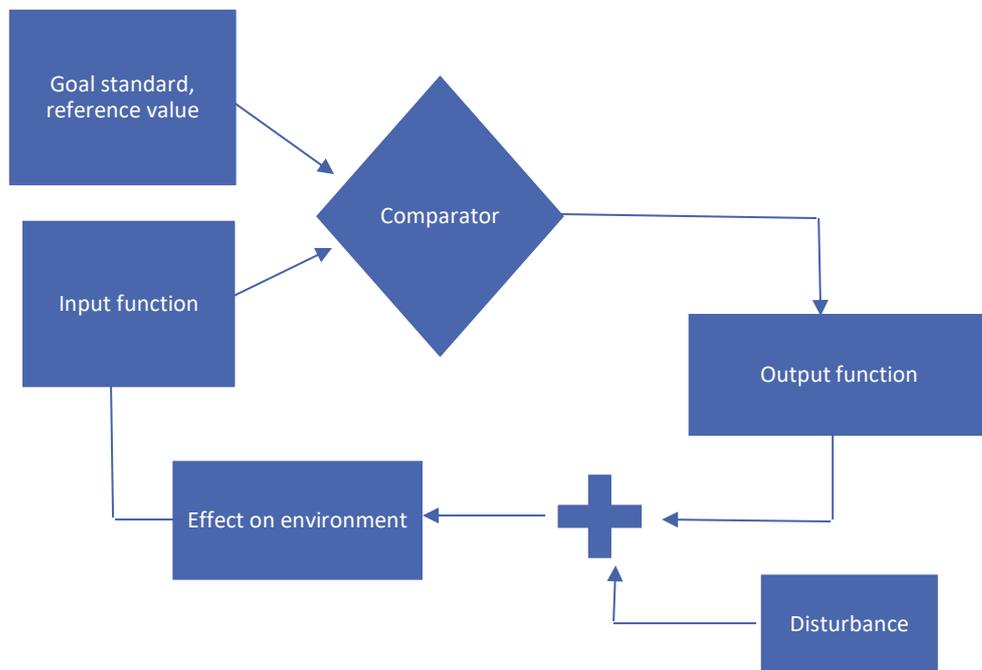
## **1.7 Theories underpinning feedback as an intervention: How does feedback work?**

As feedback of information was to form a large part of this study, it was important to identify a driving theory to underpin the design. Attribution theory, the TRA and TPB are presented as theories to predict behaviour but without defined feedback loops within their structure. Behavioural theories with feedback frameworks were therefore evaluated, aiming to identify a theory to underpin the methodological design and direction of analysis within the study.

Carver and Scheier (1982) note the progression from a basic level of self-regulation as a physiological mechanism in Cannon's (1929) work on homeostasis, to theories with basic principles of conditioning, i.e. to promoting certain behaviours with either reward or punishment (Thorndike, 1933), to development of feedback as a method of informing an individual about the consequences of their behavioural choices.

### **1.7.1 Control Theory**

Carver and Scheier (1982) developed 'Control theory' (Figure 5) where the central function of a feedback system is not to create 'behaviour' but to create and maintain the 'perception' of a specific desired condition: that is, whatever condition constitutes the reference value or standard of comparison.



**Figure 5: Control Theory**

(Carver & Scheier, 2001)

Carver and Scheier's Control Theory (1982) queried what behavioural outputs allowed people to minimise discrepancies between actual status and desired (goal) status. The standard is set by the individual as hierarchical levels where there are upper, superordinate levels and lower, subordinate levels. The system of feedback appeared to be self-regulatory, suggesting that when individuals enter a new behavioural situation, they implicitly categorise that situation, based partly on the situation's observable elements and partly on the person's previously organised knowledge about physical and social environments. It was posited that standards set by individuals could be abstract or concrete in terms of measuring superordinate and subordinate levels (Carver & Scheier, 1982).

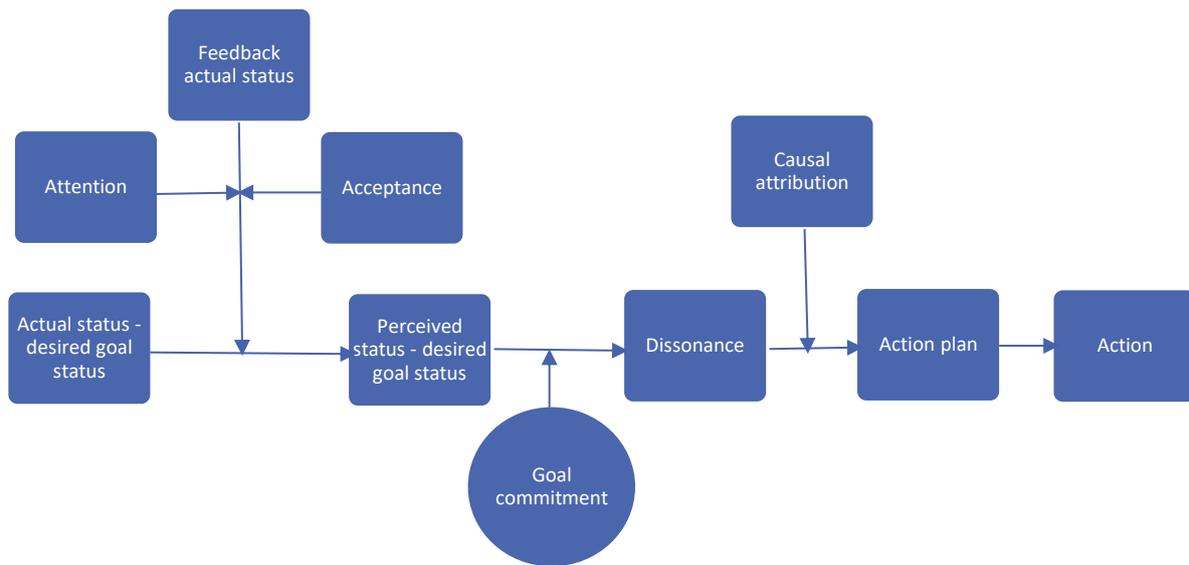
It is thought that feedback is most likely to change behaviour when the information provided indicates the individual is not meeting an established standard. This occurs when an individual makes comparisons against a goal or standard. The areas with discrepancies between actual and desired goal status will receive attention and the feedback intervention itself will prompt a change in the focus of attention (Kluger & DeNisi, 1998). If an individual is committed to the goal of improving

their performance, and aware of a discrepancy, the feedback may also reduce uncertainty regarding behaviour and can give an individual the necessary information to make judgements about performance and to make alterations and corrections to their behaviour (Michie, 2014). However, as previously described, feedback is complex, and is influenced by certain factors in addition to goal commitment and discrepancy. Feedback needs to be: credible, timely, frequent, systematic, cognitively simple, unambiguous, with concrete suggestions which are individualised and rewarding to work successfully (Hysong et al., 2006; Norcross, 2011).

### **1.7.2 Contextualised Feedback Intervention Theory (CFIT) (Riemer & Bickman, 2011)**

The Contextualised Feedback Intervention Theory (also known as the 'Complete Change model') was developed by Leonard Bickman (Bickman et al., 2006) and further builds upon Carver and Scheier's Control Theory (1982). CFIT, as posited in Control Theory, assumes that a basic mechanism in behaviour regulation is the evaluation of and reaction to a feedback-standard comparison. The CFIT predicts that feedback can be more effective where feedback emphasises features of a performance task (e.g. specifying a target performance, presenting information on how target performance can be attained, and commentary on the degree of change in performance observed since previous feedback), and less effective where it focuses on the feedback recipient (e.g., discouragement or praise of performance) (Gardner et al., 2010).

The CFIT theory helps to explain how interventions can improve outcomes. The model as described in Figure 6, page 47, was initially developed as a theory for interventions designed to improve performance by changing behaviour of professionals (Bickman et al., 2014) and was not developed for use with a patient population. CFIT is a complex theory and for the largest part untested (de Jong, 2013).



**Figure 6: The Contextualised Feedback Intervention Theory**

(de Jong, 2013; Riemer, Rosof-Williams, & Bickman, 2005)

The CFIT presents as a theory where an individual (clinician) will identify their actual status and their desired goal status. After receiving feedback, this increases attention to their actual measured status and they can decide whether to accept the feedback. The individual can then deliberate their perceived status and consider their goal status and commitment to it. Identifying new information which disagrees with existing information (dissonance) in relation to the feedback itself or the feedback process and causal attributions within or outside of their control will then affect their action plan.

### **1.7.2.1 CFIT testing**

The CFIT has been tested previously with clinician based feedback (Bickman et al., 2011). Bickman et al. (2011) studied the effectiveness of weekly feedback of outcome measures over 90 days to clinicians to evaluate its effectiveness in improving home-based mental health treatment received by youths in community settings. Bickman et al. (2011) ran a cluster randomised controlled trial and found that at sites where clinicians received weekly feedback, clients improved faster on the Symptoms and Functioning Severity Scale (SFSS) than those treated at sites where clinicians did not

receive weekly feedback. Statistical analysis was carried out to describe the change in effect on individuals caused by differing levels of exposure to feedback (dose-response analysis), which reported even stronger effects when clinicians viewed more feedback reports. Limitations of this study included the implications of clinicians volunteering their participation, and choosing clients for information feedback which may introduce selection bias. Accepting these limitations, the study concluded the use of information feedback systems in community clinical practice in a mental health capacity as a potentially effective way of improving outcomes.

## **1.8 Selected middle range theory**

Identification of a theory to aid direction of research is thought to be imperative (Pawson, 2013). Middle range theories are able to be tested empirically in the real world (Sieloff & Frey, 2007). As the description suggests, middle range theories are those which lie between minor day-to-day hypotheses posited by research and all-inclusive, grand theories such as social behavioural, organisational and change theories (Merton, 1968). Compared with the minor hypotheses and grand theories, middle range theories offer ideas and concepts about more confined phenomena of concern to the discipline (Smith & Liehr, 2014).

The CFIT was selected as the middle range theory for exploration within this study as it had previously been tested within clinical practice, albeit within a mental health capacity, and with clinicians. As it should not be automatically assumed that existing theories are adequate theories of complex systems (Wimsatt, 2007), the CFIT was suitable for testing refinement in relation to the specific study population. Importantly it included the feedback element and presented a level of complexity not too elaborate to operationalise (Ogden, 2015) with opportunity to explore patient-specific responses to feedback.

After selecting the CFIT to explore, a full review of the literature surrounding information feedback was indicated to identify current knowledge on the phenomena of feedback reported in empirical research.

## **Chapter 2 - A review of the literature surrounding information feedback of outcome data in healthcare settings**

### **2.1 Introduction**

The previous chapter has given a basic background of the theory behind information feedback processes. This chapter will consider the current empirical evidence surrounding the use of information feedback to patients in practice.

A literature review is defined by Fink (2014) as:

*“a systematic, explicit, and reproducible method for identifying, evaluating and synthesising the existing body of completed and recorded work by researchers, scholars and practitioners”*  
(page 3).

The literature review within this study was therefore undertaken to gain a greater understanding of the body of knowledge surrounding the current usage of feedback of information to patients (or clients), and the context in which it has been researched in differing patient groups. Within this thesis, a scoping review is presented as the most suitable way to scrutinise the literature as it lends itself to both tabular and narrative synthesis and quality appraisal by study characteristics and design (Booth, Sutton, & Papaioannou, 2016).

This chapter commences by summarising the outline of the scoping review with specific distinction between patient groups and types of feedback to be included. Inclusion and exclusion criteria will be discussed and data extraction outlined to meet with the Consolidated Standards of Reporting Trials (Schulz, Altman, & Moher, 2010) for quantitative studies.

The search strategy will be detailed in diagrammatic form to identify where studies were found, which were read in full, and subsequently which studies were excluded due to duplication or not meeting inclusion criteria, finally arriving at the final studies selected. Each selected study was appraised to determine quality, aiming to estimate the certainty of whether the results could be

generalised to the wider healthcare setting (Needleman, Worthington, Moher, Schulz, & Altman, 2008). The current level of knowledge is determined, aiming to explore how feedback works successfully or unsuccessfully, which patients it is successful for, and in which circumstances. The conclusion determines the limitations of the current knowledge base; what has previously been studied (what is known) and areas where further research would be indicated (what is *not* known), finally arriving at the development of the study research question.

## **2.2 The literature review**

A literature review comprises two elements: one being the current state of knowledge in the field, including theories and concepts (covered in chapter one) and a review and critique of relevant empirical research studies to show where research is lacking and needs further study (Ridley, 2012) which will be covered in this chapter.

### **2.2.1 Inclusion and exclusion criteria: Setting the scope of the study**

Developing an explicit set of inclusion and exclusion criteria is important to define which studies will (or will not) be included in the literature review, to define the population to which conclusions can be drawn, and for transparency (Card, 2015). Literature reviews are executed to evaluate and synthesise *primary* data (Aveyard & Sharp, 2013), therefore the first inclusion criteria was to include original, empirical studies only.

#### **2.2.1.1 Adults and children**

For the purposes of defining a sample it was important to decide whether adults and / or children would be preferred as a sample population. As there is a difference in the way in which children and adults approach reinforcement learning in terms of feedback (Shephard, Jackson, & Groom, 2014), it was logical only to choose either adults, or children, not both. The UK population currently stands at over 65 million people (Office for National Statistics, 2015). The NHS is a free service to all UK residents, with adults making up a larger percentage of users, presenting scope for a greater transferability; therefore this study was limited to adult participants only.

### ***2.2.1.2 English language and foreign language studies***

Time and resources for a single researcher within a PhD study limits the ability to extend to the time and cost required to translate published or unpublished work in a foreign language (Coughlan & Cronin, 2017). Considering this viewpoint, it is acknowledged that with a restriction to English language studies in a literature review, important evidence may be missed and is accepted as a limitation of this PhD study (Coughlan & Cronin, 2017). The review scope was extended to include studies found in a foreign language, but only where the original had already been translated into English. Although this study accepts this limitation, it has been found that there is no evidence of a systematic bias resulting from the use of language restrictions in systematic reviews in conventional medicine (Morrison et al., 2012) which supports this criteria for inclusion of studies published in the English language only.

### ***2.2.1.3 Health and illness populations***

A search strategy was planned and developed, aiming to access studies which would meet the inclusion criteria in addition to retrieving studies which would best inform the thesis. Preferable search areas were identified and defined.

There is a wealth of research where information is fed back to 'healthy' participants, those with no illness, but with elements of lifestyle which need addressing for health gains, for example, weight management (Hennecke & Freund, 2014) and diet control (Greene et al., 2008). The distinction therefore needed to be made between 'health' and 'illness'. Health promotion with asymptomatic individuals features highly as an instrumental part of preventative healthcare (Department of Health, 2010b, 2013a, 2013b; Michie et al., 2008) although the NHS population receiving intervention are most often those seeking treatment and of current ill health. Studies were included for symptomatic populations in 'ill health' only to ensure larger transferability across health domains.

#### **2.2.1.4 Physical and mental health populations**

Inclusion criteria for the population of interest was defined, with a distinction made between 'ill health' in mental and physical health domains. The division of the two categories of mental and physical health is a commonly used categorisation used by the medical profession and lay people alike (Kendell, 2001). The sector of ill health in a physical capacity was to be explored as the population of interest, where 'ill health' constituted a poor condition of physical state.

#### **2.2.1.5 Type of feedback**

Studies were included where information was fed back to patients in the form of outcome data. Outcome data can be classed as subjective or objective, with subjective measures involving the perception of the individual being examined, and with objective measures existing independently of the perception of the individual (Duckworth, 1999). Studies feeding back subjective or objective outcome data were accepted, including combinations of the two in PROMs or alternatively visual comparisons against the norm. The feedback *must* have been fed back to the patient to be included within the literature review.

Feedback to clinicians was excluded unless it was part of a study which also fed back information of outcome data to patients. Biofeedback as a source of information was considered initially as it is designed to help people alter their behaviour, but rejected on the terms that it is a form of feedback which is supplied by their physiology (e.g. muscle tension) rather than an interaction between a clinician and patient (Schwartz & Andrasik, 2015).

#### **2.2.1.6 Frequency of intervention**

Repeated feedback has been presented as a method of increasing its effectiveness (Kluger & DeNisi, 1996). This is supported by a Cochrane review exploring information feedback to health professionals (Ivers et al., 2012). To explore whether this conclusion was also evident in patient feedback scenarios, repeated feedback (two contacts or more) was included within the inclusion criteria.

### **2.2.2 Overview of inclusion and exclusion criteria for the literature review**

In conclusion, the empirical research studies of interest were those reported in the English language whereby adult patients with physical illness received repeated feedback of objective information from clinicians. The following research was excluded: studies reported in a foreign language, research exploring feedback to children, studies providing feedback to health professionals only, single intervention feedback, studies researching mental health populations and studies with healthy participants.

### **2.3 Search strategy**

The initial search was carried out on 9th October 2012 using four main databases: Medline (1946 to present) and EMBASE (1974 to present) via OVID, PSYCHinfo and CINAHL. In addition, specific searches of the Cochrane Database, the Database of Abstracts and Review of Effects (DARE), National Electronic Library for Health (NeLH) and Web of Science (including conference proceedings) were also undertaken. Manual searching was carried out, using forwards referencing to identify articles that cited a particular article or publication of interest to source material and original research as well as on-going research (Jesson, 2011). Manual searching also involved backwards referencing, examining the references cited in an article for further relevant articles. Proquest Nursing and Allied Health Source was searched to find unpublished literature such as PhD theses and Masters dissertations. Hand searching of relevant journals 'Physiotherapy', and 'Implementation Science' were undertaken. The search was re-run on 10<sup>th</sup> October 2016. Tables 3 to 7 (pages 55 to 58) outline which studies were found on the initial search on 9<sup>th</sup> October 2012 and studies additionally identified between 9<sup>th</sup> October 2012 and 10<sup>th</sup> October 2016. They outline the search terms used in each database when searching the literature.

The initial enquiry in Medline was carried out as a detailed and focused search, but as limited studies (3) met the inclusion criteria, a wide search was also performed. Studies which met the inclusion criteria and were accepted for the literature review are specified under the search terms in which

they were found for transparency and ability to reproduce the search (Booth et al., 2016). Boolean operators such as 'and', 'or' and 'not' are identified. Other codes were used to expand or focus searching and are described in Table 8, page 59.

**Table 3: Medline and Embase via OVID focused search (2 pages)**

Search term 1	Boolean operator	Search term 2	Number of studies up to Oct 2012	Number of additional studies 11 Oct 2016	Included studies
*Feedback, Psychological/	AND	patient.me	46	51	(Rees et al., 2013)
*Feedback, Psychological/	AND	(patient adj12 feedback).tw	25	19	
*Feedback, Psychological/	AND	monitor\$.mp	92	75	
*Feedback, Psychological/	AND	patient.tw	47	45	
*Feedback, Psychological/	AND	exp treatment outcome/	50	42	
*Feedback, Psychological/	AND	outcome assessment	9	11	
*Feedback, Psychological/	AND	outcome and process assessment.mp	3	2	
*Feedback, Psychological/	AND	(feedback adj5 (outcome\$ or monitor\$ or patient\$ or progress)).tw	88	84	
*Feedback, Psychological/	AND	(feedback adj10 (outcome\$ or monitor\$ or patient\$ or client\$ or progress)).tw	134	135	
*Feedback, Psychological/	AND	treatment outcome.me	49	42	

Search term 1	Boolean operator	Search term 2	Number of studies up to Oct 2012	Number of additional studies 11 Oct 2016	Included studies
Feedback, Psychological/	AND	patient.me	192	104	
Feedback, Psychological/	AND	(patient adj12 feedback).tw	48	33	
Feedback, Psychological/	AND	monitor\$.mp	159	125	
Feedback, Psychological/	AND	patient.tw	147	89	
Feedback, Psychological/	AND	exp treatment outcome/	94	82	(Duncan & Pozehl, 2003; Nicolaï et al., 2010a)
Feedback, Psychological/	AND	outcome assessment	2	15	
Feedback, Psychological/	AND	outcome and process assessment.mp	21	2	
Feedback, Psychological/	AND	(feedback adj5 (outcome\$ or monitor\$ or patient\$ or progress)).tw	136	109	
Feedback, Psychological/	AND	(feedback adj10 (outcome\$ or monitor\$ or patient\$ or client\$ or progress)).tw	220	182	

**Table 4: Backwards referencing**

Reference list searched	Included studies
Nicolai, Hendriks, Prins, Teijink, and Group (2010a)	Nicolai, Teijink, and Prins (2010b)

**Table 5: PSYCHinfo search**

Search term 1	Boolean operator	Search term 2	Number of studies up to Oct 2012	Number of additional studies 11 Oct 2016	Included studies
Feedback	AND	outcome assessment	31	117	
Outcome assessment	AND	feedback.ti	12	0	

**Table 6: Wide search OVID: Medline and EMBASE**

Search term 1	Boolean operator	Search term 2	Number of studies up to Oct 2012	Number of additional studies 11 Oct 2016	Included studies
*Feedback	AND	outcome.ti	20	12	
(effect\$ and feedback and patient\$).ti			71	14	(Geiger, Todd, Clark, Miller, & Kori, 1992; Mahon, Neufeld, Mani, & Christophersen, 1984)
Feedback AND adherence	AND	exercise.ti	139	40	(Duncan & Pozehl, 2002; Duncan, Pozehl, Norman, & Hertzog, 2011; Shakudo et al., 2011)

**Table 7: CINAHL search**

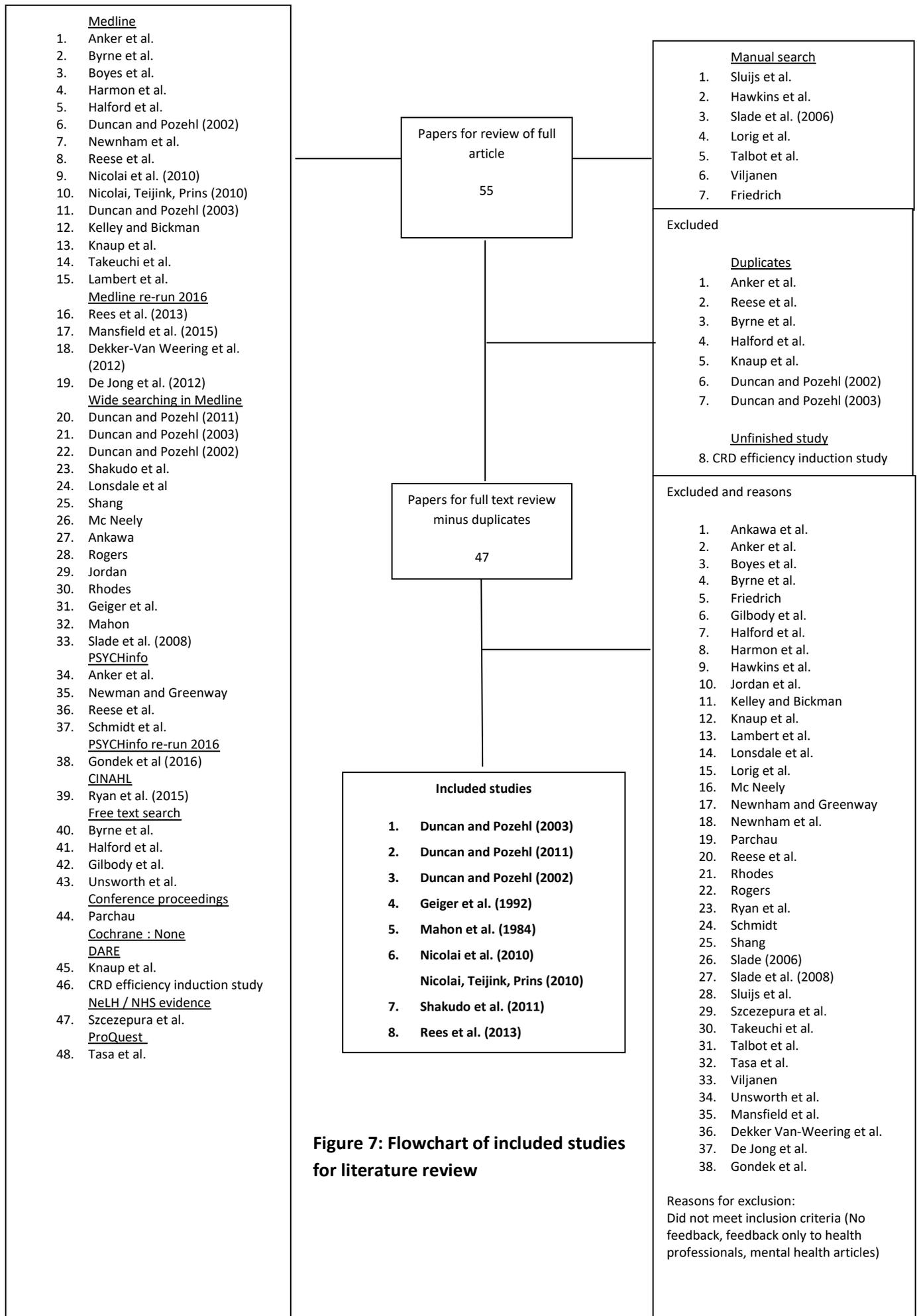
Search term 1	Boolean operator	Search term 2	Boolean operator	Search term 3	Number of studies up to Oct 2012	Number of additional studies 11 Oct 2016	Included studies
Feedback	AND	outcome assessment	AND	patient	215	106	
Outcome assessment	AND	Feedback (in title)	-	-	52	48	

**Table 8: Additional search codes and descriptions of use**

Search code	Search code description
*	Focus
.me	Medical Subject Heading
exp	Explode a term
.ti	Word in title
\$	\$ represents any character e.g. 's' or 'ing'
adj5	Adjacent within 5 words
adj10	Adjacent within 10 words
.tw	Text word (within abstract or title)

### **2.3.1 Breakdown of literature search results**

Papers were included in the literature review after a process of reviewing abstracts (in excess of 3,500); which generated 55 papers for full-text review. To display transparency of the literature review process, the 55 papers are outlined in Figure 7, showing a flowchart to illustrate how many studies were excluded at each stage with reasons for exclusion. Eight studies were included in the review which were presented in nine papers. This occurred as two papers (Nicolai et al., 2010a; Nicolai et al., 2010b) outlined the same study but differing information and were therefore both included. In further description, it was decided that both Nicolai et al. (2010a) and Nicolai et al. (2010b) papers concerning the same study would be presented together as both were based on the same initial study.



**Figure 7: Flowchart of included studies for literature review**

## **2.4 Included studies**

### **2.4.1 Quality of reporting**

Initially the quality of study design and reporting was explored using the Consolidated Standards of Reporting Trials (CONSORT) for (randomised) controlled trials (Schulz et al., 2010). An equivalent quality of reporting assessment tool is available for interviews and focus groups: The Consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury, & Craig, 2007). The CONSORT (Schulz et al., 2010) was used for eight studies (nine papers), and the COREQ (Tong, Sainsbury, & Craig, 2007) was not utilised as no qualitative studies were suitable to be included in the final selection.

### **2.4.2 Quality of study**

The Critical Appraisal Skills Programme checklists were utilised to assess quality of each study as an initial screening tool (CASP, 2013). Quality was further assessed with a data summary form, developed specifically for use within this literature review. The form was developed from CONSORT (Schulz et al., 2010) combined with a data extraction form specifically designed for data collection in a previously reported systematic review of 39 included studies centred on stroke knowledge and awareness (Jones, Jenkinson, Leathley, & Watkins, 2010), exhibiting a quality strategy for systematic reviewing and data extraction. The summary data form extracted the following information from each primary data source: period of study, participants, country, topic, research design, interventions, measurement scales used, potential for selection bias, concealment, blinding and control, generalisability, good practice conduct and itemisation of drop outs (Appendix A).

Studies were graded on a scale of 1 to 7 in accordance with the traditional hierarchy of evidence as demonstrated in Table 9 (Petticrew & Roberts, 2003), with grade 1 being deemed the most rigorous and reliable evidence. The grading was extended to include '+' or '-' depending on whether the review process determined the methods and reporting as high quality or low quality respectively.

**Table 9: Traditional grading of studies**

(Petticrew & Roberts, 2003)

Grading	Type of study allocated to each grading
1.	Systematic reviews and meta-analyses
2.	Randomised controlled trials with definitive results
3.	Randomised controlled trials with non-definitive results
4.	Cohort studies
5.	Case-control studies
6.	Cross sectional surveys
7.	Case reports

Grading alongside the data extraction form provided a clear conceptual framework for scrutinising the body of evidence, as without these quality measures it is possible that a review can lead to the wrong conclusions about an intervention's effectiveness if importance is allocated to poor quality studies (Eden, Levit, Berg, & Morton, 2011). Although traditional grading is allocated within this literature review, it must be noted that the concept of a 'hierarchy of evidence' is often problematic when appraising the evidence for social or public health interventions and it is also important to determine if the type of research is selected accurately to answer the research question, which may or may not be a higher traditional grade of research (Petticrew & Roberts, 2003).

A summary of the accepted studies is outlined in Table 10, with the main features of each study detailed to give a brief overview of each study's characteristics.

**Table 10: Included study characteristics**

<b>Author, year, country</b>	<b>Research design</b>	<b>Illness studied, number of participants (n)</b>	<b>Interventions</b>	<b>Outcomes measured</b>	<b>Hierarchy rating</b>
Duncan et al. (2011) USA	Cohort	Cardiac failure and exercise n=20	No comparison Exercise Adherence Management Program	Exercise Frequency Exercise Duration Rate of Perceived Exertion Adherence	4
Duncan and Pozehl (2003) USA	Small RCT	Cardiac failure and exercise n=14	1. Treatment as usual (exercise only) 2. Treatment as usual + intervention feedback	VO <sub>2</sub> max (maximum rate of oxygen consumption) Piper Fatigue Scale 6 Minute Walk Test Quality Of Life (Minnesota Living with Heart Failure) Exercise Adherence	3-
Duncan and Pozehl (2002) USA	Small RCT	Cardiac failure and exercise n=13	1. Treatment as usual 2. Treatment as usual + Adherence	Exercise Frequency Confidence to meet goals	3-
Geiger et al. (1992) USA	Non RCT	Chronic back pain n=17	1. Treatment as usual 2. Treatment as usual + Feedback	Walking Rate	4
Mahon et al. (1984) USA	Cohort	Burn patients and food intake n=4	1. Feedback	Calories Protein intake Fluid intake	4-
Nicolaï et al. (2010a); Nicolaï et al. (2010b) Netherlands *	RCT	Intermittent Claudication and walking distance n=169	1. Treatment as usual 2. Supervised exercise therapy 3. Supervised exercise therapy + feedback	Walking rate Absolute Claudication Distance	2-
Rees et al. (2013) Australia	RCT	Diabetic patients with retinopathy and suboptimal HBA1c n=25	1. Visual feedback of retinal images 2. Control group (No intervention)	Retinal images	2-
Shakudo et al. (2011) Japan	RCT	Hyper-tension and Body Mass Index related to health measures n=111	1. Feedback and health letter 2. Health letter only 3. Control group (No intervention)	Blood pressure Body weight/Body Mass Index Walking Distance	2

### **2.4.3 Characteristics of included studies**

As previously detailed in the exclusion criteria, qualitative studies which originally were of interest were excluded if they studied the subject area of mental health (Harmon et al., 2005; Unsworth, Cowie, & Green, 2012), which resulted in no suitable qualitative studies found concerning the area of physical illness. It can be observed that all eight included studies were quantitative in design.

The research methods chosen by all eight studies were suitable choices to answer the specific aims and objectives set by each study. The quantitative studies included in the review were of mixed quality. The most prominent feature was the small numbers of participants in the majority of studies, which did not allow a statistically significant result to be reported other than in one study, reported in two separate articles (Nicolai et al., 2010a; Nicolai et al., 2010b). The low participant numbers were mostly attributed to studies being exploratory or a pilot phase.

Of the eight studies, five were RCTs, ranging from 13 to 169 participants, one non-randomised controlled trial with 17 participants and two cohort studies with 4 and 20 participants. All types of design chosen were suitable for the research question posed or the hypothesis which was to be tested. Traditional hierarchy ratings ranged from the larger, randomised controlled trials scoring more positively, such as Shakudo et al. (2011) rating as 2, to Mahon et al. (1984), a small cohort study rating as 4-.

### **2.4.4 Types of interventions including feedback**

Of the eight studies reporting feedback of information to patients, one health condition had been explored in multiple studies by the same group of authors, with three studies focusing on patients with cardiac failure (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011). Two papers reported the same study and data set concerning patients with intermittent claudication / peripheral arterial disease (Nicolai et al., 2010a; Nicolai et al., 2010b). All other studies were stand-alone research in different health condition areas: chronic pain (Geiger et al., 1992), food intake monitoring for those with burns (Mahon et al., 1984), hypertension (Shakudo et al., 2011) and people with diabetic

retinopathy (Rees et al., 2013). All eight studies used individualised feedback to participants, but due to the breadth of research participant health conditions, there were multiple differing outcome measurements which were collected and fed back to participants. Measurements taken ranged from frequently used, standard measurements of blood pressure and body mass index (Shakudo et al., 2011) to more specialised measurements of retinopathy in a visual form (Rees et al., 2013). Walking rate as a measure was used in two separate studies concerning two separate conditions of chronic pain and intermittent claudication (Geiger et al., 1992; Nicolai et al., 2010a; Nicolai et al., 2010b). Exercise frequency was also measured in two separate studies, both concerning cardiac failure (Duncan & Pozehl, 2002; Duncan et al., 2011).

## **2.4.5 Evidence supporting use of feedback**

### ***2.4.5.1 Graphic and verbal feedback***

It has been proposed that feedback triggers a more noticeable change in graphic form (Duncan & Pozehl, 2003; Mahon et al., 1984). Two studies proposed that graphic feedback was useful, but had unsatisfactory numbers of participants to substantiate such a claim: n=16 (Duncan & Pozehl, 2003) and n=4 (Mahon et al., 1984).

Geiger et al. (1992) studied patients (n=13) with chronic pain, giving feedback of walking rate as instant feedback whilst participants were walking laps, with the feedback group showing an average increase in walking speed of 37%. This response suggests instant verbal feedback to be effective, although the size of sample (n=13) was not sufficient for conclusive statistical analysis.

### ***2.4.5.2 Feedback spacing, feedback repetition and duration of study***

The studies ranged in feedback spacing, number of repetitions and duration of feedback of outcome measures. Nicolai et al. (2010a; 2010b) gave feedback most infrequently at three months apart but over the longest period of 12 months. The most frequent feedback spacing was provided daily for five days, repeated over a two week period (Geiger et al., 1992). Other studies had durations of 12 weeks (Duncan & Pozehl, 2002; Rees et al., 2013; Shakudo et al., 2011) and 24 weeks (Duncan &

Pozehl, 2003; Duncan et al., 2011). It was unclear in the study carried out by Mahon et al. (1984) what the specific timeframe was for provision of feedback for the four participants in the study. Feedback spacing and frequency varied greatly and can be seen as a summary in Table 11.

**Table 11: Study characteristics of feedback spacing, number of feedback repetitions and duration of the study over which feedback was provided**

Study	Feedback spacing	Number of feedback repetitions	Duration of study
Duncan et al. (2011)	3 weeks	5	24 weeks
Duncan and Pozehl (2003)	3 weeks	4	24 weeks
Duncan and Pozehl (2002)	3 months	4	12 weeks
Geiger et al. (1992)	Daily (weekdays)	10	2 weeks
Mahon et al. (1984)	Twice daily	Unclear	Unclear
Nicolai et al. (2010a); Nicolai et al. (2010b)	3 months	4	1 year
Rees et al. (2013)	3 months	2	3 months
Shakudo et al. (2011)	2 weeks	7	12 weeks

There is no standardised recommendation for timescales, numbers of times for feedback provision or a period of time in which it should be provided. This is exemplified clearly in Table 11 where frequencies, number of feedback sessions and durations are all in differing combinations. It is unclear as to which combination is most productive, although previous research concerning clinician feedback suggests that feedback must be delivered in a timely manner as a minimum requirement (Hysong et al., 2006).

### **2.4.5.3 Adherence**

Studies postulate feedback increases adherence to exercise regimes in the short term with health problems concerning high blood pressure and high body mass index (Shakudo et al., 2011) and adherence to home exercise regimens for those with heart failure (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011). Shakudo et al. (2011) recruited participants (n=105) with borderline hypertension and a Body Mass Index (BMI)  $\geq 25.0$ . Participants were randomised into three groups, with only one receiving feedback based on their exercise history, calorie expenditure, walking record and a graph of body weight and blood pressure. The study showed regular provision of exercise feedback may be effective in improving adherence, although the sample size (n=105) was not large enough to make statistical claims. It was calculated by Shakudo et al. (2011) that a further 67 participants would have needed to be recruited to detect differences with power between groups. Three studies which supported the use of feedback to increase adherence had numbers of participants were not adequate to make statistical claims: n=13 (Duncan & Pozehl, 2002), n=16 (Duncan & Pozehl, 2003) and n=20 (Duncan et al., 2011).

### **2.4.5.4 Clinician guided feedback**

It has been suggested that clinician guided feedback is more helpful than independent monitoring (Duncan & Pozehl, 2002). Similarly, clinician guided intervention (with or without feedback) appears to be more effective than advice and independent management (Nicolai et al., 2010a; Nicolai et al., 2010b). It presents the apparent importance of the clinician within a health intervention, although the two studies promoting clinician guided feedback claimed two opposing views: feedback to be effective (Duncan & Pozehl, 2002) and not effective (Nicolai et al., 2010a; Nicolai et al., 2010b) so it is not clear how the clinician role contributes to the efficacy of the feedback process, if at all.

### **2.4.5.5 Implementation**

Feedback presents as a manageable task for clinicians to implement as it usually does not require costly equipment, measurements are prompt and ready to be communicated quickly and easily to individuals for tracking their progress (Geiger et al., 1992). As a low-cost intervention to implement,

feedback can easily be supported for introduction into practice, but steps must be taken to ensure it works in the way it is intended: to produce a positive impact for patients.

#### **2.4.6 Feedback not working in the way it is intended**

Papers published by Nicolai et al. (2010b) and Nicolai et al. (2010a) both reported the same study and data set, studying patients with intermittent claudication (n=304), providing feedback on the level of activity and walking using an accelerometer (measuring walking speed / acceleration). The study design detailed three randomised groups, with participants allocated to either a walking advice group, a supervised exercise therapy group or a supervised exercise therapy *and* feedback group using an accelerometer. Intermittent claudication elicits symptoms of a cramping leg pain which develops with walking and is relieved with rest. Intermittent claudication is caused by inadequate blood flow to the leg muscles because of atherosclerosis (fatty deposits restricting blood flow through the arteries) (Lane, Ellis, Watson, & Leng, 2014). A Cochrane review (Lane et al., 2014) advises people with mild to moderate claudication to keep walking, stop smoking and reduce cardiovascular risk factors. It was found that supervised exercise therapy was more effective as an intervention than walking advice but there were no differences between the supervised exercise group with or without feedback in relation to absolute claudication distance (the maximum distance able to be walked before calf pain stops the ability to walk).

#### **2.4.7 How feedback programmes might work**

Rees et al. (2013) fed back personal retinal images of diabetic patients with sub optimal HbA1c in comparison with a healthy image. The World Health Organisation (2011) conclude that HbA1c can be used as a diagnostic test for diabetes, with a score of 6.5% and above known as the recommended level for diagnosing diabetes. Rees et al. (2013) established that within their small pilot study (n=25), the intervention group showed significantly increased motivation to improve blood glucose control, increased foot care and reduced concern regarding their retinopathy compared with the control group ( $p \leq 0.05$ ). There was a suggestion that providing patients measuring sub-optimal HbA1c

scores with personalised risk information, such as these images, may need to be supported with behaviour change interventions to achieve longer term changes. This comment is supported by previous research, where personalised risk information has only achieved short term effects (Shahab, West, & McNeill, 2011). Rees et al. (2013) refer back to health behaviour theory, suggesting that newly diagnosed individuals in the diabetic community may be the best to target as they show signs of the diabetic retinopathy changes but are asymptomatic and can be identified and successfully change behaviour before symptoms occur. With all seven other studies, feedback was implemented with symptomatic individuals.

Whether symptomatic or asymptomatic, a common theme was observed between studies, whereby feedback identified specific measurements of health to individuals, aiming to heighten awareness of their current status or response to an action. Feedback of objective data is proposed to facilitate individualised problem solving, facilitate self-regulation skills and support the relationship between clinician and patient (Duncan & Pozehl, 2003; Duncan et al., 2011).

Mahon et al. (1984) suggest that the feedback identifies improvement and achievement of goal values, which in their study were the goals of set levels of protein and calorie intake for burns patients. It is posited that goal attainment then confirms behaviour changes are worthwhile and an individual can then choose to continue the behaviour.

## **2.5 Summary of the literature search**

### **2.5.1 Limitations**

Within this literature review it is evident that there is a paucity of qualitative research looking at the use of feedback of information to patients with physical illness, with no studies providing personalised participant accounts of the process to determine why and how feedback worked or did not work.

Sample size was an issue with making statistical claims in seven of the eight studies (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011; Geiger et al., 1992; Mahon et al., 1984; Rees et al., 2013; Shakudo et al., 2011), with the numbers of participants being too small to calculate statistical significance of their findings. The two papers describing the same study (Nicolai et al., 2010a; Nicolai et al., 2010b) had a higher number of participants (n=304). The participants in this study improved walking distance with supervised exercise therapy, with or without feedback. There was no statistically significant difference between the feedback and non-feedback groups. This one study, however, may have limitations as intermittent claudication is a self-limiting and chronic condition which may only have a certain amount of improvement which can be gained through supervised exercise therapy with or without feedback.

### **2.5.2 What is known?**

To conclude, small population studies in this literature review show positive results of information feedback to patients in the short term, but with no statistical power. It is suggested in these small population studies that information feedback can be effective in a visual or verbal format and it is most likely to be effective if delivered by a clinician rather than self-managed feedback.

### **2.5.3 What is not known?**

It is not known how or why the small studies had positive results as there are no qualitative studies to explore the reasoning for participants' actions. It is also not known whether information feedback of a graphic or verbal nature, fed back to patients, yields statistically significant results in larger studies as only one study (Nicolai et al., 2010a; Nicolai et al., 2010b) had a population large enough to calculate statistically significant results. This one study found information feedback to patients not to be effective. The results of one study concerned with one health condition, in this case, intermittent claudication, cannot be generalised to all health populations.

### **2.5.4 Contributions**

This review has three contributions to make to the field of information feedback to patients.

Firstly, information feedback is flexible to each healthcare area and can be used in differing patient groups and locations, with differing types, frequencies and duration of feedback depending on what is required for each patient population (Table 10, page 63 and Table 11, page 66). Feedback can be graphic (Duncan & Pozehl, 2003; Duncan et al., 2011; Mahon et al., 1984; Rees et al., 2013; Shakudo et al., 2011), verbal (Geiger et al., 1992; Nicolai et al., 2010a; Nicolai et al., 2010b) or written (Shakudo et al., 2011), but claims are made for positive effects in small studies with these variations in feedback medium. The information fed back to patients can also be flexible dependent on the condition, comprising numerical values such as a time (Duncan et al., 2011), number of sessions of exercise completed (Duncan & Pozehl, 2002, 2003), calories ingested or expended (Mahon et al., 1984; Shakudo et al., 2011) speed (Geiger et al., 1992; Nicolai et al., 2010a; Nicolai et al., 2010b), blood pressure (Shakudo et al., 2011) and body weight (Shakudo et al., 2011). Outcome data feedback can also be given where there is comparison with the norm (Rees et al., 2013).

Secondly, the review of this body of literature gives an indication of the wider context of information feedback to patients. Information feedback spans across many areas of healthcare and over a wide number of conditions but the way in which feedback works to produce a positive impact is complex. In the studies concerning physical illness in this literature review, the complexities of how and why information feedback works (or does not work) has not been explored as the eight studies reported quantitative data only. It is inconclusive which type of information feedback is superior to others although it appears that clinician led programmes of information feedback may increase adherence (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011). A limitation of this claim is the methods of adherence measurement. The self-reporting of exercise is a measurement method which is commonly used but open to potential bias (Duncan et al., 2011), reducing validity and reliability of results (Hawley-Hague, Horne, Skelton, & Todd, 2016). Adherence is the most researched area in terms of information feedback to ill patients, specifically to exercise programmes with a heart failure population (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011), with all three included studies researching this having two authors in common with an interest in this area (Duncan & Pozehl). The

potential bias and similar populations limit the application of these three papers as the population characteristics were similar, with small study sizes and high levels of bias.

Thirdly, the literature review identified a paucity of information feedback using certain research methods. There was a lack of high quality, large scale randomised controlled studies to describe conditions for effectiveness in information feedback. There was also an apparent paucity of qualitative research concerning information feedback leaving a gap in knowledge as to how and why patients respond in certain ways to the information feedback in physical illness. With these research gaps established, a study question could be developed to contribute to an area where research was sparse and would benefit from further development.

## **2.6 Development of a research question**

A lone researcher completing a PhD presents limitations to the scope of a study research question. With limited funding allocated for each year of study for consumables and training, and a single researcher to collect study data and complete analysis independently, a realistic study needed to be designed. Achievement of a quality randomised controlled trial to research effectiveness of information feedback by one sole researcher was felt to be unachievable within the given timeframe. The paucity of qualitative research methods interested the researcher. The literature review therefore opened up a line of thinking concerning exploration of mechanisms by which patients found the feedback of information (PROMs) to have a positive or negative impact. This in turn introduced concepts of analysis beyond the positivist view of PROMs purely being used as a measure of improvement but delving deeper into the 'black box' of what happens when patients are involved in the process to further understand the complexity of feedback as an intervention (Pawson, Greenhalgh, Harvey, & Walshe, 2004). This view towards study design also had implications on philosophical underpinnings and research methods, leaning towards a post-positivist approach with realist methods. This is further detailed in chapter three.

A specific question was developed from the literature review results alongside the wider context of PROMs in practice. The research question which overarched the two phases of the research study comprised:

‘Outcome feedback in physiotherapy: What works, for whom, in which circumstances?’

The pilot phase I study and the main phase II study methods were developed in accordance with answering this question.

## **Chapter 3 – Research methods and philosophical underpinnings**

### **3.1 Introduction**

Research methods refer to: the practices and techniques used to collect, process and analyse the data, the sample size, methods of sampling, how the data will be collected, the choice of measurement instruments and how the data will be processed and analysed (Bowling, 2014). The methods chapter within this thesis aims to help the reader understand the researcher's considerations of Bowling's (2014) specified practices and techniques in order to appreciate the link from the research question to the chosen method, and then to the analysis.

This chapter commences with exploring the hierarchy of evidence and the philosophical underpinnings of exploring how processes 'work' by looking at mechanisms and how this impacts on the choice of method. The selected research method for both the Phase I Pilot study and the Main Phase II study is detailed, substantiating the ability to answer the research questions suitably.

### **3.2 Philosophical underpinnings**

Research is conducted from various standpoints on what comprises nature and being (ontology), what knowledge is (epistemology), and how knowledge can best be learned (methodology) (Crotty, 1998).

#### **3.2.1 Ontology and epistemology**

Ontology describes the nature of what existed and how it existed, questioning what is abstract, what is concrete (Effingham, 2013) and the existence of reality as singular or multiple truths.

Epistemology can be described as *"the science of knowledge studied from the philosophical point of view or the science of knowledge in its ultimate causes and first principles, studies using the natural light of reason"* (Horrigan, 2007) (page vii). The origin, nature and limits of human knowledge can be included as epistemological factors.

Enquiring about the nature of reality as a philosophical question shapes the way research is designed. The three elements of ontology, epistemology and methodology combined comprise a 'paradigm', and using a paradigm within a study can help create a bridge between the research question or aims, and the methods by which to achieve the answer to the question or achievement of the aims (Houghton, Hunter, & Meskell, 2012).

Differing ontological and epistemological approaches are supported by differing paradigms. Creswell (2013) describes the four major paradigms as: post-positivism, constructivism, transformative and pragmatism. The research question can be revisited to identify the paradigm most fitting to the study:

'Outcome feedback in physiotherapy: What works, for whom, in which circumstances?'

Constructivists suggest that reality is socially constructed, with no reality which can be used as a standard, and many truths which are all equally true even if they are contradictory (Kazi, 2003). A constructivist view would undertake research on the basis that the inhabited world is a constructed one, which as a researcher cannot be understood by observation alone, but must understand what individuals perceive from their own point of view, and if reality is constructed then the knower and the known are inseparable (Shkedi, 2005).

Positivists aim to generalise statements about a research population but because the approach to natural and social sciences operates within closed systems, Bhaskar (2013) argues this actually identifies failure to generalise (Williams, Rycroft-Malone, & Burton, 2016).

The research question concerns understanding of multiple participant meanings, constructing social processes and generating theory on occurrences in line with constructivism. Elements of post-positivism were also met with study methods to include empirical observation and measurement and the underpinning of a middle range theory for verification. This study is therefore placed between post-positivism and constructivism paradigms in its approach.

### **3.3 Qualitative research**

The study was designed with qualitative methods. The word *qualitative* implies an emphasis on the quality of entities and on processes and meanings that are not experimentally examined or measured in terms of quantity, amount, intensity, or frequency (Denzin & Lincoln, 2012). Qualitative methods in essence can be described as verbal descriptions of real-life situations, methods seeking understanding, describing phenomena in context, and interpreting processes and meanings using theoretical concepts (Silverman, 2010).

With qualitative analysis relying upon researcher interpretation, rigour must be encouraged and enhanced (Barbour, 2001). The systematic and rigorous preparation and analysis of qualitative data is time consuming and labour intensive (Pope, Ziebland, & Mays, 2000) and must be planned well in terms of methods to capture the authenticity of the account of the research study phenomenon (Miles & Huberman, 1994). Rigour in relation to credibility, transferability, dependability and confirmability in this study is described in chapter four (section 4.7: Rigour, page 99).

#### **3.3.1 Previous research overview in relation to qualitative approaches**

Qualitative approaches such as interviewing allow insight into that which is not ordinarily on view and examine that which is often looked at but seldom seen (Rubin & Rubin, 2012). Qualitative research can be classified into four divisions (Ritchie, Lewis, Nicholls, & Ormston, 2013):

1. Contextual - describing the form or nature of what exists
2. Explanatory - examining the reasons for, or associations between, what exists
3. Evaluative - appraising the effectiveness of what exists
4. Generative - aiding the development of theories, strategies or actions

Previous research methods outlined in the literature review were quantitative and evaluative, appraising the effectiveness of feedback of measures such as the speed of walking, blood pressure readings or visual analogue pain scale data to patients. Such measurements determined clinical improvements rather than determining peoples' experiences of the process of feedback. In this

study the research carried out was planned to be both explanatory and generative, examining relationships between people and their responses and developing an existing theory on feedback of information in the form of outcome data to patients.

### **3.4 Mixed methods**

Mixed methods involves the use of qualitative and quantitative methods within the same study.

Mixed methods research allows the integration of results from both quantitative and qualitative data collection methods into convergent conclusions for a research study (Creswell & Clark, 2007)

and is: *“essential for applied research that addresses the complexities of what happens when new programs or interventions are introduced to groups of people, going beyond the ‘whether’ question to consider how it works, under what circumstances, in what ways and for what people”* (Hay, 2016) (page 132).

Table 12 below outlines the distinction between quantitative and qualitative research as separate approaches

**Table 12: Ontological, epistemological, methodological and data analysis distinctions between quantitative and qualitative approaches**

	Quantitative methods	Qualitative methods
Ontology	Tangible reality	Intangible reality
Epistemology	Regularities established via empirical research and deductive / inductive reasoning	Knowledge constructed via social interaction / hermeneutic understanding
Methodology	Hypothesis testing	In depth fieldwork
Data analysis	Verification / falsification	Interpretation of meaning

Historically, physiotherapy has been based upon measurement of change or effectiveness, a tangible reality which can be established by empirical research and hypothesis testing, which has seen a prevalence of clinical trials, RCTs and review articles in the physiotherapy literature (PubMed searches 1970 – 2010), with a rapid increase after 1995 (Kumar, Sisodia, & Kumar, 2013). The literature review results concurred with this trend.

Quantitative and qualitative research methodologies have previously been viewed as ‘diametrically opposed’ constructs (Duffy, Cunningham, & Jonassen, 1996) but progressively comments have been made that both should be seen for their complementary value in informing professional practice, and the integration of these two different approaches should pave the way for the future of research, specifically in physiotherapy (Herbert & Higgs, 2004). Herbert and Higgs’ (2004) research on practice paradigms identified the importance of mixed methods to achieve ‘expert practice’ in physiotherapy, focusing on optimising patient outcomes and incorporating patient beliefs and

values, supporting the view that the addition of qualitative research is useful to provide depth to our understanding (Littlewood & May, 2014).

Denzin (2012) confirms that to secure an in-depth understanding of the phenomenon in question the use of mixed methods is supported, specifically with triangulation. Triangulation is used by Denzin (2012) in this context as the combination of *multiple mixed methods* incorporating quantitative and qualitative methods as a strategy that adds rigor, breadth complexity, richness, and depth to any inquiry. Within this study, triangulating with multiple mixed methods under a post-positivist, theory based approach attempts to understand the phenomenon of feedback at a deeper level.

### **3.4.1 Quantitative indicators**

Descriptive statistics are viewed as logical, factual and subject matter orientated rather than mathematical and probabilistic (Winkler, 2010). Patient demographics and counting of occurrences can be considered as descriptive statistics within a mainly qualitative study, to include a description of the patterns or regularities in the data that have been uncovered (Sandelowski, 2000). Following identification of patterns and regularities, qualitative analysis can serve to further interpret the data (Miles & Huberman, 1994) in an effort to understand not only the frequencies and numeric data but also the underlying content of the spoken word.

## **3.5 Options for research methods**

When exploring complex situations in social research, qualitative methods are required to explore the phenomenon in question (Bowling, 2014), and despite PROMs being a quantitative measure, explaining what works for whom in which circumstances does not lend itself to quantitative research methods alone.

Quantitative research aims to collect large amounts of information, under standardised conditions, in order that they can be treated, analysed and interpreted statistically. Statistical analysis may contribute to the 'what works?', but to discover the *how* and *why* beneath the question of 'which

circumstances?' would not be answered by statistical analysis alone. As previously discussed, the problems addressed by social and health science researchers are complex, and the use of either quantitative or qualitative approaches by themselves is inadequate to address this complexity (Creswell, 2013). This research therefore lends itself to a mixed method approach, with the strongest emphasis upon qualitative research to explain occurrences and generate theory (Ritchie et al., 2013) .

Within the qualitative element of this study, there are many options for how to design, collect and approach analysis of the data. Common methods which were rejected due to inability to answer the research questions were as follows: phenomenological, ethnographic, action research and case study research.

Grounded research as another common method presented as a possible option for this research study as it can be solely qualitative or mixed methods in approach, and was therefore examined with much care as PROMs directly produce quantitative measures on completion and mixed methods appeared to be an approach to utilising this data. Corbin & Strauss (2014) outline the descriptive and theory based qualities of this method as encouraging uncovering of beliefs and meanings in addition to the behaviour and actions underpinning them, demonstrating how logic and emotion combine to influence an individual's response to an event. Despite the theory-based underpinnings of grounded theory it should not be used to test hypotheses about reality, but, rather, to make statements about how actors interpret reality (Suddaby, 2006) which concerns building new theories.

Realist research was presented to the researcher for consideration (Pawson & Tilley, 1997) after attending a conference in which a presentation was made detailing how realist evaluation was used to unpack the underlying mechanisms occurring within end of life care. The study was later successfully published as a PhD thesis (Dalkin, 2014). Realist research aims to explain interesting, puzzling, socially significant regularities, predominantly using mixed methods approaches (Pawson & Tilley, 1997). Explanation takes the form of positing underlying mechanisms, proposing how the

interplay between resources and reasoning affects processes. It also investigates how the working of such mechanisms is contingent and conditional on particular contexts which encourage mechanisms to 'fire' and produce certain outcomes (Pawson & Tilley, 1997). Realist research is 'theory-driven', using theory to inform data collection, as a framework to test the data against and to generate modified theory as an output of the research. Realist research presented as a suitable method for use within this study as it was supportive of mixed methods, suited to answering questions 'for whom' and 'in which circumstances' in social systems, using theory to inform research methods and generate modified theories.

### **3.6 Realist research: approach chosen for the phase I pilot study and phase II main study**

The pilot study was exploratory in nature and the aim of the phase I pilot was to answer the preparatory questions to inform and build upon for the phase II main study (Burnard, 1991).

The theory-driven element of research was used to explore feedback of PROMs as a working programme with use of the Contextualised Feedback Intervention Theory as a middle range theory to guide interview questioning, data collection and analysis.

The ultimate goal of realist research is to develop deeper levels of explanation and understanding of phenomena (McEvoy & Richards, 2006). The phase II main study served as an extension of the phase I pilot study; to explore more deeply the phenomena of feedback. To further investigate, realist research allowed description and interpretation to occur, both inductive and deductive, emphasising context, with an integration of manifest and latent contents, drawing thematic maps with a non-linear analysis process to explore all avenues of data activity (Vaismoradi, Turunen, & Bondas, 2013).

Intervention resources which are introduced (such as information feedback) enhance changes in reasoning in certain contexts which can alter mechanisms by which things happen, affecting behaviour of participants and outcomes (Dalkin, 2015). Observable outcomes constitute one layer of reality, with the possibility of multiple stratified layers underneath the surface of complex systems

(Alvesson & Sköldbberg, 2009). To uncover the fundamental layers and uncover hidden processes, deeper research is needed to explain and understand how outcomes might have been produced from processes hidden within the 'black box' (Pawson & Manzano-Santaella, 2012; Salter & Kothari, 2014). There is an ongoing discussion in social science as to whether research should be a critical exercise of social science (Pawson, 2006). It is posited that if social phenomena are genuinely emergent that realist explanations can be rationalised and defended (Bhaskar, 2009).

Pawson (2013) describes programme interventions as complex and intricate with multiple outcome options dependent on behaviour. To understand differences in outcomes, questions need to be asked to 'why?' and 'how?' a program works, coupled with a method which seeks to understand how the program functions to change behaviours and what contexts provide a conducive environment for mechanisms to work (Pawson & Tilley, 1997).

An approach to unpacking the complex characteristics can be attempted by using Pawson's checklist (2013), presented under the acronym VICTORE (Volitions, Implementation, Contexts, Time, Outcomes, Rivalry and Emergence). *Volitions* of therapists and patients, individually and collectively, are important to consider within studies, with decision making being affected by the *implementation* of the intervention. *Contexts* of how programmes work and over *time*, successfully and unsuccessfully, are important to consider prior to designing an intervention and choice of *outcomes* and how monitoring of these *outcomes* may affect behaviour. Pre-existing policies (*rivalry*) and *emergence* of consequences and long-term effects must be considered.

### **3.6.1 Branches of realism**

Realism as an approach is further split into two branches with slightly differing views: Empirical and critical realism. One pathway in this field is empirical realism, which encourages a researcher to aim to decide between alternative explanations, despite the knowledge that further explanatory potentials remain without investigation in the open systems in which people live (Pawson, 2006).

An alternative realist view is 'critical realism', which assumes that there will always be a plethora of explanatory possibilities, some of which will be false. The researcher investigates differing possibilities using realism to employ a critical view on the data and aim to explain and understand social happenings with differing processes. Focusing on analysing the social world with attention to what causes something to happen or change (context and mechanism), leading to observable phenomena (outcomes) leans towards critical realism (Williams et al., 2016).

Bhaskar (2013) suggests theory is required to guide enquiry within realism about what may provide order within systems and soundly based theoretical ideas may also be used as the basis to criticise false beliefs (Pawson, 2013). If there is, in fact, one single truth, it can be accepted that full knowledge of it will never be realised as realist research provides partial truth giving knowledge about a certain group of individuals at one point in time (Jagosh, 2017).

### **3.6.2 Study placing in realism**

Pawson & Tilley (1997) suggest that: *"The most powerful advocates of the privileged, progressive nature of science are the scientific realists... it is high time to reassert the need for scientific evaluation and to do so under the banner of realism"* (Page xiii).

Returning to the underpinnings of the traditional knowledge paradigms, positivism supports the search for generalised meaning and constructivism supports the search for meaning of our social world (Ackroyd & Fleetwood, 2000), with realism positioned between the two paradigms. Williams et al. (2016) propose that consideration must be made to Bhaskar's views in relation to realism. With both positivist and constructivist perspectives considered, critical realists believe an external reality exists independently of our beliefs and understanding (Ritchie, Lewis, Nicholls, & Ormston, 2013) and is constrained to the here and now (Stickley, 2006).

This study sits under the banner of realism, with awareness of both empirical and critical realism stances in the post-positivist paradigm. The study accepts there may be multiple outcomes to a single intervention dependent on human behaviour with the research able to provide partial-truths,

providing findings of what is occurring for this specific group of participants, which may be transferred to other patient groups but is non-generalisable.

### **3.6.3 Realist synthesis and realist evaluation as methods**

Realist research can be further divided into methods of realist synthesis and realist evaluation, both of which present a change in emphasis in the basic evaluative question from ‘what works?’ to ‘what is it about this programme that works for whom in what circumstances?’ (Pawson et al., 2004).

Realist synthesis is an increasingly popular approach to the review and synthesis of current evidence (Rycroft-Malone et al., 2012) whereas realist evaluation concerns the generation of primary data for analysis. This study is placed in the category of realist evaluation as it is a primary research study.

### **3.6.4 Programme theory and middle range theory**

A useful approach to unpicking the complex characteristics of social systems pulls on the core principle of realism with the use of theory. Leonard Bickman, a Professor of Psychiatry, is a prolific writer and researcher, with published work over the last 30 years spanning both programme theory development and the impact of information feedback within clinical settings (mental health) (Bickman, 1987, 2008; Bickman et al., 2014; Bickman et al., 2011; Bickman et al., 2006; Bickman et al., 2000; Riemer & Bickman, 2011; Riemer et al., 2005; Sapyta et al., 2005). He describes programme theory in healthcare as the construction of a plausible and sensible model of how a programme is supposed to work (Bickman, 1987).

The Contextualised Feedback Intervention Theory, outlined in chapter 1 (Figure 6, page 47), developed by Riemer and Bickman (2011), presented as an appropriate theory to test in its entirety as a middle range theory suitable to use as a framework as it aims to describe and predict how feedback influences behaviour. Developed by Robert K Merton (1968), middle range theory is an approach to theorising in sociological context, aimed at integrating theory and empirical research. As the CFIT is largely untested (de Jong, 2014), and had not previously been used in providing

feedback of information to a patient population, it presented as a suitable theory for testing and development.

### **3.7 Definition of terms**

It is important to identify and explain *operational definitions* to achieve clarity of what is meant by each term as this will differ between studies (Babbie, 2013). Realism uses three words which are used in everyday life: context, mechanism and outcome, which will be described in turn to define the use of the three terms throughout the thesis. The last definition is that of the study 'intervention' to clarify what is being studied.

#### **3.7.1 Context**

Context is simply 'relevant circumstances'. Jagosh et al. (2011) describes context as the 'backdrop' of programs and research, which can be understood as anything that can trigger and/or modify the behaviour of a mechanism. Context is important as it influences 'reasoning' and furthermore, generative mechanisms can only be operative if the right circumstances occur. In realism, context is a general concept and says little about the environment between the contexts and the environment except that it is (possibly) relevant, therefore contexts should be defined and the potential causal relationship clearly set out to describe in what ways the external context may have affected the events that occurred (Easton, 2010).

#### **3.7.2 Mechanism**

Mechanisms in social science are similar to mechanisms in natural science (e.g. the mechanism of gravity) but have distinct differences. Wong, Westhorp, Pawson, and Greenhalgh (2013) define social mechanisms as "*underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest*" (page 5). It is useful to view mechanisms in this way, as they can often not be directly observed, and the researcher must hypothesise which mechanism is likely to have 'fired' and then test this theory with data (Dalkin, 2014). Entities can be an individual's norms or belief systems, processes which progress depending on the previous event, and social

structures (such as gender, class, or cultural patterns of relationships). Identifying mechanisms advances the synthesis beyond describing 'what happened' to theorising 'why it happened, for whom, and under which circumstances' based on participant reasoning or reaction. Mechanisms may not be 'visible', but can be inferred from the data collected, they are context sensitive, and they generate outcomes (Wong et al., 2013).

Mind-independence suggests that real entities must not be figments of our imagination or posits of our other mental processes (Khalidi, 2015). In a mind-independent world, resources are evident with people acting as causal agents, and therefore causal mechanisms sitting within this social world (Bhaskar, 2013). It is not always as straightforward as might be assumed to map the operation of complex systems with the 'mechanism' within the explanation presented as a Context (C) + Mechanism (M) = Outcome (O) configuration (CMOc) (Jagosh et al., 2014) formula. Disaggregating the concept of mechanism into its constituent parts can help to understand the difference between the *resources* offered by the intervention and the ways in which this changes the *reasoning* of participants (Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015) which can deepen the mechanism explanation potential.

### **3.7.3 Outcome**

Outcomes can be either intended or unexpected, and defined as either intermediate or final (Jagosh et al., 2011). Outcomes can be changes such as actions, relationships, policies and practices of one or more social factors influenced by an intervention.

Outcomes can be multiple in number and difficult to manage in terms of explaining patterns, although demi-regularities can be used to aid description of similarities in outcomes. 'Demi-regularity,' is described by Lawson (2006) as an event which suggests that human choice or agency manifests in a partially predictable manner, this is therefore described as a 'demi-regularity' because variations in reoccurring, predictable patterns of behaviour can be attributed to differences in the contextual dimension from one setting to another (Jagosh et al., 2011). Where demi-regularities are

observed, there is evidence of relatively enduring and identifiable tendencies in play (Lawson, 2006), where tendencies can be described as an inclination towards a particular behaviour or characteristic.

### **3.7.4 Intervention**

As patients are receiving treatment as part of the process of this study, it could be considered that physiotherapy treatment is the intervention being investigated. The physiotherapy treatment patients received throughout the study was standard, evidence based treatment, with no changes to normal practice. The differing intervention within this study was the addition of feedback of a PROM at each appointment. The PROMs feedback is therefore defined as the intervention within this study and is the main focus of this research.

## **3.8 Research methods and philosophical underpinnings conclusion**

Chapter one described the complexities of information feedback. Chapter two outlined the complexities of adding the patient population as recipients of this information, expanding to include variations in social situations and human behaviour in a health context. Due to intricate workings within interventions of this nature, careful consideration is needed with regard to research design.

This chapter details the selection of mixed methods, with a mainly qualitative focus as an approach.

Realist evaluation was chosen, aiming to uncover patient experiences of feedback via interviews, whilst also identifying PROMs changes with concrete quantitative data and descriptive statistics to aid explanation of patient behaviour. The depth of realist ontology aims to delve into underlying internal workings in the feedback process, using an existing theoretical model of information feedback, the CFIT, with patients in a physiotherapy context to expose the underlying processes. The introduction of the Context-Mechanism-Outcome configuration supports the thinking process, aiming to illuminate the ontological position of knowing and the epistemological position of how we know it (Jagosh, 2017).

## Chapter 4: Phase I Pilot study methods

### 4.1 Introduction

The study was split into a phase I pilot study and a phase II main study. For purposes of clarity, the phase I pilot study is described in this chapter, with a summary of the findings in chapter 5, from this as a viability study informing the phase II main study. The pilot study aimed to test the tools and methods proposed for use in the phase II main study: the QuickDASH score as an outcome measure; the practicalities of feedback of information to patient participants; the interview questions and the rigour of the methodological choices. The following research questions were posited:

- Are patients accepting of the feedback process and is it feasible?
- What do patients think about the usefulness of outcome feedback?

The literature review identified that limited studies concerning feedback of information to patients are completed within a physical health setting, therefore a physical health setting was to be chosen for this study. The researcher, studying at the University of Central Lancashire and working for one North West NHS with strong research connections between the two institutions, saw an opportunity to collaborate between both settings. The North-West NHS trust (the researcher's employer) was approached to be the main source for recruitment in the phase I pilot study. The North-West Trust predominantly provided mental health services with less physical services being provided. The physiotherapy department, as one of the remaining physical services, consented to allow access to their caseload. Management consent was gained before research design was finalised to ensure the intervention could be tailored to this specific service.

To be specific with the participant population, inclusion criteria were created. The literature review identified a paucity of feedback interventions with physical ill health. With acute musculoskeletal conditions a branch of physical ill health, it was reasoned this would be a suitable area to be researched. Shoulder Impingement Syndrome (SIS) is the most common disorder of the shoulder (Karim, Sah, Rasheed, & Awais, 2016) and the researcher had a special interest in shoulder

physiotherapy, previously publishing work on the treatment of SIS (Dewhurst, 2010). SIS was therefore selected as a population to be researched within this study. Inclusion criteria consisted of adult patients 18 years or over, diagnosed with SIS, a good understanding of spoken and written English, a willingness to attend the weekly class that was being offered as part of treatment, an ability to provide informed consent and able to participate in an interview. Participants were excluded if there were co-existing health problems that would limit them from participating in all elements of shoulder rehabilitation: warming up (fast walking), lifting weights and stretching. Examples of people who were not able to take part fully were those awaiting orthopaedic surgery, patients with heart conditions and those without full mobility in terms of walking. They were still able to take part in shoulder rehabilitation but with modified activities to a level they could manage with their co-existing problems.

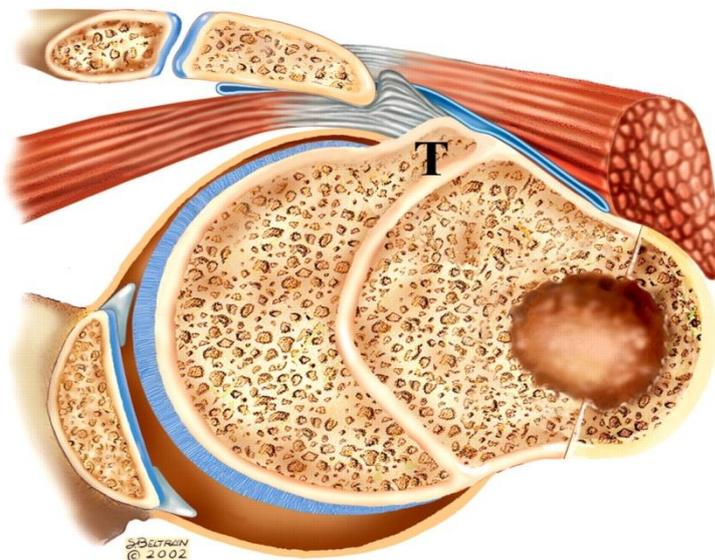
## **4.2 Shoulder Impingement Syndrome (SIS)**

Shoulder impingement syndrome is a complex condition which requires explanation to understand the scale of this shoulder problem in the NHS, the intricacies of SIS aetiology, the reasons for pain and dysfunction, and the evidence base to how it should be treated within a health care setting. The section aims to provide the reader with context surrounding this patient group and the issues they face.

Shoulder pain in general accounts for 1% of GP consultations, 30% of these are referred to physiotherapy, with 50% due to SIS (Chartered Society of Physiotherapy, 2016b). The British Medical Association (2014) estimates the annual number of consultations to total 340 million, which equates to 3,400,000 consultations per year for shoulder pain, with approximately 1,020,00 referred to physiotherapy, with 510,000 patients per year presenting with shoulder pain to physiotherapists. SIS is therefore a condition requiring significant physiotherapy resources.

SIS has been defined as compression and mechanical abrasion of the rotator cuff structures as they pass beneath the coraco-acromial arch during elevation of the arm (Ludewig & Cook, 2000). It is

more specifically outlined as a syndrome resulting from chronic irritation of the supraspinatus tendon against the undersurface of the anterior one third of the acromion, the coracoacromial ligament, and the acromioclavicular joint as shown in Figure 8 (Bureau, Beauchamp, Cardinal, & Brassard, 2006). Shoulder impingement can cause irritation of the rotator cuff tendons, tears (unilateral or bilateral) in the tendons and in chronic cases is coupled with a type I, II or III shaped acromion. Figure 8 (Bureau et al., 2006) shows a drawing of subacromial impingement with upward migration of the humeral head. The upward migration of humeral head in relation to glenoid cavity prevents passage of greater tuberosity (T) and the outlet for soft-tissue structures such as supraspinatus beneath the acromion.



**Figure 8: Diagram depicting rotator cuff tendinopathy**

(Bureau et al., 2006)

Shape of acromion can contribute to SIS by further reducing the soft tissue outlet space and the three types were originally classified by Dr Louis Bigliani, a world-renowned orthopaedic surgeon and expert in the treatment of shoulder disorders. The three classifications by are described as type I, II and III (Bigliani, Ticker, Flatow, Soslowsky, & Mow, 1991), with each grade progressively hooked

and space occupying. A hooked acromion is thought to be an independent risk factor affecting shoulder impingement syndrome (Tangtrakulwanich & Kapkird, 2012).

A Cochrane review undertaken by Green, Buchbinder, and Hetrick (2003) suggests SIS responds well to physiotherapy and a programme of exercises to restore strength, range, stability and scapula-humeral rhythm is recommended (Chartered Society of Physiotherapy, 2016b). Green et al. (2003) outline that physiotherapy interventions for shoulder pain include manual physical therapy where passive joint mobilisation is employed to mobilise and stretch the soft tissue; supervised and prescribed exercises aim to improve range of movement and muscle function by restoring shoulder mobility and stability. An article published during the course of the PhD by the researcher provided a review of studies, concluding with evidence-based exercises for SIS (Dewhurst, 2010), detailing specific exercises for physiotherapy use:

- Serratus anterior strengthening
- Pectoralis stretching
- Triceps, deltoid and rotator cuff strengthening through abduction range
- Cervical side flexion stretches away from the painful side
- Scapular setting with lateral rotation

Success from exercise therapy depends largely on a patient's ability to retrain these specific muscles, which requires advice, guidance, and progression in relation to exercises from their treating physiotherapist to ensure strengthening occurs in the correct muscles.

### **4.3 Choice of PROM: Disease specific QuickDASH**

Previously outlined on page 24, Table 2 described the five differing types of Patient Reported Outcome Measures. The five PROMs approaches were considered for use within this study: generic, disease specific, utility based, item response theory (IRT) and individualised. A disease specific PROM was appropriate to use as the measure within this study, as the chosen PROM was required to be able to identify changes associated specifically with shoulder dysfunction. SIS presents specific restrictions in daily life such as difficulty with sleeping and lifting, and improvements during treatment can be small yet significant, and require specialised questions on arm function to identify change.

The chosen PROM to use within this study was the Quick Disability of the Arm Shoulder and Hand (QuickDASH) (Institute of Work and Health Canada, 2013). Mintken, Glynn, and Cleland (2009) carried out an empirical study with 101 patients with shoulder pain, collating baseline and follow-up scores to determine the test-retest reliability (how consistent the results of a test are over time), construct validity (the degree to which a test measures what it claims to be measuring) and Minimal Clinically Important Difference (MCID) for of the QuickDASH (and also the Numeric Pain Rating Scale). Test-retest reliability can be interpreted to indicate excellent reliability  $\geq 0.75$  although it is recommended that a measure of 0.90 is required to evaluate ongoing progress of patients receiving treatment (Gallagher, Desmond, & MacLachlan, 2007) which was particularly relevant within this study. Test-retest reliability supported suitability for use, calculated as 0.90 for the QuickDASH within the Mintken et al. (2009) study, with responsiveness to shoulder pain as a PROM, and the MCID calculated as 8.0 points on the QuickDASH score.

### **4.4 Recruitment in the phase I pilot study**

In musculoskeletal practice, patients with shoulder pain in the North-West NHS trust attended an assessment visit with a physiotherapist. Specific assessments are carried out to test for shoulder

impingement syndrome (SIS). SIS can be diagnosed with the Neer's and Hawkins Kennedy tests (Papadonikolakis, McKenna, Warme, Martin, & Matsen, 2011).

In this study, if a patient presented with SIS, the physiotherapist usually referred them to the shoulder class (up to eight sessions) as per normal procedure or treated the patient individually if they required more specialist treatment or could not attend the class. This process was standard within the service to allow patient choice of treatment at times convenient to them. Patients attending the shoulder class with SIS were invited to participate in the study by the physiotherapist and provided with a participant information sheet.

The participant information sheet was developed with shoulder pain patients in a physiotherapy setting. Patients on the researcher's caseload with shoulder pain were asked to review the information sheet and provide comments on what they found useful, readable, understandable and also what could be removed, re-phrased and what they could not understand in relation to terminology. The information sheet was continually modified until it met with positive comments from the potential shoulder pain group of reviewers but also met the standards to be able to be submitted for ethical approval (Appendix I). The information sheet was provided to potential participants by their treating physiotherapist prior to starting the shoulder class to read through in detail.

At the start of the first session in the shoulder class, consent was gained for the study if participants agreed to take part. At the first shoulder class session, as in normal practice, an upper limb specific outcome assessment was provided to the patient to complete. This was a usual part of practice at this North-West NHS Trust on the first session of treatment. The QuickDASH (Appendix H) was chosen by the department prior to this study as it is a quick and easy to administer in a clinical setting and as previously described, can be used to provide an objective measure of treatment response for the shoulder (Su, 2014). As described previously (section 4.3, page 92) it exhibits a good test-retest reliability and responsiveness in patients with shoulder pain (Mintken et al., 2009). As a

disease-specific PROM, it was also recommended by the Chartered Society of Physiotherapy (Chartered Society of Physiotherapy, 2016b).

The scores were recorded before each session commenced and plotted visually by the physiotherapy staff on a graph with the visual display discussed with the participant within the shoulder class. This was an addition to the usual procedure within this North-West NHS Trust. The shoulder class set-up consisted of a warm-up session and then two minute circuit stations, continued until the warm down at the end of the 45 minute session. One of the circuit stations was the feedback station where the physiotherapist showed the QuickDASH graph to the patient and discussed their progress. For patients who chose not to take part in the study or did not meet the inclusion criteria, the two minute circuit station (used to provide feedback of information from the QuickDASH to the study participants) was used in a more generalised way to discuss their progress without the graph.

Participants attended differing numbers of physiotherapy sessions as they were able to withdraw from the class before the maximum number of eight sessions if they wanted to discontinue treatment. Examples for discontinuing were if patients felt they had reached their full potential or were unable to attend further classes. The outcome data generated severity scores (mild, moderate or severe) based on their initial outcome score (Fan, Smith, & Silverstein, 2008) and improvement gradings (graded as no change, minimal, much or very much improved) on score change between the first and last session QuickDASH scores (Polson, Reid, McNair, & Larmer, 2010). Both severity and improvement scores are described in detail in the cumulative findings chapter (7) (Table 15: Fan et al. (2008) study synopsis, page 145 and Table 16: Mean score changes on the QuickDASH for improvement categorisation and calculated score range, page 147).

## **4.5 Interviews**

After the final treatment session, the participant was contacted by the researcher to arrange a time and date for an individual interview. The researcher was a female physiotherapist, holding a Post-Graduate Certificate in research, with experience of interviewing patients for assessment purposes

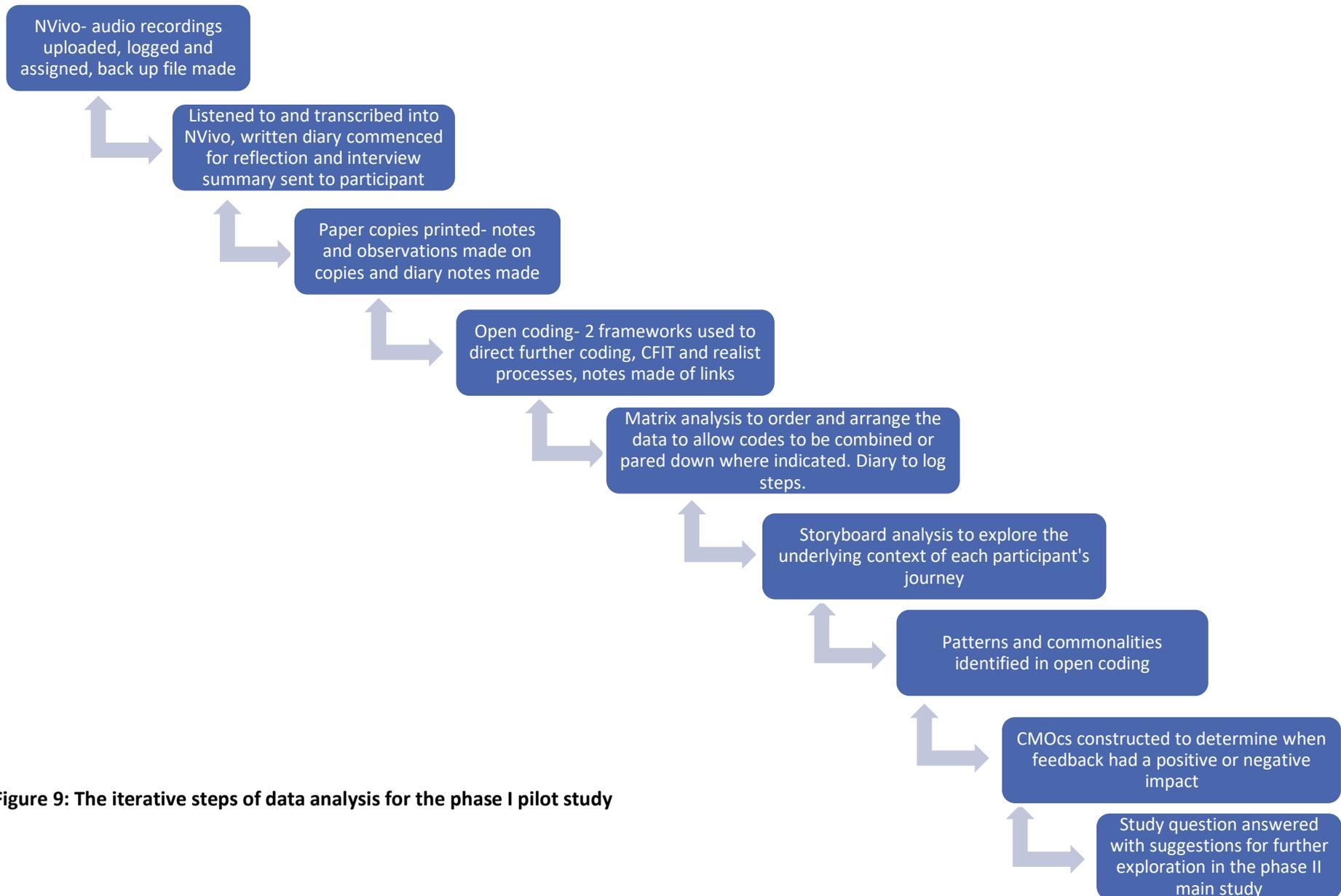
in clinic for 12 years. Semi-structured interviewing had to be developed as an essential skill for the researcher to reveal subtle nuances, attitudes and behaviours between individuals surrounding feedback of outcome data and to give depth of understanding to the issue (Rubin & Babbie, 2012). The semi-structured interviews with the researcher were carried out at the patients' NHS treatment centre and were digitally recorded. The schedule consisted of questions based on the CFIT theory elements of goals, feedback (including QuickDASH score feedback), dissonance, causal attributions and actions. Specific questioning covered their shoulder condition, control of their problem, feasibility of receiving the QuickDASH feedback, its usefulness and how it made them feel, how they used the feedback and how they set and reached (or did not reach) goals throughout the period of class attendance. The interview schedule was reviewed and modified with the researcher and supervisor after the first three interviews to reflect on the researcher's skills to modify approaches and questioning (Appendix L).

## **4.6 Analysis**

The analysis for the pilot was in-depth and systematic, theory-driven by the CFIT and based on realist evaluation principles. A full summary of the iterative steps taken to analyse the data is detailed in Figure 9.

Firstly, the interview audio files were uploaded into NVivo and transcribed. A written diary commenced for reflection within the pilot study to ensure steps and inferences could be traced. A summary of the interview was made as bullet points, compiled and sent to the participant (email or post, dependent on participant choice) for checking (Appendix M). The participant checking their own interview summary ensured there were multiple analysts to review findings (researcher, supervisors and participant) which ensured triangulation (Patton, 1999) with the participant able to corroborate, refute or refine findings (Barbour, 2001). Paper copies of the transcriptions with coding were printed to record notes and observations in addition to the written diary. The supervisory team

observed selected printed transcripts within supervision sessions to review the interviewing technique and to challenge or confirm the coding where appropriate.

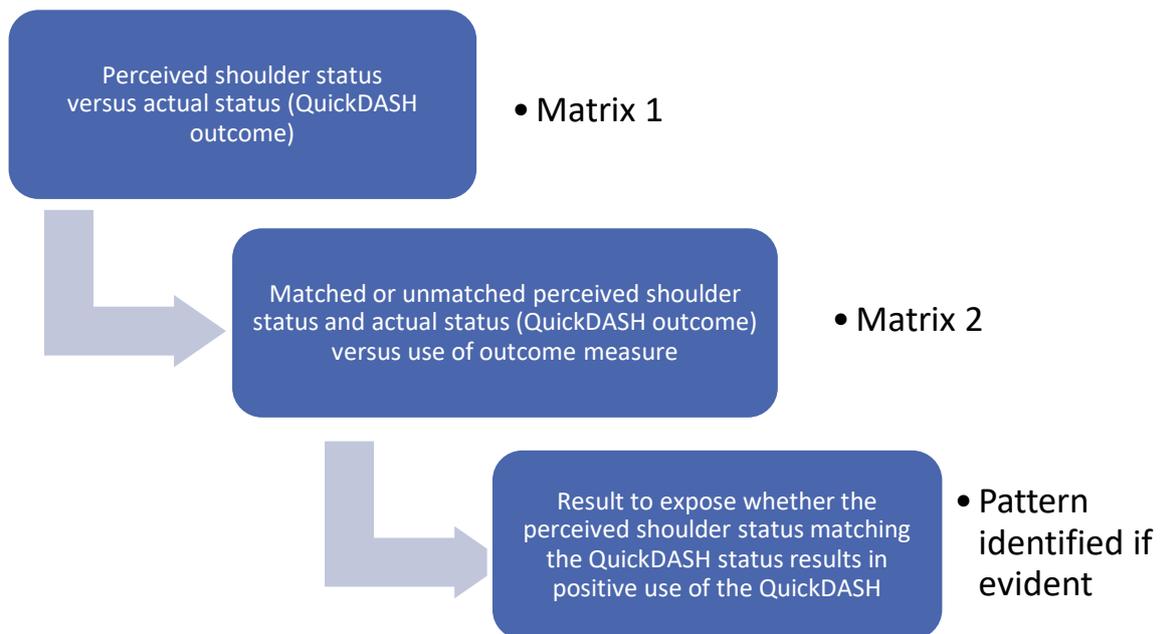


**Figure 9: The iterative steps of data analysis for the phase I pilot study**

Open coding followed to identify the most common, frequently discussed areas in response to open question and further, deeper questioning. Matrix analysis then commenced to reach a higher precision in partitioning individual participant factors to aid ordering and explanation (Miles, Huberman, & Saldana, 2013), presenting as a structured approach within a qualitative study to detect patterns in the interview data and coding (Elo & Kyngäs, 2008).

Examples of matrix analysis using participant data can be observed in Appendix O. Matrix analysis in this study involved a crossing of two factors, which in this study were combinations of open codes and demographics to determine if links were evident between factors within the pilot study participants. Examples of basic matrices were: age and use of outcome measure, age and severity of starting score. Matrix headings could be in a yes / no format (e.g. use of outcome measure) or descriptive in nature (e.g. type of goal).

The initial basic matrices were developed to be more complex structures and the results from one matrix analysis were developed to inform another. An example was the matrix to determine if participants' perceived shoulder status matched that of the QuickDASH outcome. The result from this matrix analysis was then linked to a second query as to whether the QuickDASH was used positively by each participant. A flowchart of this example is shown in Figure 10. This particular type of matrix analysis allowed exploration of links between two unknown factors, for example whether the perceived versus actual status concurrence was related to the use of the outcome measure.



**Figure 10: Example matrix analysis flowchart**

Descriptive analysis of the data was also undertaken by storyboard analysis (Appendix P) to explore facts, and the meanings participants give to those facts, conveying them in a coherent and useful manner (Sandelowski, 2000), allowing the researcher to become acquainted with each participant's data (Appendix N).

Open coding, patterns from matrix analysis and storyboard analysis were combined to produce descriptions of processes, labelled as Context, Mechanism, Outcome configurations, which will be referred to as 'CMOCs' throughout the thesis. The CMOCs described what constituted a positive or negative feedback process.

## 4.7 Rigour

Phrases often used within quantitative research to demonstrate rigour are listed below:

- Internal validity, ensuring the least number of variables (Berg & Latin, 2008)
- External validity, referring to generalisability (Neuendorf, 2002)
- Reliability, describing consistency (Kirk & Miller, 1986)
- Objectivity, referring to the minimisation of bias and promotion of neutrality, by increasing distance between researcher and subjects (Krefting, 1991)

These elements are not able to be controlled within a qualitative research study, therefore methodological rigour is important to increase trustworthiness of research, with coding, triangulation and participant validation as part of the process to strengthen rigour, but only if embedded in a broader understanding of qualitative research design and data analysis (Barbour, 2001). Credibility, transferability, dependability and confirmability are four elements which can constitute rigour within qualitative research and are terms more suited to this study.

Credibility describes how credible and believable the results of the qualitative research study are to each participant. Credibility was increased by sending data summaries from each individual interview to the participant for checking and subsequent modification (if requested). This was essential to the study as participants were the population experiencing the feedback phenomenon and were the only individuals who could judge the results. Credibility was strengthened by triangulation of findings with the treating physiotherapists to corroborate or oppose the patient participant views.

Transferability refers to the degree in which the results of a study can be generalised to other settings. Realist evaluation as an approach accepts that research findings produce partial truths (Pawson, 2013), applicable only to the participant population studied. Dependability is also limited within this study as it is unknown as to whether similar findings would occur if the study were to be repeated. The ever-changing context of the participant group is acknowledged in the production Context, Mechanism, Outcome configurations (also described as programme theories) and the modification of middle range theory (the Contextualised Feedback Intervention Theory) to create 'reusable conceptual platforms' which can be further tested and refined in alternative populations as variations may occur with differing participant groups.

Confirmability was enhanced by transparency in documentation with detailed methodological steps, involvement of the supervisory team in development of open codes, utilisation of peers to independently open code alongside the researcher and peer review at multiple conferences at all

stages of the study (Parish, 2013, 2014, 2015, 2016). These processes allowed opportunity for critical appraisal of research processes and analysis, and modification where indicated.

## **4.8 Ethics**

The Helsinki declaration (World Medical Association, 1964) was developed to ensure patients had the choice to consent to medical research prior to their involvement within any study . To ensure research is carried out ethically, it is essential to receive ethical approval. In this study, NHS patients were approached to participate and three organisations required approval before patients could be approached: the local research ethics committee, the North-West NHS trust Research and Development department and the University of Central Lancashire ethics committee. Ethical approval was gained for the phase I pilot study from Lancaster Research Ethics Committee on the 18 April 2012 (Reference: 12/NW/0229) (Appendix B), governance approval was gained from NHS Research and development of the North-West Trust on 1<sup>st</sup> May 2012 (Appendix C) and the University of Central Lancashire Built, Sport and Health (BuSH) Ethics committee on the 27<sup>th</sup> June 2012 (Appendix D).

## **4.9 Phase I pilot study preliminary findings informing the phase II main study**

Patterns in open coding, descriptive analysis and matrix analysis were used to answer the phase I pilot study research questions and to explore the positive and negative impact of feedback, presented as Context, Mechanism, Outcome configurations (CMOCs). These findings were pivotal in shaping the next phase of the study to ensure the correct methods were chosen for continuation of the study and the direction of research focused the issues found to be of interest in the phase I pilot study.

Modifications were introduced as the researcher gained confidence in qualitative, semi-structured interviewing, developing the questioning framework as the mechanisms surrounding feedback theory were explored within a realist research context.

Due to the inductive nature of qualitative research, the pilot study elicited reasoned and logical changes to the protocol, procedure and direction of questioning. A new ethics application was required for the phase II main study, to allow development on the phase I pilot study findings, allowing more directed aims and objectives with deeper analysis.

The findings from the phase I pilot study will now be presented in chapter 5, to report findings in a chronological order, prior to explanation of the modifications in methods for the phase II main study and subsequent main study results.

## **Chapter 5: Findings phase I pilot**

### **5.1 Introduction**

This first findings chapter refers to the data collected as part of the phase I pilot study for 10 participants recruited between 29/08/2012 and 26/06/2013 with shoulder impingement syndrome and under active physiotherapy treatment in an NHS class setting. This chapter will only deal with answering the research questions asked of this phase of the study. It details the contextual findings of the first 10 participants, exploring the meanings of participant interview data depending on the context in which phrases are expressed. This phase I study was designed to pilot the practical research processes and feedback processes informing the main study. It was concerned with the feasibility of the feedback process and the value patients placed in the outcome information. Specifically, phase one was designed to address the following research questions:

Question 1: Are patients accepting of the feedback process and is it feasible?

Question 2: What do patients think about the usefulness of outcome feedback?

It was anticipated that by addressing these questions, the phase I study would provide data that would inform the design of phase II and provide evidence for the suitability of the selected research tools.

### **5.2 Participant summaries**

All 10 participant summaries were accepted as factual accounts of the interviews as no changes were requested by the participants, verifying the researcher's written accounts as accurate. An example of a participant summary can be observed in Appendix M.

### **5.3 Overview of analysis**

Storyboards were drawn up to map participant's data in relation to the CFIT (Appendix R) and feedback processes (Appendix S), aiming to 'see' patients, both individually and combined, aiding the researcher to become closer to the data. Matrix analysis (Miles & Huberman, 1994) was carried

out combining headings, for example, acceptance and feedback use. Content analysis of the data surrounding acceptance exposed regularities of accuracy and relevancy which participants considered to be important. Accuracy and relevancy were then added to the matrix analysis to look for patterns in the participant responses.

## **5.4 Question 1: Are patients accepting of the feedback process and is it feasible?**

The feedback of information process as previously described in the methods chapter encompasses collection of the QuickDASH score as a Patient Reported Outcome Measure (PROM), plotted on a graph with all other scores from previous physiotherapy sessions. Scores were calculated from the paper-based score sheet, completed by the participant and plotted on the graph for the patient by the physiotherapist to discuss together. The analysis indicated that patient acceptance of feedback was based on either perceived accuracy of the feedback or relevance of the QuickDASH questions.

### **5.4.1 Accuracy**

Accuracy appeared to be gauged as to whether their perceived status (how they thought they were performing / current status) matched actual status (how they scored on the QuickDASH).

Of the 10 participants, eight made reference to accuracy of the QuickDASH in relation to how they felt, not necessarily using the word 'accurate' but alluding to it by using phrases suggestive of accuracy, with two examples outlined below:

Example 1: Participant 07

Interviewer: *"And were the scores ever a surprise or did you know...?"*

Participant 07: *"I knew what was coming, yeah. Because I knew the questionnaire, I got used to the questionnaire, I knew what was coming because of what kind of week I've had...I think you forget about it, the back of your mind you had a trigger point every time [with the QuickDASH] and I think it was quite good to know where you were at every week, you know*

*so I think it's quite positive maybe because I kind of remained neutral [points at level points on chart]."*

Example 2: Participant 1

Participant 1: *"I was going up and down so my more recent results are slightly lower than my first one that I recorded."*

Interviewer: *"Right, so it was slowly going up and down?"*

Participant 1: *"Because I am trying to do more now with the shoulder."*

Interviewer: *"So you felt like the scores were sometimes going down but because you were trying to do more?"*

Participant 1: *"Yes I was trying to do more."*

The QuickDASH scores over time did not always progress positively in a linear pattern and scores could increase or decrease in an irregular pattern. An example could be a participant having a period of time with higher levels of pain than usual, and this being mirrored on the QuickDASH, showing a worsened score, or conversely having an occasional period between treatment sessions with lessened pain, showing temporarily improved scores. QuickDASH scores tracking irregular scores were identified within the interviews with five of the 10 participants. The following quotes identify cases where participants linked the parity of the QuickDASH scores to their irregular scores:

*"One week I was quite bad but as I say I think that was when I had been tiling" (05).*

*"It went down due to circumstances" (07).*

*"It depends on what I've done that week as well" (10).*

For the two participants who didn't identify accuracy in the QuickDASH, they felt that this method of data collection may not be accurate. With the QuickDASH being a Patient Reported Outcome Measure (PROM), this suggested they were not confident in their marking of the assessment itself,

or not confident in the QuickDASH as a sensitive and credible instrument for calculating their shoulder status:

Example 1: Participant 04

Interviewer: *“Were you interested to find out what your score was like at the next session, or did you know yourself how well you were doing?”*

Participant: *“I think I knew myself, if I relied on the markings on there... it would be, it would be alright for someone else I think it’s a different situation with me but I think with myself I know exactly how I feel about the situation... The scoring system may be a bit out.”*

Example 2: Participant 03

*“Pain at night was a problem, the questionnaire said did it keep you awake? Well it didn't keep me awake, but if I turn over in bed it really does hurt, but I think the only way I've described it to my friend is that I think maybe during the night is that your muscles tense up or whatever and I wouldn't be aware of it, I'd be dozing and I would turn over and suddenly I would be like 'argh!' and it really did hurt. But I didn't feel I had answered like that on the questions because it wasn't keeping me awake it was just when I turned over, or like if you forget first thing in a morning to turn the alarm clock off suddenly, you know, painful, so I wouldn't class that as keeping me awake at night though, so I wasn't quite sure on that question... I felt I wasn't being totally honest in what I was writing down.”*

#### **5.4.2 Relevancy**

Participants commented on the relevance of the QuickDASH questions. They were deemed to be relevant if the questions asked were congruent with problems they faced in everyday life. Relevance of the questions was identified by seven out of the 10 participants:

#### Example 1: Participant 08

Participant 08 was a busy working mother who talked of the consequences of her shoulder problem within her interview: *“Because I've got a two-year-old, plus the job I'm doing at the moment needs lifting and putting on the shelf, so it's like, you know, moving quite a lot.”* She found the QuickDASH relevant as the questioning mirrored the problems she was experiencing in her daily life:

*“Daily tasks... Yes... If I have any difficulty lifting a bag, there's quite a lot, sleeping as well [Looking at the QuickDASH outcome measure form].”*

#### Example 2: Participant 09

Participant 09 was an active 40-year-old man who enjoyed kayaking and water sports and used to work as a joiner, and although had become more sedentary as his career progressed to a management role he was still very active outside of work. He found the QuickDASH questions very basic in comparison with his active lifestyle, but agreed that the questioning was fitting to the specific restrictions that SIS presents to the majority of people:

Interviewer: *“And what did you think about the questions you were asked on there [QuickDASH]?”*

Participant: *“It was fair because sometimes you think ‘is cutting a job?’ but that's what you've got to ask because there are people at other extremes who've got that and it's actually preventing them doing that and it's an everyday task: opening a jar, cutting something, washing your back. It covers all the points doesn't it? Again, it's right against the ailment that's being assessed.”*

### Example 3: Participant 07

Participant 07 had multiple health conditions which limited different areas of her life. Despite her health issues, the QuickDASH was able to act successfully as a disease-specific PROM by asking questions that directed her thoughts towards relevant limitations of SIS on a daily basis:

Participant: *“Yeah, I think they were quite positive, well you know I thought what the questions were asking were appropriate.”*

Interviewer: *“And how would you deem them to be appropriate? What would you be looking for in the questions?”*

Participant: *“You know, daily tasks and stuff. That's what I really looked at. Whether it was relevant, yeah.”*

## **5.5 Question 2: What do patients think about the usefulness of outcome feedback?**

Usefulness was gauged by multiple factors within participant responses. Feedback was considered useful and used by participants if they speculated that any of the following would occur: Increased patient knowledge, increased therapist knowledge, setting of common goals, behaviour confirmation and / or change, and helping others.

Five respondents gauged utility by determining whether they (or the therapist) had improved management via the feedback of information process, two examples are outlined below:

### Example 1: Participant 04

*“If I hadn't had the session you wouldn't know what could have happened and she [the therapist] wouldn't know.”*

Example 2: Participant 06

Interviewer: *“And when you did actually fill the form in and you got your 9.1 score did it make you realise that you were actually nearly there?”*

Participant: *“Yes, although I knew I was anyway really.”*

Interviewer: *“So it just confirmed things for you?”*

Participant: *“It just confirmed things, yes, but that above all things it showed me what I should be doing.”*

Participants used the QuickDASH for differing reasons. It helped with giving a goal to work towards, knowledge of progress and confirmation to participants their actions were correct when seeing improvements:

*“Something to work for...aim for...I think when you see the graph you try and work”* (05).

*“I don't think I would have got as far as what I have without knowing any scores”* (02).

*“It felt like it's got easier the more that I know that I'm doing it properly”* (09).

Although most participants in the pilot study found the QuickDASH to be accurate, relevant and useful, there was a small number of participants who presented as anomalies to the trend.

## **5.6 Anomalies**

An irregularity in the data concerned two of the respondents (03 and 04) who did not value the accuracy of the QuickDASH and did not utilise it for this reason. 04 was concerned mainly about returning to work and commented on the reduced relevancy of the QuickDASH related to his activities as work:

*“[The QuickDASH] may have the wrong conclusion really because the biggest part of it is getting back into work then finding out it's not right...it's been a false reading”* (04).

Participant 03 answered the questions in an alternative way to all other pilot study participants which made her question the accuracy and usefulness of the QuickDASH. She found some questions challenging to answer as she could do the activities with her other arm, so the QuickDASH scoring did not represent how she felt.

Interviewer: “So would you say it was more because it wasn't relevant because it didn't show your progress?”

Participant: “Yes, well because it's the other arm.”

## 5.7 Realist presentation of conclusions from the pilot phase I study

Conclusions will be outlined in a realist presentation using a Context-Mechanism-Outcome configuration (CMOc). Jagosh et al. (2012) describes CMO configuring as a heuristic used to generate causative explanations pertaining to the data. The process draws out and reflects on the relationship of context, mechanism, and outcome of interest in association with the study setting and intervention (Jagosh et al., 2012).

The following CMOc configuration (Figure 11) presents a generalised view of when the feedback process has a positive impact:

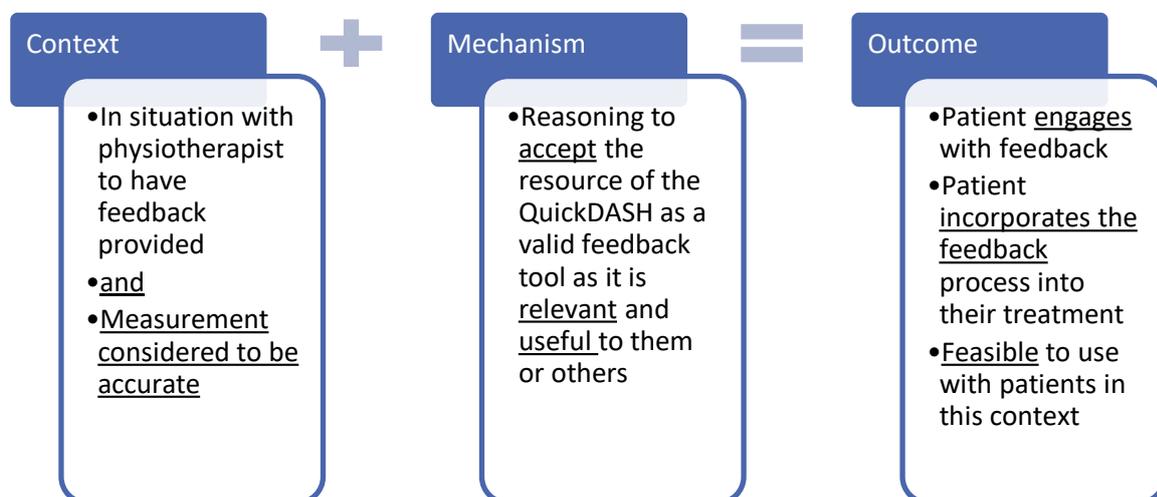
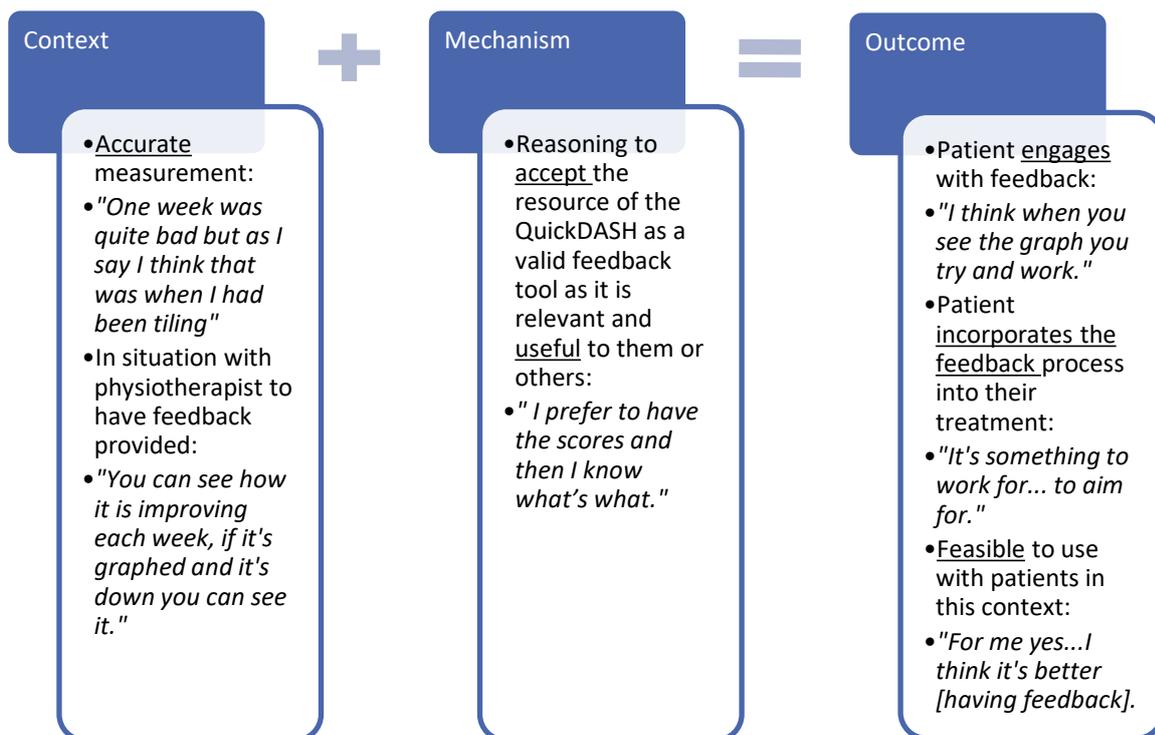


Figure 11: Generalised CMOc describing a positively conducive feedback process

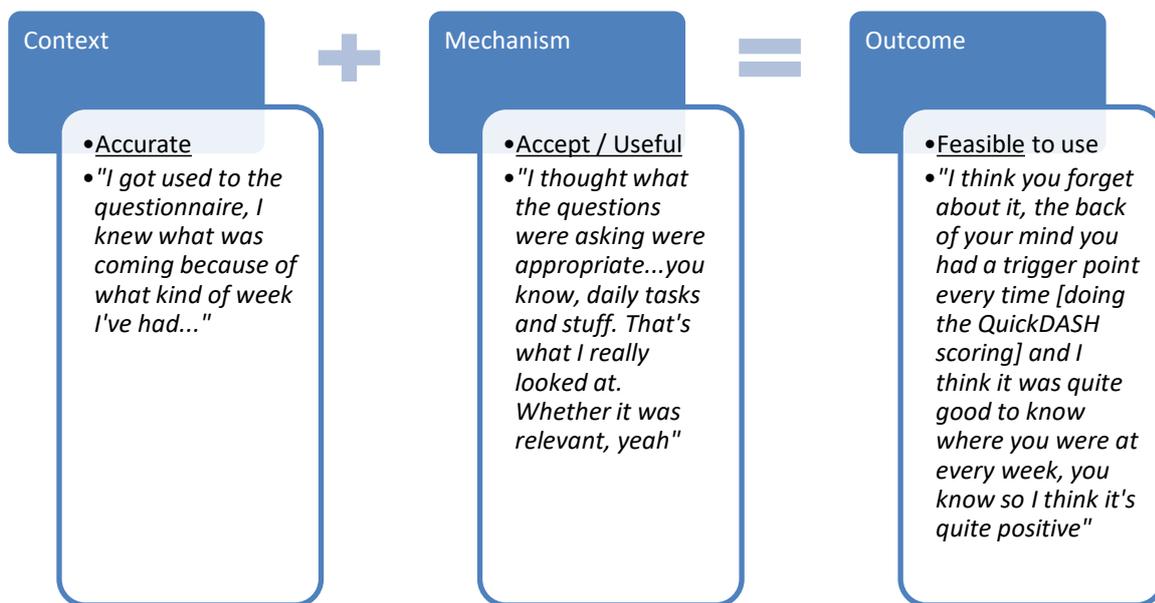
The physiotherapist needed to be available and present to provide feedback using an accurate outcome measure for the shoulder condition, in this case the QuickDASH (context). This circumstance created a conducive situation allowing patient reasoning to deduce if the feedback process was relevant and useful to them and others (mechanism). If the patient identified relevance of the questions being asked, congruence with the feedback scores, and deemed the feedback to be useful, the patient was encouraged to engage with the feedback and incorporate the process into their treatment journey (outcome). The intervention of information feedback using outcome measures presented as a feasible option to explore for use in practice based on this CMOc.

The CMOc below in Figure 12 describes the processes which occurred with participants in this study when feedback produced a positive outcome. Quotes are used from interview data from one participant (05) to demonstrate C, M and O, outlining the context which acts successfully as a precursor to the mechanism firing, to then produce a positive outcome.



**Figure 12: CMOc describing a positively conducive feedback process with quotes from participant 05**

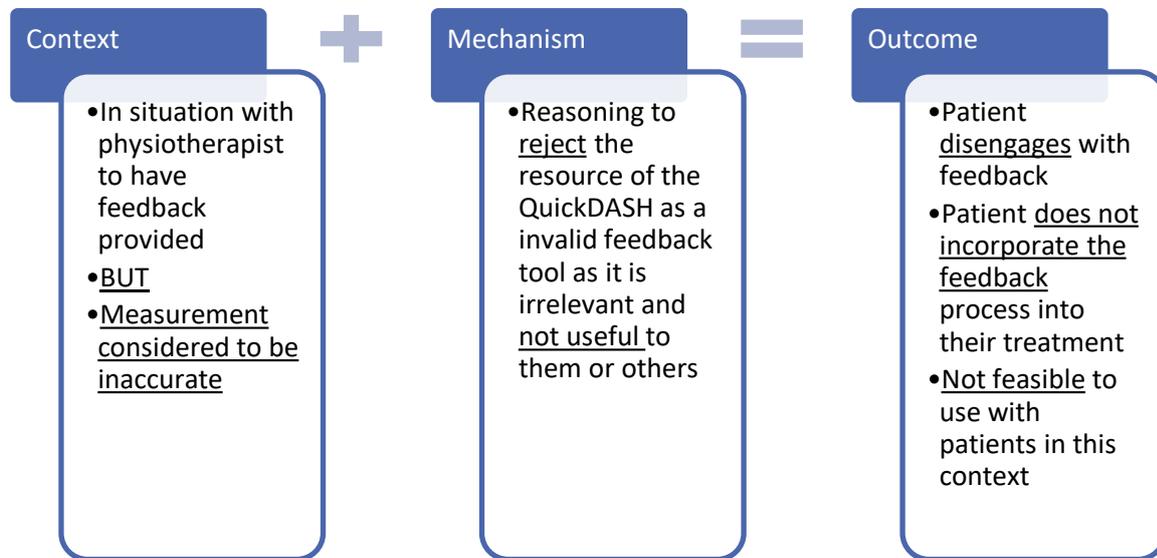
This CMOc occurred for eight out of 10 participants in the phase I pilot study. To demonstrate the context in another case, below is a CMO configuration for another participant who showed a positive response to the feedback process (Figure 13). The CMOc for participant 07 presents as a second case where the circumstances were conducive to fire the mechanism to fire, encouraging the feedback process to be used in practice.



**Figure 13: An example of a positive outcome CMOc using quotes from participant 07**

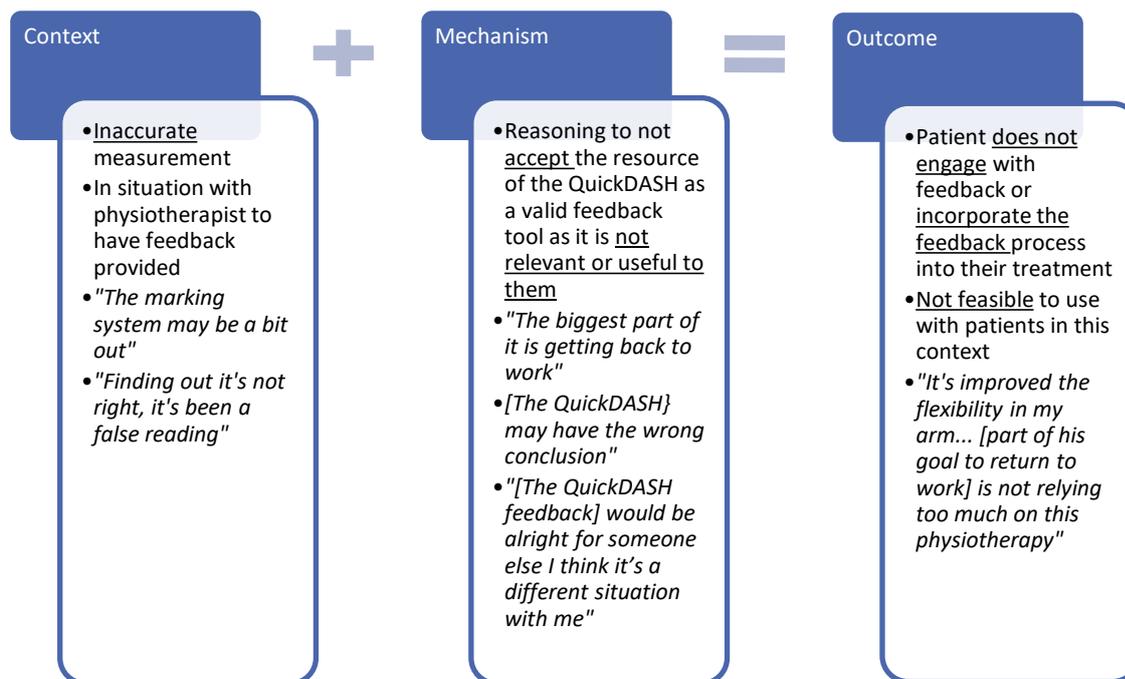
For the remaining two participants, the CMOc produced a negative outcome. It is important to describe what processes occur when interventions do not work to understand what is lacking in the background context and resources which restricts mechanisms from firing to produce a positive impact. A CMOc was developed based on the interview data for participants 03 and 04 to describe a negative outcome of information feedback (Figure 14). The circumstance of feedback from the physiotherapist was unchanged (congruent with the eight positive outcomes) but with a variation for these two participants: the view that the QuickDASH feedback was inaccurate (previously mentioned in section 5.4.1 Accuracy), finalising their responses with: *"The scoring system may be a bit out,"* (04)

and “... I felt I wasn’t being totally honest in what I was writing down,” (03). The CMOc below demonstrates their response:



**Figure 14: CMOc describing a negative outcome from the feedback process**

Figure 15 illustrates a feedback process which produces a negative outcome CMOc with quotes from participant 04. Part of the context, as previously described, was identical to the positive outcome CMOc as the QuickDASH feedback was provided to all participants. Participants 03 and 04, concurring with the negative outcome CMOc gauged the outcome measure (QuickDASH) as inaccurate (context); with reasoning to reject the outcome measure scores as feedback as they felt it was not valid (mechanism). Participants 03 and 04 therefore disengaged with the feedback as part of treatment (outcome). With participants such as these, who concur with this CMOc, feedback will not produce a positive outcome.



**Figure 15: CMOc describing a negative feedback process with quotes from participant 04**

In further response to the research questions asked of this initial study (Chapter 5, page 103), the CMOcs confirm that the majority of participants were accepting of the feedback process (8 of 10). The participants who accepted the information feedback only found it useful if they felt the QuickDASH questions were relevant on a day to day basis and accurate to how they felt about their shoulder status. The phase I pilot study therefore suggested that the use of information feedback in this setting was operational, having the possibility of being successful and feasible to use for most patients. It was therefore considered a suitable line of enquiry for further exploration in a phase II main study to find out when feedback worked, for whom and in which circumstances.

## **5.8 Additional findings to the pilot study questions**

There were additional, engaging, incidental findings, which varied from the focus of the research questions, which presented during analysis as interesting features to be considered for the next study phase. Feedback and the therapist-patient relationship was noted in the interview with

participant 02. It was not a relevant theme in relation to the research questions but was discussed at length by participant 02 which presented the idea as an important concept which may play a larger role in the feedback process. Participant 02 identified the scores helping him, but also expressing the desire for the feedback process to help the therapist as well as himself and the extended patient community:

*“I didn't mind at all because if it helps you to help others... When I first started here I was quite happy to do what I was asked to do and I knew what they told me to do would improve it... she said that I was doing alright and I was quite happy with her comments... I feel that they are here to help you and you have got to be truthful with them for them to help you and I think that is part of the job to do that... I knew that you were interested otherwise you wouldn't have been asking me to come here would you?” (02)*

The patient-therapist relationship element was noted within the research diary, with plans to return to the area in more detail in the main phase II study if it reoccurred.

## **5.9 Reflections on using a realist lens**

The phase I pilot study met realist evaluation ideals as the study used an interpretive, theory-driven approach to evaluating evidence from mixed-methods research (Jagosh, 2014). Realist research was used appropriately and successfully as an exploratory phase with the 10 participants of the phase I pilot study to draw conclusions in relation to the research question. It was felt that the realist lens encouraged focus on the real issues within the study participants' interviews and acknowledged the complexities of social influence (Williams et al., 2016), with realist evaluation presenting as a favourable approach to be used further within the phase II main study, but in a more complex form. This decision secured the continued theory-driven approach to data collection and analysis, supported by a recognised and reliable approach: realist evaluation (Pawson & Tilley, 1997).

## **Chapter 6: Phase II Main study methods**

This chapter will outline the more directed and detailed aims and objectives for the phase II main study, the subsequent ethical approvals which took place to continue with the study in a modified direction and the adjusted methods utilised to reshape the direction of the study.

### **6.1 Aims and objectives: How the research question will be addressed**

This study phase takes a realist approach, aiming to test the existing theoretical models of information feedback with patients in a physiotherapy context. A basic assumption of realist evaluation is that programmes are complex interventions introduced into complex social systems (Pawson, 2013) and due to intricate workings within these programmes they need careful consideration with regard to research design. Theoretical models of information feedback to patients exist, with most participants finding information feedback useful in the pilot study, but as the results of the literature review suggest, studies in practice expose feedback responses to be inconsistent.

Feedback of outcomes to patients in physiotherapy is delivered in a clinical setting and is commonly considered quantitative in nature due to the mere collection of numerical values. Quantitative research alone does not explain what works for whom, and in which circumstances, how and why, identifying the need for qualitative methods to be included. Realist evaluation was selected for use, to explore data with mixed methods, using an approach that encompasses research of social behaviour, allowing for differences in a single population and embracing the complexity of human choice.

## **6.2 Focused aim**

The aim overarching both studies was to answer the question: "Outcome feedback in Physiotherapy: What works for whom in which circumstances?"

Within the main phase II study, specific questions developed from this to ask:

1. What works for whom, in what circumstances?
2. What part does feedback of information (Routine Outcome Monitoring and other feedback types) play in the participants' response (behaviour and actions)?
3. How are the processes shaped in terms of context-mechanism-outcome configurations?
4. How does the overarching context-mechanism-outcome configuration align with, or enhance the CFIT?

## **6.3 Ethics**

Ethical approval was gained on 3<sup>rd</sup> July 2014 West of Scotland Research Ethics Committee 5 (14/WS/1038) (Appendix E), governance approval was gained from NHS Research and development of the North-West Trust on 26<sup>th</sup> August 2014 (Appendix F) and ethical approval from UCLan Science, Technology, Engineering, Medicine and Health (STEMH) ethics committee on 3<sup>rd</sup> October 2014 (Appendix G).

## **6.4 Method of sampling**

The phase II main study had an alternative method of sampling to the phase I pilot study as the realist sampling strategy is driven through sets of ideas and theories about the social world we seek to investigate in a particular context (Emmel, 2013). The SIS population being studied, is treated in the NHS in groups, in the NHS in 1:1 sessions and in the private sector. The phase I pilot study sampled from a group setting, so it was indicated within the phase II main study that the second two groups would be sampled to complete the locations in which this population of SIS patients are seen. This change from the phase I pilot study shows progression through strategic sampling so that the research can specify what the research will know about the whole population (Emmel, 2013).

#### **6.4.1 Physiotherapist participants providing patient feedback**

Two physiotherapy settings chose to participate in the study to support research in practice and extend the scope of the two settings to include research activity. In this part of the study, physiotherapist participants were included to provide a testing ground against patient participant data and to be an aid for development of CMOcs. Permission to approach the physiotherapists was gained from the North-West NHS Trust physiotherapy provider (an outsourced private company) and the private practice managers. The physiotherapists participants who would provide the feedback of PROMs to the patients volunteered to take part in the study after receiving an email outlining the study. Written consent was gained from each participating physiotherapist by the researcher. Three physiotherapists consented to be involved in providing the PROMs feedback to patient participants.

Recent research has suggested that exercise has a useful role to play in the treatment of shoulder impingement, however, the optimal parameters of exercise are unclear (Littlewood, Ashton, Chance-Larsen, May, & Sturrock, 2012), leading to variation in individual patient exercise plans. Training was provided for physiotherapists in both the NHS and private practice settings by an upper limb specialist orthopaedic practitioner on current evidence-based treatments for shoulder impingement syndrome. This took place to standardise the assessment and treatment of shoulder impingement syndrome patients with an evidence based focus, provided by multiple therapists. It allowed the physiotherapists to ask any questions of the researcher regarding the study before consenting to take part.

Physiotherapists providing the feedback of the QuickDASH scores were provided with guidance notes to indicate and standardise sequences of information letters given and consent. Guidance notes also provided suggestions on presenting the PROMs feedback, including prompts for wording, and how to present a feedback graph to a patient. These measures allowed standardised and smooth implementation of the feedback process in practice.

### **6.4.2 Patient participants**

Sampling in qualitative studies can be a contentious issue (O'Reilly & Parker, 2013) and participants in a qualitative study should be experts on the phenomenon being studied and must be chosen carefully (Rudestam & Newton, 2014).

Patient inclusion criteria consisted of adults aged 18 or over, diagnosed with shoulder impingement syndrome. Patients were invited to be participants if they were able to attend three or more sessions of treatment (weekly or fortnightly), able to read the information sheet (English language), able to provide informed consent and were able to participate in an interview. Patients were excluded if co-existing health problems would limit them from taking part in treatment. Participants were recruited from one of two locations in the North West: NHS 1:1 assessments and private 1:1 assessments. The patient participants were then added to the 10 phase I pilot study participants from the NHS based shoulder class for final analysis.

All patients in normal physiotherapy practice undergo a full subjective and objective assessment of their shoulder. On objective assessment, range of movement is observed and shoulder specific diagnostic tests undertaken. The most sensitive diagnostic tests for shoulder impingement (described previously in section 4.4: Recruitment in the phase I pilot study) are the Hawkins test (92.1%) and Neer test (88.7%) (Calis, Akgun, Birtane, Karacan, Calis, & Tuzun, 2000). These specific tests were used to diagnose SIS and identify potential participants in the Phase II main study. Following a full shoulder assessment, physiotherapists could determine whether a patient met the inclusion criteria and was eligible to take part in the study.

The assessing physiotherapist in all cases made the first contact with the patient on their first appointment. Potential patient participants were invited to participate once they were identified as meeting the inclusion criteria, and were recruited sequentially. They were invited to participate by the assessing therapist and given a participant invitation letter and information sheet to read over a 24-hour period or longer before signing the attached consent form if they wanted to participate

(Appendix J). Informed, written consent was obtained on the next available treatment session (in excess of 24 hours) if the patient wished to participate.

## **6.5 PROMs feedback**

After patient participants consented to take part, the information feedback element was added to their treatment sessions. In the main phase II study, the assessing physiotherapist was also the treating physiotherapist.

At each session, the physiotherapist asked each patient to fill in a Quick Disability of the Arm Shoulder and Hand (QuickDASH) form (Appendix H). The QuickDASH is a disease specific PROM, asking 11 questions regarding functional ability, interference with social activities, limitations at work and home, pain, pins and needles, and sleeping (Beaton, Wright, & Katz, 2005). Each question is rated on a scale of 1 to 5, 1 indicating no problem or limitation and 5 indicating severe or extreme problems and limitations. A calculation is made to produce a final score. A score of 100 indicates maximal dysfunction and conversely 0 indicates no dysfunction. As with the phase I pilot study, the QuickDASH was again selected for this study as it has been shown to exhibit good test-retest reliability and responsiveness in patients with shoulder pain (Mintken, Glynn, & Cleland, 2009) and was considered acceptable, utilisable and feasible for patient use by the majority of the 10 respondents in the pilot study.

Feedback of outcomes in a mental health setting often involves use of visual measures as they are perceived as helpful for progress reporting (Unsworth et al., 2012). Visual measures were used at each appointment with the scores each week plotted on the same visual graph shown to each patient individually within the treatment session (Appendix K). The scores were discussed with each patient by the treating physiotherapist.

## 6.6 Data collection of the QuickDASH PROM

Each QuickDASH PROM was completed on a paper copy and retained by the treating physiotherapist with a calculated written score and the date it was completed. These data were collected for each participant throughout treatment, and kept in the patient notes.

The QuickDASH scores were collected as a quantitative measure. From the QuickDASH measures, scores were calculated from the starting QuickDASH calculation to determine severity as mild, moderate or severe. Fan et al. (2008) assessed the predictive, discriminate, and concurrent validity of the QuickDASH and SF-12 (a generic assessment of health-related quality of life) among 231 workers with specific clinical diagnoses of neck or upper extremity musculoskeletal disorders, where 175 had active symptoms.

Table 13 describes the severity ratings, sample sizes for which each was based upon and the average QuickDASH score for each group (Fan et al., 2008). Based on the average QuickDASH scores, it was possible to calculate ranges for mild, moderate and severe ratings.

**Table 13: Mild, moderate and severe ratings**

(Fan et al., 2008)

Symptom severity considered as:	Sample size	Average QuickDASH score	Calculated ranges using average QuickDASH scores
Mild	22	12.6	0.1 to 16.55
Moderate	41	20.5	16.56 to 31.55
Severe	16	42.6	31.56 to 100

Calculations were made from the start of treatment and end of treatment QuickDASH scores to determine change of score during intervention. Improvement categorisation was based upon a study completed by Polson et al. (2010), placing participants into four categories of: 'Very much improved' (improvement of 25.11 to 100.00 points or QuickDASH score 0 at end of treatment), 'Much improved' (improvement of 16.46 to 25.10), 'Minimally improved' (improvement of 11.65 to 16.45)

or 'No change' (improvement of 11.64 or less). The QuickDASH scores throughout treatment were collected as quantitative indicators of clinical outcome in addition to serving as descriptive statistics.

Participants completed treatment at differing numbers of sessions. Participants could either self-discharge (if a participant chose to cease treatment due to circumstances or recovery), the physiotherapist could discharge the patient if they were deemed to be self-managing and recovering, or if they completed the maximum number of sessions in the shoulder class (eight) they could also be discharged.

At the end of physiotherapy treatment, the researcher interviewed the patient participants independently. A semi-structured interview schedule was developed, based upon the CFIT framework and as described previously in the pilot phase I study (section 4.5), was developed inductively throughout this process, with close monitoring from the researcher's supervisory team. The interview schedule was modified after the first 10 participants (Appendix Q) to ensure focus on relevant issues, identification of points of interest that could be expanded upon from the initial findings and to meet the general aim set at the start of the study and answer the specific questions generated from it.

The second and main phase of the study saw further participants recruited until data saturation which is described and debated later in this chapter (section 6.14.1, page 137). At the completion of all patient participants' treatment at data saturation, the treating physiotherapists were also interviewed in line with the interview schedule (Appendix Q).

## **6.7 Interviewing style and schedule**

The interviews themselves were the main measure within this study, generating qualitative data. The interview schedule was semi-structured, but adaptable, with some questions prepared in advance although this was flexible dependent on the participant focus and direction. An important aspect of semi-structured interviews is focus, in this case, focus on theory, allowing the researcher to probe aptly, through eliciting stories.

With flexibility in the interviewing schedule, it increases risk of the researcher imposing his / her definitions of what is important onto the interviewee (Symon & Cassell, 1998). It is therefore important that an interviewer reflects on the impact their position may have on the interview process (Holloway, 2005). Each patient participant was aware from the information sheet of the researcher's relationship with the treatment providers and this may have had an impact in their responses. It was imperative that the researcher became skilled in explaining the research purpose and keeping the interview questions on track in line with the questions being asked of the study.

Each physiotherapist participant knew the researcher as a fellow clinician, which may also have influenced their responses. The physiotherapist participants were reminded that as a researcher in this role, not a physiotherapy colleague, the data would be analysed neutrally and the most important factor in answering questions was to keep the responses truthful whether positive or negative about the intervention. This reflexivity was required to describe relationships between the researcher and participants to clarify the restrictions that these circumstances create (Reeves et al., 2008).

The success of the semi-structured interview method, in this study with a realist approach, relies upon the skills of the interviewer in making a number of difficult decisions in the field (Barriball & While, 1994). The realist interviewing technique is a 'craft' (Jagosh 2017), requiring deeper questioning of the latent content during the interview, in addition to conscious intentions and meanings. This approach aimed to tease out information which was important to the study, but could have been considered by the participant to be less relevant and more difficult to describe, as occurrences are often not tangible and concepts can be latent.

Each interview carried out with participants was audio recorded. Interviews with patient participants ranged from 10 minutes to over an hour, with an average of 29 minutes. The mean average interview duration was longer in the phase II main study in comparison with the phase I pilot as the researcher had developed more exploratory interviewing skills to question responses with more

depth. Interviews with physiotherapy participants, which only happened in the phase II main study had a mean average of 37 minutes.

Themes of enquiry were probed with each individual participant and were followed up accordingly if they were relevant to the study focus. Questions were open in nature at the start of questioning of a subject, and then often became more focused, if required, to identify specific participant meanings and to determine the context in which phrases were expressed.

An example of an open question to start a line of conversation (and subsequent reply from patient participant 13) is outlined below:

Interviewer: *"If you hadn't seen the scores at all how would you describe your progress?"*

Participant 13: *"I don't think you'd know really to be honest it would be a lot more difficult. You'd have an opinion but you forget what pain is like very, very quickly so you might have been in excruciating agony one week and then next week you might have felt a little bit better but you wouldn't have noticed the difference so at least doing it this way you can actually see on a graph how you're progressing sort of thing from that point of view. You can see whether you're making progress and you know. And then something like that it helps I think when you see a chart. You've made it. You ask the same questions. You've got a view on it. Then from one week to the next, maybe you've had a bad time like this one (points to graph) like the 3rd week then it's, you know, you can picture it and know exactly what it's like compared to where you've been so I did find it helpful on the chart."*

## **6.8 Overview of analysis**

Transparency within a realist evaluation is of importance and should include the following specific factors (Westhorp, 2014): explanation as to what data were used to test which aspects of the theory; explanation of analytic techniques used with particular data sets, explicit presentation and discussion of disaggregated outcomes for different sub-groups identified in the theory; explicit

alignment of evidence (on CMOcs against the theory) as a transparent basis for judgements about the programme and the theory to help explain *how* and *why*. Finally, Westhorp (2014) advises presentation of the refined theory and its implications for policy and programmes.

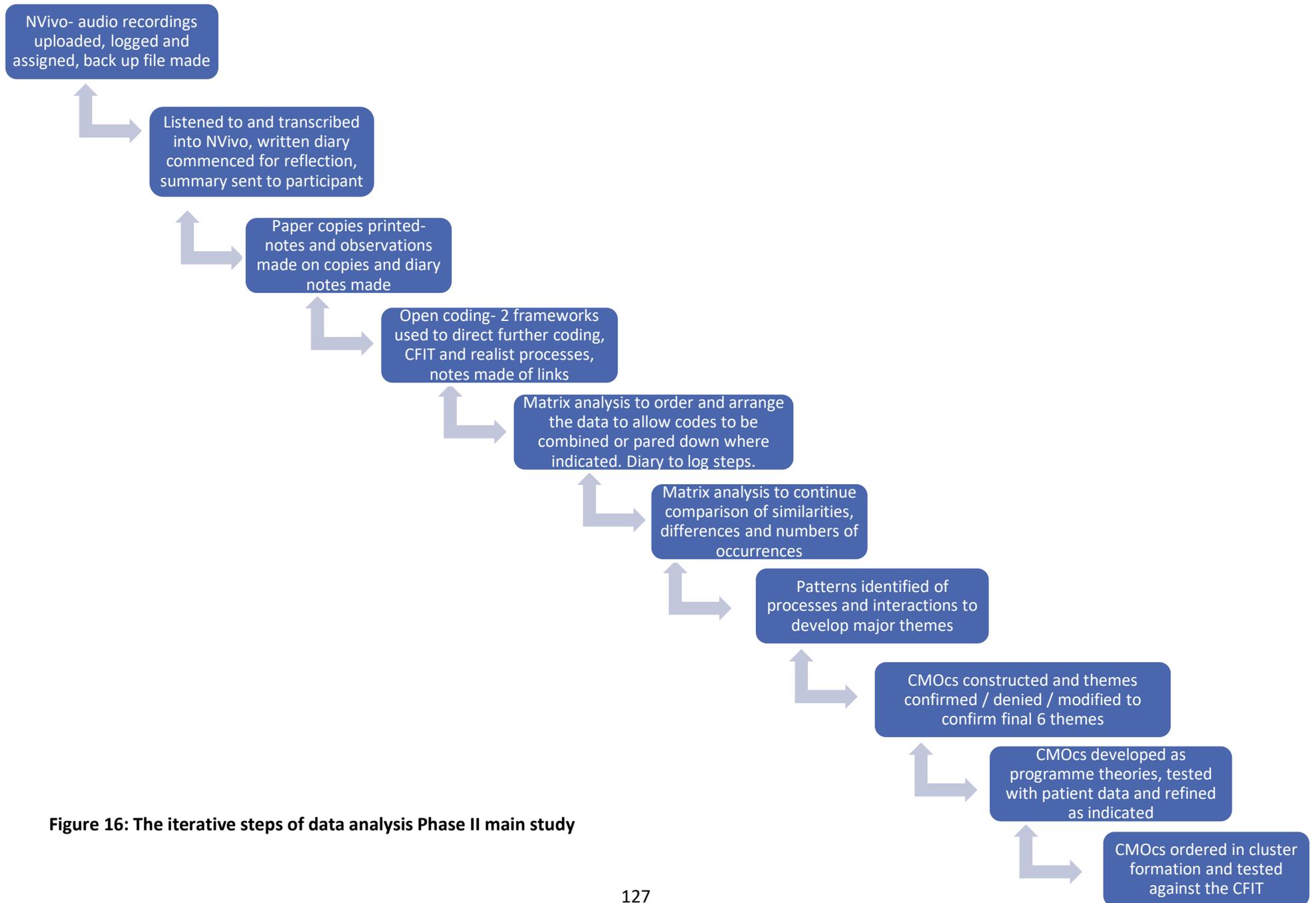
On this basis, transparency is shown initially with a brief overview and diagrammatic presentation of how the analysis was completed in a step-by-step description of key activities. Following the brief overview, each step is then described in detail for total transparency of methodological choices.

The analytical process consisted of 10 steps (Figure 16, page 127), a time-consuming, complex iterative process, but was of benefit, not as a repetitive mechanical task, but as a process to spark insight and develop meaning within the data (Srivastava & Hopwood, 2009). The diagram of analysis methods intentionally has arrows moving up and down the ladder as this process was not linear due to the iterative process of data collection and analysis. Stages of analysis could be revisited, carried out at the same time with differing data sets and stages restarted in full if findings were inconclusive.

The process started with uploading each audio recording into NVivo, logging each as a participant number and a back-up file made. Each audio file was listened to and transcribed into NVivo and a written diary commenced for reflection, with entries made at each step of the analysis process. A summary of the interview (Appendix M) was compiled and sent to the participant (email or post, dependent on participant choice) for checking and triangulation (Patton, 1999). If any changes were to be requested there was opportunity for this to be completed in a joint manner between the researcher and participant. Paper copies of the transcriptions were printed to record notes and observations in addition to the recording of notes in the written diary. Initial open coding followed, using the Contextualised Feedback Intervention Theory (CFIT) and realist processes as frameworks, with continual notes made of apparent links between any codes noted. Where there was overlap between content, codes were combined, or pared down where there was indication that data were insignificant.

Matrix analysis was used to order and arrange the data to observe patterns in the interview data (Elo & Kyngäs, 2008) as previously described in Figure 10 (page 99). Matrix analysis continued to compare data for similarities, differences and numbers of occurrences, with identification of patterns relating to processes and interactions. Major themes emerging from the data were identified at this stage.

From these major themes, preliminary CMOcs were constructed and themes confirmed, denied or modified to confirm the final (six) themes, with CMOcs then modified based on the final themes. Each CMOc was then developed as a programme theory, tested with patient data and refined as indicated. The last step was a large process CMOc, involving ordering the CMOcs in cluster formation to identify which CMOcs were happening in which order, and which were occurring together. Finally, the cluster of programme theories as a cumulative process were tested against the middle range theory of the CFIT.



**Figure 16: The iterative steps of data analysis Phase II main study**

## **6.9 Transcription and computer assisted qualitative data analysis software**

Computer assisted qualitative data analysis software (CAQDAS) was used to manage the large quantity of data from Phase I and Phase II combined. NVivo Pro Version 11.0 © QSR International Pty Ltd was the selected CAQDAS for use within this study. The researcher undertook a basic training course prior to the phase I pilot study, and advanced NVivo training was accomplished before the phase II main study data was analysed along with the phase I data.

Each audio recording was logged separately and assigned to each participant by number and downloaded into NVivo. A back up of each recording was also kept as a Windows media audio file. Audio recordings were then listened to and transcribed within NVivo using the function keys to allow reduction in speed and movement forward and back within the recording. The interviews in the pilot study were transcribed by the researcher (six of 10 interviews) and an NHS administrator (four of 10 interviews).

On reflection from the phase I pilot study it was felt that the process of transcribing helped the researcher to 'connect' with the data as prior to the interview had not met the patient participants. Using a transcriber was useful in terms of time management but the researcher, with intimate knowledge of occurrences during the interview, was considered the most equipped person for accurately deciphering the transcription, in addition to providing an opportunity to reflect on the data (Roller & Lavrakas, 2015). For the second and main phase of the study the researcher transcribed all 15 interviews, giving increased exposure to the data to explore the participant responses in sufficient detail, and at this stage of transcription, the written diary was used extensively to make notes on participant responses. Transcriptions were typed into NVivo with a back up saved as a Windows document (.doc) file.

## 6.10 Coding methods

The processes of data collection and analysis occurred simultaneously, as interviews were continuing to take place, whilst pre-existing data continued to be analysed. The process of data analysis was iterative, involving cycles of movement back and forth within the data in order to achieve clarification of thoughts, reflection and revealing any gaps in understanding which required further thought (Strauss & Corbin, 1998). Rigour is demonstrated by multiple levels of data analysis and abstraction, and revisiting previous coding to modify broad and narrow codes, and explore abstract dimensions (Creswell, 2007).

Initial transcripts were printed as paper copies and note taking took place after listening and transcribing the interview onto the transcript copy. Notes recorded the researcher's initial thoughts, ensuring these observations were logged from the outset of data collection, with appropriate comments also added to the written diary.

Open coding into NVivo was initiated by organising and comparing the data using the driving theory within the study (CFIT) as the first coding framework to arrange the data into initial categories reflecting elements of feedback intervention. The spoken word of participants was explored whilst listening to and reading the transcripts, identifying CFIT elements, highlighting portions of text to code to a 'node'. Codes within NVivo are documented and referred to as 'nodes' within the package.

Theory-driven research has been viewed as having a perceived weakness as it uses theory a-priori, rather than using reasoning or knowledge from observation or experience, therefore a second coding framework was applied to allow data outside of the theoretical frame to emerge (Meyer & Ward, 2014). The second framework was underpinned by realist evaluation: any element which could construct part of a process was identified and notes made of any linkages. At this stage, the coding did not identify these elements as CMO configuration components (contexts, mechanisms or outcomes) but by description of what was occurring. By coding independently, it allowed exploration of different connections or constellations of specific contexts and outcomes that participants

themselves identified, allowing examination as to whether these differed from what existed in the driving theory (CFIT) and formal literature (Jackson & Kolla, 2012). Apparent links were again noted within the diary to log items to be explored in further detail.

Once open coding had been completed for both patient participants (and subsequent physiotherapist participant interviews open coded), the coding presented as extensive and scattered. To make sense of the data, the principles of Miles and Huberman (1994) were adhered to, aiming to reduce data by displaying and verifying links and patterns, aiming to preserve meaning, yet simultaneously reducing and ordering the data set. Tabular formations of codes were used to determine relationships between them and confirm or deny the apparent links identified by previous note taking.

Open codes were thus pared down, removing insignificant or minor codes only if they were considered to be irrelevant *and* had no possibility of being outlying codes which may have revealed small but important irregularities in eventual themes. Recontextualization was accomplished by searching, sorting and assembling similar codes with slightly differing labels (Basit, 2003), for example 'Type of goal' and 'Goal choice' were combined together into main nodes (adult nodes). The adult nodes were then split into sub-nodes (child nodes) to expand each single adult node in detail but continuing a structure from generalised adult nodes to specific child nodes. Figure 17 details a screenshot of one adult node titled 'Feedback of improvement' which had been created from combining other similar nodes, then split into 11 child nodes to show the detail within one large code title. Steps of changes were noted to allow reversal of modifications if considered incorrect.

Patient open coding (theories and more)			
Name	Sources	References	
Feedback of improvement		22	86
Claims improvement but QuickDASH and status ISQ		1	3
Comparison against others		7	13
Exertion to create symptoms		6	9
Frequency		1	1
Function		18	40
Out of 10 or percentage		2	2
Pain		17	32
Pins and needles		3	3
Posture		1	1
QoL		2	2
QuickDASH		6	11

**Figure 17: Example of adult node split into multiple child nodes**

The number of adult nodes at this point of analysis was still large and to make further sense of the data, additional data reduction was required. At this stage, there was difficulty in confident movement from coding which had been condensed into nodes to the next step of confirming the major themes within the data. The process was complex and lengthy, involving many steps, which were recorded in a written diary to document stages throughout the analysis process. Elements of this complex stage involved matrix analysis to identify similarities and differences in responses and the number of participants exhibiting each type of response (Miles et al., 2013) concluding the major themes which were appearing in the data.

### 6.11 Theme development

Themes were developed with the realist approach consciously in mind, seeking participant's common change of experience and regularities in addition to rates, associations and patterns (Pawson & Tilley, 1997). Utilising NVivo to collate data into groups of adult nodes and further split into child nodes allowed all coded text sections to be retrieved easily and enabled the instant revision of decisions.

The theoretical frame is the starting point at which retroductive inference can be employed (Meyer & Lunnay, 2013). Retroductive inference suggests social reality consists of structures and internally related objects, but that we can only attain knowledge of this social reality if we go beyond what is empirically observable by asking questions about developing concepts that are fundamental to the phenomena under study (Meyer & Ward, 2014). Within the written diary, memos were kept on theory structure, apparent links between themes, thoughts and problems and a running list of themes was continually modified.

Themes unrelated to the CFIT elements emerged via open coding and creation of nodes in NVivo. These nodes were created and added to, when participants expressed frequent or strong feelings about a subject area. NVivo as a CAQDAS, aided tracking of the number of participants coded into each node and whether each node had higher numbers of participants quoted within the category. It also allowed the number of separate quotes to be monitored. To determine which themes were occurring most frequently, analysis was completed by drawing up matrices and notes made to identify whether recurring themes were related to the CFIT elements or whether new themes were being identified and numbers of quotes and participants identified within each table. As interventions can generate unintended outcomes (Wong et al., 2013) themes outside of the CFIT elements were carefully considered as patterns emerged.

Themes at this analysis step consisted of overarching titles, comprising multiple codes which could be grouped together. Themes found at this stage of conception were still considered in the development stage as were still to be tested with Context – Mechanism – Outcome configurations (CMOCs) to determine if they were truly occurring within the area of feedback processes or if modifications needed to be made or data revisited.

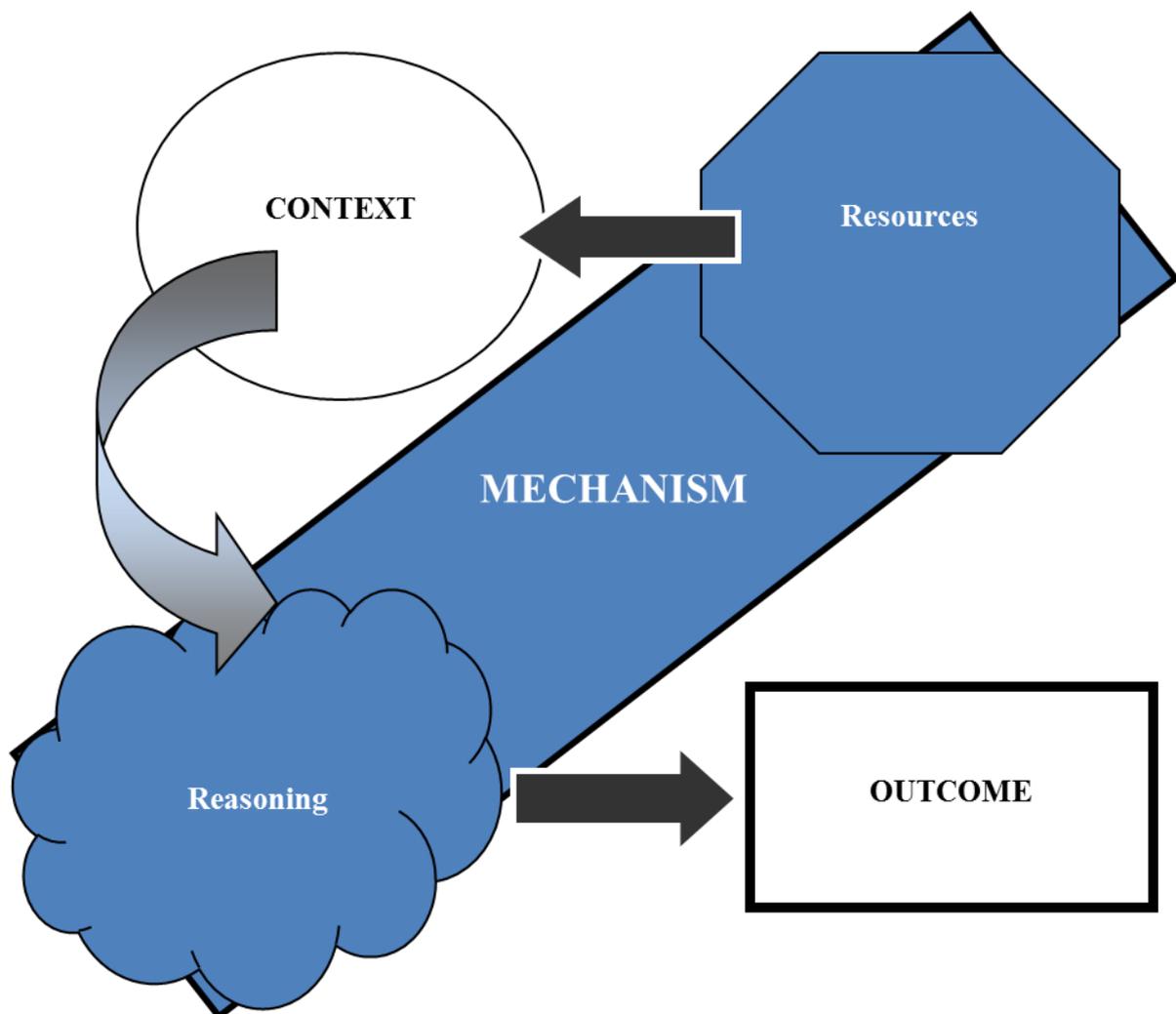
## **6.12 Progression of analysis: Context – Mechanism – Outcome configurations (CMOCs)**

The basic task of social inquiry is to explain socially significant regularities (Pawson & Tilley, 1997). As previously described, patterns were identified to attribute links and relationships, cases were cross-examined and links between quotes in single and multiple cases explored further than surface open coding. This identified links in behaviour and common responses, which resulted in themes being identified. To ensure the themes generated were authentic to the data set, the next level of analysis was used to test the themes. Within the data sets a differing approach was taken, at this level to identify process based elements within the data, contexts to which mechanisms were fired, what outcomes meant to different participants and how the process of outcome feedback had affected each participant differently.

The final analysis was therefore based upon realist study design using the underlying principles that mechanisms can be triggered by particular contexts to produce certain outcomes. This final stage of Context – Mechanism - Outcome configuration (CMOCs) production forms the final framework against which the data were examined. Interactions were mapped out as CMOCs alongside collation of pertinent data to aid explanation of behaviours and actions inside and outside of the theoretical framework. This was completed by combining coding generated within NVivo and mapping participant interactions, using quotes from the transcripts and manually moving them around to interact with each other to identify which category each could be allocated to within a process. This process was continually modified and within this analysis it was monitored as to whether the initial themes identified continued to appear. During analysis themes were revisited and eventually reduced to six major themes. Other pre-existing themes which were evident prior to CMOC formulation were found to be less populated with data pertaining to processes which were occurring, and were therefore dismissed.

The visual presentation of each CMOC was summarised by a diagram. The inspiration for using a visual form was observed by the researcher at a realist summer school presentation (Dalkin, 2015).

Figure 18 details the mechanism element of the CMOc as reasoning and resources. It was originally used within a realist PhD thesis (Dalkin, 2014) which has been reported publicly using this proforma to explain CMOcs (Dalkin et al., 2015).

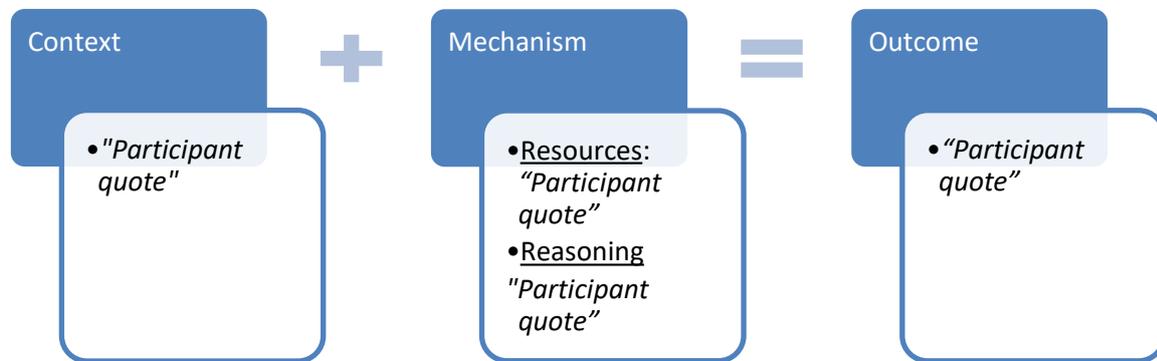


**Figure 18: A visual representation, which has been used to explain CMOcs**

(Dalkin, 2014)

The diagram can be used to explain CMOcs to realists and non-realists alike due to its pictorial nature. It effectively separates mechanisms into elements of resources and reasoning. This diagram

was modified for use in this study to allow text to be inserted alongside the context, mechanism and outcome headings, which can be seen in Figure 19. The researcher found it to be a visual aid to simpler structural explanations with patient data to help explain complex patient behaviours and therefore the preferred model for reporting findings.



**Figure 19: Example of visual depiction of CMOc with quotes**

### **6.13 Testing of CMOcs as programme theories**

Preliminary CMOcs were developed to generate 'programme theories', to determine processes occurring with the group of participants in the study. Wong et al. (2013) specifically describes 'programme theory' as an explicit idea of *"what a programme or intervention is expected to do and in some cases, the theory about how it is expected to work"* (page 10). The next step following formulation of programme theory is to go about gathering evidence in a systematic way to test and refine this theory (Pawson, Greenhalgh, Harvey, & Walshe, 2004) as realist evaluation is avowedly theory-driven and it searches for and refines explanations of programmes (Pawson & Manzano-Santaella, 2012).

Verification of links and meaning were taken to discuss at supervisory meetings and within the realist network of post-graduate students and researchers which was built by the researcher during the PhD process. Links within the RAMESES network were also utilised to give opinions on the preliminary CMOcs and challenge thought processes of the researcher to refine them further. The realist network also provided mentorship through formal summer school courses for time to discuss and reflect on cases, posit CMOcs to researchers publishing in the realist field, and group work to

further verify or modify existing CMOcs. Critical discussions surrounding the research findings were essential to maintain credibility of the analysis and exhibit triangulation with other researchers and academics. Academic discussions with all levels of researchers from early career researchers doing in-house audit, to leaders in the realist field, ensured that there were opportunities for constructive criticism of the links made in the findings from different stand points. This facilitated refinement of CMOcs to the most developed form.

It was an essential part of analysis to 'test' the CMOcs to allow parts of the processes of each to be confirmed or denied and modified as necessary where patient data did not corroborate with initial thoughts. This was carried out visually to enable full transparency of data which were projected onto each CMOc as shown in Figure 19. Each CMOc could have various parts, for example, the same CMO could identify the same contexts which produce two separate outcomes, due to a mechanism of identical resources but differing patient reasoning. These examples are all outlined visually, and described in detail in the cumulative findings chapter (Chapter 7).

### **6.14 Testing combined CMOcs**

Whittaker (2008) uses an analogy to aid the explanation of the interlinked processes occurring within social systems, describing CMO configurations as interwoven like a patchwork quilt, with each piece of fabric containing separate stitches where different patterns can occur, dependent on the order of stitching. One piece of fabric made up of patterns cumulatively creates larger designs (Whittaker, 2008) which implies that CMO configurations can be pieced together to form a larger process and, dependent on the individual, the pattern could be different. After CMOcs were tested and agreed as the final set of processes occurring within the data, consideration was given to how each CMOc could be 'stitched' to another if it was possible. Firstly, it was considered which CMOc would occur first within those found, aiming to provide a timeline of CMOcs. In reality, the complexities of the feedback process meant the CMOcs did not present in a linear representation but more in clusters of processes, interwoven, occurring together which required explanation on

how the processes played out separately and combined. With the linked presentation of the CMOcs, two types of analysis were used to aid unpicking of the interwoven CMOcs, firstly a visual representation of the clusters of CMOcs occurring as one large context, mechanism and outcome map and secondly, each CMOc projected back onto the CFIT to piece together where and when CMOcs were occurring within the process.

To make sense of the complex occurrences in terms of answering the research question, combined CMOcs were then tested with individual participants to map their journey through the feedback process to test what works for whom in which circumstances in relation to information feedback using outcome measures. In this analysis process the combined CMO configuration order and clustering could also be modified as participant data were arranged using the clustered and combined CMOcs, and projected onto the CFIT. At this final stage after many levels of analysis, conclusions were drawn from the data to modify the existing CFIT to a new framework suitable to describe feedback to a patient population.

#### **6.14.1 Data saturation**

Figure 17, previously shown on page 131, shows the number of sources who have data highlighted in each specific node (number of patient participants in Figure 17) and the number of references (excerpts highlighted by the researcher) within the interview transcripts. Numbers of participants slotting into each node was paramount, helping to guide identification of themes. Whilst exploring themes, saturation point was considered, as it can be a contentious issue in qualitative studies (O'Reilly & Parker, 2013), with 'saturation' recognised as a stage when no new information or themes were observed in the data (Guest, Bunce, & Johnson, 2006).

Although 'saturation point' is recognised as a point to cease gathering data, there is no agreed method of establishing this (Francis et al., 2010). Specific research (Guest et al., 2006) has previously reported that the first 12 interviews elicited 97% of the important codes (out of a total of 60 interviews in this study). In an alternative, theory-based interview study (Francis et al., 2010) study-

wise saturation was achieved at interview 17 suggesting a number of participants above this figure would be suitable to ensure data is available to achieve saturation.

Within this study the method planned to carry out 30 interviews or continue to data saturation (whichever came first) as an indication to stop data collection. Data saturation was achieved in this study, with no new themes identified, at 25 patient participant interviews (two participants dropped out), in addition to the three physiotherapist participants who were providing the information feedback, totalling 28 interviews.

### **6.15 Limitations**

The effect of an individual analyst can be regarded as an issue in qualitative approaches (Madill, Jordan, & Shirley, 2000). As the explication of meaning within realist evaluation in particular requires inference beyond the data and retroductive reasoning, qualitative approaches can be criticised for the opportunity for subjectivity of the researcher (Madill et al., 2000). Subjectivity was reduced by utilising the supervisory team to monitor interview questioning, discuss and agree modifications to the approach and be involved in the development of the study methods of analysis. Peer, post-graduate researchers were also utilised to open code sections of data for comparison, identifying similarities and differences, ensuring triangulation occurred, questioning the researcher's coding choices and introducing new thoughts on themes.

Study findings at differing stages of completion were also presented by poster at the NHS Research and Development North West: Let's Talk Research conference (2014) at the Macron Stadium in Bolton, the Chartered Society of Physiotherapy annual conference 'Physiotherapy UK' (2015) at the BT Convention Centre in Liverpool and the 2<sup>nd</sup> International Conference on Realist Evaluation & Synthesis: Advancing Principles, Strengthening Practice (2016) at the Barbican Centre, London. Over the three events delegates presented from differing backgrounds: NHS employees from all backgrounds, physiotherapy students and staff, academic researchers and fellow PhD students. Each conference community had a different perspective on the data, questioning particular points of

interest to them in their daily roles. These poster presentations allowed prompt presentation of up-to-date data and effective reflection based upon delegates' varied questions. Despite ongoing reflection and accurate documentation of research notes and thoughts, the process of analysis for a lone researcher is still open to criticism, therefore within this study, this methods section has transparently detailed every step of analysis to allow full understanding of the methods which have been used to analyse the findings.

## **Chapter 7: Cumulative findings phase I pilot and phase II main study**

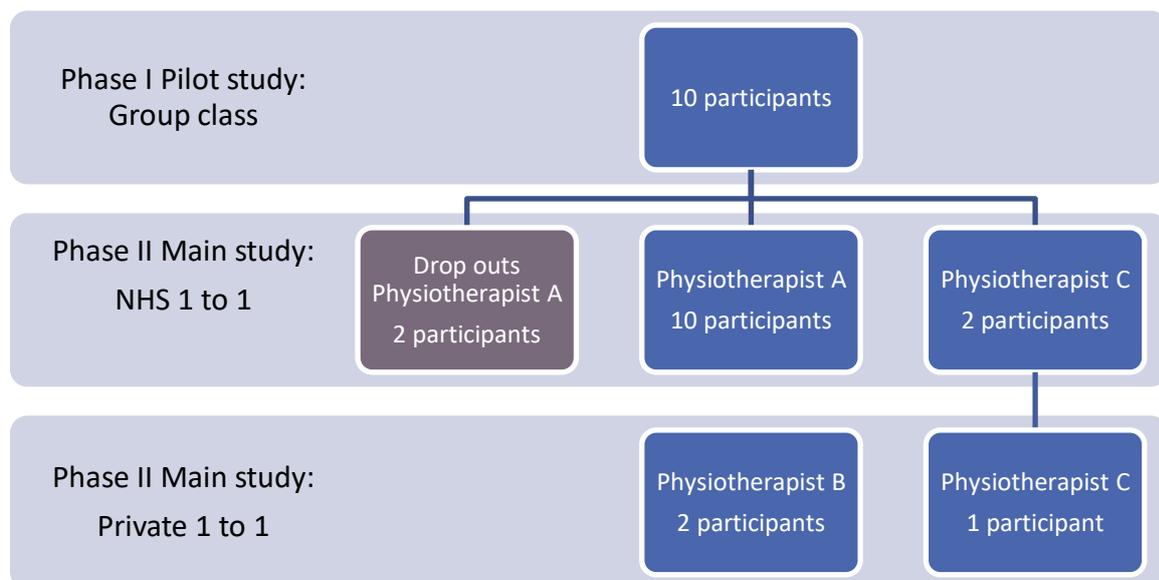
This second findings chapter discusses the demographics of the study participants (pilot phase I and main phase II study combined) followed by the qualitative data collected from the 25 patient participants consenting to take part in the study after two drop outs (pilot phase I and main phase II study combined) and the three physiotherapists interviewed who provided the feedback in the phase II main study. The chapter commences with background demographic data for the participant group. The second part of this chapter outlines the development from open coding of interview data to identifying emerging themes to confirming the key themes for deeper analysis. The results are then finally reported in line with realist methods as 'Context-Mechanism-Outcome configurations (CMOCs)' to posit what works for whom, in which circumstances. Specific examples of individual cases for each CMOC are detailed in Appendix W to support the processes developed from the study findings, using one participant's data to describe each CMOC in its entirety. This chapter concludes by exploring the links between the singular CMOCs to give an overall view of how the process as a whole occurs with this study population and how this contributes to modification of the Contextualised Feedback Intervention Theory (CFIT) as a middle range theory.

### **7.1 Number of participants in the study population**

Cresswell (1998) suggests that 20-30 participants in total is a reasonable sample for qualitative research of this nature. The research physiotherapists recruited 27 patient participants in total. As previously discussed, in section 6.14.1 (page 137), saturation was considered when emerging themes presented as consistent core topics. No new themes emerged with participants towards the end of this sample size of 25 completed patient participant interviews. Themes were comprehensively explored and relationships with other aspects of the theory had been exhausted, collectively concluding data saturation.

The detailed recruitment of the 27 participants over both the phase I pilot study and the phase II main study and can be seen below in Figure 20. The two drop-outs in the study were both recruited within the NHS 1 to 1 category. One drop-out completed the interview process, but due to his condition not being investigated further as he wished within the NHS, he decided to withdraw from both NHS treatment and the study. The second drop-out was unable to be contacted after receiving the feedback of QuickDASH over the course of treatment. This participant was contacted by phone, over a 2-week period, with messages left on an answerphone with no response from the participant, therefore he was not able to be recruited with consent for the interview process.

One physiotherapist gave information feedback of outcomes to 10 participants in the phase I pilot study. This physiotherapist was not interviewed (as per the phase I pilot protocol). In the phase II main study a further 17 participants were recruited, with two drop outs, therefore 15 participants in the phase II main study completed the feedback and interview process with three physiotherapists, as detailed in Figure 20. 25 patient participants were therefore included in the study in line with the ethical proposal restrictions for consent and ability to withdraw from the study at any point.



**Figure 20: Diagram to show recruitment through both study phases and recruitment of participants from individual physiotherapists**

## **7.2 Descriptive statistics**

The description of patients gives context to the findings of a study, which is pertinent to realist studies, where there is an explicit interest in context. The participants will be described in terms of basic demographics, with reference to gender, age and employment status to directly compare the study population with the known demographics of the shoulder impingement syndrome population. Specific reference is made to the QuickDASH scores at the start of physiotherapy treatment, and change of these scores between starting and finishing physiotherapy. These factors are framed differently to the basic demographics as the QuickDASH scores serve as specific indicators to participants' shoulder condition severity, and the change in scores indicate how much improvement has been made in relation to their symptoms. These two factors may have an impact on each other, so a relationship, if any exists, must be identified.

### **7.2.1 Demographics**

The patient participant demographics were collected to determine age, gender, location of data collection and employment status (Table 14). 27 participant details were collected, although as previously detailed in Figure 20, there were two drop-outs (participants 20 and 25), therefore only 25 sets of data will be reported in full throughout this chapter.

**Table 14: Combined demographics showing age, gender, location of data collection and employment status for all participants**

	Age	Gender	Location	Employment status
01	49	Male	NHS group	Retired
02	74	Male	NHS group	Retired
03	54	Female	NHS group	Employed
04	50	Male	NHS group	Unemployed
05	52	Female	NHS group	Carer
06	60	Female	NHS group	Retired
07	45	Female	NHS group	Unemployed
08	44	Female	NHS group	Employed
09	40	Male	NHS group	Employed
10	57	Female	NHS group	Employed
11	28	Male	Private 1:1	Self-employed
12	49	Female	Private 1:1	Self employed
13	57	Male	NHS 1:1	Employed
14	71	Female	NHS 1:1	Retired
15	32	Female	NHS 1:1	Employed
16	57	Female	NHS 1:1	Employed
17	60	Male	NHS 1:1	Retired
18	55	Male	NHS 1:1	Retired
19	44	Female	Private 1:1	Employed
20	No data			
21	62	Female	NHS 1:1	Employed
22	68	Female	NHS 1:1	Retired
23	79	Female	NHS 1:1	Retired
24	70	Male	NHS 1:1	Retired
25	No data			
26	75	Female	NHS 1:1	Retired
27	69	Male	NHS 1:1	Retired

### 7.2.2 Age

The average age of a patient with SIS in the general population is reported to be approximately 52.5 years of age (Çalış et al., 2000). Initially within the Phase I pilot study, with the group NHS participants averaged 52.5 years of age, congruent with the literature (Çalış et al., 2000). In the phase II main study, the NHS 1:1 treatment group averaged higher at 62.9 years of age, and the private 1:1 participants were slightly lower at 40.3 years of age. The mean average of the 25 consenting patient participants was 56 years of age, slightly higher, yet similar to the average in the general population (Çalış et al., 2000).

### 7.2.3 Gender

In practice, it has previously been suggested that more women present to their General Practitioners with shoulder pain than men, with one study in Norway estimating a prevalence of 15.4 % in men and 24.9% in women (Hasvold & Johnsen, 1993). A more recent study concurs with this trend of shoulder pain occurring more frequently in women than men, suggesting a prevalence rate ratio of 1.4 (Sarquis et al., 2016). The purposive sample in this study recruited more women than men and comprised 10 male participants and 15 female participants. The male population therefore comprised 40% of the study sample, and the female population 60%, supporting the suggestion that more women present with shoulder pain than men.

### 7.2.4 Employment

Studies report a higher incidence, of SIS within specific populations such as upper limb athletes (Sørensen & Jørgensen, 2000), high level activity jobs (Hsiao et al., 2015) and overhead workers (Ludewig & Cook, 2000). Eleven participants were retired, nine participants were in employment, two were self-employed, two were unemployed and one was a full-time carer. Highly repetitive work, forceful exertion in work, awkward postures, and high psychosocial job demand are associated with the occurrence of shoulder impingement (Van Rijn, Huisstede, Koes, & Burdorf, 2010).

Employed participants included those with highly repetitive jobs or those which involved exertion in terms of lifting, for example: administrators, a radiology assistant, supermarket workers, engineers and media workers. The participant who was the main carer for her husband commented on the physical nature of her role within the household on many occasions, and often referred to the high physical demand of her caring role in explaining how she used her shoulder during the day:

Interviewer: *“Tell me a bit about what you do with your shoulder during the day.”*

Participant 05: *“Well the normal, cleaning, cooking, looking after my husband, he is disabled so that does affect it. Shopping, taking the dog out, that affects it, the weather affects it. Lifting my*

*husband's scooter in and out of the car, that affects it you know. When you are cooking, lifting pans, kettles and things, but I just work through it, it's niggly there all the time but I just get on with it."*

### 7.2.5 Severity of starting QuickDASH scores

As previously reported in Table 13 (page 121), Fan et al. (2008) constructed a study to determine an average QuickDASH score for mild, moderate and severe upper extremity (arm) problems. A synopsis of the participant findings is shown in Table 15. Calculations were made from the study figures to produce a range of QuickDASH scores for each category of mild, moderate and severe, so each patient participant could be allocated into a group for their starting severity.

**Table 15: Fan et al. (2008) study synopsis**

Symptom severity considered as:	Sample size	Average QuickDASH score	Calculated ranges using average QuickDASH scores
Mild	22	12.6	0.1 to 16.55
Moderate	41	20.5	16.56 to 31.55
Severe	16	42.6	31.56 to 100

Each participant's starting QuickDASH measurement was calculated to be one of the above three categories. Of 25 consenting patient participants completing all stages of the study, 3 scored as mild, 6 scored as moderate and 16 scored as severe.

Appendix V outlines the exact outcome measurement for each participant at the start and end of treatment, the starting severity and the change in score. One participant (06) did not have a separate start and end score. She ceased treatment after the first QuickDASH outcome measure was completed as she felt she was not in enough pain or dysfunction to continue using the physiotherapy services when there were other people waiting to start treatment: *"even after three days of painting and decorating I've only got a small niggle at the top of the shoulder... I'm aware of holding the phone, but I'm not in actual pain...the next person can step in and have that place, to take it."* She was keen to be interviewed as she had opinions on the QuickDASH as an outcome measurement tool

and was thus still interviewed in addition to the inclusion of her incomplete QuickDASH scores to the data set.

### 7.2.6 QuickDASH change of score during information feedback

Change of QuickDASH score during treatment was calculated, detailed previously in **Error! Reference source not found.** Using these scores the improvement of each participant could be determined. A previous study by Polson et al. (2010) compared the Global Change in Status Questionnaire with the QuickDASH and the mean changes required to identify shoulder pathologies to be 'Very much improved', 'Much improved', 'Minimally improved' or 'No change'. Table 16 below shows the mean change of the QuickDASH as described in the study (Polson et al., 2010) alongside the calculation of ranges for each categorisation.

**Table 16: Mean score changes on the QuickDASH for improvement categorisation and calculated score range**

Global Change in Status Questionnaire status	Mean change on QuickDASH	Range for each categorisation
Very much improved	- 30.45	-25.11 to -100.00 or QuickDASH score is 0 at end of treatment
Much improved	- 19.78	- 16.46 to - 25.10
Minimally improved	- 13.07	- 11.65 to – 16.45
No change	- 10.22	- 11.64 and under

The minimally improved lower threshold at - 11.65 is similar to the Minimal Clinical Important Difference (MCID) for the QuickDASH. The MCID, to clarify, is a patient derived score that reflects changes in a clinical intervention which are meaningful for the patient (Cook, 2008). The MCID for the QuickDASH has been estimated to be – 11.0 points (Polson et al., 2010), although has alternatively been reported to be as low as – 8.0 points (Mintken et al., 2009).

Of the 25 participants with complete data, the following numbers of participants were identified for each change category: 11 no change, two minimally improved, eight much improved, four very much improved.

### 7.3 Matrix analysis

Cross-case analysis was conducted using a matrix analysis to condense the data set to clarify significances of data relationships describe patterns between data (Miles & Huberman, 1994).

Severity and demographic factors were cross-referenced with employment status, age and gender for links in responses to feedback.

Severe, moderate and mild shoulder scores at the start of treatment did not link to a certain employment status. Of the 16 severe cases, seven were retired, five were employed, two were unemployed and one was a full-time carer; the three mild cases comprised two retired participants and one employed.

Age of the severe cases ranged from 28 to 75 years, with a mean average of 54.18 years of age, only slightly below the mean average of the whole group which was 56 years of age. Severity of scores did not present as linked to a certain gender, with the 16 severe scores comprising 43.75% male participants and 56.25% female, similar to the 40%/60% split of the total study population.

Using matrix analysis (Miles & Huberman, 1994) it was able to be identified how many participants combined starting severities of mild, moderate and severe with the change status of no change, minimally improved, much improved and very much improved. This matrix analysis is shown in Table 17.

**Table 17: Number of participants exhibiting different combinations of starting severity and change status**

		Starting severity		
		Mild	Moderate	Severe
Change status	No change	3	2	6
	Minimally Improved	0	0	2
	Much improved	0	4	3
	Very much improved	0	1	4

It can be observed that the four participants with the categorisation of ‘very much improved’ (02, 04, 15 and 22) were all classed as severe on their QuickDASH starting score. It could be posited that a poorer start score gives more scope for change of scoring, which was the reasoning behind adding

achieving 0 (full recovery) to the 'very much improved category'. This observation suggests that despite shoulder impingement giving severe impairment to patients (identified by the QuickDASH), that some of these patients can make significant improvements over the course of physiotherapy treatment. These higher achieving participants in terms of QuickDASH improvement were two males and two females, with ages of 32, 50, 68 and 74 with a mean age of 56, concurring with that of the whole study group.

The employment status of the 'very much improved' group was as follows: two retired, one employed and one unemployed. The results of gender, age or employment status did not suggest any patterns in demographics of higher level respondents.

The 'no change' category was explored for patterns using a matrix analysis. Of the 11 participants showing no change there were variations in starting severity (three mild, two moderate and six severe). There were six females and five males in this category, with employment status as follows: five retired, five employed and one unemployed. There were no patterns in gender or employment status. The age range for this category was 40 to 70, with a mean average of 53.82 years, only slightly lower than the study average.

The descriptive statistics presented the study demographics as a similar population to that of a predicted shoulder impingement cohort. None of the demographic information gathered predicted heightened QuickDASH improvements which may have suggested use of the information feedback in facilitating the improvement. The descriptive statistics conclude that the demographics collected in this study did not give information as to what works for whom in PROMs feedback for SIS in physiotherapy. This conclusion supported further analysis with qualitative data, to delve further into the nuances for what makes feedback work in the way it is intended to work, for whom and in which circumstances.

## 7.4 Qualitative analysis

### 7.4.1 Conclusion of themes

The interview data were initially open coded with further analysis to identify developing themes from the most frequently mentioned areas, independently by participants or in response to open questions (Francis et al., 2010). The open coding lists were surveyed by the researcher and grouped together under higher-order headings. This process involved condensing data by abstracting descriptions and interpretations on a higher logical level (Graneheim & Lundman, 2004) from the initial open codes which covered a wide range of areas. Manual grouping (Appendix T) and NVivo grouping (Figure 21) took place to ensure themes were identified successfully during analysis. This process aimed to reduce the large data set, but preserve the core themes and data quality.

Patient open coding (theories and more)			
Name	Sources	References	
Dissonance and difference	21	73	
Expectations	14	20	
Feedback of improvement	22	86	
Frustration	6	8	
Goal	14	28	
Improvement	13	37	
Intention dissonance	2	3	
Knowledge	5	7	
Long term shoulder pain	6	6	
Looking after myself	1	1	
Monitoring	6	7	
Onset	5	5	
Pain	13	47	
Passive treatment as improvement	6	18	
Perceived status	6	7	
Pleasing self not therapist with scores	3	3	
Pleasing therapist	4	17	
QuickDASH	21	94	
Severity	11	14	

Figure 21: Open coding listing from patient participant interviews

Within NVivo the data can be separated into adult and child nodes to create a hierarchy, with general topics as the adult node, divided into more specific topics as child nodes (O’Neill, 2013). The open code list shown in Figure 21 (current on 25/04/2016) includes the adult nodes between D and S alphabetically, with each adult node outlining an area of similarity between patient responses. Figure 21 is a shortened list of the patient participant interview open codes from the NVivo 11 Pro software, as the ‘+’ show areas where the open codes as adult nodes can be expanded into child nodes.

Expansion of a node, revealing child nodes embedded within it, is shown in Figure 22 for the specific open code / adult node of ‘QuickDASH’. This illustrates how each open code (as an adult node) was expanded (into child nodes) to explore the node properties in terms of data, prior to reduction into themes.

Name	Sources	References
QuickDASH	21	94
Accurate and useful questions	11	12
Answering inaccurately for personal gain or other reasons	1	3
Concordance noted	14	22
Dissonance with QuickDASH scoring	10	17
Doing it to help the therapist rather than themselves	3	6
Feedback made try harder	2	8
Generalised measure only	2	3
Honesty in answering	8	10
Identification of changes which may have gone unnoticed	3	6
Made it!	1	1
Progressing quicker with feedback	2	6
Scores up or down due to circumstance	9	21
Tracking progress	13	27
Useful as a baseline or actual status	8	14
Wanting more options on the QuickDASH	6	8

Figure 22: Expanded QuickDASH open code

The inductive process of thematic content analysis which followed reduced the number of adult and child nodes by 'collapsing' some of the ones that were similar into broader categories (Burnard, 1991). Data were classified as 'belonging' to a particular group of nodes together, aiming to create a means of describing and understanding the information feedback intervention phenomenon.

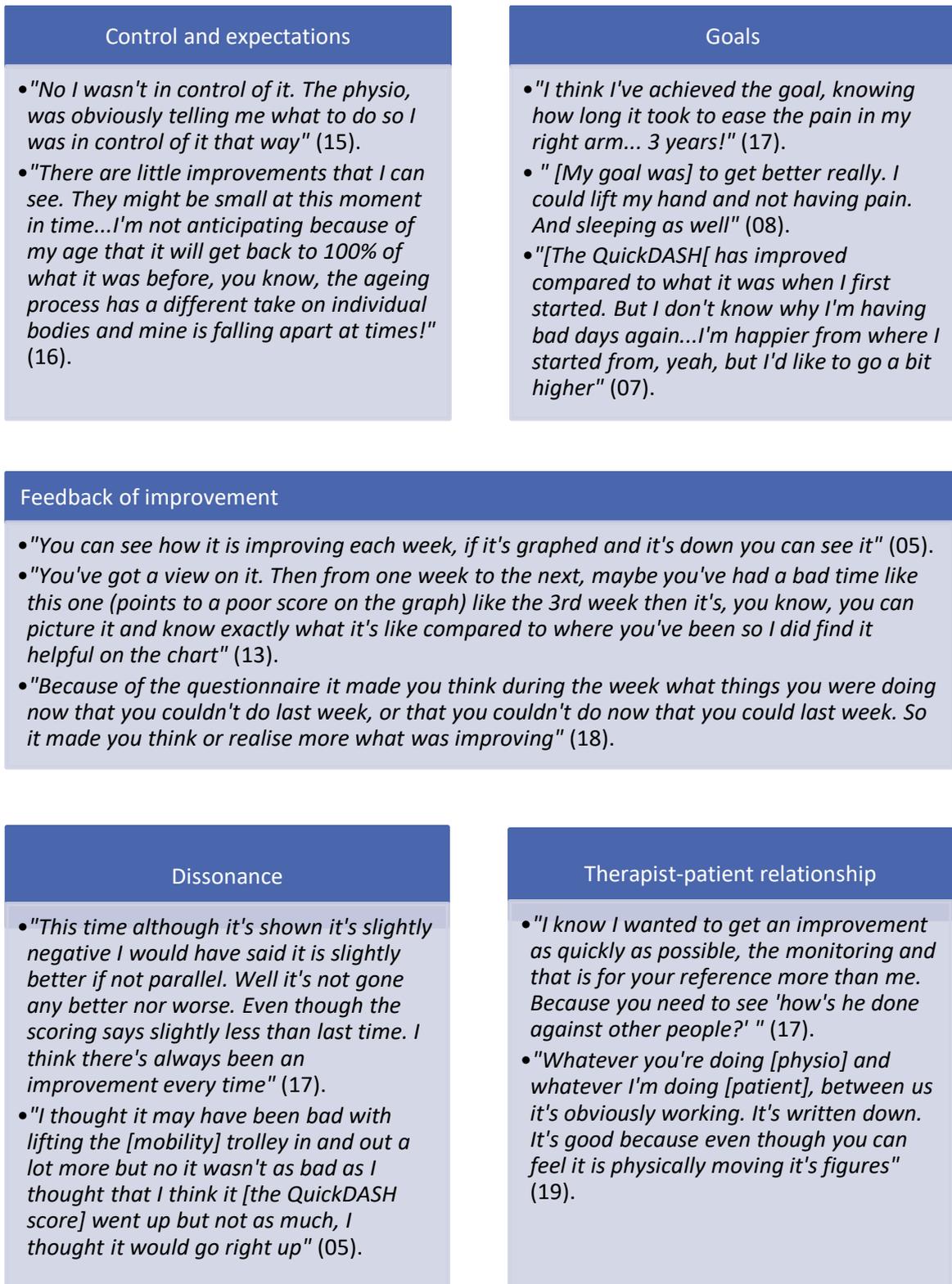
The identification of themes was fundamental within this research approach (Sandelowski & Leeman, 2012) to identify underlying mechanisms. Mechanisms at play generate outcomes, both of which are able to be identified within social programmes (such as information feedback of PROMs in this study) (Tilley, 2000) and then grouped together for analysis. Groups of nodes contributing to a main theme demonstrated commonalities. Analysis also attempted to discover, from interviewees, which were the most 'salient' beliefs, which was achieved by identifying the views or beliefs that were most frequently mentioned, independently, by participants or in response to open questions (Francis et al., 2010). Categories occurred in multiple themes and this can be observed in Figure 23 (page 153), showing the finalised grouping of categories which were developed from the open codes, which could be adult or child nodes, to comprise the five themes which emerged from the data.

Control and expectations	Goals	Feedback of improvement
<ul style="list-style-type: none"> <li>•Acceptance</li> <li>•Attention</li> <li>•Chronicity</li> <li>•Control</li> <li>•Co-problems</li> <li>•Longer or shorter than expected to improve</li> <li>•Worry about prognosis</li> <li>•Frustration</li> </ul>	<ul style="list-style-type: none"> <li>•Type of goal</li> <li>•Near recovery</li> <li>•Re-evaluation of goal</li> <li>•Still improvement to be made</li> <li>•Achievement</li> <li>•Goal commitment</li> <li>•Happy not reaching 100%</li> </ul>	<ul style="list-style-type: none"> <li>•Symptoms up and down in line with QuickDASH</li> <li>•Near recovery</li> <li>•Exertion to create symptoms as feedback</li> <li>•Frequency of symptoms</li> <li>•Function</li> <li>•Measurable feedback (% of pain score)</li> <li>•Pain</li> <li>•QuickDASH as feedback</li> <li>•General feelings of recovery</li> </ul>

Dissonance	Therapist-patient relationship
<ul style="list-style-type: none"> <li>•Goal closeness</li> <li>•Longer or shorter than expected to improve</li> <li>•Symptoms up and down not in line with QuickDASH</li> <li>•Improvement stated but QuickDASH unchanged</li> <li>•Near recovery</li> <li>•Scores different to expected</li> <li>•QuickDASH inaccuracy</li> <li>•Re-evaluation of goal</li> <li>•Improvement but not related to work or hobby</li> </ul>	<ul style="list-style-type: none"> <li>•Control</li> <li>•Compliance with physiotherapy</li> <li>•Expectations</li> <li>•Knowledge</li> <li>•Pleasing therapist</li> <li>•Pleasing self not therapist</li> <li>•Taking part</li> </ul>

**Figure 23: The five themes and the open coding categories developed to generate the themes**

Interpretive rigor is demonstrated in Figure 24 (page 154), showing consistency and transparency of inferences by presenting clear excerpts from the data to illustrate how themes were developed from the raw data (Fereday & Muir-Cochrane, 2006), shown under the five theme headings.



**Figure 24: The five themes with example quotes from raw interview data which were allocated to each theme**

The emergent themes were then cross referenced with the CFIT headings to explore the working relationships between patient data and the middle range theory chosen. Notes were made to further the process of immersion to increase the awareness of the 'life worlds' (Burnard, 1991) of the participants with shoulder impingement in conjunction with how the phenomenon of feedback was impacting on the participants. In line with realist evaluation methods, analysis of data and events were studied with respect to what may have, must have, or could have caused them, a process otherwise known as retroductive reasoning (McEvoy & Richards, 2006).

#### **7.4.2 Themes, CMO configurations and the CFIT**

Outcomes from research must be understood in terms of how a particular outcome was arrived at, understanding the underlying mechanisms which give rise to their occurrence, and the contexts which sustain them (Pawson & Tilley, 1994). 'A priori' knowledge, that formed from theoretical deduction, informed retroductive reasoning to infer beyond the empirical data collected. In grouping codes under themes, writing detailed memos and searching for patterns, a deeper and more comprehensive understanding of what worked for whom in which circumstances with reference to PROMs feedback emerged from the data.

The main themes, patterns and similarities were observed, leading to groupings of which contexts needed to be present for a conducive environment to allow mechanisms to occur, in turn producing a certain outcome. Context Mechanism Outcome configurations (CMOCs) were identified and compared against the CFIT elements to determine which CMOCs were relevant under the theoretical construct of the CFIT to answer the research questions. CMOCs were rejected if they had no relationship to the CFIT, but were included if new knowledge appeared to inform any element of it. Five CMOCs were identified as being under the scope of the CFIT and are summarised in Figure 25 under the heading of each element to which they were most informative, with an additional element of 'Therapist patient relationship'. They are expanded upon separately, in detail from page 158.

Control and expectations	Goals	Feedback of improvement	Dissonance	Therapist patient relationship
<ul style="list-style-type: none"> <li>•Causal attribution</li> </ul>	<ul style="list-style-type: none"> <li>•Goal choice</li> </ul>	<ul style="list-style-type: none"> <li>•High / low impact</li> <li>•Tracking changes and closeness to goal</li> </ul>	<ul style="list-style-type: none"> <li>•Dissonance</li> </ul>	<ul style="list-style-type: none"> <li>•Collective impact of feedback</li> </ul>

**Figure 25: CMO configurations categorised under each broad theme heading**

The feedback as an intervention appeared to be a dynamic programme with multiple layers, and some CMOs presented as related to each other, suggesting a ripple effect between processes. Jagosh et al. (2015) describe the ripple effect as a scenario where the outcome of one CMO becomes or informs the context for the next CMO, suggestive of interlinked processes occurring. This is described in detail later in this chapter, in Figure 42, page 215.

In theory-driven research the next step after thematic content analysis is to compare the data back with the initial theoretical framework (Meyer & Lunney, 2013). CMO configurations under their headings were then projected back onto the CFIT diagram to posit *where* the mechanisms may be occurring within the ‘bigger picture’ of the CFIT middle-range theory. Figure 26, depicts the projection of CMOs onto the CFIT, suggesting at what stage of the middle range theory each CMO configuration may be occurring. Relationships between CMO configurations were also explored as the CFIT moves through its constituent elements, identifying CMOs which stood alone as a process and those which informed another in a ‘ripple effect’ (Jagosh et al., 2015). This facilitated deeper understanding of how behaviours can progress in stages, with the analysis informing which CMO outcomes inform or transform the context for subsequent stages.

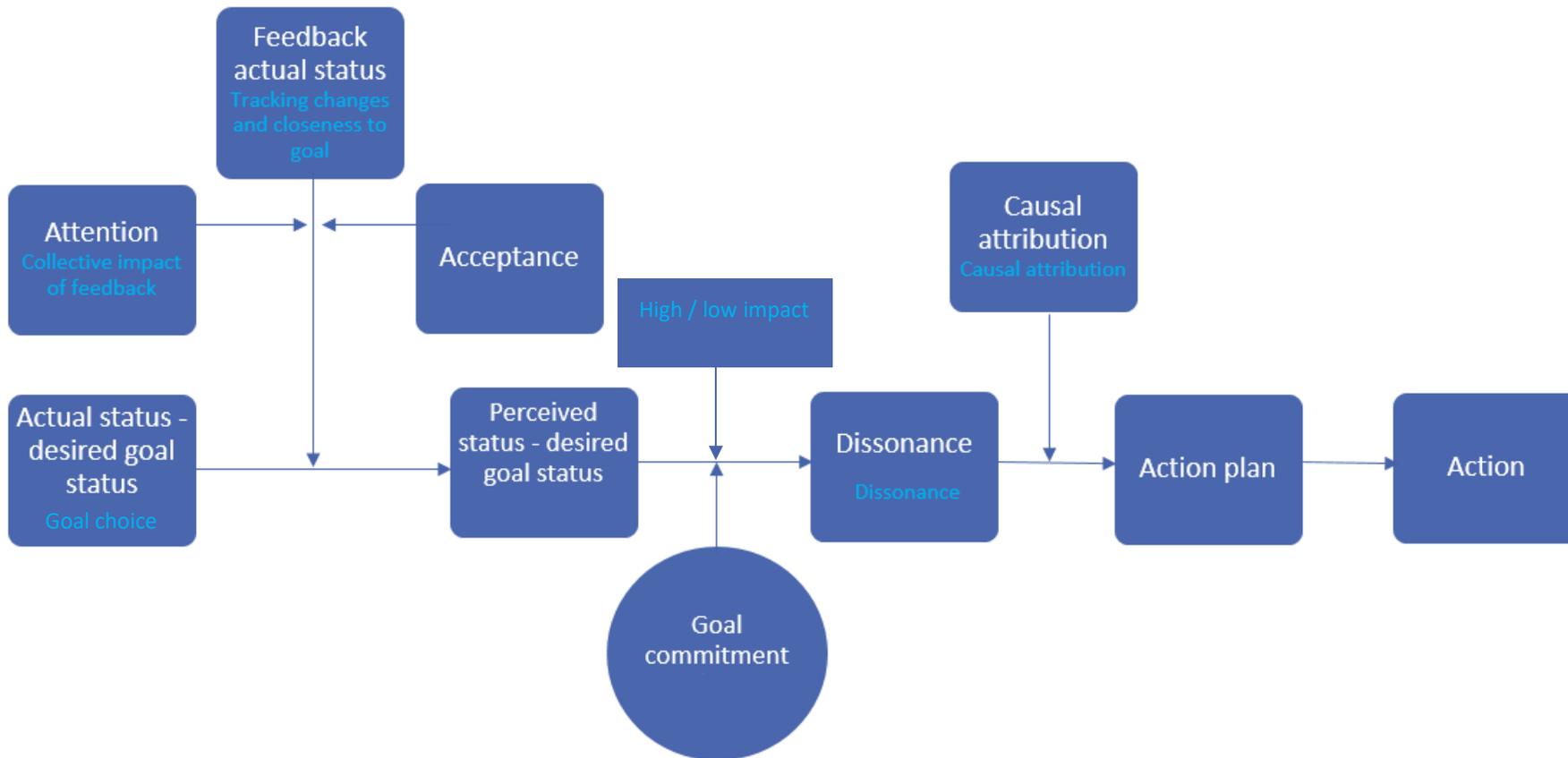


Figure 26: CFIT with CMOs projected onto the framework

### **7.4.2.1 CMOc presentation**

Each CMO configuration (CMOc) is described in detail in this chapter. The CMOcs will be explored in line with the CFIT working through the theoretical structure, loosely from left to right (as in Figure 26) and then further examined to explore where there are relationships between CMOcs.

The description of each singular CMOc is structured firstly to provide an underpinning of the area of interest, followed by a description of the CMOc. Each description comprises a context, mechanism and outcome presented as statements, clarified as to which element of the CMOc it is highlighting by determining the element in brackets e.g. (outcome). For clarity of understanding, the CMOcs are described with the outcome first, working in reverse to explore which mechanisms create a specific outcome and which contextual circumstances are conducive to activate the process. The CMOc will then be presented in a visual format, followed by at least one specific participant example, inclusive of participant quotes to illustrate the full CMOc. Participant quotes will be designated by using italic text, with identification of each participant by their participant number in brackets.

## **7.5 CMOc 1: Goal choice**

### **7.5.1 Overview**

Patient goals are traditionally based on reaching a designated state concerning their health condition. A patient will have perception of whether they are close to attaining their goal and may use this as a potential source of feedback on their condition. From the pilot study, the data confirmed patient goals could be generalised or specific, and this was mirrored in the main study.

#### **7.5.1.1 Generalised and specific goals**

Generalised goals were based around normality: *“I wanted it to just be all alright... I wanted to be able to go back to a normal life”* (13), *“To try and sort it, and get rid of some of the pain. To see if it would help. Before we had to go down any other route if there was another route”* (21).

Specific goals were more concrete, with measurable achievements to gauge whether they had been met: *“I'd like to see myself between 20 and 30, at least [on the QuickDASH]. I might not ever get to 0*

*because I've had it for so long, but maybe if I did carry on with the exercises maybe it might improve, but that's a question isn't it?" (07), "I wanted it to be reduced so I could reduce my pain medication" (17).*

The studies revealed that generalised goals were often expanded to detail specific goals on further questioning. One participant (06) spoke of a generalised goal of returning to normal: *"the idea was to improve it as much as possible, so that I could just live normally."* On in-depth questioning, she revealed she had expanded her goal to exhibit the manifestation of her shoulder problem in day-to-day life, detailing the specific, personalised impact on her work: *"I need to lift bags of clay and throw pots... get myself to various venues where I'm running workshops."* This illustrates the two-fold aspect of participant goals, an overarching generalised goal with specific, personalised, measurable goals encompassed within.

#### **7.5.1.2 Individualised goals**

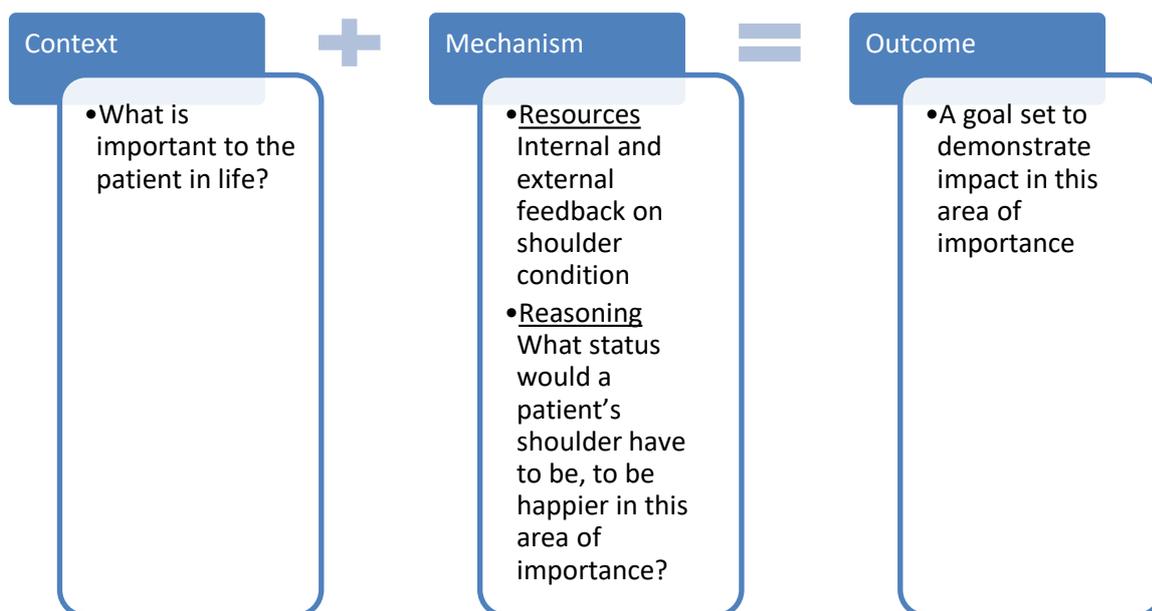
Goals are unique. They are individualised to each patient and goal setting is an important process between a patient and their physiotherapist. It is known that individual care, decision-making, information, the physiotherapist relationship, and organisation of care are important to patients (Cooper, Smith, & Hancock, 2008). Goals within the process of feedback need to be determined and it is pertinent to discover what a goal *is* to a patient and to explore what goals patients set themselves within the feedback process, and why. Goals were different for each participant dependent on their life circumstances and priorities, traversing areas such as normality of life, a specific movement or activity, pain reduction, a certain level of improvement (measured by percentage or QuickDASH score), and the desire for reduction in use of medication.

#### **7.5.1.3 Type of goal**

This section will present a CMOc to describe how participants' circumstances and encircling frames of reference (context) facilitated how goals are chosen, using resources and reasoning to facilitate decision making (mechanism), arriving at a specific goal (outcome).

Participants consider the activities and functions that cannot be completed because of their shoulder problem in conjunction with what is important to them as an individual in everyday life (context). Participants in this study utilised feedback resources from their own mechanisms of function, monitoring and range of movement (internal feedback) in addition to feedback from their therapist and the QuickDASH scores (external feedback) to decide what status they were currently at with their shoulder. Patients considered the status they would like to realise, to be in a more desirable position with their shoulder problem (mechanism). It was then possible to set a goal to demonstrate a change in status if the goal status was accomplished (outcome).

In terms of what works for whom in which circumstances, the 'Goal choice' CMOc (Figure 27) can be observed for all participants, with an individual goal set (outcome) when a patient's life circumstances need altering to be closer to normality. Normality as a term is not intended to refer to a value-laden or prejudiced description of what is classed as a 'normal person' or what 'normal' people are able to do, but simply refers to that which an individual would perceive as usual, ordinary, common or typical in terms of activity, freedom and quality of life (Hall, Rubin, Dougall, Hungin, & Neely, 2005).



**Figure 27: CMOc to give an overview of how participants chose goals**

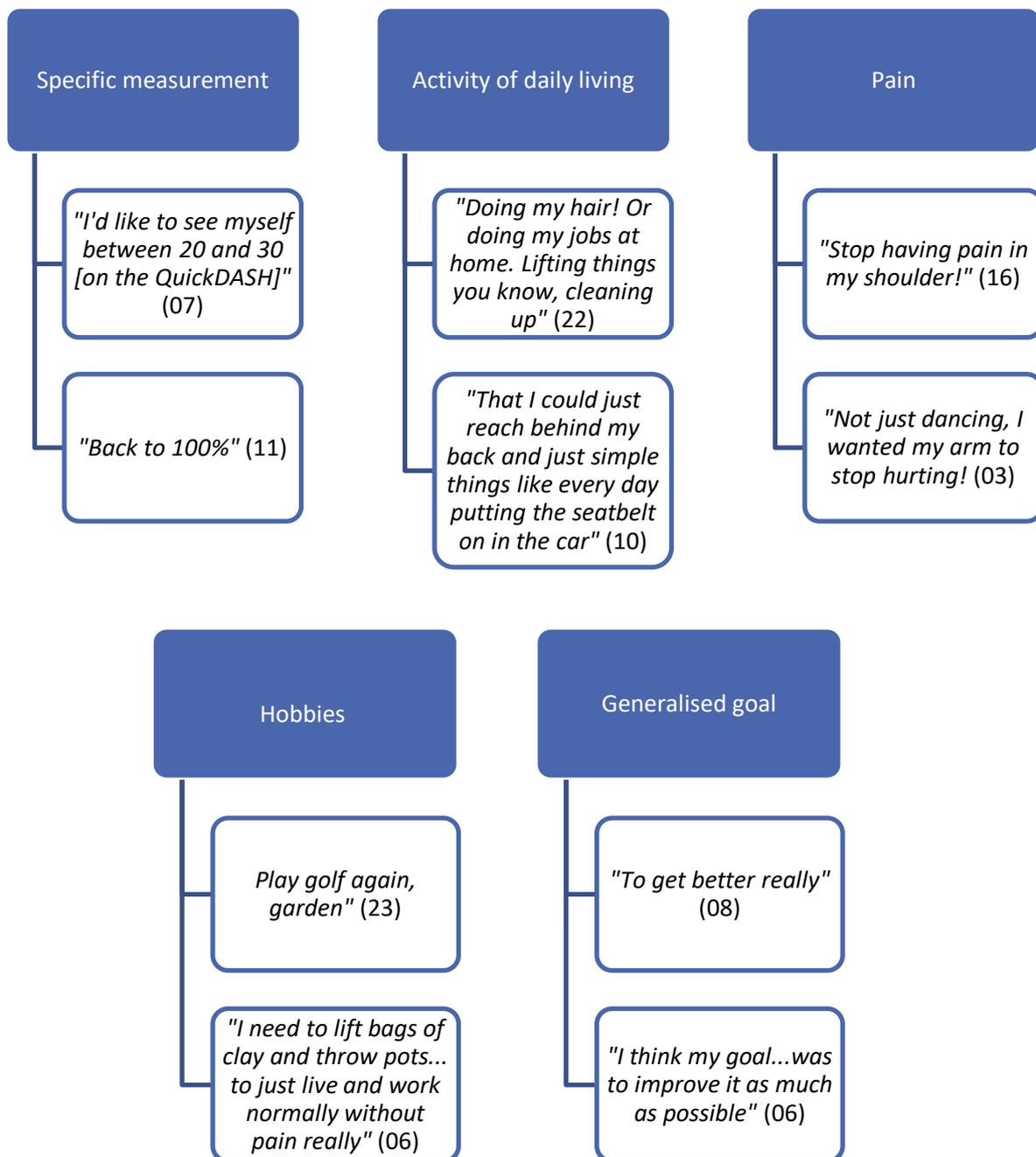
The 'Goal choice' CMOc will now be explored using multiple patient data sets to narrate the process.

As previously described, the CMOc will be presented in order of outcome first, the mechanism by which that outcome occurs and the context which provides the conducive environment to trigger the CMOc process.

### 7.5.2 Outcome

All 25 patients interviewed had a goal they wanted to achieve. Goals were sometimes made prior to treatment commencing but also appeared to be modified whilst undergoing the feedback intervention process. Some goals were not mentioned directly on questioning but on deeper questioning within the interview, expanded discussions about what was important in day-to-day life revealed previously undisclosed important goals for some patients. Interviews also identified that patient goals were not always specifically related to improvement of their condition. The most number of participants had goals related to function (15 participants). It appeared the activities of daily living were particularly important to patients and they were aware that these problems existed from daily restrictions.

The outcome in this CMOc was a goal that was either: a specific measurement to allow patient monitoring, an activity or a group of activities important in daily living as it was a frequent occurrence or a frequent limiting factor or a hobby outcome, a generalised goal of reduction of symptoms, or pain. Examples of these types of goals are shown below in Figure 28. Participants often had multiple treatment goals which could span more than one goal type.



**Figure 28: The five different classifications of goals with relevant quotes from participants to demonstrate each classification**

The outcome comprised an important goal to the patient's life, valued as something they wished to change that would make an impact on their current restriction from their shoulder condition.

### 7.5.3 Mechanisms

In this study, participants had two resources influencing the process, broadly described as internal or external feedback. Internal feedback is that generated by the participant about their status and external, as described is a source of the feedback that is external to the learner. This source is typically a content expert and this type of feedback is generally concerned with knowledge of results and performance (Rogers, Regehr, Howdieshell, Yeh, & Palm, 2000), demonstrated in this study with the physiotherapist treating the patient as the content expert feeding back the QuickDASH scores. External feedback within this study was therefore classed as the QuickDASH score provided at each session by the physiotherapist. Internal feedback can be gained from indicators of a patient's current shoulder status as a resource, for example how they felt it impacted their life and perceived levels of pain and dysfunction.

Patients had to consider levels of effort and commitment required to achieve an improved status. Life circumstances in terms of family, work, and hobbies and the restrictions their shoulder forced on life appeared to encourage patients to consider what they wanted to achieve.

One participant (08) was discussing her home life and the impact it had on her shoulder: *"Because I've got a two-year-old plus the job I'm doing at the moment needs lifting and putting on the shelf so it's like, you know, moving quite a lot."* Her goal was: *"To get better really. I could lift my hand and not having pain. And sleeping as well. After coming from work you know, done that job, I couldn't sleep"* (08).

Referring back to middle range theory, in the CFIT there is a component encompassing motivation to reduce dissonance between where a patient is in terms of their condition and where they want to be. Patients had to decide what they would like to achieve in comparison with their current status. Some patients' mechanisms explored realistic achievements, giving thought to their current status

and where they could realistically get to, whilst others did not have specific goals other than full recovery:

*"It'll never get 100% but as long as it doesn't restrict me, there's no severe restrictions I can think of. It's just a pain in the backside sometimes... As long as I can do all the things I need to do like" (17).*

*"Back to 100%", and when asked what 100% would look like he replied: "Not having pain in a full range of movement. I'm still aware of it if I do certain things, so, I was trying to turn my steering wheel round fast the other day, I noticed it started hurting" (11).*

#### **7.5.4 Context**

Differing contexts can trigger different mechanisms (Pawson & Tilley, 1997). There is importance of certain activities or function for each patient thus constructing the context behind facilitating a formation of priorities for consideration and finally a choice of goal(s). Importance was stressed by some participants in terms of how much it affected general life, work or activities in terms of severity or frequency.

One participant (22) was limited with day-to-day tasks, causing her concern regarding severity and longevity of her shoulder problem: *"It didn't stop me sleeping but when I first started I couldn't even lift my arm up to brush my hair and I thought I'm going to be cripple!"* She then used her daily limitations to form the basis for her goal: *"Doing my hair! Or doing my jobs at home. Lifting things, you know, cleaning up" (22).*

Participant 04 worried extensively about his return to work and at the time of interviewing was not employed: *"The biggest part of it is getting back into work."* This context impacted on his reasoning throughout the information feedback, and within this CMOc his *"main"* goal was *"getting back into work, not relying too much on this physiotherapy."*

One gentleman had a variety of other co-morbidities which affected his mobility and reliance on other people and a high-level use of painkillers with a low function level. Having an additional

problem in his shoulder with high levels of dysfunction meant that he was struggling frequently, more than usual in daily life: *"...get the movement back so I could try and carry on doing things for myself. Instead of having to get other people to do things"* (17). His reliance on other people created a context of wanting independence from feeling dependent on family and friends with his current situation.

There was a spectrum of functional ability within the study participants as a group. Higher functioning individuals were more often physically well, and therefore able to be more active in regards to work and hobbies. Higher functioning individuals also found frequent limitations in basic activities of daily living which they deemed to be important as they affected day-to-day life: *"Just simple things like every day putting the seatbelt on in the car"* (10).

Patients having a goal which was focused and important to them was paramount. The CMOc for this process began at the level of context.

## **7.6 CMOc 2: Tracking changes and closeness to goal via feedback**

### **7.6.1 Overview**

CMOc 2 can be split between two groups of patients: those who have already met their goal and those who have not. Both CMOc groups will be outlined to demonstrate the similarities and differences in patient behaviour.

#### **7.6.1.1 *When a goal is met***

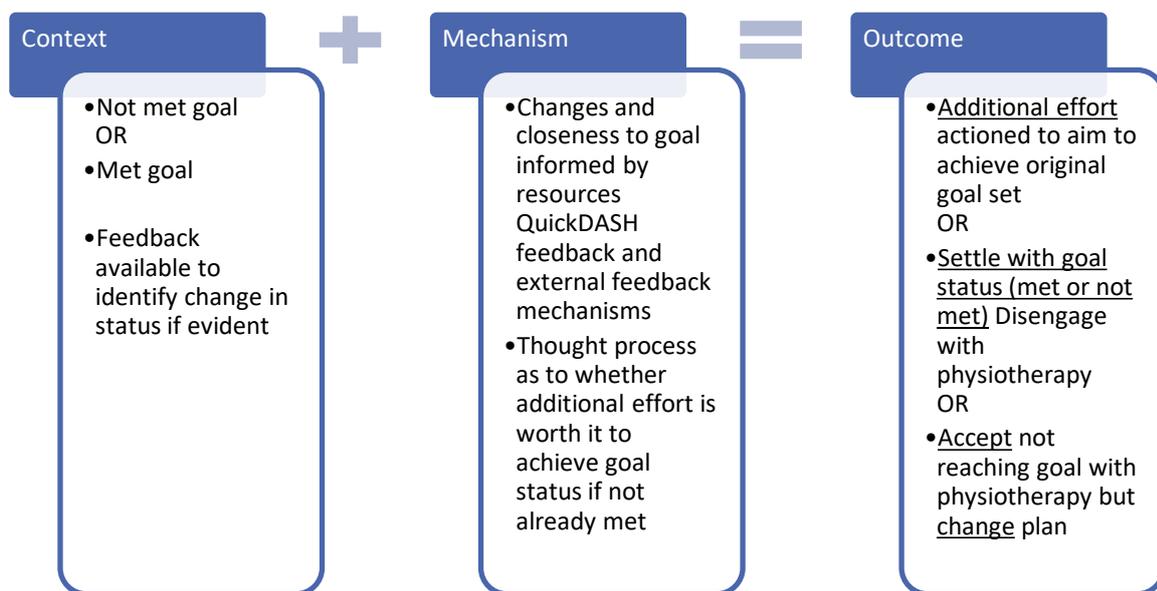
It is essential to consider what may occur if a participant has already met their goal. If a participant's goal has been met they will most likely feel improvement and identify they have achieved goal status (context), the feedback resource will confirm their goal achievement (mechanism), and they must then decide whether to disengage with their current actions if they think they can cease intervention (outcome) or to continue the current level of effort with the idea of maintaining their condition (outcome). This process is shown in Figure 29 in combination with what occurs when a goal has not yet been met which is described in the next section (7.6.1.2).

#### **7.6.1.2 *When a goal has not yet been met***

'Discrepancy reduction' is a phrase which is used in this study to describe the efforts to change the discrepancy between an individual's current shoulder status and their goal status (Carver & Scheier, 2001). When an individual is close to reaching their goal there can be stark variations in effort or engagement as some people would be continuing to exert efforts, at the same point where others would be exhibiting a giving-up response (Carver & Scheier, 2001). Patients with the same context and mechanism process could therefore arrive at two disparate outcomes (Figure 29) in terms of effort, arriving at an action of either increased effort, or reduced effort and disengagement.

If a participant has not met their goal (goal discrepancy), the feedback must be available to provide an environment to receive this information to confirm their current status (context), to compare against their goal status. If the goal discrepancy is confirmed by the information feedback, reason to change their level of effort may occur (mechanism). There are three possible outcomes of this

mechanism of goal discrepancy identification: Firstly, the level of effort may increase to try to reduce the discrepancy to achieve their goal (outcome), secondly they may determine not reaching their goal as their maximum status able to be achieved, accept not reaching the goal they originally set and disengage with treatment (outcome) or thirdly change their treatment approach and plan to try and achieve their goal (outcome).



**Figure 29: CMOc to explain how participants track changes and closeness to their goal**

## 7.6.2 Outcome

### 7.6.2.1 Goal met: disengage with treatment

If full potential has been identified, patients are most likely to disengage with treatment. They may choose to continue with current levels of effort towards physiotherapy independently or cease effort to maintain their current status if they feel their goal status will continue without effort.

Participant 11 wanted to get “back to 100%” and on returning into his hobbies, commented, “I went caving for the first time on Saturday... I’m going skiing tomorrow”, he subsequently decided to cease private physiotherapy treatment. He felt his goal was met as he had returned to his physical hobbies which relied upon full strength and movement of the shoulder.

### **7.6.2.2 Goal not met: additional effort**

Wanting to achieve their full potential may encourage increased effort to achieve goal status and participants were aware of the outcome of their actions, such as exercise compliance. This following example from participant 14 illustrates awareness that there is a reaction to every decision made about actions, in this case, that additional effort is required to improve further:

Interviewer: *“Do you feel like your condition is stuck with you now or that it will improve?”*

Participant 14: *“It could improve a bit more if I stick and do them [the exercises] a bit more.”*

### **7.6.2.3 Settle with goal status: disengagement**

Some participants exhibited an outcome of disengagement from the process after not reaching 100% improvement, but having goal status met. This may or may not have been their choice of goal to meet 100% recovery but 100% is classed as the standard norm of no pain or dysfunction.

Participant 02 had a goal of *“a bit more movement”* which was generalised and was not measurable by an objective marker. His outcome was disengagement with treatment, reaching his generalised goal although he knew he wasn't 100% improved. His goal reflected his expectations of treatment:

*“I think I have got to more or less where I thought it might be, as I might not be able to go any further with it... I am very pleased with how I am going on. I can move it freer more now than I could, the only thing is if I do lift anything heavy then it lets me know.”*

### **7.6.2.4 Goal not met: change treatment plan**

Acquiescence towards not achieving a goal may encourage an outcome of disengagement from the formal treatment process or the feedback process. Participant 17 had two goals:

*“Stop having pain in my shoulder! And being able to fasten my bra more than anything.”*

She was able to fasten her bra after treatment but still had pain, so did not achieve both goals. She finished seeing the physiotherapist and decided to opt for a different treatment option to see an orthopaedic consultant for a steroid injection. She felt she would never reach her goal of no pain:

*“It is something that is going to take a long time to get back to what it was before. I'm not anticipating because of my age that it will get back to 100% of what it was before, you know, the ageing process has a different take on individual bodies and mine is falling apart at times!!”*

### **7.6.3 Mechanism**

Despite differences in outcome, the mechanism concerning resources is analogous between participants. Participants exhibit the same mechanism of using resources to determine changes in status and closeness to their desired goal status (goal discrepancy). The resources participants used were varied and involved internal and external feedback. Participant 18 was aware of using the external feedback provided by the physiotherapist to become cognisant of her improvements:

*“Because of the questionnaire it made you think during the week what things you were doing now that you couldn't do last week, or that you couldn't do now that you could last week. So it made you think or realise more what was improving or what wasn't”.*

Participant 19 was aware of using the external QuickDASH feedback to compare to her own internal feedback:

*“I did actually say to my physio “I think that's better”[the QuickDASH score}, and she said “actually it is” and all that's good because it boosts you then. It makes you want to push through, it's too easy to say “I don't have any movement and I'm in pain, I'm just not going to do that” and that's how I were previous, but yeah, it's good to see because then you see the difference.”*

This participant's reasoning of *“It makes you want to push through”* suggests reasoning to continue efforts to improve based on her resources of the QuickDASH feedback tracking improvement.

#### 7.6.4 Context

Feedback must be available to provide a conducive environment to trigger information feedback to be used as a resource and thus identify a change in status. Physiotherapist C identified two participants who had internal feedback of what they could not do as a contextual circumstance conducive to this CMOc:

*"These ones [pointing at participants 26 and 27]: [as if speaking as the patient] 'I can't sleep, I can't do this, I can't do that.... I have to do something about it'."*

This was confirmed by participant 26 concerning her own feedback:

*"I don't usually go to the doctor's that much, I'm forced to go... it was getting that sore. It was getting that sore I thought something was wrong you know... Drying my hair and that it was sore" (26).*

After starting treatment due to dysfunction and pain, participant 26 used internal feedback and external feedback as resources:

*"I think this [QuickDASH graph] helped as you could see it progressing up (external feedback) and you felt a bit better as well... I felt better in myself (internal feedback) as the pain was better and I could do more things, sleep better as well."*

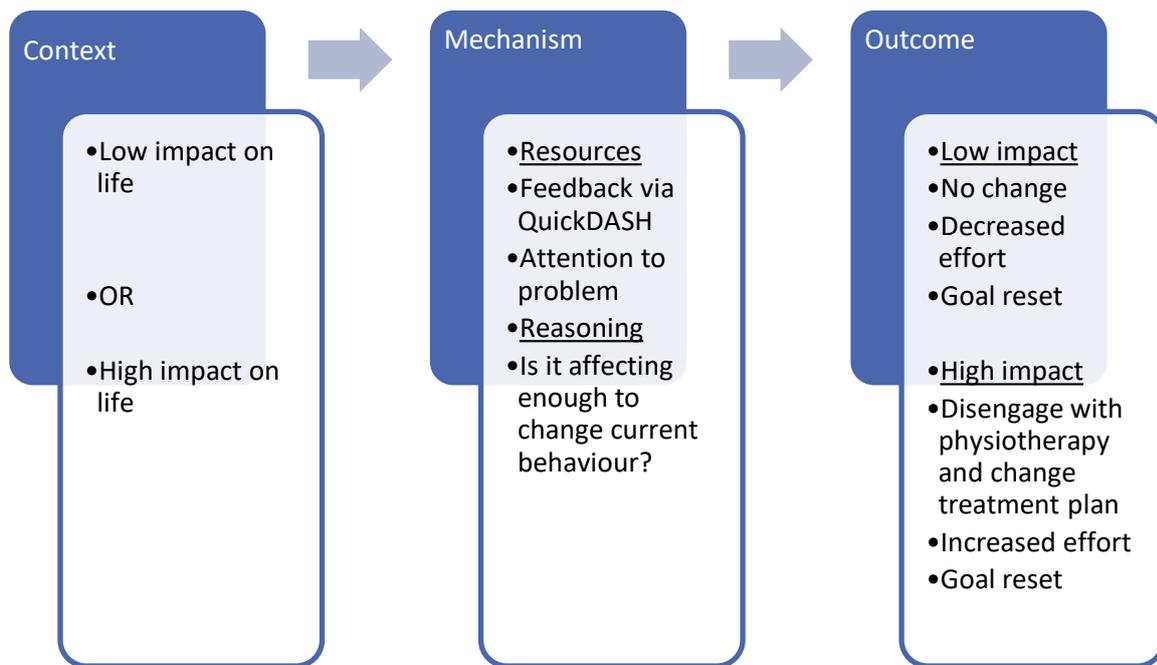
## **7.7 CMOc 3: Low impact or high impact of feedback**

### **7.7.1 Overview**

Attention is said to be limited, and only gaps between where a person's status is and where they want to be will receive attention to change behaviour actively (Kluger & DeNisi, 1996). Shoulder impingement symptoms expose problems in terms of restricted activity or painful tasks in daily life (internal feedback). As the QuickDASH questions functional activity, pain and restrictions on life, feedback from this also provides attention to their level of problem (external feedback).

Figure 30 describes both high and low impact processes, which occurred with the study participants. Both are presented on the same CMOc as the mechanism of resources and reasoning in terms of questions participants asked of themselves were identical, although the outcomes were disparate depending on the individual patient's answer to the questions.

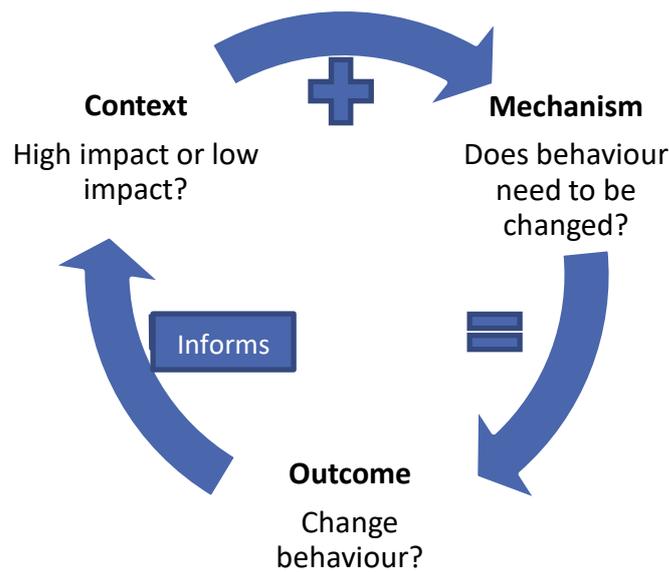
A person with shoulder impingement will have knowledge of how much their current symptoms and restrictions impact on their daily life (context). If the shoulder problem has a substantial effect on daily life or important activity it can be classed as high impact, and if it has minimal effect, can be classed as low impact. A patient will consider how much the shoulder problem is affecting their life, and if they feel that they need to change their current behaviour to try and improve their symptoms (mechanism), and may make modifications to behaviour if they feel changes are required (outcome).



**Figure 30: CMOc to show differing outcomes from low impact and high impact of a participant's shoulder impingement**

### 7.7.2 Outcome

Desired modifications to behaviour (outcome) may be influenced by feedback interventions (Hysong et al., 2006). Whether high or low impact, this CMO configuration can work repeatedly in a cyclical way, with the outcome becoming the next context, as in Figure 31.



**Figure 31: Cyclical process to inform high or low impact**

Depending on progress, a patient could, for example, make a transition from a high impact CMOc to a low impact CMOc, for example, if behaviour is changed which elicits a response to reduce their symptoms, where the outcome of behaviour change restarts the cycle with a low impact context. The outcomes from impact of feedback appeared to be multiple, concerning changes in behaviour, effort and goals.

### **7.7.2.1 High impact**

If a patient's shoulder condition has a high impact on life (context) and actions are not having the desired response, it is likely that continuing current behaviour would prolong their current level of dysfunction and / or pain at the same level (mechanism). It was observed within this study that when feedback confirmed current behaviour was *not* producing the desired response, they would decide that a change in behaviour was indicated (mechanism). Changes in actions were noted including disengagement with physiotherapy to seek other treatment options, changes to increase effort levels and goals re-evaluated to be more realistic (outcomes).

Participant 23, a retired lady, who was a captain at the local golf club, had high levels of dysfunction and could not play golf (context). She increased effort levels so she could try and rehabilitate her shoulder to be able to return to her hobby, which had a high impact on her social life (mechanism):

*"I've really done as I was told with the arm. Because I'm a golfer and so, I've got to be carrying, so I've not been back golfing... I've really done my exercises because I really wanted to get going. I've not shied off doing them. I've really done them... I really tried."*

She improved greatly with treatment, commenting:

*"I could tell they were helping me. I couldn't even do that at one time (hand reaching up). Now I can do it all. No problem."*

#### **7.7.2.2 Low impact**

A low impact of the shoulder condition implied minor consequences of the shoulder problem in daily life (context). This low impact on life was not substantial enough to create a conducive environment to trigger thoughts to modify behaviour and activity (mechanism). This manifested in a reduction in effort, lowering goal standards or continuing with the same activity (outcomes).

Participant 14 had other co-existing arthritic problems and reasoned that her aches and pains were normal for her: *"It's purely arthritis. Pretty sure that. It did go very bad, suddenly"*, as she started treatment she had already improved somewhat so had a lower level of impact as she engaged in the physiotherapy treatment and feedback process, and a lower level of dysfunction compared with her other joints (context): *"I felt like I was stuck but it was lots better in lots of ways which is where we set off at."* Despite still not being 100% her impact was low, and she reasoned that her efforts did not need to increase (mechanism) and she was aware of this:

*"I admitted to him when he was starting with the first lot of exercises, I said 'I will tell you, I haven't done... you said things 30 times, I've only got to 20'. I said also 'if you've said sometimes, I haven't done them like 4 times a day. It's been less'"* (outcome).

### **7.7.3 Mechanism**

The resources and reasoning presented as the same for high and low impact. The participants received the feedback resources via the QuickDASH and each would reason if the feedback confirms or denies the level of the shoulder problem. The reasoning would be his or her own internal feedback (for example activities at home or pain) in addition to the external QuickDASH feedback. The combination of these factors was frequently mentioned by participants in interviews. The participants had to reason with this collection of information whether they should continue or change their behaviour and actions. Participant 19 outlined the decision to change (mechanism) resulting in a planned action (outcome):

*“It's like anything else, you just think, ‘It'll be ok’ and you just carry on, but like I said it's not until you have the pain and you've got to go through it and you think ‘I'm not doing this anymore’ I knew what I had to do.”*

This mechanism was also mentioned by Physiotherapist C in a generalised comment, suggesting high impact of a problem initiates action:

*“People have a niggle for years and years and years and suddenly it gets worse, that's when they do something about it.”*

### **7.7.4 Context**

The context involves the participant perception of severity and feeling of impact on their life, informing the reasoning in the mechanism. Participant 06 sets the context of high impact by commenting:

*“it was permanently painful, and it stopped me sleeping and prevented me from doing everyday tasks which, you know, household tasks. Even sitting at the computer typing, it ached. I couldn't pick up my grandchildren, and so there was a big impingement.”*

Participant 16 described the context of an underlying problem which initially was not a prominent feature giving a low impact in life, which increased to a higher impact, giving context to visit the GP for a referral to physiotherapy:

*“I mentioned it to the doctor one day I went for something else and initially what she said was it is probably related to your neck. And I never thought anything else about it, and then it carried on getting worse and worse so I was not sleeping very well, it was painful at night and I'd wake up with it, so I decided to mention it again.”*

## **7.8 CMOc 4: Collective impact of feedback CMO**

### **7.8.1 Overview**

It has been documented that a therapeutic relationship between a patient and a physiotherapist can affect patients' attitudes and behaviour, for example physiotherapists with a good rapport can encourage individuals to take control of their problem (Klaber Moffett & Richardson, 1997).

Interaction skills of experienced therapists are also thought to enhance the resources patients use, and lead to positive patient outcomes (Gyllensten, Gard, Salford, & Ekdahl, 1999). The interview data suggested the therapeutic relationship and the feedback process impacted upon each other.

The relationship between the physiotherapist and the patient was fostered by the feedback process, maintaining a continuous positive relationship and encouraging focus on the feedback process, and mutual goal setting.

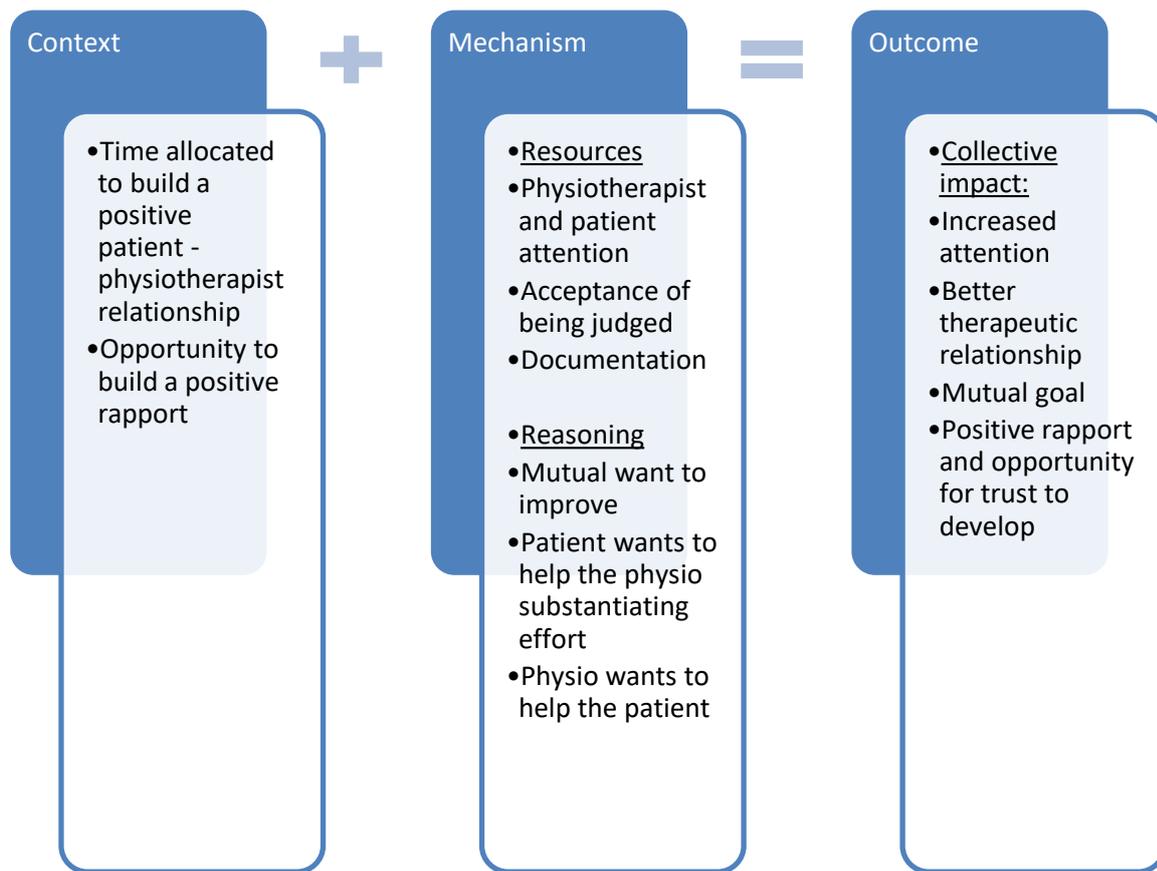
This process of joint working to achieve a better outcome can be described as 'collective impact'.

First coined in the social change sector, 'collective impact' was a phrase used to describe large scale organisational collaborations which had potential to successfully bring about long-term change in complex social systems (Hanleybrown, Kania, & Kramer, 2012). Collective impact can be scaled-down to smaller scale collaborations such as the feedback of information between therapist and patient within this study. Collective impact collaborations, however large or small, must exhibit five specific elements to be successful (Hanleybrown et al., 2012). The five elements are outlined below, with a description of how each element is demonstrated for this study in brackets:

1. A common agenda (goal)
2. Shared measurement systems (QuickDASH)
3. Mutually reinforcing activities (feedback)
4. Continuous communication (feedback)
5. The presence of a backbone organisation (NHS or private physiotherapy organisation)

In terms of what works, for whom and in which circumstances, collective impact appears to occur when there is a positive patient-physiotherapist relationship for the patient. This is commonly described as a positive 'rapport'. Rapport can be defined as a process of building and sustaining a relationship of mutual trust and understanding (Bayley, Chambers, & Donovan, 2004), which occurs spontaneously, fostering a conscious feeling of responsiveness (Sadock, 2012). In this instance, rapport is able to be built upon as time is made available for feedback to be discussed, to further develop that relationship and collectively work towards mutual goals. Belcher and Jones (2009) describe that rapport is needed *before* trust can be developed between a patient and their health care professional. With an opportunity for rapport to build in this scenario, other positive outcomes from the relationship can be developed, such as trust (Belcher & Jones, 2009).

The collective impact process is described in a CMOc in Figure 32. The patient and physiotherapist must be provided with an environment to build a relationship to enable the existence of positive rapport to exist (context). If the positive rapport has opportunity to develop, the physiotherapist and patient can use the documentation resources (QuickDASH) to increase focus by means of judgement, deciding whether improvement is being made (mechanism). In this scenario, the patient aims to help the physiotherapist and in reverse, the physiotherapist aims to help the patient (mechanism). The patient-physiotherapist co-operation process increases attention towards the mutual goal to improve the patient's status thus creating an outlook of collective impact where the collective efforts of both patient and therapist produce a better therapeutic relationship with increased attention and mutual goals (outcomes).



**Figure 32: CMOc to explore the collective impact of the physiotherapist and participant in the feedback process**

### 7.8.2 Outcome

The relationship between patient participants and physiotherapists was explored using interview data from both patient and therapist sources, aiming to expose whether collective impact was felt by both parties. Patient participants who fostered a therapeutic relationship during the feedback process with their physiotherapist were more likely to have a positive outcome.

Participant 02 was happy with treatment and in his opinion had a positive therapeutic relationship:

*“as far as the treatment that they give you here I am over the moon with it.”* He acknowledged improvement in his condition and collective working, attributing his improvement to using the information he was given:

*“things are improving... I was quite happy to do what I was asked to do and I knew what they told me to do would improve it... I feel that they [the physiotherapists] are here to help you ... the effort is that to get yourself right you have got to put your heart and soul into it to get it right”.*

He also acknowledged the feedback process helped him progress, commenting: *“I don't think I would have got as far as what I have without knowing any scores”* (O2). This flow of comments showed increased attention between the two parties to the feedback of outcome data in terms of the QuickDASH to aid the management and progression of this participant's condition (outcome). The feedback process was then able to support a positive rapport between patient and therapist, which was repeatedly reinforced with each information feedback and treatment contact. The opportunity for repetition of this process suggests this CMO configuration is cyclical and the impact of collective feedback can be enhanced with ongoing feedback of information, *if* a positive rapport is continually maintained.

Participant 19 was a busy lady with two jobs and not much time to exercise, she was being seen at a private clinic which she had chosen as it suited her job commitments in terms of appointment times. She had a positive rapport with her physiotherapist in terms of knowledge transfer and feeling like she was empowered with her shoulder condition: *“Yeah, I felt a lot more confident. I was able to aid it to make it better. What the physio was doing was great. What she had advised me to do was helping as well so I suppose a bit of a power thing really rather than it taking over me.”* Due to the positive rapport and therapist-patient relationship being fostered, there was a collective impact shown with the feedback of information.

All five elements are identified in the participant's own words. The first excerpt from participant 19 exhibits three elements the therapeutic relationship needs to possess to produce a collective impact: a common agenda, shared measurement systems and continuous communication:

*“Like I say it [the QuickDASH graph] was more of a motivator, a driver really to say things are going the right way... It's written down. It's good because even though you can feel it is physically moving, it's figures. It speaks doesn't it and that's what you see... 40%... 88% ooh. you see the difference. Absolutely. It's better.”*

The second excerpt displays the final two elements required for collective impact: a backbone organisation, in this instance the private physiotherapist within the practice and mutually reinforcing activities, with participant 19 expressing this clearly:

*“Whatever they're doing [physiotherapist] and whatever I'm doing [patient], between us it's obviously working.”*

Building a rapport and subsequent trust was an outcome of this CMOC, with patients identifying their relationships progressing, building confidence in their therapist. Participant 16 required a steroid injection and during treatment had built a positive rapport with Physiotherapist B: *“I did everything he told me to do... If I get an option then yes I would go to Physiotherapist B”*, which gave her confidence in the physiotherapist and trust in his skills: *“...the choice I would plump for someone [Physiotherapist B] who knows my shoulder and that I have been working with and I have confidence in.”*

### **7.8.3 Mechanism**

The mechanism for collective impact appeared to be complex, involving participants wanting to show effort and progress when being assessed and judged on their progress. The physiotherapists were also active within the mechanism, wanting to clarify and demonstrate to the participants they were improving.

### **7.8.3.1 Patients accepting assessment and judgement of improvement via QuickDASH documentation**

In this study, the time resources made available for the QuickDASH to be fed back allowed increased attention to the scoring and progress. Participants appeared to accept the assessment and judgement of improvement by means of the QuickDASH measurement as professional in nature rather than unwanted judgement and appeared to be comfortable discussing their progress:

*“I preferred it. Well it's professional view isn't it?! If I wasn't going to get monitored then you wouldn't know would you, and wouldn't have all this [points at graph]. I know it's obviously all over the place but it's to be monitored” (15).*

Participants looked on the process favourably concerning the additional time and effort spent documenting the QuickDASH measure at each appointment, discussing progress with the information feedback:

*“I think the only way that anything can be improved is if the people being treated are prepared to give the information of what's happening when they are being treated. I think I'd be more concerned if I wasn't asked anything! I'd sooner actually take the time to fill out a questionnaire to see how things have been or speak to the practitioner to see how things have been than just come in for you to do something and walk out again” (18).*

### **7.8.3.2 Substantiating effort and showing improvement: Mutual working between patient and physiotherapist**

Patients were keen to substantiate the prominence of their effort towards treatment and show their improvement by providing this information clearly to their physiotherapist:

*“I think really I just kept wanting it to show it were improving. I just wanted... I just wanted it to show it were improving” (10).*

*“What you've asked me to fill in there is useful to you... I know I wanted to get an improvement as quickly as possible” (17).*

It was also clear that participants wanted to help their physiotherapist by providing them with information that could be used in their day-to-day audit of patient data, even though in this study, the patients were fed back the QuickDASH information mainly to explore the benefit to themselves:

*"If it helps. If it helps you doing what you're doing but also helps someone... If no-one filled it in, no-one is going to get anywhere, it is important" (09).*

*"The monitoring and that is for your reference more than me. Because you need to see 'how's he done against other people'" (17).*

The physiotherapists also identified patients' positive responses when they had been engaging in the feedback process, when as therapists they were able to identify improvements, such as functional movements, pain and scores on the QuickDASH:

*"Usually they were improving and they were like 'you can actually see'... It always seemed to correlate with how they were feeling. It correlated really well actually, but it was nice for them to see as well 'Oh yeah, I've jumped up quite a bit'. Especially that one [participant 19]" (Physiotherapist A).*

*"...Trying to please your therapist, and we're wanting them to get better so we're trying to please them. Yeah. But people do come in and say 'look look look, I can get my hand up here, yay!!' and we say 'Well done'. And that's why isn't it. 'Well done you've got your full range of movement back!!'" (Physiotherapist C).*

With accepting assessment and judgement, substantiating effort and showing improvement, patients started to try to help their therapist in terms of documenting their progress, reasoning in a way which would not have occurred without the introduction of the QuickDASH feedback. The participants talked about completing the feedback documentation to help the therapist: *"you need the graph for you, for you to monitor it basically "* (17), *"to me, the scoring part was for documenting"* (11). Some participants were perceptive to the mutual feedback process helping both

themselves and the therapist: *"It helps you, it helps me doesn't it?!"* (26), and *"I didn't mind at all because if it [filling in the form] helps you to help others that's fine"* (02),

The patient attention to the feedback of scores was confirmed by all three physiotherapists with some identifying the mutual working which the process of feedback was encouraging:

*"They were quite happy they were always wanting to know [their scores] 'Where am I on this graph now?' [as if a patient talking]. It was always nice to see visually 'Oh actually I'm getting better' [as if a patient talking] rather than me just saying I think you're getting better"* (Physiotherapist A).

*"I would probably say this lady here in that she was compliant but I think she really bought into the fact that there was some recording mechanism there of her work and her effort which would maybe put her along to do better"* (Physiotherapist B).

*"Maybe because we are documenting it more than other people who aren't on it [the study]... these lot are coming back and saying "Yep, yep, done, done, done!" as we are writing it down officially... part of them that is quite excited to be part of a trial"* (Physiotherapist C).

#### **7.8.4 Context**

The patient-physiotherapist relationship needs to be positive for the mechanism to be triggered. Time allocated to the patient - physiotherapist relationship and the opportunity to build a positive rapport is the starting point for this CMOc at contextual level. The QuickDASH feedback process encouraged this time allocation, giving opportunity for the therapeutic relationship to be fostered over and above the opportunity provided without the additional time.

A positive relationship would be one where the patient feels they have a connection with the therapist, where mutual trust and understanding is built and sustained. Patient participants and physiotherapists were able to orate this within their interviews:

*"I feel that they are here to help you and you have got to be truthful with them for them to help you and I think that is part of the job to do that and I think, well I can't find any fault with them at all... I knew that you were interested" (02).*

*"I did everything he told me to do. Even tried a bit harder...I followed all the instructions he gave me and did them as often as he told me... he [the physiotherapist] comes across as being very honest and genuine." (016).*

Physiotherapist B was perceptive to the patient-therapist relationship and the effect of this positive relationship:

*"I suppose it was the rapport you had with the patient and if you could get them to buy in to the study and sort of the outcomes we hoped to get from the study that they really wanted to participate... I suppose a big part of physio is motivational talk as well. Picking up on the positives and trying to say it's going in the right direction or maybe we need to focus or re-jig that to try and improve things."*

It was evident that physiotherapists had allocated time for the QuickDASH, as comments surrounding the results were referred to by all three physiotherapists, with examples of phrases they had made to patients:

*"You [as a physiotherapist] always ask them 'How are you doing with x, y, z?' ... 'I'm sleeping a bit better' [speaking as if participant]... 'So there you go, it means it's improving' [physiotherapist]. I found it very helpful with this though, like I said before, 'you were able to wash your back better this week' [physiotherapist]... 'oh yeah right' [speaking as if participant]. In this sense it is handy for more functional stuff and actually making clients aware that actually getting better although their pain might not be that good"*  
(Physiotherapist A).

*“...’How you getting on, has there been any change?’ [pretending to ask a participant] Just the nature of that clinic that it couldn't be weekly... Picking up on the positives and trying to say it's going in the right direction” (Physiotherapist B).*

It can be noted that the physiotherapists identified patients' responses to the QuickDASH feedback, communicated in the interview with direct quotes as if they were speaking as the patient themselves which indicates awareness of the communication fostered by the feedback process. A further example is shown below:

*“These ones (026, 027) said ‘I can't sleep, I can't do this, I can't do that.... I have to do something about it’” (Physiotherapist C).*

These quotes support time being made available to discuss the QuickDASH feedback, giving opportunity to build a rapport between the physiotherapist and the patient.

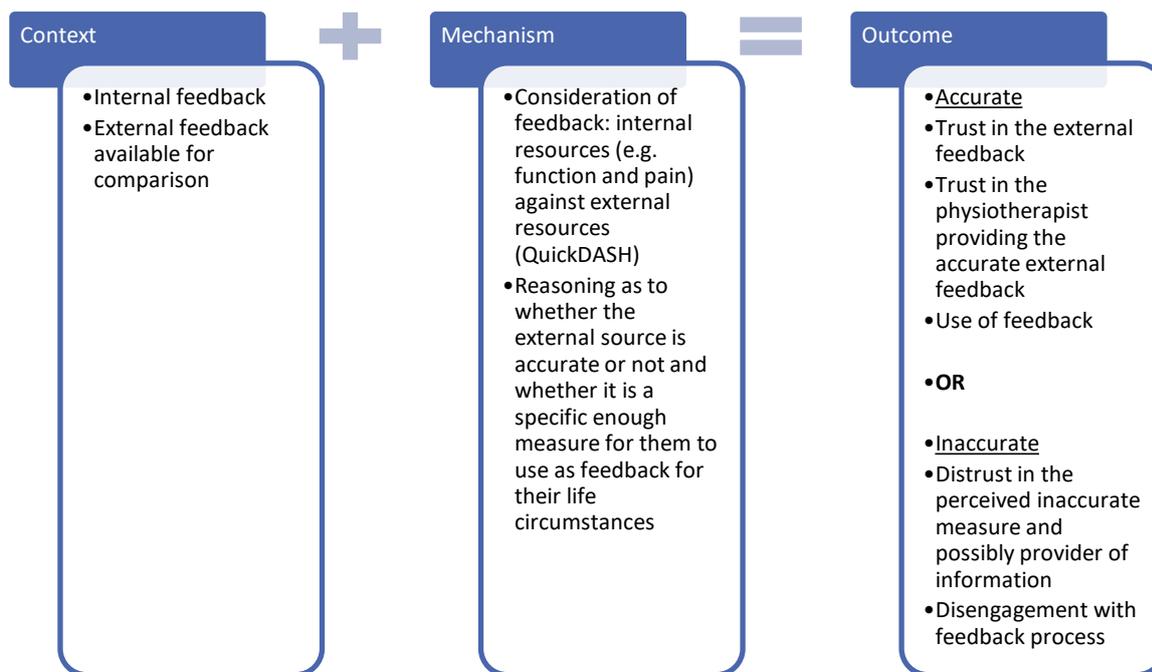
## 7.9 CMOc 5: Dissonance or consonance

### 7.9.1 Overview

Patient identification of new information which conflicts with existing thoughts or beliefs is known as dissonance, whereas agreement of new information and existing thoughts or beliefs can be described as consonance (Festinger, 1962). With feedback of information, in this instance, the QuickDASH outcome score is the new information and how they gauge their own shoulder to be in terms of status as their existing thought or belief. CMOC 5 (Figure 33) presents scenarios in which the use of an information feedback tool such as an outcome measure can vary depending on participant reasoning.

A participant will compare their own internal feedback with the external feedback (if it exists and is provided by the therapist) (context). Festinger (1962) describes dissonance as an everyday occurrence, and in this particular instance it is conceivable that a participant will compare the resources of the internal and external feedback for dissonance or consonance (mechanism). A participant will speculate if the QuickDASH is either both accurate and relevant, or inaccurate and irrelevant (mechanism). As previously reported from the pilot phase I study, participants considered the QuickDASH to be relevant if the questions appeared congruent with problems they faced in everyday life (mechanism). If it is considered irrelevant this may be due to the participant perception of the QuickDASH as a non-specific, generalised measure, which does not take into account their circumstances (mechanism).

The two disparate outcomes were based on the perception of accuracy or inaccuracy as originally identified within the phase I pilot study. Those trusting in the accuracy of the feedback from the physiotherapist used the feedback (outcome), and conversely those finding it inaccurate, and distrusting feedback from the physiotherapist, appeared not to use the feedback and disengage with the process (outcome).



**Figure 33: CMOc to explore the two outcomes arising from dissonance or concordance of new information via the feedback process**

### 7.9.2 Outcome

The mechanism of resource and reasoning could trigger one of two contrasting outcomes.

Those finding accuracy in the measure, for example: *“It’s measuring the progress accurately”* (01), appeared to trust in the feedback and physiotherapist: *“Whatever you’re doing (physio) and whatever I’m doing (patient), between us it’s obviously working. It’s written down”* (19), and was more likely to be used: *“It’s good because even though you can feel it is physically moving, it’s figures. It speaks doesn’t it and that’s what you see”* (19).

Others found inaccuracy in the outcome measure; with participant 03 identifying she would have liked different questions:

*“What would I like to have been asked? Well more the questions that were related to my arm... I didn’t feel I had answered like that on the questions because it wasn’t keeping me awake”* (03).

When asked about accuracy of the QuickDASH, participant 03 reported an apparent lack of confidence in accuracy of the feedback measure:

*“Probably not [accurate] because it was difficult, because I am right handed, so I can open a jar easily, I can wash my back, because I use my right hand, so I felt I wasn't really being totally honest in what I was writing down.”*

This resulted in an outcome of distrust in the measure and disengagement, changing plans for management of her condition:

*“I am wondering is it going to get right, does it need a scan, does it need an injection? That is what I am beginning to think now because I didn't have that at the start obviously but it doesn't seem to really be improving.”*

This outcome of distrust and disengagement for participant 03 could have been consistent without the feedback process, although dissonance with the QuickDASH accuracy compounded her interpretation of the events as when asked about the impact of the feedback process she replied:

*“It has been a long time and it doesn't seem to be getting right really... It [the feedback] wouldn't have affected the pain because if the pain is there it's there.”*

When asked if feedback of scores affected rates of recovery, she remarked:

*“I wouldn't have said so, no.”*

### **7.9.3 Mechanism**

The resources used for each participant were similar: internal resources of feedback (e.g. function and pain) and external resources (QuickDASH).

Participants reasoned as to whether the external source of feedback was accurate or not and in particular, whether it is was a specific enough measure for them to use as feedback for their life

activities in comparison with their own thoughts (internal feedback). The majority of patients found it mirrored their own feelings on how they were progressing:

*“I think most of the time it actually felt it was how I felt during that period... I like to see something visual like that to see I'm improving” (16).*

*“The score sheets were fine it was just thinking, alright, in between each visit it was 3 to 4 weeks and it's remembering what has improved. There's odd times something's gone backwards, then at the end other things have moved forward. It depends on what you've been doing... I think that is actually quite accurate” (17).*

Two specific participants (03 and 04) found the QuickDASH to be inaccurate and felt the questions did not reflect their day-to-day activities and restrictions. Participant 03 suggested the QuickDASH questions were erroneous, commenting:

*“Pain at night was a problem, the questionnaire said did it keep you awake? Well it didn't keep me awake, but if I turn over in bed it really does hurt” (03).*

The second participant (04), who also found error in the questioning, felt it did not reflect his duties on returning to work and therefore would not reflect his fitness for work:

*“This marking system [QuickDASH] may just be a bit out.....and may have the wrong conclusion really because the biggest part of it is getting back into work then finding out it's not right, it's been a false reading.”*

#### **7.9.4 Context**

Within this context, patients must have had the opportunity to be given external feedback by the physiotherapist to compare against their own internal feedback. Each participant within this study was provided with the QuickDASH feedback (as their external source), at every treatment session and a discussion initiated on their progress.

A participant's known status can be informed by internal feedback. Every participant commented on his or her own feelings of progress. Internal feedback was expressed by distinct comments about function, pain or other means by which a participant measures dysfunction:

*"My arm has been sore over this last week or so because, this time of year you are doing a lot more shopping and carrying" (05).*

*"So I think my quality of life is improved to what it was before" (07).*

*"I'm not saying it wakes me every night, and whereas there was a point where it was waking me every night" (09).*

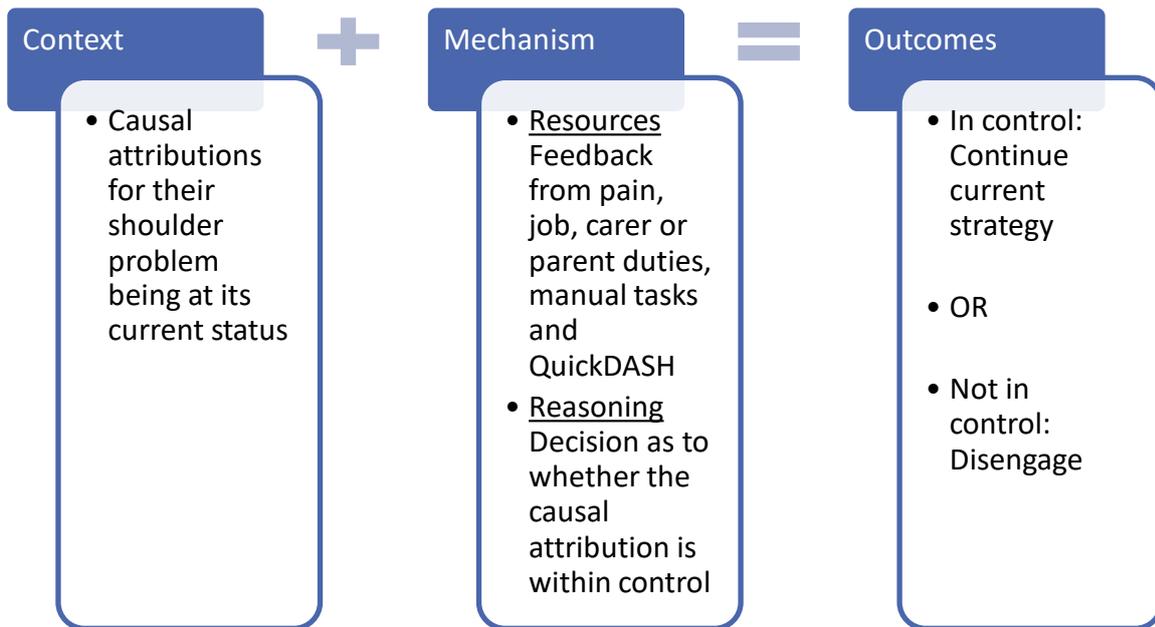
## 7.10 CMOc 6: Causal attribution

### 7.10.1 Overview

Figure 34 details the process in which participants made decisions on causal attribution of their shoulder dysfunction, trying to decipher whether they were in control of their problem. Participants often have an idea of why their problem is at its current status. This idea may be founded or unfounded, but a patient will usually still consider reasons for their pain starting, and for their pain improving or worsening. Participant 09 describes his thought process to arrive as his decision of causal attribution:

*“The canoeing, and the bag on your shoulder, originally I was a joiner...You add them all together and you think it's wear and tear”.*

Feedback for these types of comments may come from many internal resources: pain levels, job tasks and attitudes, carer duties, parent duties, manual tasks, and externally from the QuickDASH feedback being provided at the time of treatment. With all of this as information, a patient has thoughts as to why they are at their current status (context), which will trigger the reasoning as to whether they believe they are in control of their shoulder problem or not (mechanism). If they feel they are in control of their problem, whether it is improving or not, they continue with their current strategy (outcome). If they are not in control they may disengage with the physiotherapist, the feedback intervention and treatment, or they may just struggle on if the causal attribution is an activity or influence they are unable to reduce (outcome).



**Figure 34: CMOc to outline causal attribution for a patient with a shoulder problem engaging with treatment**

### 7.10.2 Outcome

There were two possible outcomes from this CMOc, dependent on if a participant felt in control or not in control. To continue a current strategy the participant had to be controlling the situation with their current behaviour to want to continue it.

Participant 19 had a positive relationship with her physiotherapist and had control of her condition. She attributed her problem to work, commenting: *"I thought it was related to work because I do lift a lot of heavy boxes so I initially thought 'ooh, I've hurt myself'."* Despite her attribution to work she was able to use the physiotherapy intervention to control her condition, which could have either been due to the treatment itself, the feedback, or both combined. When asked if she was in control of her condition she replied:

*"Yeah, I felt a lot more confident. I was able to aid it to make it better. What the physio was doing was great. What she had advised me to do was helping as well so I suppose a bit of a power thing really rather than it taking over me."*

She was keen to continue working with her current strategy, maintaining muscle training after treatment had ceased, to stay in control so the problem would not reoccur (outcome):

*“Because we’ve not got to the 100% I’m a little bit wary of are we going to go so many weeks, months down the line then it’s going to kick in again? But like I said... get the muscle back again. And hopefully, that will work in my favour.”*

If a participant felt they could not control their condition with their current behaviour it was more likely that these participants would disengage from the feedback process and treatment. Participant 08 disengaged with treatment to follow the route of further investigations as work was continuing to aggravate her problem (outcome):

*“But going to work again, I’m damaging it and coming back it’s the same thing... I think I’d go to the doctors as they’ve not done any x-rays or anything, you know. They’ve just sent me to physio first to see if anything gets better. But I’m not getting any better... I’m still having a pain.”*

### **7.10.3 Mechanism**

Internal and external feedback as resources helped to inform participants as to whether they were improving. Examples of this can be gleaned from participant 09, who utilised the QuickDASH scores (external feedback) and his day-to-day ability to do activities such as sleeping (internal feedback) to monitor progress:

*“You’re getting closer to being better looking at your scores on there, you are on your way up, that’s for sure, looking at those... I’m not saying it wakes me every night, and whereas there was a point where it was waking me every night.”*

If improvement was being made it was more likely that they would feel in control over the causal attribution for their shoulder pain. Participant 09 found the external feedback (QuickDASH)

confirmed his improvements he had already noted from internal feedback, and on occasion improvements that he may not have previously noticed:

*"I filled it in but I knew my score sort of, so I thought, yeah, because it was negligible the first couple of weeks and it was only a bit later on when it started increasing and by that time I think I'd actually forgotten the exact score and then thinking 'yeah I think that was a bit of an improvement'."*

The feedback from the QuickDASH aided his reasoning, helping him to conclude that improvement was being made.

If the feedback showed no improvement or inability to control the situation it was more likely that the participant would assume the causal attribution to be something they could not affect, and these participants were more likely to disengage from the feedback process. Although participant 08 commented that she was in control, she had a contradictory follow up comment that she was not in control due to causal attribution:

*"I'm not out of control, but the thing is, in the long run I'm going to have an even worse pain because of my job."*

This suggested that she attributed her work to causing the shoulder problem and was in fact *not* in control so felt it would never improve with whatever interventions were available.

#### **7.10.4 Context**

A participant commonly has an idea of the cause for their shoulder problem, but variations do occur, with patients unsure of why their problem exists, for example, if it is not a memorable injury or they have many other co-existing problems. Although all participants presented with the same shoulder condition, there were many reasons put forward for the start of the symptoms. Participant 14 felt the worsening was due to age:

*“Possibly something that happens you can't alter because you can't alter age. You know, everything has gone slower and you know, not the same strengths which a lot of that I put down to an ageing thing as well is what it is anyway isn't it?”*

Work related duties were a common attributing factor, with participant 15 commenting on her increased lifting and carrying due to mobile working:

*“I don't have an office. I don't have a static office if you will, so I'm walking around mobile quite a lot of the time, having to carry quite a lot of my kit around. And I do educational radio sessions across the whole of the north west. So with my work, I'm here, there and everywhere so I've got lots of baggage when it comes down to lifting certain things and everything so that's my main port of call really at the beginning of the pain.”*

Participant 22 identified historical reasons for her current status:

*“I used to work at a well-known clothing, food and home store and probably my condition has come from over the years, working 15 years on the food department lifting things, filling shelves.”*

Causal attribution was therefore able to be suggested by most patients, but not usually an exact mechanism of injury, just possibilities of exacerbating factors. All participants, however, knew their aggravating factors in terms of current activities. A demonstration of this knowledge of limitation can be observed with participant 11, who was able to identify all his irritable activities in one interview response:

*“Driving was hard, even though I have an automatic, driving was hard. There were no activities, washing my hair was a problem, so basic functions like cleaning your house and things you never really think about prior to it, making your bed, putting socks on. All them sorts of things. I only had function of lifting my arm to about 90 degrees, that was about it, and that was painful. Sports I didn't even bother with.”*

The initial injury or thoughts of causal factors, combined with current exacerbating factors formed a basis for their current status and the reason for their continuing shoulder pain.

## **Chapter 8: Integration of findings: relationship of CMOcs and modification to theoretical framework**

### **8.1 Combined CMOcs: Ripple effects and relationships**

CMOcs do not always occur in isolation (Porter, 2015). The outcome of one CMOc can become the context for the next CMOc when there is a chain of implementation steps (Jagosh et al., 2015). Jagosh et al. (2015) coined the phrase 'ripple effect' to describe this occurrence.

Throughout data analysis and formation of the six CMOcs the researcher noted that particular relationships were appearing between configurations and justified further inquiry to determine associations between CMOcs.

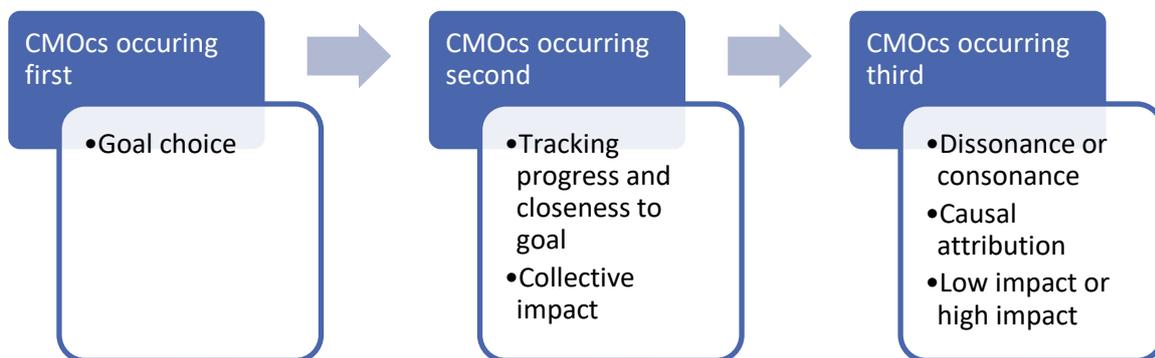
#### **8.1.1 Chronologically ordered CMOcs**

Firstly, consideration was given to which CMOcs occurred before others and which occurred concurrently. The CMOcs occurred for participants at certain points in time related to treatment starting and when they received feedback. The CMOcs were therefore constructed in a linear presentation, aiming to present a participant journey through the treatment and feedback process articulated in CMOcs. The CMOc ordering was tested with participant quotes to determine which ordering was appropriate, with CMOcs moved around on separate pieces of paper to create a timeline which showed the generative mechanisms, and how each CMOc informed the next stage. Some mechanisms did not appear to occur singularly, which is common in complex social programmes (Porter, 2015) and CMOcs could occur simultaneously.

Figure 35 outlines the chronological progression of CMOcs. 'Goal choice' (CMOc 1) occurs *before* any other CMOc as this process usually precedes the start of active treatment and in the scope of this study, 'goal choice' precedes the start of the feedback process. *During* feedback provision by the therapist, 'tracking progress and closeness to goal' (CMOc 2) can occur simultaneously with the 'collective impact' of feedback (CMOc 4). The QuickDASH feedback provision ensures the patient-

therapist relationship and can be fostered by means of time spent monitoring improvement or change in scores and encouragement of mutual goal setting and achievement (collective impact).

After the feedback process a participant can then decide whether the scoring and progress are 'consonant or dissonant' with their expected progress (CMOc 5), 'attributing cause' for improvement or decline (CMOc 6). Depending on their impact on life being 'high or low' in conjunction with whether improvements are being made or not (CMOc 3), a participant can then decide what actions to take. The description in Figure 35 outlines the distinctive phases of CMOcs, occurring in consecutive steps.



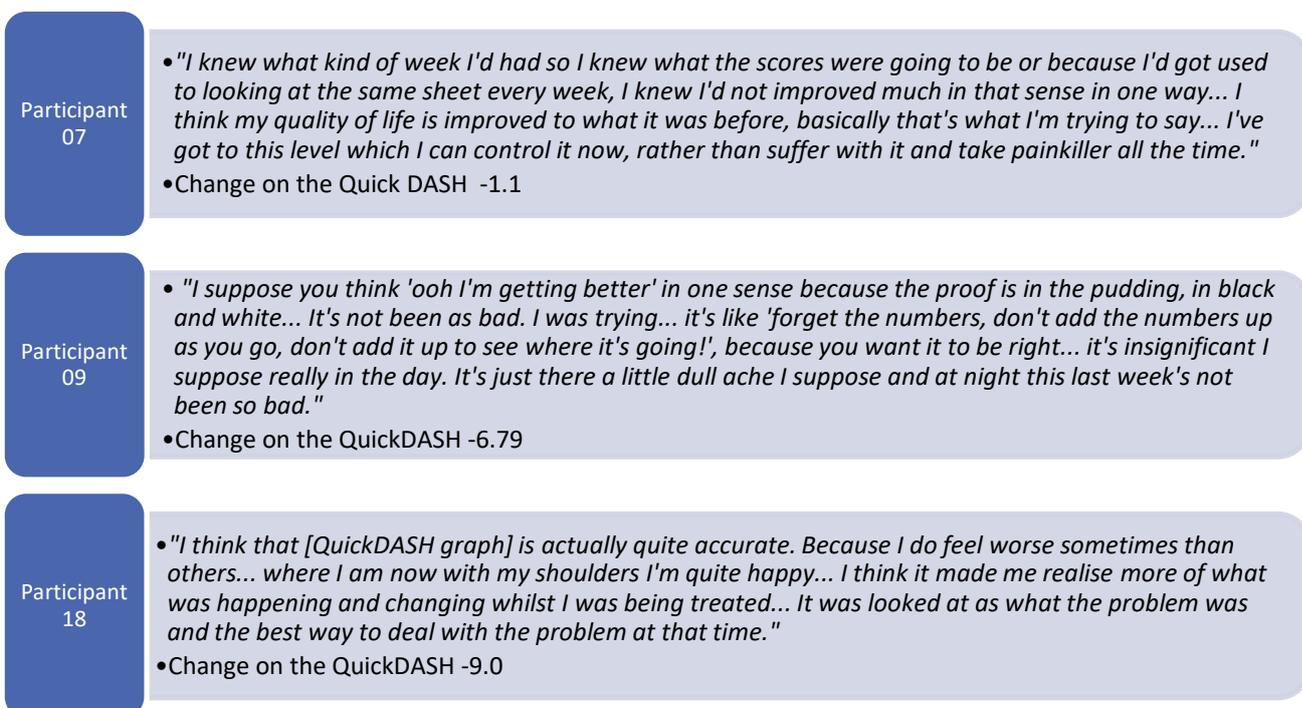
**Figure 35: Chronological CMOc progression through the feedback process**

### **8.1.2 Positive and negative impact status**

Prior to discussion of the summary examples it is pertinent to explore, in the context of this study, positive and negative impact as outcomes for a patient receiving feedback. A positive impact constitutes feedback working in the way it was intended to work by taking positive action or eliciting a behaviour to deal with, or control, their shoulder problem, with an outcome of engaging with the feedback process. A negative impact would constitute feedback failing to act in the way it was intended, which in this study could be dissonance with the treatment process or the feedback process with an outcome of disengagement.

### **8.1.2.1 Positive impact with or without PROMs improvement**

Within this study, positive impact of feedback was observable and communicated by participants in their interviews. On matrix analysis (Miles & Huberman, 1994) it became clear that positive impact overall sometimes corresponded to improvement on the QuickDASH although this was not evident in all cases. The previously described study by Polson et al. (2010) quantified 'no improvement' on the QuickDASH as a change of - 11.64 or less, where a reducing score indicated by '-' implies less dysfunction and fewer symptoms. Three participants exhibited a combination of no improvement, but positive impact: participants 07, 09 and 18. All three of these participants had severe starting scores on the QuickDASH of 63.6, 34.09 and 68.1 respectively. On discharge their scores were largely unchanged at 67.5 (severe), 27.3 (moderate) and 59.1 (severe). Figure 36 details comments from these three participants which demonstrate their positive use of the feedback process, despite exhibiting only small changes in their QuickDASH scores which are classed as not showing improvement (Polson et al., 2010), and discharge from care occurring with moderate and severe QuickDASH scores.



**Figure 36: Three participants' quotes exhibiting positive outcomes from feedback without significant improvement on the QuickDASH**

Figure 36 thus confirms a positive impact was able to occur as an outcome for some participants via the QuickDASH feedback despite no significant change in status from the feedback itself. These results suggest there are complex processes underlying which in which patients can benefit from information feedback of PROMs, without a significant change in the PROM score itself.

### **8.1.3 Summary example: Combined CMOcs with a positive impact (no improvement on the QuickDASH)**

Figure 37 outlines the positive impact of feedback for a participant with no improvement on the QuickDASH. Participant 07 was a 45 year old lady who had multiple areas of joint pain. The shoulder dysfunction had been ongoing for many years and she was getting frustrated with her condition, commenting:

*"I've had it so long...good days and bad days, I just had to look at, if I was having a good day I could get on with my things and it was great and felt really good, but if I'm having bad days I'd just struggle, I'd get frustrated with having so much stuff to do. I'd get frustrated."*

Her main goal was to be pain free although she realised that this was possibly unrealistic due to the chronic nature of her problem and she would be pleased with improvement in pain, even if it was not pain free:

*“I knew in the back of my mind, because I've had it so long... I would have liked to have had it disappeared, I would have liked to, but I mean, I've got to this level which I can control it now... And how can I go further?”*

Tracking progress and closeness to her goal was served by the QuickDASH, showing minimal improvement between her start and finish scores of 63.6 and 62.5 respectively. Both scores were classed as severe.

The collective impact of feedback is observed in this case, without improvement on the QuickDASH. The monitoring process, despite no improvement in QuickDASH scores still fostered a positive rapport between patient and therapist, ensuring a common focus on symptoms management and transfer of information which would be useful to participant 07:

*“I think it's knowledge base as well. And the exercise is what I've gained and I've learned I can use. Do you know? In the end it is knowledge, you know, and basically it's knowledge and what you use after the class. It's up to you if you use it or not, you know? I think you're stupid if you don't use it.”*

This lack of significant change for participant 07 on the QuickDASH measure appeared to be concordant with her feelings and observations of her condition:

*“It was a bit tough so it went down due to circumstances... Because I knew the questionnaire, I got used to the questionnaire, I knew what was coming because of what kind of week I've had.”*

The weekly monitoring appeared to be beneficial, despite the lack of improvement on the graph. This was indicated by her suggesting improvement with the exercises, *"It's when I do my exercises. That's the bottom line. That's what's helping me."* Improvement for this participant was not classed as reduction in terms of pain or achievement of goal status but improvement in terms of controlling her condition and not worsening. She felt the exercises were improving her condition and she was now able to manage her shoulder more effectively than previously. Although still limited in activity and not pain free she could participate in more activity and manage her pain, creating a lower impact on her life, commenting:

*"I can push myself a bit further now rather than struggling, I used to hold back but now I can push myself a bit more... I think my quality of life is improved."*

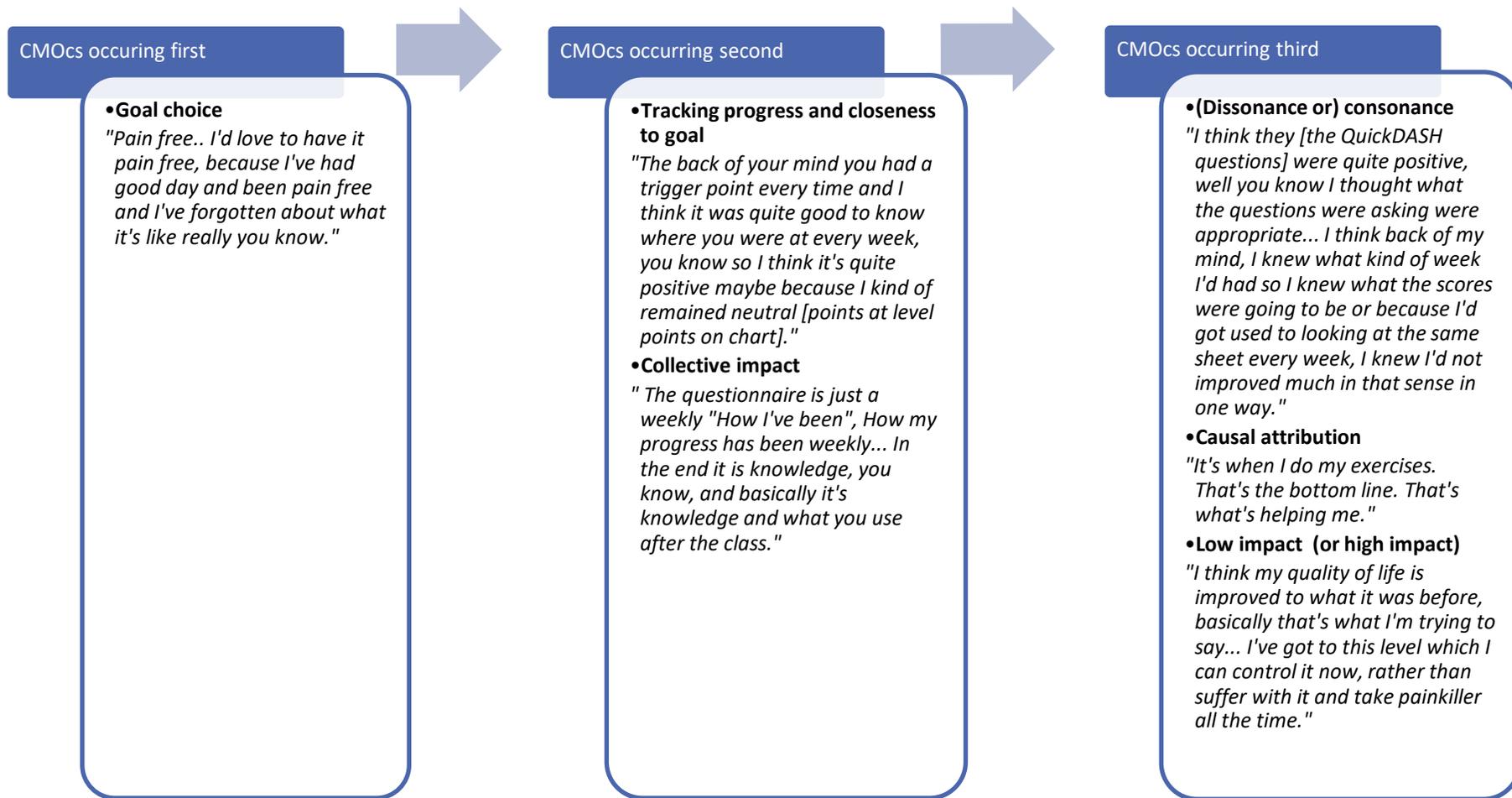


Figure 37: Linear CMOs with quotes to show timeline for combined CMOs with a positive impact with no improvement on the QuickDASH (07)

#### **8.1.4 Summary example: Combined CMOcs with a positive impact (improvement on the QuickDASH)**

Participant 13 began treatment hoping to “go back to a normal life”, starting with a ‘moderate’ QuickDASH severity score of 29.5 (Fan et al., 2008). He found the QuickDASH scoring useful in terms of plotting his progress, commenting:

*“You can actually see on a graph how you're progressing... it helps I think when you see a chart.”*

He proceeded to foster a working relationship with his physiotherapist throughout treatment, building trust despite painful interventions:

*“I got pummelled by your mate, various things, various angles and one thing and another and I really struggled. About the third week I thought ‘this is getting nowhere’. It was really, really poor. And then she started using the pins... and I have to say you can see from the results [pointing at the graph]... it tended to be quite a sharp improvement on it. I don't know why, because having pins stuck in you isn't necessarily the sort of thing you'd think of as a good time. But it did make a difference.”*

This statement suggests he believed the changes in his symptoms were due to passive treatment from the physiotherapist, and that he identified this improvement as concurrent with the graph.

After finishing treatment, he planned to increase his exercises:

*“What I'm doing and what I'm intending to do are two different things!... I try and do the exercises when I remember. Do I do enough? No, probably not.”*

He was ‘much improved’ by the end of treatment using the classification categories from the study completed by Polson et al. (2010), giving a low impact on his life with a score at the end of

treatment, classed as mild at 6.8. This was supported by his interview stating he was “*about 80 to 85% [improved].*”

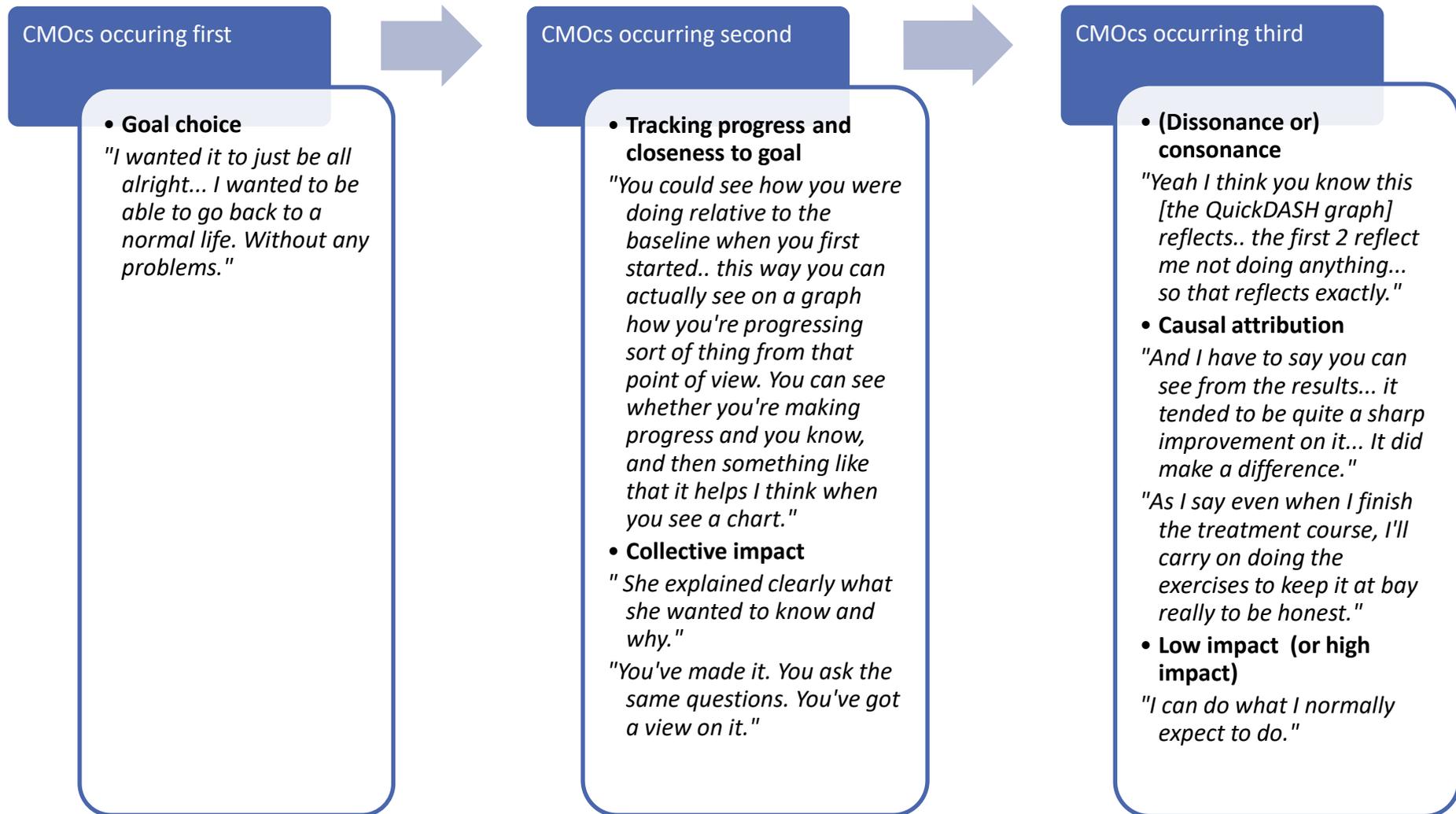


Figure 38: Linear CMOs with quotes to show timeline for combined CMOs with a positive impact with improvement on the QuickDASH

### 8.1.5 Summary example: Combined CMOcs without a positive impact

Participant 12 lived on a farm, which was also her workplace, where she was a dairy farmer. Her job entailed heavy manual jobs including lifting bags of feed, using the milking machinery, opening heavy metal doors and driving tractors and four-wheel drive vehicles on the farm land. Her attitude to work and the need to continue doing jobs around the farm delayed her seeking treatment: *“I reckon I’d had it 2 or 3 months because I didn’t come as early as I should really.”* Figure 39 (page 210) details specific examples from the interview data to narrate each CMOc. Participant 12 described her pain as *“aching right across the shoulder blade”* at the start of treatment so she was keen to relieve her pain (goal choice). She used generalised feelings of recovery to gauge if she was progressing: *“I think I’m about halfway [to my goal] I think”* and also used pain as a guide to improvement:

*“the shoulder blade... that is much much better now, so it’s just this twinge in the elbow and it’s been coming down here a bit. That’s not been sorted.”*

The QuickDASH, however, did not mirror the progress she felt in her shoulder. This was possibly due to her answering questions in a particular way due to additional pain in the elbow, despite pain improvement in the shoulder: *“I think because I’ve still had the twinges in the elbow and maybe I’ve been thinking about those coming from my shoulder.”* The QuickDASH did not therefore show a closeness to her goal (lack of tracking progress), with the participant feeling she did not benefit from the feedback process, mentioning the lack of progress on the graph was *“frustrating”*, commenting, *“I would say that I wasn’t getting anywhere with it. It wasn’t improving.”* This lack of closeness to goal and confirmation of lack of progress on the QuickDASH graph did not encourage the conducive context to initiate the collective impact CMOc to fire, limiting opportunities for a patient-therapist relationship to form.

Participant 12 identified dissonance with the process in terms of not being helped by the feedback, but also improvement in shoulder pain which was not registering on the QuickDASH (dissonance). As she considered the impact of her shoulder problem to be *“mild”* (low impact) and the possibility of

her lack of improvement to lack of exercise compliance, the initial assumption would be that she would increase her compliance to treatment advice and increase her exercise frequency. On the contrary, her planned action was to try with more passive treatment in physiotherapy which had not yet improved her condition over nine sessions. Her causal attribution for ongoing pain was linked to not receiving enough physiotherapy. This combination of CMOcs did not produce positive changes for participant 12 in terms of the impact of feedback as part of treatment Figure 39: Linear CMOcs with quotes to show timeline for combined CMOcs without a positive impact, without improvement on the QuickDASH (Figure 39).

Negative impact of the feedback was observed at the second phase of CMOcs, where tracking progress and closeness to goal (CMOc 2) and collective impact (CMOc4) occur. The negative tracking was followed with dissonance towards the feedback process (CMOc 5).

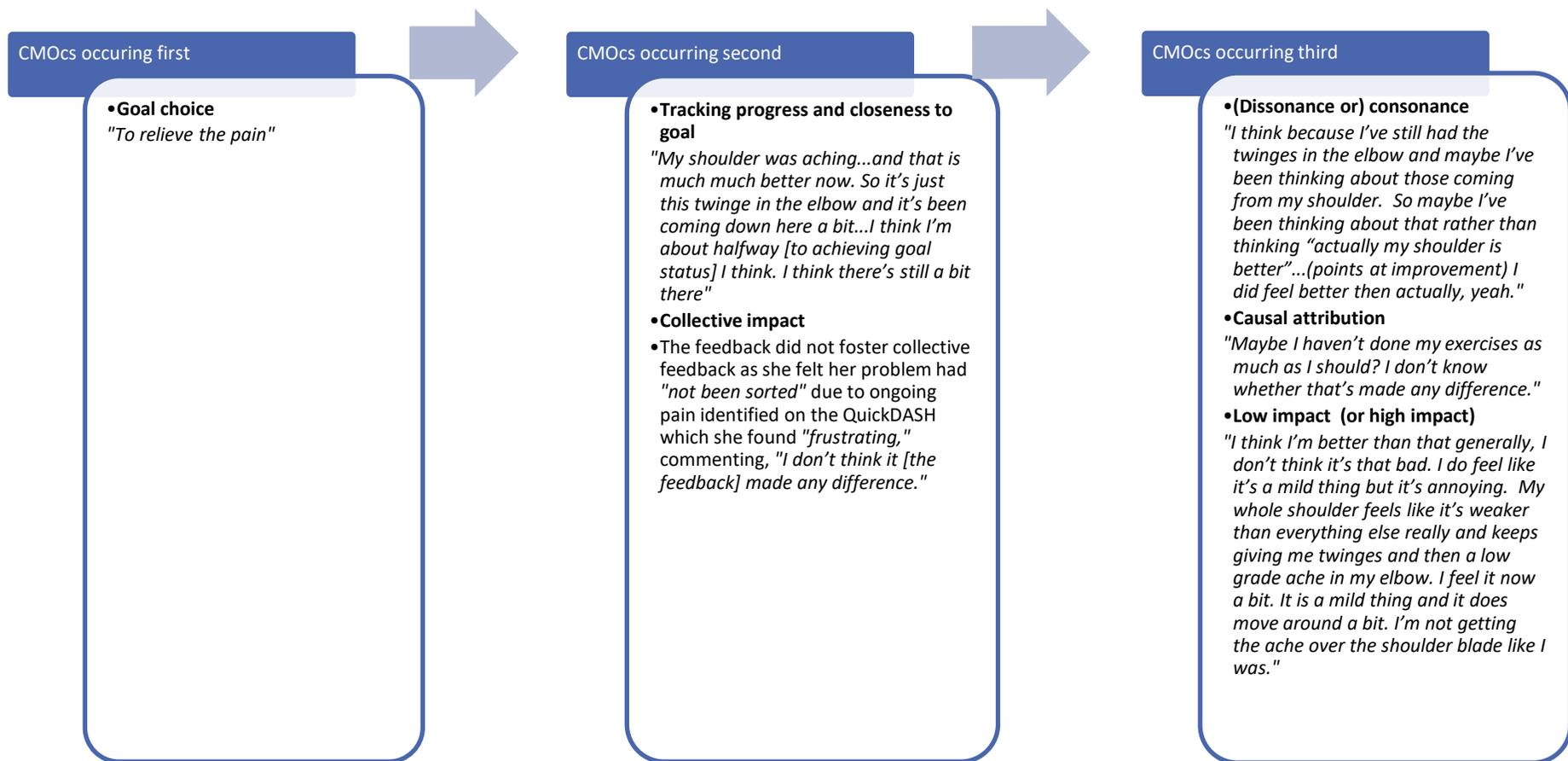


Figure 39: Linear CMOs with quotes to show timeline for combined CMOs without a positive impact, without improvement on the QuickDASH

### 8.1.5.1 Observation of negative impact of feedback

Negative impact at the second phase of CMOcs was observed with three other participants: 03, 04, 15 (Figure 40). All cases had a goal choice prior to impact being observed. The negative impact in all cases was produced from tracking the feedback, noticing the goal had not been met, with a reduction in collective impact. This combination of CMOcs was then followed by dissonance towards the feedback process in all cases. Despite differences in impact (high and low) between participants and differences in causal attribution, the action in all cases of negative impact the outcome was withdrawal from active physiotherapy treatment.

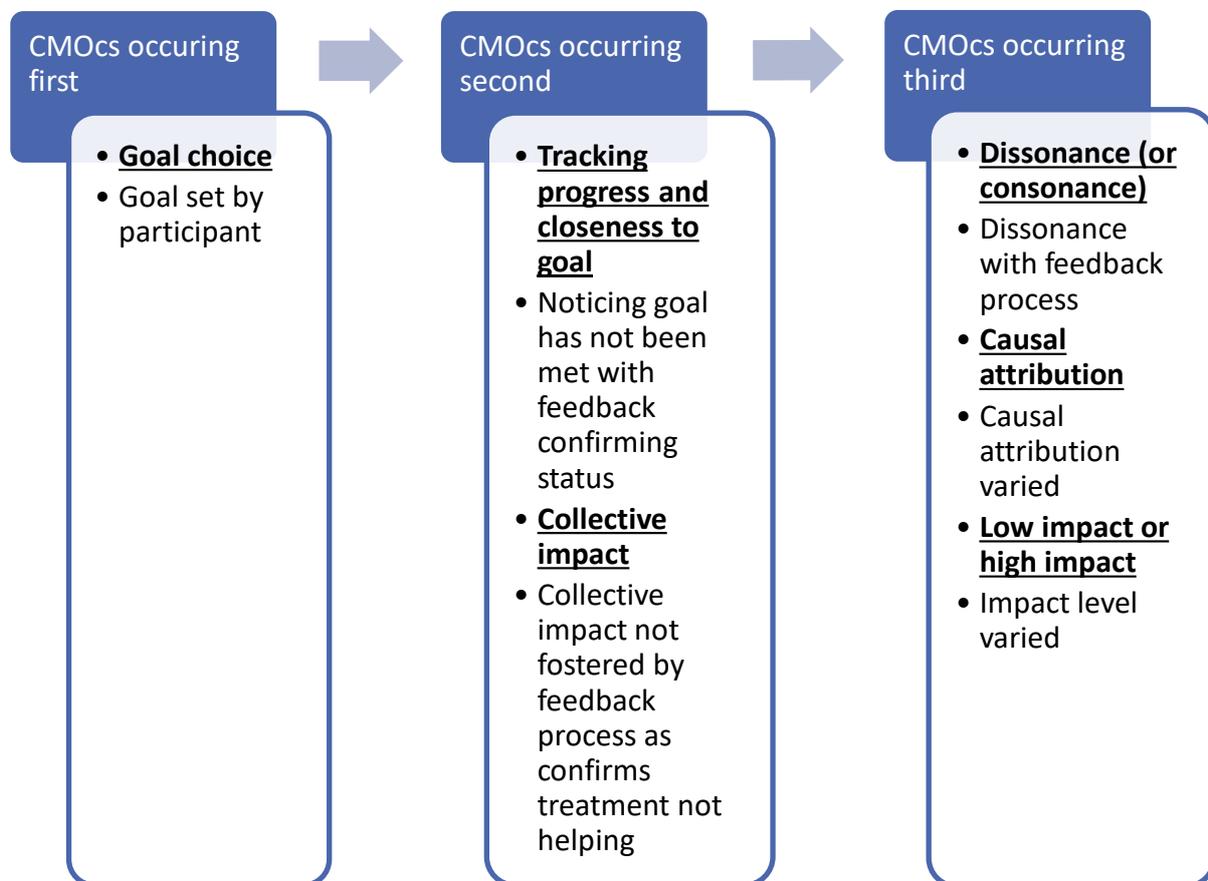
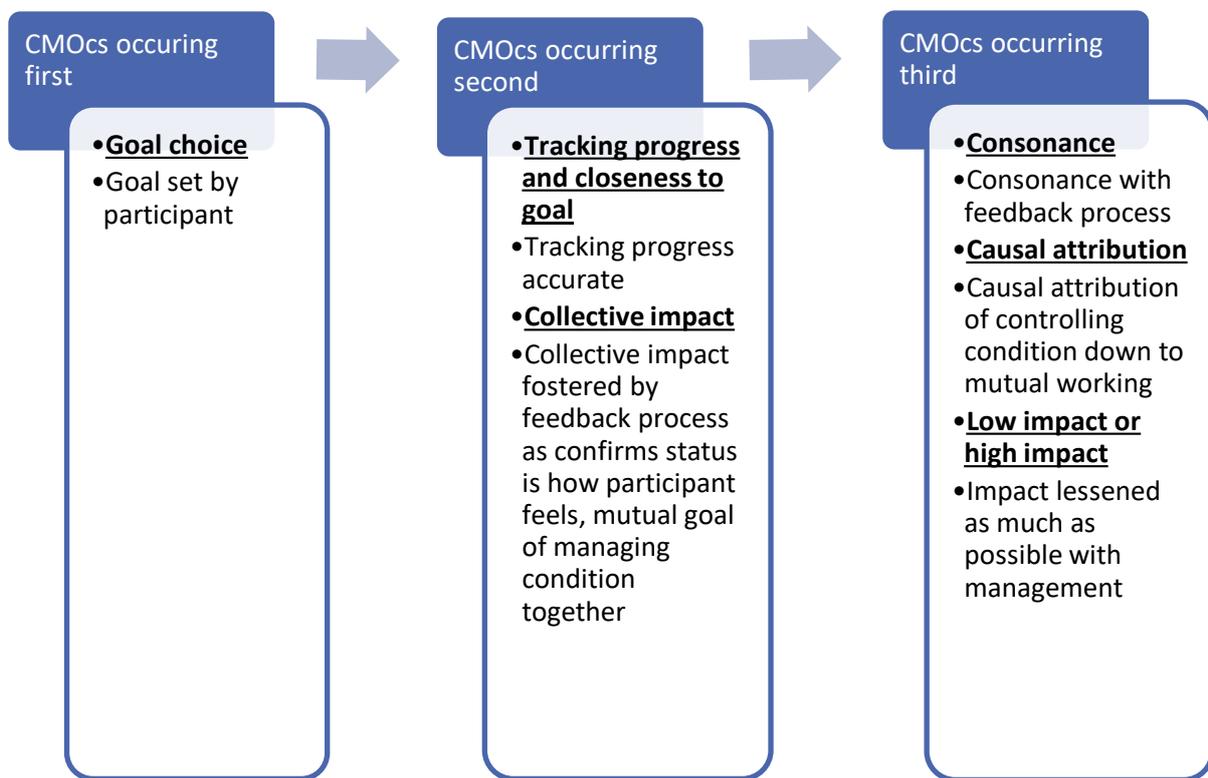


Figure 40: CMOc processes occurring with negative impact of feedback

### 8.1.5.2 Observation of positive impact of feedback

Positive impact of feedback presented a differing combination of CMOc *outcomes* which can be seen in Figure 41. Positive impact of feedback was observed fully with participants 01, 02, 05, 07, 11, 13,

17, 18, 19, 21, 23, 26 and 27. The two common denominators with all these participants were accurate tracking with the QuickDASH, and evidence of collective impact between participant and therapist. There were participants from each patient group who demonstrated a positive impact from the feedback: four attended the NHS class setting, three underwent private treatment and six in NHS one to one treatment. Following fostering of the collective impact, consonance was noted with the feedback process with attribution of the controlled and managed situation to the therapist-patient relationship of working together towards mutual management. Within these participants their level of shoulder dysfunction could be high or low impact.



**Figure 41: CMOc processes occurring with positive impact of feedback**

## **8.2 Combined ripple effect: The cumulative CMOc**

Introducing feedback is thought to confirm or change intentions, thoughts and behaviour, specifically directing attention toward task details to improve performance. Hysong et al. (2006) describes this improvement in performance to involve increasing the ability of the provider to interpret the PROMs data into something that is meaningful to him / her, which in turn is likely to direct attention to the details of the PROM in question, thereby increasing the likelihood of subsequent performance improvements. Performance changes in terms of shoulder impingement syndrome could be activities such as modifying exercise activity, changing sleeping position, modifying working postures or controlled medications management. With such performance changes, the intended outcome of information feedback to patients within this study is to help individuals manage and / or improve their shoulder condition.

### **8.2.1 The overall shape of the six CMOcs: a non-linear process**

In observing the linear CMOcs together it was noticed that the progression of CMOcs presented an insight into the broader view of the feedback process when linked together. Porter (2015) describes the complexities of social situations and the difficulty of simplifying these complex processes into singular CMOcs, which are in fact more complicated than a linear structure of events. Greenhalgh et al. (2017) explain that contextual factors exist in configurations, shaping the mechanisms through which the completion and feedback of PROMs work in multiple and complex ways.

An overall shape was evident in this study when considering the structure of all CMOcs as a whole. The six CMOcs produced from the data presented as two distinctive categories: three CMOcs which gave an overall context of the whole feedback process and three CMOcs which contributed towards the mechanisms of the whole feedback process. The end result (outcome) was behaviour and action.

### **8.2.2 The overall context of the feedback process**

Returning to the initial description of context (3.7.1, page 85) as the ‘backdrop’ of programs and research, context can be understood as anything that can trigger and/or modify the behaviour of a mechanism (Jagosh et al., 2011). Considering the overall ‘shape’ of the cumulative process, three CMOcs create circumstances which provide a context for feedback to work in the way it is intended:

- **Goal choice (CMOc 1)**
- **Tracking progress and closeness to goal (CMOc 2)**
- **Collective impact of feedback (CMOc 4)**

If a goal choice is set, tracking progress and closeness to a participant’s goal is accurate and noted, with a good patient-therapist relationship, collective impact can occur, creating a conducive environment for feedback mechanisms to fire.

### **8.2.3 The overall mechanisms occurring within the feedback process**

Wong et al. (2013) define social mechanisms as *“underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest”* (page 5). After the ‘context’ defining CMOcs, one group of CMOcs consisted largely of processes contributing towards resources and reasoning (presenting as mechanisms).

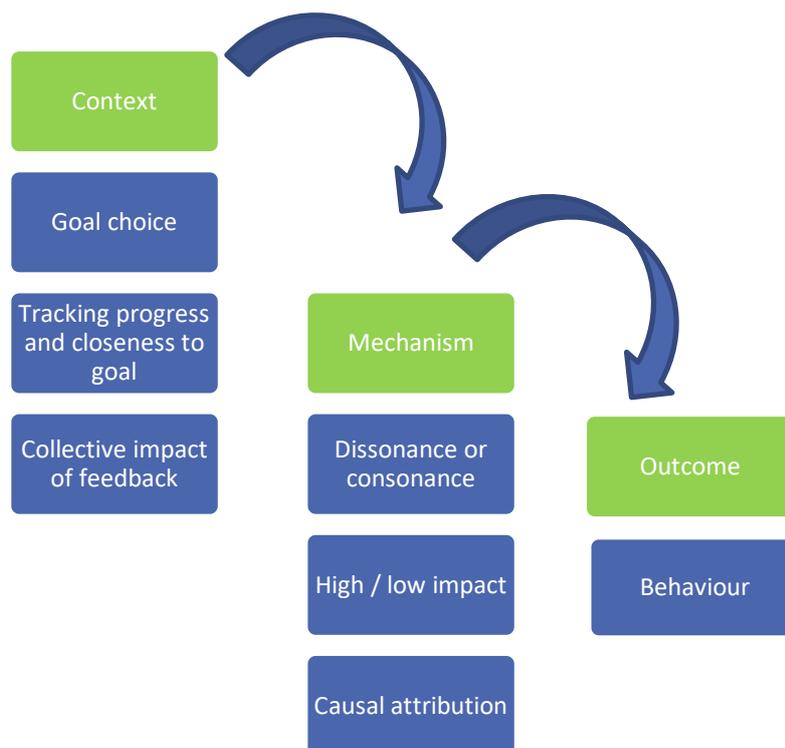
- **Dissonance or consonance (CMOc 5)**
- **High or low impact (CMOc 3)**
- **Causal attribution (CMOc 6)**

With resources of the QuickDASH feedback to reason consonance (in positive impact) or dissonance (in negative impact), decisions of whether their problem is impacting their life enough to change action (high or low impact) and if their shoulder condition is within their control or not (causal attribution). All these processes occurring together as mechanisms create action plans for behaviour.

### 8.2.4 Overall outcome and the cumulative CMOc

These two groups of combined contexts and mechanisms are then processed together to create an overall *outcome* which culminated in whichever ‘behaviour’ or ‘action’ a participant chose.

The cumulative CMOc is depicted as an overall process below in Figure 42 to describe the six CMOcs and how they are shaped in the whole feedback process.



**Figure 42: Combined CMOcs to create a combined ripple effect ‘cumulative CMOc’**

### **8.3 Research question revisited**

The overarching research question was revisited at this stage to refocus the analysis to answer:

‘Outcome feedback in Physiotherapy: What works for whom in which circumstances?’ with a realist lens of theory testing.

The CMOcs grouped as ‘context’ and ‘mechanism’ defining CMOcs were projected back onto the Contextualised Feedback Intervention Theory (CFIT) diagram to observe where each singular CMOc occurred within the process as a whole to confirm the order of their occurrence. All six CMOcs were able to be placed within the CFIT as a framework. Figure 43 details each CMOc and its placing within the original CFIT, with each CMOc represented by a red flag so there is a distinction between the original CFIT headings and those of the additional CMOcs identified within this study.

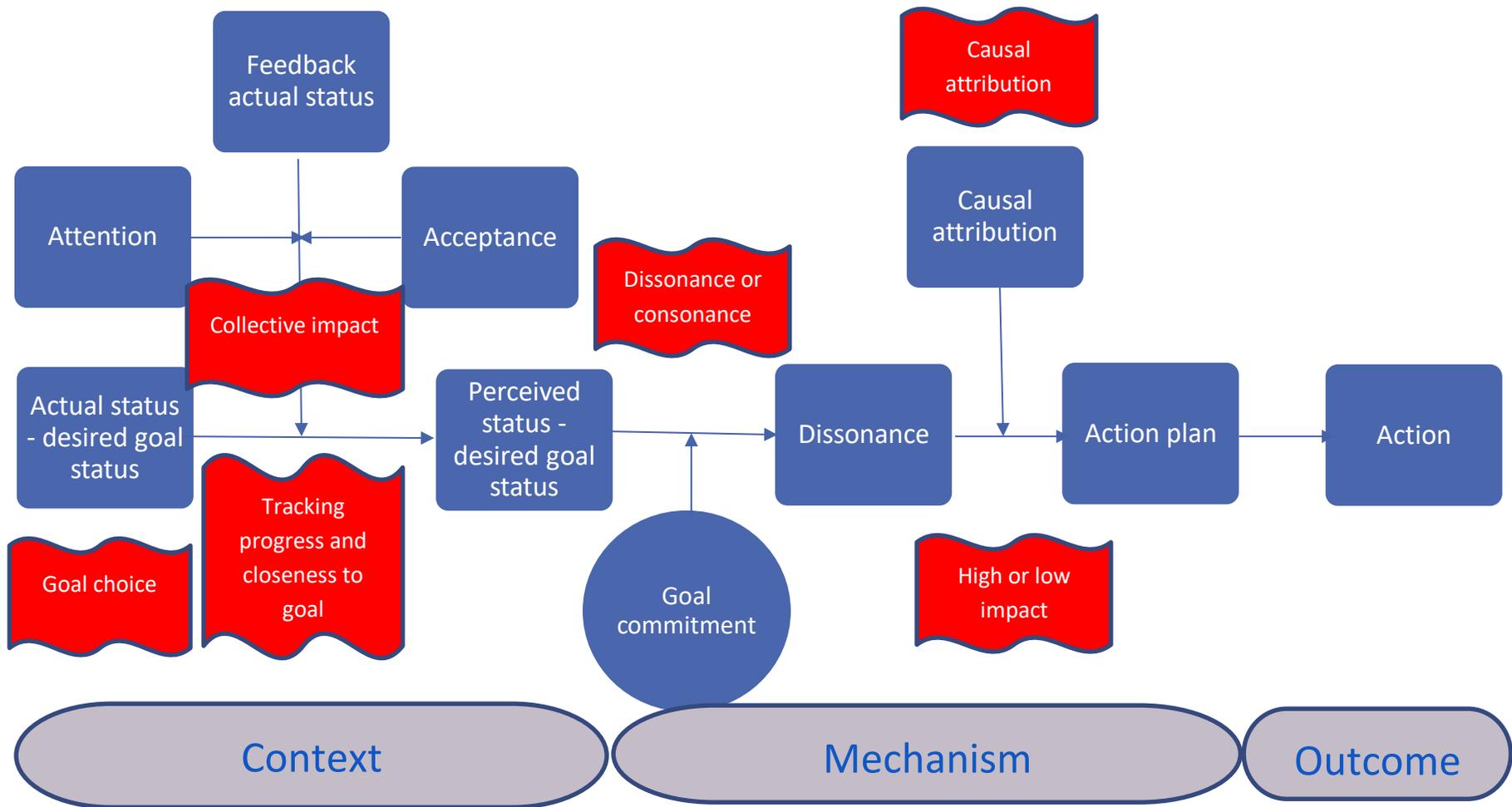


Figure 43: CFIT with CMOs projected onto the framework

## 8.4 Modification to theory

Pawson and Manzano-Santaella (2012) state that: *“realist evaluation is avowedly theory-driven; it searches for and refines explanations of programme effectiveness”* (page 178). With refining theory playing a large role in realist evaluation, the CFIT with CMOcs projected onto the framework (Figure 43) was developed from the original CFIT (Figure 6, page 47) to incorporate the additional elements identified by the CMO configurations. This framework, with all CFIT and CMOc elements was then able to be further developed to propose a middle range theory of feedback suitable for a patient population.

When the individual CMOcs were combined to form the cumulative CMOc, it was evident that were ‘critical points’ at which there was a potential to diverge towards two disparate positions: either success or failure of feedback to work as it is intended, providing positive outcomes (with or without improvement on the QuickDASH). These significant ‘critical points’ occurred at CMOc 2, CMOc 4 and CMOc 5, ‘tracking progress and closeness to goal’, ‘collective impact’ and ‘dissonance or consonance’ respectively. These ‘critical points’ which can effectively render the feedback process ineffective, are important elements to add to the initially proposed middle range theory, the CFIT.

Addition of these ‘critical point’ CMOcs to the original CFIT thus produced a final, modified middle range theory, which is posited by this thesis. As a newly developed theory it is suitable for further testing to clarify and refine its constituent parts. The modified CFIT, developed from the data in this study is outlined in Figure 44 as the final, refined theory and will be further explored within the discussion.

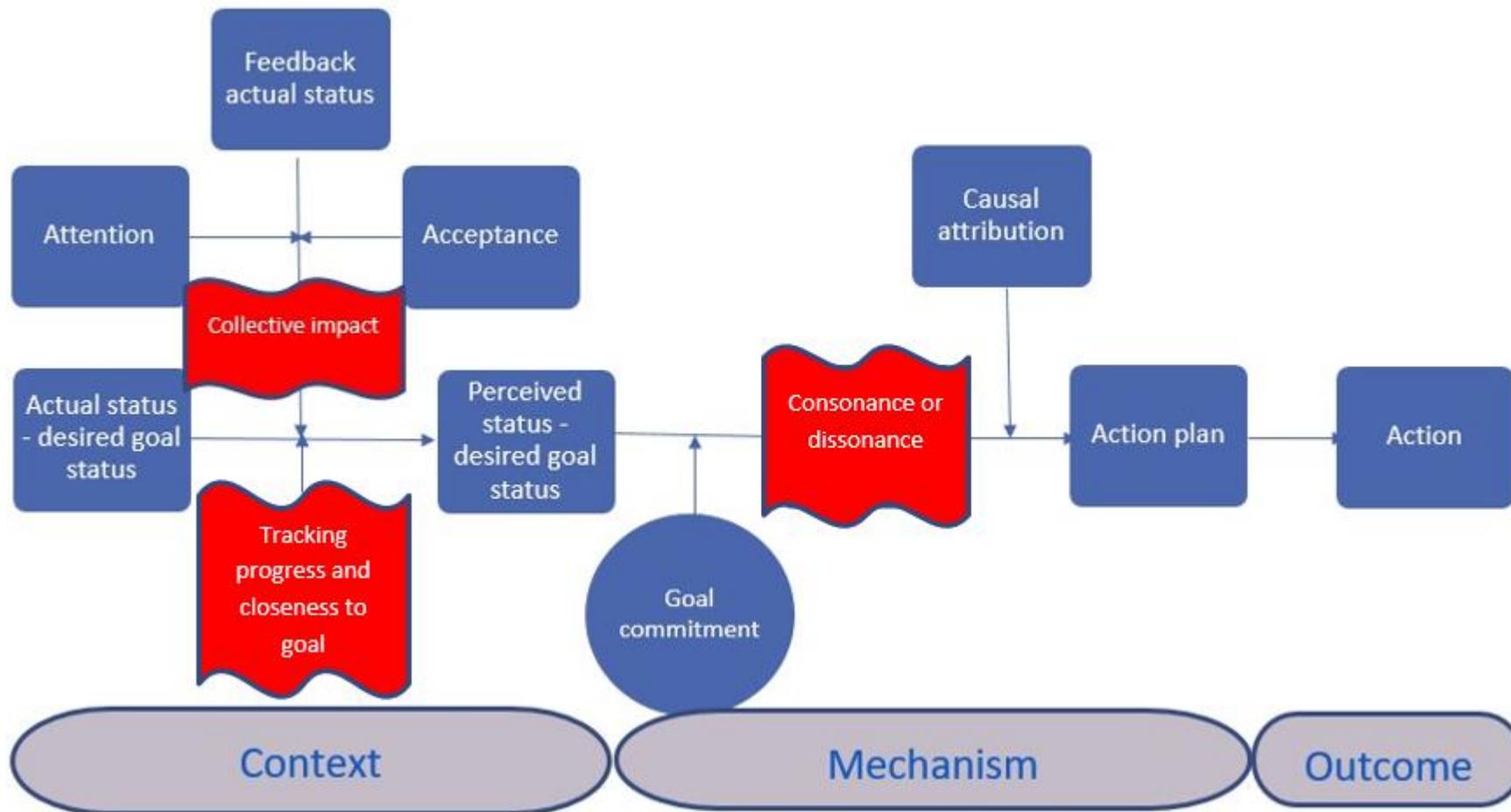


Figure 44: Modified CFIT with three CMOs added to the framework

## **Chapter 9: Discussion**

### **9.1 Summary of findings**

Prior to the main discussion, the findings are summarised to guide the direction and flavour of this chapter. This study concludes with a modification to the theory of feedback, positing a framework in which feedback ‘works’ with a patient population. The main additional elements to the CFIT to aid explanation of patient behaviour comprise: collective impact, tracking progress and closeness to goal and consonance or dissonance.

The study findings suggest PROMs feedback in this circumstance, used as an intervention, can promote positive impact in terms of management, as participants without positive clinical changes on the PROM could still exhibit a positive impact. This suggests feeding back PROMs as an intervention is more complex than just measuring clinical change and informing patients of their scores.

The literature review demonstrated the clinical changes, where evident, on the PROMs measurement with feedback as an intervention. This study’s findings, with a realist approach using semi-structured interviewing, contribute new insight, exposing the mechanisms underpinning patient behaviour in response to feedback of PROMs in circumstances of positive or negative impact.

### **9.2 Discussion introduction**

In this chapter the findings based on patients’ and physiotherapists’ experiences of Patient Reported Outcome Measures (PROMs) feedback are discussed to compare the findings to previous studies and address the over-arching question of ‘Outcome feedback in Physiotherapy: What works for whom in which circumstances?’, encompassing the four separate sub-questions:

1. What works for whom, in what circumstances?
2. What part does feedback of information (Routine Outcome Monitoring and other feedback types) play in the participants’ response (behaviour and actions)?

3. How are the processes shaped in terms of context-mechanism-outcome configurations?
4. How does the overarching context-mechanism-outcome configuration align with or enhance the CFIT?

The study was developed to unpack the underlying mechanisms underpinning behaviour in relation to feedback of PROMs, and the relation of them as Context-Mechanism-Outcome configurations to the Contextualised Feedback Intervention Theory (CFIT). This discussion chapter deliberates the extent to which these questions have been answered by the study. The findings produced captured numerous issues which are complex and inter-woven in patient experiences. Many of the discussion themes highlighted by the research were relevant to several of the research questions. As it is difficult to comment on mechanisms without background context and consequential outcomes, the issues are grouped into themes which encompass the research questions and will be answered within the thematic headings. Questions one to three will be addressed under the theme of **'The use of PROMs'** and **'The holistic use of PROMs feedback in clinical practice'** and question four is addressed under the theme of **'CFIT modification'**.

This discussion is then used to suggest recommendations for future practice and highlight issues that remain to be addressed by future research. The findings reported in this study expand further than answering the research questions, providing circumstances to review the use of PROMs in practice. The thesis presents an original view of the feedback of PROMs to patients, and a deeper understanding of some of the benefits and limitations of their use in practice. Inter-woven in PROMs feedback response is the therapist-patient relationship. This relationship, if fostered and built upon, can produce superior outcomes from the feedback process alone, even without significant PROMs improvement as it aids management and patient experience. This phenomenon is described as 'collective impact' within the thesis. This leads further discussion to consider what constitutes an 'outcome' for a patient, which can differ from clinical outcomes. The study supports the use of

PROMs and feedback by the therapist to the patient in physiotherapy, to build relationships and aid management, rather than just to measure clinical change as they were first designed.

Consideration will therefore be made to the use of PROMs in practice, and how they can be used for patient benefit to promote quality services in addition to providing healthcare departments with the statistical figures they require. As feedback does not seem as simple as just providing scores of improvement to patients, a more holistic approach is considered. Feedback should be utilised for patients *and* clinicians by way of promoting quality care through positive experiences rather than proof of effectiveness, whilst giving the opportunity to increase control, self-management and responsibility.

The discussion in this chapter will revisit the CFIT, discussing the changes made to the framework in the findings, which is described as the 'modified CFIT' (page 219) to incorporate the critical points which are essential to describe patient behaviour in relation to feedback. This discussion as a whole will therefore be used to assemble the key themes emerging from this realistic evaluation of the use of PROMs feedback.

Recommendations for practice will be discussed including education to undergraduates and post-graduates alike regarding the benefits of PROMs, in addition to the limitations, to ensure they are used for maximum benefit to bring about the changes at clinical level which are required to support a change in organisational culture.

The discussion concludes with ideas for further research to explore feedback of PROMs and behaviours exhibited in this study, to determine whether the same behaviours would be exhibited if self-monitoring of scores as feedback was compared with a clinician feeding back the scores and the long-term implications of PROMs feedback on re-referral to physiotherapy.

The conclusion (chapter 9) brings the thesis to completion by summarising the original contribution to knowledge and subsequent changes which would be of benefit to improve use of PROMs for patient benefit.

## **9.3 Comparison with empirical studies in the literature review**

### **9.3.1 Differences in findings**

The direct PROMs measures produced by this study were different from the type of outcome measure used in the empirical studies in the literature review. This study utilised the QuickDASH as a validated PROM, whereas the literature review revealed studies which used patient reported measures, but those as singular objective markers such as exercise frequency, exercise duration and rate of perceived exertion (Duncan & Pozehl, 2002; Duncan et al., 2011; Shakudo et al., 2011). The results, as objective measures, are therefore not directly comparable but can be discussed in terms of generalised differences and similarities.

Goal values appeared to be important within this study as a means of facilitating realistic outcomes of physiotherapy, but presented as less specific and more varied than the study carried out by Mahon et al. (1984), where goals constituted a specified level of protein and calorie intake for burns patients. The difference in this importance of goal presents as a difference in set goals and modified goals, with burns patients requiring specific calorie and protein intake in order to successfully heal and regenerate scar tissue. The study described by this thesis, where shoulder patients set a personalised goal to work towards, is more fluid and subjective, rather than the specific bodily requirements from a nutritional perspective. Goal attainment can confirm current behaviour provides the outcome the patient desires, and can be continued if the patient chooses, which is a common factor between both Mahon et al. (1984) and this study.

Shakudo et al. (2011) researched adherence as an alternative outcome of the feedback process. This thesis did not research adherence to an exercise regime and is therefore not comparable in terms of results. Shakudo et al. (2011) focused upon the outcomes of the provision of regular feedback to

participants in an exercise programme and found that it may be effective in improving adherence. The theoretical underpinnings of this improved adherence were not discussed within the article but may share similarities with the programme theories as CMOcs created within this PhD study. It is possible that the increased clinician-therapist time within Shakudo et al.'s (2011) study could have played a part in increasing the adherence via the same processes identified as cumulative CMOcs within this study, creating increased adherence via creating goals, tracking changes and collective impact of both clinician and patient working together. Geiger et al. (1992) concurs with Shakudo et al. (2011), suggesting a theoretical underpinning of feedback can be utilised as a reinforcement process, with reinforcement of behaviour in Shakudo et al.'s study focusing upon adherence.

This study was classified as mixed methods, as quantitative measures were collated, although the main focus was upon qualitative analysis with the additional use of descriptive statistics only. Nicolai et al. (2010b) chose a quantitative method by testing effectiveness using a randomised controlled trial (RCT) to compare three groups of participants receiving treatment with supervised exercise therapy (SET), supervised exercise therapy (SET) and feedback, and walking advice (WA). The study contributing to this thesis cannot be compared fully with this RCT due to the differences in approach, although findings can be discussed. Nicolai et al. (2010b) concluded patients following a SET program, with or without feedback, regained significantly more walking distance, with no statistically significant difference between the two groups, with SET found to be more effective than WA in improving walking distance. This suggests the larger improvement in the SET groups versus WA only is due to the supervised exercise therapy, with feedback playing no part. It can again be argued that an intervention such as SET creates an opportunity to build a stronger rapport, with more time spent between patient and therapist. This view concurs with CMOc 4, detailing collective impact to aid increased attention to the problem at hand, a better therapeutic relationship, mutual goals and a positive rapport and opportunity for trust to develop. With further study, combining the results from this thesis with a group without feedback, results could be directly compared, this is discussed later in the chapter, in section 9.19.5, 'Opportunities for further research' (page 259).

### **9.3.2 Common findings**

Feedback identified specific measurements of health to individuals, aiming to heighten awareness of their current status or response to an action. This was evident within this PhD study, and all those within the initial literature review (Duncan & Pozehl, 2002, 2003; Duncan et al., 2011; Geiger et al., 1992; Mahon et al., 1984; Nicolaï et al., 2010a; Nicolaï et al., 2010b; Rees et al., 2013; Shakudo et al., 2011).

Rees et al. (2013) differed from the remaining studies in the literature review, and this study, with their participants being the only asymptomatic group. The visual images of QuickDASH feedback used within this study, however, had a similar impact to that of the images showing retinopathy in the study by Rees et al. (2013), where both feedback types presented a practical strategy for clinicians to discuss management with patients.

Feedback facilitating management was also identified by Duncan and Pozehl (2003) and Duncan et al. (2011) where feedback was specifically suggested to facilitate individualised problem solving, facilitate self-regulation skills and support the relationship between clinician and patient, also evident within this PhD study. Individual problem solving and self-regulation (Duncan & Pozehl, 2003; Duncan et al., 2011) relate to this study, with feedback facilitating the management of participants' shoulder conditions within this study, which was considered a positive outcome of the feedback process.

## **9.4 Common experiences**

One focus of realistic evaluation is to identify commonalities amongst the population being studied in relation to the phenomena being observed. Although exact processes cannot be predicted, common experiences can be formed from study findings to assemble 'regularities' (Pawson & Tilley, 1997) and form partial truths about the phenomena (Pawson, 2013). Within this study, the phenomenon of feedback was under inquiry, aiming to understand the common experience of positive or negative outcomes.

#### **9.4.1 Contextual conditions for a positive or negative outcome of feedback**

Previous research concerning feedback with clinicians from Sapyta et al. (2005) suggests an individual is likely to experience a positive outcome from feedback and change their behaviour if they have an important goal to accomplish, they notice a significant discrepancy between the goal and their current status regarding the goal, and they believe they can reduce the discrepancy. Aspects of this viewpoint were evident in the patient population within this study. Firstly, all 25 patient participants who completed the interview stage and consented for their data to be used, had an important goal they wanted to accomplish. This was evident as each patient independently sought treatment due to wanting to change their shoulder symptoms and dysfunction, and also each participant identified a goal they wanted to achieve in their interview. CMOcs formulated from the results of this study gave further depth of information and insight into discrepancy status. The following specific occurrences within the participant group can be used to describe cases when feedback does not work as intended, and produces a negative impact and overall outcome:

- Low impact of the shoulder condition and participant too close to their goal to change behaviour therefore disengages with feedback
  - Example participant 17  
(CMOc 2: Tracking changes and closeness to goal and CMOc 3: Low impact)
- High impact of shoulder condition and participant too far from goal to change behaviour and disengages with feedback
  - Participant 15  
(CMOc 2: Tracking changes and closeness to goal and CMOc 3: High impact)
- Causal attribution out of participant control and feel they can not reduce the discrepancy
  - Participant 04  
(CMOc 6: Causal attribution)

Conclusions from Sapyta et al. (2005) in relation to positive outcomes of feedback are also congruent with the patient population in this study. Participants striving towards an important and achievable goal, confirmed with progress accurately tracked by the QuickDASH feedback, presented within multiple participant cases (example participants: 01, 02, 18, 21, 26):

- The goal setting process, if achievable and accurately tracked by the QuickDASH, encouraged therapist and patient interaction regarding the shoulder problem, enhancing management and control, thus producing a positive impact and overall outcome of the QuickDASH feedback.

- Participants 01,02,18,21,26

(CMOc 1: Goal choice, CMOc 2: Tracking changes and closeness to goal, CMOc 4: Collective impact, CMOc 5: Consonance, CMOc 6: Causal attribution)

Feedback appears to function successfully in this study when multiple positive mechanisms are occurring, with one outcome of a CMOc triggering another, allowing multiple positive CMOcs to occur, resulting in a positive impact and outcome of feedback.

CMOc 4 (collective impact) is present in the positive impact cases, but not in the negative impact cases, and is therefore a pivotal CMOc which can change the chain of events and eventual outcome. Identification of this as a common experience indicates further discussion to determine why it is such a critical point in the feedback process.

## 9.5 The patient-therapist relationship

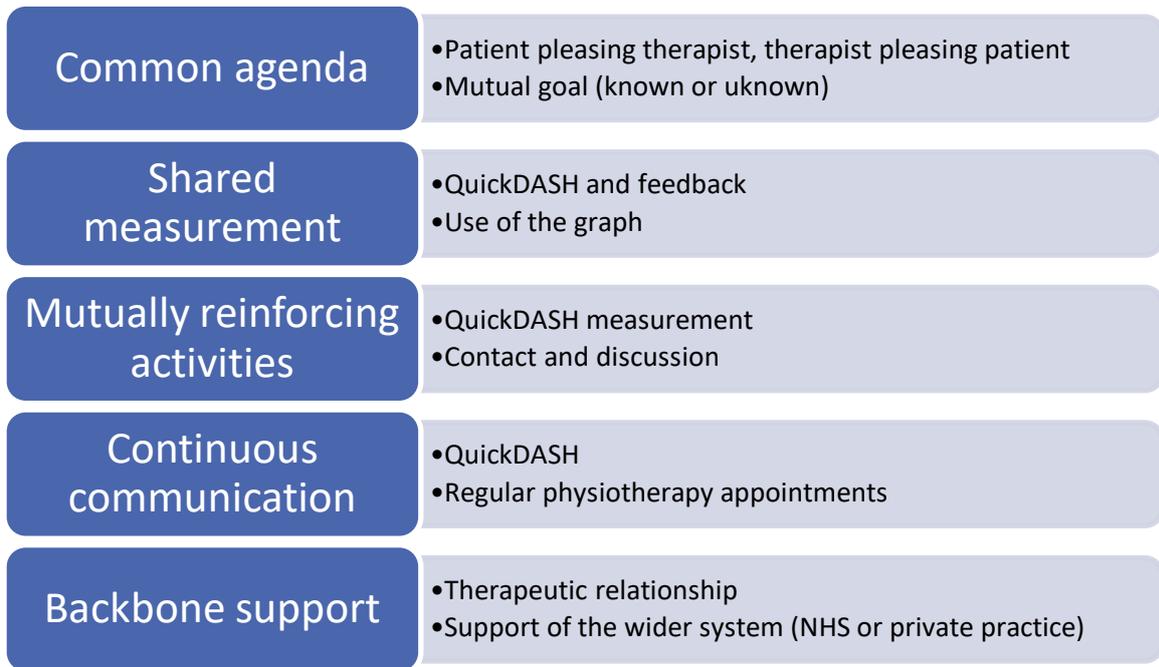
Patients and therapists referred to the *patient-therapist relationship* repeatedly within the interviews. Words and phrases participants used to describe the relationship often described collaborative working: “*integration... controlled... discussed*” (participant 18), “*a motivator... between us it’s obviously working*” (participant 19).

### **9.5.1 The patient therapist relationship as a stratified reality**

At the patient level, it is important to consider the ontological depth of the relationship. Our stratified reality, even when hierarchically ordered, is still limited, suggesting that we can only know what we know based on our constructed realities of how different people construct different meanings of reality (Jagosh, 2017). Reality is therefore different for each single person based on emergence, where emergence assumes society as a separate ontological entity, emerging from, but separate to the activities of individuals (Mingers, 2006), and the impact of emergence upon our understanding of experiences, events, entities, and causes (Elder-Vass, 2004).

In considering the ontological depth of the patient-therapist relationship it is important to consider patients' philosophy of values, also known as axiology. The value patients hold in their physiotherapist and the relationship they foster appears to be pertinent. Observing from the patient perspective, in one exploratory doctoral study, it was acknowledged that most patients hold their physiotherapist in high regard and value their professional judgement (Sexton, 2011). Observing from the physiotherapists' perspective, previous research from Gyllensten et al. (1999) found 'interaction' to be a key factor which was important to physiotherapists to feel they could foster a therapeutic relationship. Within the key factor of interaction, the therapeutic process was highlighted (Gyllensten et al., 1999).

Within a business domain it is well researched that successful collaborations are forged when all parties of the partnership understand and work for mutual benefit, not just individual benefit (Lasher, Ives, & Jarvenpaa, 1991). Collective impact as a concept also relies upon the presence of this partnership, expanding to the following five factors (Hanleybrown et al., 2012): common agenda, shared measurement, mutually reinforcing activities, continuous communication and backbone support. Within this study these five factors were met in the following way (Figure 45):



**Figure 45: The five elements required for collective impact and the demonstration of how each element is met within this study**

### 9.5.2 Communication and relationships

In 2014, Greenhalgh et al. set out a protocol for a realist synthesis exploring the functionality and feedback of PROMs data to describe how PROMs data are collated, interpreted and utilised. Findings reported in 2017 highlighted the importance of considering how PROMs feedback in the care of individual patients affects not only the information-exchange and decision-making functions of the consultation but also the relationship-building function. Greenhalgh et al. (2017) also proposed that PROMs function more as a tool to support patients in raising issues with clinicians than they do in substantially changing clinicians' communication practices with patients. This study is in agreement with Greenhalgh et al. (2017) as findings suggest PROMs feedback can encourage discussion about patient-centred problems and can promote individual treatment and management.

It is accepted that the quality of communication between a patient and their chosen clinician is a determinant in experiencing a positive impact from treatment (Carlier et al., 2012; Priebe et al., 2007). The results from this study concur that communication is important and feedback provided

by the physiotherapist can be one intervention that can direct conversations towards a common end goal between a patient and their physiotherapist (Norcross, 2011).

### **9.5.3 Importance of the feedback source**

Feedback has previously been found to be accepted if it comes from a source that has credibility and has personal relevance to the receiver (Sapyta et al., 2005). Patients are the source of their own measurement in the case of PROMs, and clinicians primarily value the patient's perspective on progress (de Jong, 2014). Utilising the therapist in feeding back this information contributes to a more holistic conversation, promoting a two-way working relationship, and influencing patient actions after receiving the feedback.

Ontologically, the patient-therapist relationship is not just a shallow, perceived reality as it holds more depth than 'empirical' reality alone (where occurrences are only observable or perceived by an individual). CMOc 4 (collective impact) describes the real depth, uncovering generative mechanisms occurring independently of the mind and social influence. Positive impact from feedback was evident in many participants, all of which detailed their therapeutic relationship, a view also supported by the physiotherapists' accounts. A mutual process presented, where patients, in addition to improving their condition, wanted to please their therapist by showing improvement, and therapists wanted to help and please their patients.

## **9.6 The use of PROMs**

### ***9.6.1.1 How PROMs are designed and used***

Clinicians have developed outcome measures to guide and inform their clinical practice, which have provided important and relevant information about the impact of health care. The King's Fund suggest that whilst PROMs are useful, they typically fail to inform wider questions crucial to measuring the overall output and quality of the NHS (Devlin & Appleby, 2010). This suggests that modification and development of PROMs is required to reflect the request for suitable measurement of output and quality.

### **9.6.1.2 PROMs as a patient experience improvement strategy**

A qualitative study was conducted in a psychotherapy service by Unsworth et al. (2012), providing visual feedback of PROMs to patients and clinicians. The study concluded that clients appeared happier when routine outcome measurement was used, confirming an enhanced patient experience. Specific comments outlined interest in the visual representation of their feelings and progress in addition to appreciation of the therapists' work with them, highlighting the importance of the patient-therapist relationship. This PhD study, in a physical health capacity, agrees with and expands upon the findings from Unsworth et al. (2012) in a mental health capacity. The PROM feedback works in the way it is intended: to create positive impacts and a positive overall outcome, but via enhancement of patient experience for participants in physiotherapy who utilise feedback tracking as a positive experience in conjunction with their therapist to produce a collective impact, demonstrating consonance with the feedback process.

### **9.6.1.3 PROMs as a patient experience measure**

The study expands on the function of a PROM which has previously been described as a quality measure (Benbassat & Taragin, 2000; Boyce & Browne, 2015; Boyce et al., 2014). The clinical improvements, indicated by change of a PROMs score by comparison with the Minimal Clinically Important Difference (MCID), constitute the clinical effectiveness. If the MCID is met for the majority of a patient population, this can be used as evidence of the provision of quality healthcare services, as improvements can be demonstrated for patients (Donetto et al., 2014).

With a disease specific PROM such as the QuickDASH it is assumed that to make a minimal clinically important difference, a change of at least -8.0 must occur (Mintken et al., 2009). This perception of improvement has long been linked to 'feedback', described by Bandura and Cervone (1983) as information about the quality of performance and how it might be improved.

Of the 25 patient participants completing the study process, QuickDASH score changes were rated in line with suggestions made in a study by Polson et al. (2010) and were reported as follows: 11

participants no change, two minimally improved, eight much improved, four very much improved. This suggests that 44% of participants did not improve with treatment. Considering an alternative marker, the Minimal Clinical Important Difference as an improvement on the QuickDASH is posited to be between 8 points (Mintken et al., 2009) and 11 points (Polson et al., 2010). Nine participants did not meet this level of change, suggesting a slightly lower percentage of 36% failing to improve.

The result from this study, if analysed on outcome measure scores alone, would suggest improvement was only observed for between 56% and 64% of patients. The qualitative analysis in this study broadens the depth of understanding concealed behind the figures. Although many participants did not show improvement based on the QuickDASH, using the disease-specific PROM as a feedback tool as part of treatment encouraged an outcome of supportive management of the participants as individuals and a collective impact of working together.

The QuickDASH data alone is suggestive of poor quality of treatment and poor clinical effectiveness for this group of individuals. This view, however, only illuminates one aspect of the patient story. For those who did not improve, but felt they had improved to be able to manage their shoulder dysfunction better, the PROM did not convey this experience. This was evident in four of the nine participants who did not meet the MCID (participants 01, 07, 09 and 18). The QuickDASH PROM, like other PROMs, presented in this study as measuring overt clinical differences for all participants, but was not able to identify the patient experience of treatment for those not meeting the MCID and thus their quality of treatment or quality of experience.

PROMs, in this instance the QuickDASH, therefore have limitations in their usage.

#### **9.6.1.4 Patient Reported Experience Measures (PREMs)**

PREMs could be viewed as a potential method to measure patient experiences and outcomes concurrently. The national PROMs audit recently extended to collating PREMs (in addition to PROMs) for hip replacement, knee replacement and groin hernia repair, aiming to identify if there were relationships between responses (Black, Varaganum, & Hutchings, 2014).

Black et al. (2014) suggested further study was indicated to determine if an improvement in clinician communication was associated with better PROMs scores as the initial results were unclear. This PhD study suggests that the participants who benefitted from a positive patient-therapist relationship, fostering rapport and patient-centred management, did not necessarily have improved PROMs scores. This indicates that PROMs as a clinical outcome in this study present as a stand-alone measure, often unrelated to a positive patient-therapist experience. This concurs with Black et al. (2014) and the initial suggestion that assessment of experience alone is insufficient for measuring quality of care, recommending outcome assessments such as PROMs as additional tools.

## **9.7 Quality measures**

With quality care an essential requirement in NHS services, ability to produce evidence of quality is fundamental. Effective care and well managed care can contribute to quality services. This study confirms that effective care in terms of clinical improvement can be measured by PROMs but suggests that well managed care cannot.

Quality care can present in the form of a positive patient experience, which is not measured by PROMs. As PREMs measure patient experience separately and there are no strong correlations between PROMs and PREMs in research studies, it leaves clinicians to fill in multiple outcomes, aiming to piece together the standard of the quality of care. Each single verified measure (PROM or PREM), contributes information regarding quality, but is only one part of a large and complicated jigsaw puzzle. Complex social systems are difficult to piece together, and this study identifies the benefit of mixed methods studies with a realist evaluation focus to unpack the mechanisms, in this instance, mechanisms occurring behind PROMs use in clinical practice.

With holistic quality measurement tools lacking in practice, this affects NHS departments' ability to identify quality care or identify reduced care, indicating the need for change. Patient Centred Outcome Measures (PCOMs) as a new approach have been introduced, aiming to put patients, carers and families at the heart of deciding which goals are most valuable for individuals in

developing the PCOMs. This ensures the outcome measures reflect what is important to patients themselves rather than clinicians, but will not necessarily also illuminate the effectiveness of treatments. There is therefore no single measure which provides both patients and clinicians with the information they require.

This suggests the need for a single patient reported measure, able to assess all three factors together of management, outcomes *and* experience, all contributing to quality care. Using qualitative interviews and PROMs is an ideal mixed method combination to illuminate factors of quality care, effective patient management in addition to clinical effectiveness. Interviews, however, are time-consuming and as a global measure would not be suitable for widespread NHS use. An alternative for practice is required which is quick and easy to use to determine service quality, to include elements to measure safety, patient management and experience, and clinical effectiveness (Donabedian, 1988; Donetto et al., 2014).

There is therefore an opportunity for further development of PROMs, aiming to combine factors such as pain, dysfunction and quality of life related to outcomes, a feeling of safety whilst undergoing treatment, patient-centred management *and* overall experience. This would ensure easier collection of patient data across all fields of quality, which could be combined or separated for statistical analysis. A suggested direction for patient reported measurement is formulation of a combined measurement tool to determine a core-outcome set, to include factors which are important to patients, but which also underpin quality medical care.

## **9.8 What is the desired outcome of PROMs feedback?**

Comparing this study with the original introduction section surrounding outcomes (section 1.3: Key issues in practice, page 20), this research questions what an outcome from PROMs feedback is, traditionally this has been based upon clinical improvement in PROMs use. Some outcomes, such as life and death, are straightforward to measure, however some are not so clearly defined. Patient

attitudes and satisfactions, social restoration and physical disability and rehabilitation are complex and outcomes are more challenging to clarify (Donabedian, 2005).

### **9.8.1 PROMs and feedback as a quality indicator**

The QuickDASH PROM and feedback did not present as a quality indicator. The QuickDASH as a PROM encouraged quality management of a patient's shoulder condition, which was not linked to an improvement in the outcome measure itself. This builds on Donabedian's quality framework (1988), suggesting that through the interpersonal exchange (in this study, feedback), the patient communicates information necessary for arriving at a diagnosis, as well as preferences necessary for selecting the most appropriate methods of care and management.

The findings in this study present a case to support PROMs use specifically for patient management. Use of PROMs in practice for this gain is also supported by the Chartered Society of Physiotherapy to ensure meeting the CSP quality standard for 'working in partnership', where goals, expectations, preferences, capacity and needs of patients form the focus of all activity (Chartered Society of Physiotherapy, 2013).

The findings from this study concur with Greenhalgh et al. (2017), confirming that an individualised PROM fed back to patients, such as the QuickDASH, can be a useful assessment and treatment tool, but is not useful as an indicator of service quality. 'Quality' healthcare treatment is thus not always concurrent with improvement in outcome measures. Within this study of patients with shoulder impingement syndrome, participants utilised the feedback of the QuickDASH to help track their progress and closeness to their goal (CMOc 2) showing concurrence with the QuickDASH (CMOc 5) and utilised the directed time with their therapist to encourage achievement of their mutual goal (Collective impact CMOc 4). This could be considered as 'quality' healthcare as the intervention helps the patient communicate their needs for management (Donabedian, 1988), with individualised management of goals, expectations, preferences, capacity and needs (Chartered Society of Physiotherapy, 2013). This was evident for participants in this study with both improvement on the

QuickDASH and those without improvement, confirming with this group of study participants, quality care was not a function of outcome measure improvement alone.

## **9.9 The holistic use of PROMs feedback in clinical practice**

As previously discussed, the use of the PROMs and feedback in this study improved management for some patients without any clinical improvement and thus was used as an holistic tool, rather than just a measure of clinical change.

### **9.9.1 Supporting patient-centred care**

The use of feedback is complex, with multiple processes impacting on patients. 'Impact' presents as a possible preferential phrase to describe patient responses to PROMs feedback rather than 'outcomes'. Impact can refer to a much broader effect, inclusive of other factors constituting what matters to patients in terms of quality and effect on their individual lives, which can be ongoing and changeable, whereas outcome describes a more concrete and final end-point.

Holistically, impact aims to describe changes to each person as a whole, and individually, to create a more effective, cumulative process to build upon, rather than looking at the PROMs measure as a stand-alone intervention producing only outcomes.

The PROMs feedback aided communication, discussion and identification of patient-based problems, promoting patient-centred care. In focusing on the needs of the individual rather than simply on the provision of advice; self-management can be enhanced (Klaber Moffett, 2002). PROMs feedback, if a positive impact was evident, allowed patient control in self-management and responsibility for their condition.

With current policy supporting patient-centred care but also patient management of conditions to prevent re-admission, re-referral or reoccurrence, the use of PROMs in this way may help to reduce re-referral to physiotherapy services for the patients who benefit from a positive impact of PROMs feedback as they feel they have more control in management of their shoulder problem.

Alternatively, the converse may be true. If the patient feels they benefited from the support and feedback of the PROMs from the therapist, they may continue to re-access the service for the same condition to achieve reassurance. The longer-term impact of PROMs is unknown and requires a longitudinal study to determine whether those who find feedback of PROMs useful re-access the service more or less than patients who do not receive feedback, and further qualitative study to determine why and in what circumstances certain individuals return to physiotherapy services.

### **9.9.2 Holistic approach to quality**

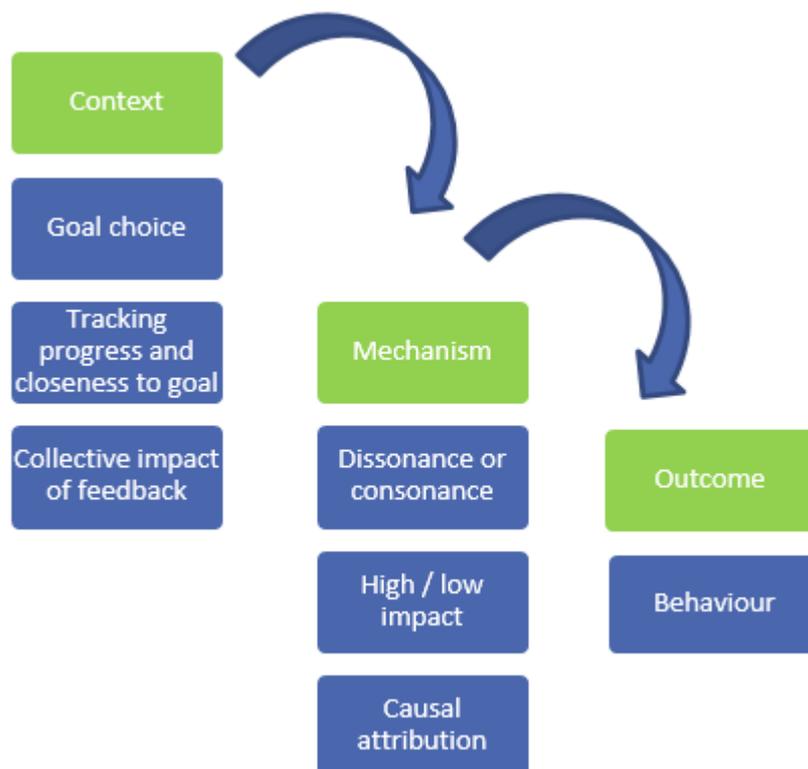
If PROMs can be utilised holistically to promote quality, a similar standpoint in regard to patient care must be utilised. Holistic approaches to safety, management, experience and efficacy of treatment can then promote an overall quality of service, which can be measured on all aspects. Holistic approaches must be championed by the therapist, in which the PROM as a tool can promote discussion of the outside influences of a patient's circumstances which affect their condition in addition to the clinical situation which is often the main focus of a consultation.

## 9.10 Answering the research questions

Research questions one to three can be addressed by extending the discussion regarding the holistic approach. The three questions revisited are:

1. 'What works for whom, in what circumstances?'
2. 'What part does feedback of information (ROM and other feedback types) play in the participants' response (behaviour and actions)?'
3. How are the processes shaped in terms of context-mechanism-outcome configurations?'

The cumulative CMOc process is revisited to answer these questions and is outlined in Figure 46.



**Figure 46: The cumulative CMOc developed from participant data**

The cumulative process indicates an holistic approach is needed as many differing factors interact to create context for multiple process occurring in mechanisms to produce behavioural outcomes.

Cumulative context, mechanism and outcome will be discussed in turn to explore the processes occurring in each section.

#### **9.10.1.1 *The cumulative CMOC***

The cumulative process begins with the context of the patient's individual goal and the provision of feedback being made available by the therapist, to create a conducive environment for feedback to work in the way it is intended. A patient begins by making a goal choice (CMOC1). The inclusion of external feedback (new information) using the QuickDASH then gives an added opportunity for tracking progress and closeness to goal (CMOC2) in addition to a participant's internal feedback (existing information). With both physiotherapist and patient focusing on the same outcome of improving the goal, feedback of new information in the form of the repeated QuickDASH influences the relationship between the physiotherapist and the patient receiving feedback of the new information (CMOC 4: Collective impact).

The cumulative mechanism composes reasoning with the QuickDASH resources, deciding on dissonance or consonance with the feedback intervention (CMOC 5) coupled with how much impact the shoulder condition has on an individual's day-to-day life (CMOC 3: Low or high impact). The final part of the cumulative mechanism focuses on whether the patient feels they have control over their condition or whether it is attributable to an external source despite their ongoing treatment.

Information feedback using the QuickDASH PROM in this study appeared to produce a positive outcome for some patients, showing behaviour of engagement with the feedback process but a negative impact for others exhibited by disengagement in treatment and the feedback process for others.

Detailed interpreting of the CMOC processes in the previous summary examples (negative impact: Figure 40, page 211 and positive impact: Figure 41, page 212) illustrate the links from one CMOC to the next. The concept of the cumulative CMOC is supported by the summary examples, illustrating an outcome from one CMOC can directly affect the subsequent CMOC and so forth for further

CMOCs (Jagosh et al., 2015), changing the eventual outcome of the cumulative effect (Figure 46).

The links between CMOCs present as 'ripple effects' (Jagosh et al., 2015) serving to provide an explanatory illustration of what mechanisms are at play when CMOCs have differing outcomes.

Feedback as a resource will always have an influence on a patient's mechanism of reasoning to generate an impact, whether positive or negative. In a clinical setting, the desired outcome is a positive impact, enabling rather than inhibiting feedback working in the way it is intended according to the Contextualised Feedback Intervention Theory (CFIT).

To summarise, the three research questions will be answered with a summary statement:

***9.10.1.2 Question 1: What works for whom, in what circumstances?***

Feedback works in the way it is intended (to create a positive impact and overall positive outcome) for participants in physiotherapy who utilise feedback tracking as a positive patient experience, in conjunction with their therapist, to produce a collective impact, demonstrating consonance with the feedback process and an overall perception of condition management.

***9.10.1.3 Question 2: What part does feedback of information (ROM and other feedback types) play in the participants' response (behaviour and actions)?***

Feedback has been shown to have distinct points where it affects participant response. Firstly, feedback from the PROM tracks progress and can show they are progressing well or not progressing with treatment, which can initiate a positive or negative experience. Secondly, the PROM as external feedback (new information) is directly comparable with a patient's own internal feedback (known information). If there is repeated dissonance between the new information and the known information, the feedback process can also have a negative impact. If there is consonance, the feedback process is more likely to be positive.

#### ***9.10.1.4 Question 3, 'How are the processes shaped in terms of context-mechanism-outcome configurations?'***

The processes which have been identified in the six CMOcs shape a much larger process when they are combined together in a 'combined ripple effect' presented as a cumulative CMOc in this study (Figure 46, page 238). Goal choice (CMOc 1), tracking progress and closeness to goal (CMOc 2) and collective impact of feedback (CMOc 4) combine to provide the context for the next group of CMOcs to fire: dissonance or consonance (CMOc 5), high or low impact (CMOc 3) and causal attribution (CMOc 6), with the overall outcome of response being patient behaviour.

### **9.11 Feedback**

Feedback using PROMs data does not present as a simple cycle of output returned as input. It also does not present as completely concordant with the CFIT as feedback of PROMs to patients (rather than clinicians in the original CFIT) presented as a more complex system.

#### ***9.11.1.1 How does feedback 'work'?***

The PROMs feedback is suggested to function in this study by identifying a patient's clinical change, presenting 'new' information, encouraging awareness of their current score (which may show improvement). Many study participants already knew their clinical status, commenting the PROM feedback only confirmed their progress or lack of it, rather than informing them of something of which they were unaware. It is therefore not always *new* information being fed back to the patient, but can function as confirmation of status. Feedback of PROMs for these participants still produced a positive impact. It can therefore be suggested that PROMs feedback functions positively when it helps patients' perception of their condition and how they can manage it, and is less focused on informing patients of clinical change regarding their injury or condition.

The PROMs feedback as 'hard' concrete scores (to track progress and closeness to goal: CMOc 2) may not necessarily be accepted by a patient and only exposes a fraction of the potential for feedback to work in the way it is intended. The addition of the therapist feeding back the

information (CMOc 4: Collective impact) gives the opportunity for an holistic approach to be taken, where the patient is seen as an individual, and treated as such, giving the potential for feedback to extend further than a clinical outcome indicator by acting as a management system, to aid patient discussion, challenge perception and understanding of their condition and keep lines of communication open, focused on the individual problems each patient faces.

Despite the positive impact of focusing on the patient at the heart of their care, it may be evident that causal attribution is outside of the control of the physiotherapist and the patient when discussing the wider context of the patient's life circumstances. In this scenario, looking holistically, the 'hard' scores may appear different from patient perception, when outside influences are taken into account which causes dissonance with the process (CMOc 5). In these instances, feedback of scores, even if outlining a successful recovery may not be accepted by the patient as they are not reflective of their wider influences. This was evident for participant 04, who despite an impressive recovery on the QuickDASH scores felt his duties at work would put him "*back to square one*" if the QuickDASH score was inaccurate and showing "*a false reading or something like that*".

Feedback must therefore be presented according to individual patient needs, not as a didactic part of treatment. Patients living with their condition are experts of their own health status, and experts of the tasks they need to complete on a daily basis. With PROMs feedback, discussion can be encouraged to help patients make informed choices and take responsibility for their health. It can be argued that the wider social context is more complex in the patient population in comparison with the CFIT, initially formulated for clinicians receiving feedback.

### **9.12 CFIT modification**

The CFIT was chosen as the middle range theory to shape the study methods and compare results against. This section will respond to study research question four: 'How does the overarching context-mechanism-outcome configuration align with or enhance the CFIT?'

**9.12.1.1 Question 4: 'How does the overarching context-mechanism-outcome configuration align with or enhance the CFIT?'**

In answer to this question, the CMOcs could be aligned with the CFIT, which served as a framework to build upon. As the CFIT was originally designed for use with clinicians, its use within a patient population was unknown and the study findings were used to enhance the framework to develop a 'modified CFIT' by addition of the wider patient context and additional mechanisms at play.

Similarities were found within CMOcs 1 (goal choice), 5 (dissonance) and 6 (causal attribution), which matched elements within the original CFIT. Additional elements which presented with the patient population in this study encompassed issues which revolved around the physical issues of their shoulder problem, the patients' wider social influences and the interpersonal impact of the patient-therapist relationship which presented as new phenomena to the population for which the original CFIT was developed. As these elements would not present in a clinician feedback scenario, it was a logical step to adapt the framework to include the additional phenomena, presented as a new and modified framework.

In developing the original CFIT, it was important to place the CMOcs from this study in the correct position to determine where they were placed on the CFIT to determine whether the CMOcs aligned or enhanced the CFIT to answer question four. A reminder of the CMOcs projected onto the CFIT is outlined in Figure 47 (page 244).

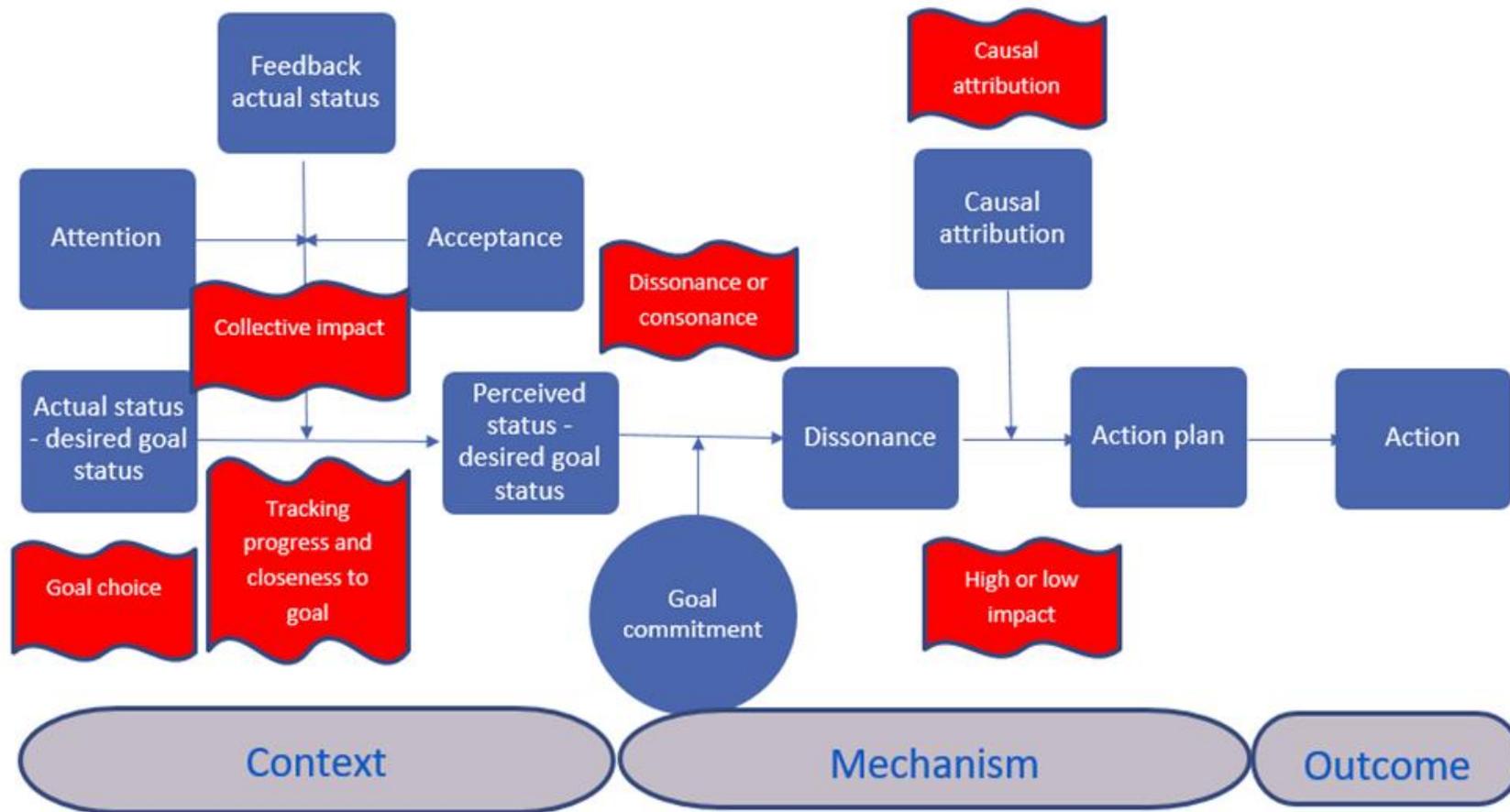


Figure 47: The CFIT and projection of CMOs on the theoretical framework

### **9.12.2 Modified CFIT as a middle range theory**

The CFIT required modification to accommodate explanation of patient behaviour in relation to feedback. The addition of six CMOcs as an explanatory theoretical framework for this study, revisited in Figure 47, were suitable for this thesis as an explanatory diagram to show the 'shape' of the results in relation to current theory, but to be further applied and tested, the theory needed a simpler framework to allow direct utility for a specific problem in a specific setting (Sussman, 2000).

Pawson (2000) describes middle range theory within realism to offer a research strategy of the appropriate form and scope to lead and to organise empirical inquiry. With future thought for further theory testing in empirical studies, a modified CFIT for patient use was developed. It was decided that the six CMOcs projected onto the CFIT presented a very specific framework of feedback tailored individually to this study. To make the theory generalisable and suitable for re-testing, the pertinent 'critical points' as the most distinctive features of this study were added to determine the specific points in the CFIT at which feedback was facilitated or hindered in its effectiveness. Figure 48, as the final modified CFIT, includes the addition of CMOc 2 (tracking progress and closeness to goal), CMOc 4 (collective impact of feedback) and CMOc 5 (consonance or dissonance) and presents the modified CFIT developed from this study as a middle range theory and a reusable conceptual platform, which is further discussed on page 247.

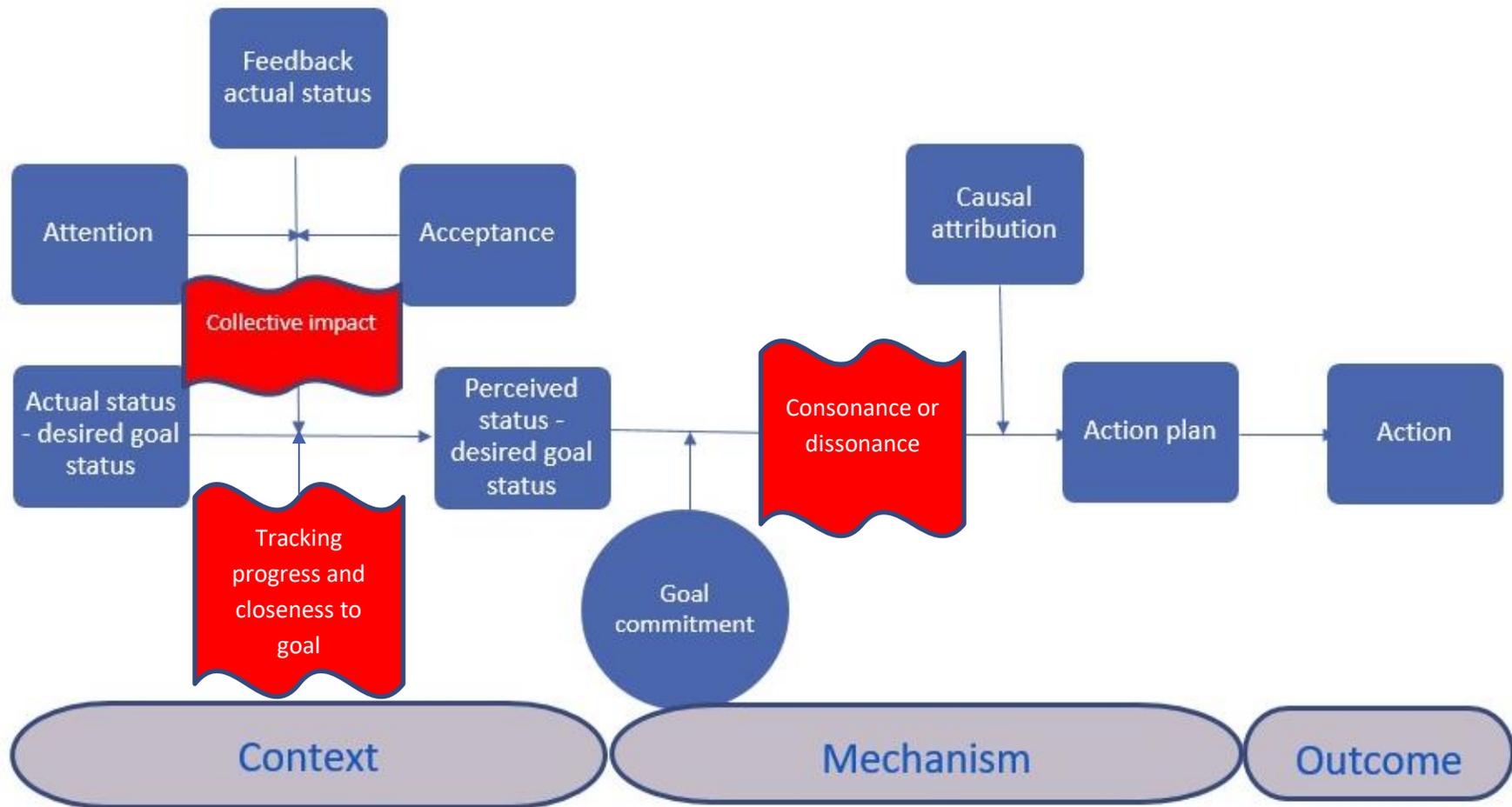


Figure 48: The modified CFIT, inclusive of the three 'critical' points found within this study

### **9.12.3 Contribution to feedback theory**

Theories vary in the extent to which they have been conceptually developed and empirically tested (McAlister, Perry, & Parcel, 2008) and theories are interpreted by organisations and individuals in different ways depending on the stage of development within the field of study (Bandura, 1986). This thesis develops feedback theory, making a contribution to the field of patient feedback by presenting evidence for the modified CFIT, for use with a patient population, to aid explanation and understanding of patient behaviour in a clinical setting. The modified CFIT as a middle range theory is suitable for development through further research with alternative patient populations, allowing further refinement to its constituent elements for patient use.

### **9.13 Generalisation and the use of re-useable conceptual platforms**

Generalisability describes the extent to which study findings can be applied to settings other than that in which they were originally tested (Kukull & Ganguli, 2012). Externally, generalisation can be applied if a study describes the true state of affairs outside its own setting as well as the setting under study. This study describes what is occurring in only one setting, and in line with a realist approach, can only produce partial truths in its reporting (Jagosh, 2017). Although this method choice reduces generalisability, it can be argued that a framework is available in the form of a 're-usable conceptual platform' which involves the principle of recycling a generic structure and applying it to a different domain (Pawson, 2013).

The CMOc frameworks as singular elements and the modified CFIT constructed within this study lend themselves to be further tested as programme theories (either singularly or cumulatively) to confirm, deny or modify their structure. The CMOcs could be tested using a realist evaluation approach in an alternative health setting to explore whether the processes occurring are reproduced in different populations who would benefit from the PROMs as a tool to facilitate communication about patient-based problems and facilitate management.

An example of a service which could potentially benefit from PROMs feedback is community physiotherapy, where patients with reduced mobility are treated at home, aiming to increase their

function and manage their mobility to support patients in their choice of residence, whether in their own home, with or without carers, supported living or in a residential home. Difficult conversations about management are often required and future study would illuminate whether PROMs feedback has a positive impact within alternative, complex social systems.

This proposed future research could strengthen the CMOcs which have been proposed as both programme theories within this study *and* as a middle range theory in the form of the CFIT. With further testing and refining, trust in the validity of the additional CFIT elements can be increased, therefore rendering the theory more generalisable. This pertinent point concurs with Pawson (2016), who debated generalisability and transferability in his plenary session at the 2nd International Conference on Realist Evaluation and Synthesis: Advancing Principles, Strengthening Practice. Pawson concluded that collaborative research such as this can build programme theory and may help contribute in the future to 'mechanism banks' which may help the realist research community to provide re-usable conceptual platforms for testing across domains.

#### **9.14 Contribution to realism: The cumulative CMOc**

This study confirms the complexities of patients' social systems and illuminates the value of realism as an approach to uncover the processes which may otherwise remain concealed. The cumulative CMOc and the modified CFIT support the view that singular CMOcs do not tend to occur in isolation, and more usually occur in multiples when describing complex behavioural systems (Porter, 2015).

With human agency involved in any decision making, there is wide variety of responses due to individuals exercising their agency by making sense of their situations and what they become through the continued exercise of self-influence (Bandura, 1989). This concurs with Porter (2015), suggesting that within realist research, a basic CMOc can be too simplified when there are multiple outcomes, and therefore multiple choices of behaviour. With agency to make decisions at each CMOc level, a participant can intentionally influence their functioning and life circumstances and according to Bandura (2006), this presents as part of the causal structure as people are self-organising, proactive, self-regulating, and self-reflecting, and are

not simply onlookers of their behaviour but contributors to their life circumstances, not just products of them.

Patient behaviour is thus complex, affected by PROMs feedback in this study, but not isolated in its effects. This thesis contributes to realism by supporting multiple CMOcs as linked processes to allow richer, deeper description and explanation of complex social systems.

### **9.15 The use of outcome research in practice and within physiotherapy**

This doctoral thesis has generated knowledge enabling a bridge between the outcomes of research and the social usage of that knowledge (Lafont, 2014). It has been suggested by this study that using PROMs such as the QuickDASH create a collective impact between patient and therapist, consonance with the feedback and treatment processes, and provide an environment conducive to feedback working as it is intended. PROMs use requires no costly equipment and staff training to use, and if selected wisely, with input from the practitioners, an outcome measure can be chosen which is straight-forward, relevant and able to be completed in the time available in practice. When completed, PROMs results are readily measurable, efficiently reported and easily communicated to patients for the purpose of tracking their progress (Geiger et al., 1992).

Physiotherapists exhibit positive attitudes towards the use of outcome measures but they are infrequently used despite their ease of use (Van Peppen, Maissan, Van Genderen, Van Dolder, & Van Meeteren, 2008), with resistance repeatedly reported as an issue when introducing outcome measures in physiotherapy practice (Abrams et al., 2006; Duncan & Murray, 2012; Van Peppen et al., 2008). Unsworth et al. (2012) identified voluntary participation as a key concept in reducing resistance to the introduction of outcome measure use in practice in their qualitative study of psychotherapy outcome measures, used by clinicians and fed back to patients. Duncan and Murray (2012) in their systematic review found allied health professionals' barriers for use in practice to be level of knowledge and confidence about using outcome measures, and the degree of organisational and peer-support. Outcome measurement use (PROMs and ROM) is therefore only deliverable if appropriate action is taken firstly at therapist level to

increase confidence in their use. This study further justifies that PROMs have benefits for patient management, but to be of use to a wider population, integration of PROMs needs to occur in a physiotherapy environment. Multiple changes over and above the therapist level need to occur in practice for this to materialise: interpersonal network change, organisational change and institutional change (Punton, Vogel, & Lloyd, 2016). Starting from the largest, institutional change has occurred within the Chartered Society of Physiotherapy (2013, 2016b) with introduction of outcome measures as a standard of practice. Advice and support is offered via CSP representatives in each physiotherapy department alongside comprehensive online advice on validated outcome measures (Chartered Society of Physiotherapy, 2016b).

Organisational change is more difficult to tackle, with each NHS trust proposing different services, appointment lengths and their own individual budget cuts creating difficulty in implementing even minor changes due to the disruptions it causes in already strained clinical routines (Sanders, Nio Ong, Sowden, & Foster, 2014). Although PROMs are now easier to complete due to the online presentation of many forms, it is suggested that although technological innovation helps, behavioural changes have a higher ability to change patient outcomes (Schroeder, 2007). Michie et al. (2011) produced three essential conditions for change: capability, opportunity, and motivation. Each of these must be evident for organisational change to embrace PROMs as routine practice. This requires the outcome measures to be available for use in practice (opportunity), time available for completion (capability), and the initiative to complete them from the individual and the organisation (motivation).

Interpersonal networks are available to support physiotherapists with promotion of individual change to their approach of using PROMs in practice. Free PROMs resources are made available for use in practice such as the QuickDASH (Institute of Work and Health Canada, 2013) and other outcome measures via the Chartered Society of Physiotherapy website (2016b). In the context of this study, specialist shoulder workshops, provided free of charge, champion the use of PROMs and research, such as the Manchester Arm Clinic (MAC), run by North West Orthopaedic surgeons and information provided for physiotherapists from The British Elbow & Shoulder Society (BESS). Allied health support groups such as

the Council for Allied Health Professions Research (CAHPR) provide regional networks for professionals to share experiences and information on research, with all options described serving as a low-cost way to link to other professionals with a research agenda. These events run during daytimes and evenings, (some by video link), with free PowerPoint slides available, allowing clinicians with busy caseloads to access up-to-date research if they are interested in pursuing self-education.

Within this specific study, dissemination of the results and implications for use in practice are essential and will need to engage the wider community of physiotherapists treating patients with shoulder dysfunction for this research to be of use.

### **9.16 Dissemination and reflection**

*“Dissemination does not happen if we wait for it”* (Brownson, Colditz, & Proctor, 2012) (page 4).

Dissemination of research findings serves as an essential part of a PhD project, initially during the research planning and pilot phases to receive critical feedback from the target audience (Brownson et al., 2012) to allow the researcher to modify and improve methods and thought processes. Dissemination is also essential at the research findings phase to share results within the correct sphere of researchers and clinicians, aiming to impart relevant information to the correct audiences to inform or change practice. Brownson et al. (2012) suggests more targeted, active approaches to dissemination and implementation are needed and innovative ways of reaching communities are required, specifically as research from a university level can take over a decade to reach evidence based policies and programmes for the public.

During the time span of this PhD study, research has regularly been formally presented to peers at conference proceedings to notify appropriate groups of the research currently being carried out. The initial pilot study findings were first discussed in an oral presentation and poster presentation to the North West Chartered Society of Physiotherapy at the group’s annual meeting (Parish, 2013). The response of the group was positive towards finding out what would work in practice as a group of professionals. Many discussions queried the reason for not proceeding with a quantitative approach. Debating these questions confirmed that the physiotherapy profession is historically quantitative in terms

of research (Hutchinson, 2004) and discussion confirmed that carrying out research in line with quantitative research methods only would show effectiveness but not participant experience or impact to answer the questions 'how?', 'why?', 'for whom?' and 'in which circumstances?'. The physiotherapy profession aligns with both quantitative and qualitative research methodologies to support clinical reasoning and decision making (Shaw, Connelly, & Zecevic, 2010), and at this stage of completing the pilot study, the phase II main study was being designed, which prompted development of the realist approach to questioning, supporting a mixed methods study.

The second presentation was to a group of researchers, academics and clinicians at the NHS Research and Development North West conference (Parish, 2014), entitled 'Let's talk research'. The researcher's innovative poster included anonymised sound-bites from the interviews which delegates could play to demonstrate each point which was made. The study was received well, and won the conference poster prize. At this conference the researcher had developed a better ability to field questions from researchers with varied backgrounds, and was able to take on board comments about study practicalities and theoretical underpinnings for the next phase of study.

Physiotherapy UK is the largest physiotherapy conference in the United Kingdom and hosts researchers, clinicians, academics and promoters and was one of the main clinical conferences the researcher hoped to present findings at. The researcher secured a poster at Physiotherapy UK (Parish, 2015) which was itemised on the poster walk for delegates to view as a good example of practice development and was well visited by delegates. This conference hosted delegates mainly from a clinical background, who were interested mainly in the application of PROMs in practice for patient and therapist benefit.

A poster was accepted at the Centre for Advanced Research and Evaluation Synthesis (CARES) conference the following year, entitled: Patients' view and experiences of outcome data feedback in physiotherapy: a realist evaluation study (Parish, 2016). Presenting to the realist community was an ambition of the researcher from starting the study, and the interaction with fellow realist researchers was thought-provoking and stimulating. Nick Tilley approached the researcher to discuss the poster presentation

(Appendix U). As one of the founders of realist evaluation, his comments were crucial for a realist viewpoint on the research methods and the formation of the study CMOcs (of which CMOc 4: Collective Impact was presented on the poster). The discussion was influential in terms of analysis and development of the CMOcs. Nick Tilley questioned the 'collective impact' CMOc, querying if the input of the physiotherapist and if the feedback could be disassociated within the CMOc. Within this study, as the physiotherapist was providing the feedback, it could not be separated. This sparked thought for further research ideas which are outlined later in this chapter (section 9.19.5: Opportunities for further research, page 259). Discussions with Nick Tilley confirmed the ontological depth gained by the 'collective impact' CMOc in relation to the CFIT and the new knowledge gained to modify the theoretical structure.

## **9.17 Limitations of the study**

### **9.17.1 Literature review type**

This study produced a scoping literature review to identify suitable literature surrounding repeated feedback within a physical illness domain. Due to the part time nature of this PhD, the initial searches were completed in October 2012 and re-run in October 2016. The initial search was completed without knowledge of realist approaches, with requirements set by the researcher and supervisory team at the time of planning as empirical studies investigating physical illness, using repeated feedback of outcome measures (ROM or PROMs).

The 'scoping review' done as part of this thesis was successful in one of the essential roles of a literature review in identifying a research gap (Aveyard, 2014). The literature review identified a paucity of qualitative research within physical illness research, which indicated research in this area would be a useful contribution to knowledge. It is accepted that limits must be applied to ensure a literature review is manageable for a researcher (or research team) and the scope of the review should be clearly defined, with limits set to physical illness only within this study. The scoping review made sense of the literature within the physical illness domain but did not extend further than this area.

Reflecting on the chosen type of review, using a different type of approach may have identified studies which were more comparable with the research within this study. A realist review, for example, would have provided a different lens for viewing the empirical studies, synthesising the research with an explanatory focus. The initial explanatory focus would then have deviated from the traditional style, aiming to unpack the mechanism of how complex programmes work (or why they fail) in particular contexts and settings, with programme theories then generated at this stage to test empirically (Pawson, Greenhalgh, Harvey, & Walshe, 2005). In further work relating to this study, it would be appropriate to consider approaching the literature review with a realist lens.

### **9.17.2 Realist evaluation as an approach**

Realist evaluation as a method was a time-consuming approach, and although the CMOcs appear ordered and coherent in this thesis, the conclusions concerning generative causality of each separate CMOc and subsequently the cumulative CMOc and modified CFIT were achieved though much negotiation and contestation. Realist evaluation was chosen, knowing that the methods involved would be challenging, but that as an approach it was well-suited to answer questions about processes, concentrating exclusively on the characteristics of interventions to explain their success or failure (Porter, 2015). With realist evaluation methods of study design and analysis encouraging variations in contexts, mechanisms and outcomes (Tilley, 2000) it was an approach able to embrace difference rather than aiming to reduce it.

With a realist evaluation approach, it is accepted that only partial knowledge is produced (Jagosh, 2017), and it is limited to knowledge of the participant group at the period of time in which the research is completed. Although this could be viewed as a limitation within this study, each methodological approach has its own limitations, even in the case of Randomised Controlled Trials (RCTs), viewed traditionally as a gold-standard approach for empirical research in the health domain. This study, if trialled as an RCT would have been able to answer research question 1 only: “What works for whom in what circumstances?” but would be unable “to explore the factors that may influence how routine outcome monitoring feedback relates to patient behaviour and response” which comprised the overarching aim. As Sanson-Fisher, Bonevski, Green, and D’Este (2007) debate, RCTs are limited by many factors including:

population availability, contamination, time for follow-up, external validity, cost, ethics and informed consent, and the inhibition of innovative research questions. With the innovative and exploratory nature of this study, realist evaluation was a suitable choice, using descriptive statistics served to further interpret and explore the qualitative data.

Recent advances in thought within realist circles suggest that it is possible to use both RCT and realist methods in combination under the banner of realist research (Pawson, 2016; Porter & O'Halloran, 2012). In a larger scale study, it would therefore be possible to extend a mixed methods study to include rigorous statistical analysis of PROMs, with randomised groups of participants to determine 'what works for whom in which circumstances', for example, comparing practitioner feedback of PROMs versus patient-led independent feedback of PROMs.

### **9.17.3 The practitioner role**

The researcher is a practising physiotherapist, qualifying over 16 years ago with extensive patient interaction and experience. With a background in patient contact, the interviewer – participant relationship was fostered easily with the majority of participants, which felt particularly important when entering peoples' homes to carry out interviews and asking personal questions about their lives.

The practitioner role was managed by clear preliminary introductions, explaining the interview would be conducted by the study researcher, who was also a practising physiotherapist. The physiotherapist title was included for transparency, although this in turn affected the dynamics between the researcher and the participants. Often participants would ask clinical questions and create diversions from the line of questioning originally set in the interview schedule. The researcher had to learn skills to remember the point at which the conversation became irrelevant to the study, and where to restart questioning. Clinical discussions were often not curtailed as each participant's current situation clinically often gave contextual background to their behaviour.

The method of 'bracketing' was considered for use to manage the bias as a physiotherapist as it aims to put aside the pre-conceived ideas and experiences of the researcher. With a realist evaluation study

requiring retroductive reasoning, combined with the researcher's extensive background of PROMs use and physiotherapy for the shoulder, it was decided that bracketing was impractical, as the researcher's assumptions representing how the world is could not be suspended (Hammersley, 2003).

### **9.18 Research reflection**

The researcher has successfully learned to navigate the field of research at a doctoral level by completing this study. With a two-phase study requiring LREC, NHS R&D and university ethics approval, skills were learned over time, encompassing ethical approval paperwork and organisation, and the specific requirements for research when working with NHS participants. The amount of preparation prior to a study is overwhelming for a novice researcher and these precursory duties are now part of the researcher's skill set and processes are now familiar.

The practicalities of research were experienced first-hand: recruitment taking longer than expected, NHS re-organisation part-way through the phase II study and life circumstances requiring an authorised break in study. The researcher has learned to manage the research workload, by completing alternative duties whilst waiting for other areas such as recruitment and re-organisation, an essential skill when dealing with research in the field.

The PhD process has proven to be time-consuming, thought-provoking, educational and rewarding. Skills have been learned to progress from a lone PhD researcher to participation in larger projects. Currently a study in the researcher's NHS workplace is being developed to study the impact of Magnetic Resonance Imaging (MRI) on patient management, with the researcher taking the lead role in the qualitative part of the study, to follow patients through from assessment, to MRI, to diagnosis and management, interviewing participants to determine what impact the MRI results have had for them individually. Projects such as this will allow the researcher to continue clinical work and research combined.

## **9.19 Recommendations**

### **9.19.1 Education**

Educating clinicians in the uses of PROMs is an essential part of ensuring outcomes data are used correctly and to maximum effect. Currently physiotherapists have a positive attitude towards PROMs but due to the lack of usage routinely in practice (Abrams et al., 2006), education promoting PROMs use would be appropriate at undergraduate and postgraduate levels alike. If undergraduate staff are exposed to new practices such as routine PROMs collection, at an early stage in their course curriculum, an institutional culture is built which can be more self-reflective and open to change (Christianson, McBride, Vari, Olson, & Wilson, 2007). Continuing professional development for physiotherapists in-line with the CSP quality standards (Chartered Society of Physiotherapy, 2013) includes the use of outcome measures in practice (Chartered Society of Physiotherapy, 2016b) and would therefore be well placed in an educational curriculum.

A previous study researching use of outcome measures (Abrams et al., 2006) found physiotherapists increased their reported use of a range of outcome measures over the study period of six months, where PROMs collection was mandatory, receiving encouragement via active education initiatives and professional support. This supports ongoing education to physiotherapists and other clinicians as standard at a post-graduate level, to educate on the benefits of PROMs, outlining how they are instrumental in starting conversations, building rapport and allowing clinical conversations to work towards a patient-centred approach, encouraging collective impact and improved patient impact.

### **9.19.2 Recommendations for practice**

In England, PROMs use has been driven by government wishes for public comparisons of providers' performance, although in Sweden and the United States the medical profession has introduced outcome measures to focus on improving the clinical care of individual patients (Black, 2013). Educators should focus on the clinical benefits for patients to further encourage physiotherapists to utilise PROMs as part of assessment and treatment. It is recommended that PROMs should be used to complement current

practice, to provide a further tailored and personalised service for each individual patient, helping to manage their condition more effectively.

Commissioners shaping service design can utilise PROMs research in promotion of use in practice.

Acknowledgement of the contribution of PROMs to individualised management by commissioners would ensure inclusion of PROMs both for service audit purposes, and to benefit patients and therapists. It would also provide support for PROMs use at the clinician level within services.

### **9.19.3 PROMs use**

PROMs data have been routinely collected for four elective procedures (varicose vein removal, groin hernia repair and hip and knee replacements) since April 2009, with continued collation of data to provide accurate comparisons between the average scores of different providers (Health and Social Care Information Centre, 2016). This large-scale introduction of PROMs has promoted collection of outcome measures as a standardised procedure, which has been noted by clinicians across services.

The way is being paved in clinical services for widespread use of PROMs, and with the potential for additional education at undergraduate and postgraduate level, support from commissioning bodies and large scale projects run nationwide, PROMs needs to be promoted at all levels as a strategy to manage patients better.

The feedback of the QuickDASH to individual patients in this study illuminates the wider effects of PROMs, postulating that feedback of outcome measures can enhance patient experience and patient management, improving quality with a recommendation to feedback PROMs to patients individually to improve individual care.

### **9.19.4 Patient experience and management**

PROMs should be used in clinical practice in ways which are of benefit to the public as patients and potential patients, in addition to the clinicians, service providers, commissioners and policy makers.

PROMs present to accurately track progress in terms of validated measures such as the disease specific QuickDASH in this study. They are clear indicators of improvement, measured by the patient, and if the questions asked are relevant to a patient they are more likely to value feedback of the scores.

In this study, patient experience appears not to be measured by PROMs and therefore a recommendation from this study is not to use them as such. Nor do PROMs present as a service quality indicator, as patients happy with their treatment and management within this study did not consistently show improvement on the QuickDASH. Despite patient experience and quality not being exhibited in the change of PROM scores, both are *enhanced* by PROMs.

This study recommends PROMs as an adjunct for quality patient management, to personalise and tailor treatment by putting the individual patient at the heart of care. A further recommendation would be to further develop PROMs and PREMs to create a combined measure which can incorporate both clinical outcomes and experience, for use across health domains.

### **9.19.5 Opportunities for further research**

#### ***9.19.5.1 The impact of the feedback provider***

With the feedback intervention influencing participant behaviour, it is pertinent to explore other factors which present as influences on the study population whilst participating in a study. The Hawthorne effect describes a reactive occurrence describing how individuals modify their behaviour in response to their awareness of being observed (McCarney et al., 2007). Within this study, participants were fully aware of engaging with a research project through the consent process. This study, with the addition of feedback at every appointment added extra attention from therapists in terms of higher levels of clinical surveillance, although the time spent with their physiotherapist was equal to those not taking part in the study.

A more recent term 'research participation effects' aims to encompass a wider group of influences, inclusive of the Hawthorne effect. Effects can occur prior to an individual taking part in a research study, affecting who decides to take part and who does not which has potential to create bias within the study

population. Certain types of data collection (completing questionnaires such as PROMs and increased observation) comprise a chain of events that occur for participants in research studies that have potential to shape their behaviour (McCambridge, Witton, & Elbourne, 2014) from recruitment, to intervention response to interview. Participants who take part may bias results, not purposefully, but in seeking conformity and social desirability considerations which may then lead to behaviour change in line with these expectations (McCambridge et al., 2014). The design of the study aimed to minimise the research participation effects by ensuring the researcher was not the treating therapist and that the time allocation per patient, per appointment was identical to those not taking part in the study. Despite efforts within this study design to reduce the effect, it is accepted and acknowledged that 'research participation effects' occur and may have occurred within this study as it is an unavoidable occurrence of study participation and interventions.

A conversation with Nick Tilley at the Conference on Realist Evaluation and Synthesis (Parish, 2016) elicited future research thoughts on the use of repeated feedback and its impact on patients. The question was raised whilst talking over the researcher's poster presentation as to whether the feedback response was due to the repeated, visual nature of the feedback or the person providing the feedback, and to whether they were affecting patient behaviour together or whether it was one in isolation. To research this specific question, further study would be required, with this research project repeated, but with a change in method.

A proposal is made in this thesis to combine realist research with an RCT, a combination which has recently been encouraged by the realist community and specifically by Ray Pawson (2016). The potential study would investigate the use of repeated visual feedback of PROMs as an autonomous process, with the patient recording their own QuickDASH scores and plotting them on the graph, therefore completing the monitoring unaided. This would constitute one randomised cohort of participants, the other cohort would consist of participants with the patient completing the PROM, but with the therapist recording the scores and plotting them on a graph, completing the monitoring together. This would determine if the feedback alone would give the same outcomes compared with feedback presented by the physiotherapist

with the patient as a collaboration. A hypothesis would take the form of the modified CFIT as the middle range theory and proposed programme theories based upon the cumulative CMOcs from this study, hypothesising that the collective impact CMOc is required for feedback to work in the way it is intended in the patient population.

#### ***9.19.5.2 Comparison with no feedback***

The cumulative CMOc process and the modified CFIT developed in this study presented multiple processes which related to the feedback of the QuickDASH outcome measure. To test the hypothesis that the feedback alone produced the occurrences which were observed in this study, participants receiving feedback would have to be compared with those not receiving feedback. A study replicating the intervention in this study, including a comparison group who received outcome measure recording but no feedback, would test the hypothesis that *feedback* of the outcome measure scores as a resource elicited the responses, rather than the outcome measure alone.

## Chapter 10: Conclusion

This thesis introduced the concept of PROMs use in relation to quality services and the use of feedback as a tool to involve the patient further within their own care. Throughout both the pilot phase I and main phase II studies, continued publications have argued the use of PROMs and feedback as a useful adjunct in healthcare services, but with accepted limitations (Greenhalgh et al., 2017). Patients continue to value both standardised and individualised PROMs as a tool to raise issues, but it has been unclear which patients may benefit from such feedback (Greenhalgh et al., 2017).

As PROMs have had continued prominence in elective surgery for measuring outcomes, their extension to use in other areas of healthcare has been the topic of continued discussion. The purpose of this thesis was to generate an understanding of how PROMs feedback affected patient behaviour and why. In previous mental health studies, clinicians viewed individualised PROMs as a useful tool to build rapport and support the therapeutic process which is supported in this study in a physical health domain. The patient therapist relationship presented as fundamental to this experience, with physiotherapists playing a key role in building rapport through the feedback intervention to produce a situation where the management of the patient's condition produced a positive impact and a favourable outcome.

Feedback of PROMs creates an individualised service, building relationships to allow patients to learn new information for condition management, whether they improve clinically or not on the PROM as a clinical outcome tool. Improved condition management is as a positive impact which can create a more positive overall outcome. The perceived accuracy of the feedback process was a factor which affected the feedback working in the way it was intended, which could create a negative impact. If at any point in the process, dissonance with the feedback occurred and was repeated it could create a withdrawal from both the feedback process and treatment.

In this study, the patients who benefited from feedback were those who felt they were in control of their condition in their social world, and those who did not benefit were those who attributed their cause to an external influence over which they have no control. Control of a patient's condition can be facilitated by

the PROMs feedback to enhance the patient-therapist relationship and promote individualised management.

The findings demonstrate that through using realist evaluation methods, underlying mechanisms can be exposed to explore the patient behaviour occurring behind the PROMs outcomes as hard quantitative data. These findings discussed as part of this thesis contribute to an understanding of the way the feedback process works (or does not work), offering an alternative perspective on the CFIT framework for use with a patient population rather than clinicians.

The findings also demonstrate that in using realistic evaluation, a researcher can unpack multiple, linked CMOcs. Shaped together as a cumulative process, the CMOcs were able to display the complex mechanisms surrounding the feedback of PROMs to further understand how patients behave in response to feedback of information and why. This study concurs with current research to support PROMs as useful individualised measures for *clinicians* when assessing and managing patients (Greenhalgh et al., 2017) with additional insight that PROMs feedback can also be useful specifically for *patients* to improve experience and aid condition management. The impact of PROMs feedback is thus two-fold and benefiting both clinicians and patients.

The findings surrounding feedback of PROMs and the impact on patients is observable and potentially transferable. Testing of the theory created the modified CFIT with the additional elements of tracking progress and closeness to goal, collective impact, and dissonance or consonance with the process. These new findings are informative to practice, potentially transferable to other domains, and identify important issues that indicate a need for further testing with empirical studies for refinement. Further research is indicated to determine whether this collective impact of feedback is experienced outside of the physiotherapy domain. The modified CFIT and singular programme theories (CMOcs) generated by this research require further testing and refinement to validate or refute the findings from this study.

The thesis findings are applicable to physiotherapists, researchers, policy makers, commissioners of services and those educating physiotherapists at undergraduate and postgraduate levels. The challenge is

to ensure PROMs are used to best effect for patient and practitioner benefit alike, and that development of PROMs continues to make best use of the information given by patients, for patients. The ultimate challenge is to change the NHS culture in relation to PROMs use, encouraging widespread acceptance. With improved support from training physiotherapists, through to policy maker support, cultural change can occur.

# Appendices

## Appendix A: Data extraction form

### DATA EXTRACTION FORM

Title of review	Feedback PROMS.
-----------------	-----------------

RefMan	
Study ID	
Author	Nicola et al.
Year	2010
Title	promising supervised-extherapy
Publication details:	
Notes re publication e.g. multiple formats/papers, translation, unpublished etc	Multiple papers.
Notes re authors e.g. professional group, country	

STUDY CLASSIFICATION	
Mental Health	Physical Health
Psychology	Physio <input checked="" type="checkbox"/>
Counselling	Diet
Couple therapy	Other
Other	

Setting	
In-patient <input checked="" type="checkbox"/>	Outpatient

Further details of setting will be included in the study participant's table

Comparisons				
	Comparison 1	Comparison 2	Comparison 3	Comparison 4
NAME	WA walking advice	supervised ex therapy	SET + FB.	
VA vs ?				

Measurement scale	Timescale for measurements (Days / weeks / months)			

### RESEARCH DESIGN AND QUALITY ASSESSMENT

NB When filling out the data extraction form, please include some indication of the source of the data if you think it will be necessary to check e.g. (583, 1, 3) = page 583, Column 1, Para 3

<b>Type of trial</b> e.g. RCT, pilot RCT, crossover					
<b>Power calculation?</b> State if done and comment on adequacy of recruitment					
<b>RANDOMISATION</b>	<b>Total</b>	<b>Group A</b>	<b>Group B</b>	<b>Group C</b>	<b>Group D</b>
<b>Name of group</b>		WA	SET	SET IFB	
<b>Number of subjects randomised</b>					
<b>Description of method used to generate randomisation sequence</b> (include stratification)		Computer generated list by  researcher blocks size of 9 + stratified.			
<b>1. ALLOCATION CONCEALMENT</b>					<b>Give reason for coding if necessary</b>
<b>1.1. Quality of random allocation concealment</b>					Says concealed.
<b>A</b>	good attempt at concealment, method should not allow disclosure of assignment (telephone, third party etc)				
<b>B (i)</b>	states random allocation but no description of procedure given		✓		
<b>B (ii)</b>	attempt at concealment but real chance of disclosure of assignment prior to formal entry (envelopes without third party involvement, 'random numbers table' but procedure not described)				
<b>C</b>	definitely not concealed (open random numbers tables or quasi randomised e.g. day of week, date of birth, alternation)				
<b>D</b>	No attempt at allocation concealment				

NB If randomisation and allocation procedure is reasonable in practice, with a low likelihood of disclosure, code A.

2. POTENTIAL FOR SELECTION BIAS IN ANALYSIS			Give reason for coding if necessary
<b>2.1. Was there a description of withdrawals, drop-outs and those lost to follow-up?</b>			NB. Details of withdrawals, drop-outs and those lost to follow up are given later, so are not needed here.  <i>see consort.</i>
<b>A</b>	states overall numbers and reasons for withdrawals	✓	
<b>B (i)</b>	states numbers of withdrawals only		
<b>B (ii)</b>	states withdrawals but no sub-set numbers given		
<b>B (iii)</b>	states withdrawals but no overall number given		
<b>C</b>	not mentioned		
<b>2.2. Were all the participants who entered the trial properly accounted for at the end?</b> The standard to judge against is available case analysis: i.e. trial participants were analysed in the groups to which they were randomised, regardless of which treatment they received			NB Look for exclusions from analysis on the basis that people did not receive (or comply with) the treatment allocated. Drop-outs or lost to follow up are not exclusions.
<b>YES</b>		✓	
<b>UNCLEAR</b>			
<b>NO</b>			
Identify if it is <b>true intention to treat</b> i.e. all participants included in analysis regardless of whether their outcomes were actually collected, and specify the method by which results were imputed. <i>"Intention to treat" notified - includes all data from pts. that had been randomised + completed + per protocol test</i>			
<b>3. CONTROL OF INTERVENTION</b>			Give reason for coding
<b>3.1. Apart from the treatment under investigation, were the groups treated equally during intervention?</b> i.e. equal time/attention			<i>to quantify walking dist after 12/12 Rx. lost to follow up or died not included</i>
<b>YES</b>		✓	
<b>UNCLEAR</b> i.e. not stated			
<b>NO</b>			
<b>3.2. Apart from the treatment under investigation, were the groups treated equally during usual care?</b> i.e. <b>cointervention</b> : avoidance of unintended additional care to any group			
<b>YES</b>		✓	
<b>UNCLEAR</b> i.e. not stated			
<b>NO</b>			

<b>4. TREATMENT/OUTCOME ASSESSMENT BLINDING</b>		Give reason for coding if necessary	
<b>4.1. Were participants 'blind' to treatment status?</b>			
A	action taken at blinding likely to be effective		
B (i)	blinding stated but no description given		
B (ii)	attempt at blinding but reason to think it may not have been successful		
B (iii)	no mention of blinding		
C	not blinded		✓
<b>4.2. Were usual health care providers 'blind' to treatment status?</b> to prevent the provision of the intervention to the control group			
A	action taken at blinding likely to be effective		
B (i)	blinding stated but no description given		
B (ii)	attempt at blinding but reason to think it may not have been successful		
B (iii)	no mention of blinding		
C	not blinded		✓
<b>4.2. Were intervention providers 'blind' to treatment status?</b>			
A	action taken at blinding likely to be effective		
B (i)	blinding stated but no description given		
B (ii)	attempt at blinding but reason to think it may not have been successful		
B (iii)	no mention of blinding		
C	not blinded		✓
<b>4.3. Were outcome assessors 'blind' to treatment status?</b>		<i>Outcome assessors blinded.</i>	
A	action taken at blinding likely to be effective		
B (i)	blinding stated but no description given		✓
B (ii)	attempt at blinding but reason to think it may not have been successful		
B (iii)	no mention of blinding		
C	not blinded		

NB Blinding: assessors = single, assessors and participants = double, assessors, participants and providers = triple

**PARTICIPANTS**

<b>Description of patient population</b>	intermittent claudication.
<b>Number of people assessed for inclusion</b> (tells us something about suitability to client group)	—
<b>Inclusion criteria</b>	ankle brachial index < 0.9 then: PAD < stage II Absolute claudication dist. of 500m. on treadmill test
<b>Exclusion criteria</b>	<del>Prior exs therapy pre. peripheral vascular intervention Non-dihydropyridine, CVD limitation, arrhythmia, psychiatric instability + serious comorbidities</del>
<b>FOR JUDGEMENT OF STUDY GENERALISABILITY – report for whole group</b> NB If not given for whole group, don't work it out	
<b>Age</b> Mean, SD, range Other: please specify	
<b>Gender</b>	
<b>Stroke details given</b> e.g. type/side of lesion	
<b>Comorbidities/functional abilities</b> Condition/ability reported, and how measured	NB Report baseline values for functional outcome measures here. Report significant differences under baseline comparisons
<b>FOR JUDGEMENT OF GROUP EQUIVALENCE PRIOR TO INTERVENTION</b>	
<b>Baseline comparison of treatment groups?</b> State if reported or not.  Include ONLY any reported or detectable significant difference in baseline characteristics + clarify source.  Report raw data on significantly different baseline functional measures.	
<b>Details of setting/context</b> e.g. rehabilitation unit	11 Dutch hospitals
<b>Country/Region</b> e.g. USA, Wisconsin	

INTERVENTIONS	GROUP A	GROUP B	GROUP C	GROUP D
<b>Name of intervention</b> NB Keep the order in which the interventions are presented in the original report	WA	SET	SET + FB	
<b>Description of intervention and task</b>				
<b>Task guidance, feedback or assistance.</b> Code included/not included and give details				
	<b>GROUP A</b>	<b>GROUP B</b>	<b>GROUP C</b>	<b>GROUP D</b>
<b>Length of training session</b>	Approx 15-20 mins	34-45 mins		
<b>No. of sessions per day/week</b>	1			
<b>No of subjects per session</b>				
<b>Treatment duration</b>				
<b>Who delivered</b>				
<b>Where delivered</b>				

09/07/2012 based on Version 5: 26/04/06 provided by M. Leathley

**GOOD PRACTICE IN STUDY CONDUCT**

Were interventions additional to standard care? describe standard care	Standard care SET.
Was the intervention delivered as specified in the protocol? Was delivery 'per protocol' monitored? (monitoring needs to be stated)	
Was participant compliance with the intervention monitored? (i.e. attendance at sessions, not performance)	
Are there likely to have been any intervention related reasons for withdrawal?	

**OUTCOME MEASURE DETAILS:**

	Scale/instrument used e.g. unvalidated scale, DASH, SF-36	Measure of: e.g. functional ability / speed / pain / prognosis	Details e.g. calculation, cut off	Data availability at time points				
				Time 1	Time 2	Time 3	Time 4	Time 5
Outcome 1				Base line	3/12	6/12	9/12	12/12
Outcome 2	Treadmill test	Dist. incline	1 <sup>o</sup> = change into	✓	✓	✓	✓	✓
Outcome 3	AED assessment	Speed walking	2 <sup>o</sup> = stop 3-2 km/h	✓	✓	✓	✓	✓
Outcome 4		Dist. before stopping						
Outcome 5								
Outcome 6								
Outcome 7								
Outcome 8								

NUMBER OF PARTICIPANTS FOR WHOM OUTCOME DATA ARE AVAILABLE					
NB Use number randomised to work out loss to follow up. Give cumulative numbers and percentages lost to follow up					
	Timing	GROUP A WA	GROUP B SET	GROUP C SETFB	GROUP D
Number randomised	304	102	109	93	
Lost between randomisation and baseline			0	3	
Number at baseline		↓ 102	↓ 109	↓ 109	↓ 90
Number post treatment		83	93	76	
Number lost, and % loss to follow up					
Reason for losses			€ see comment p 1228	→	
Number at follow up 2					
Number lost, and % loss to follow up					
Reason for losses					
Number at follow up 3					
Number lost, and % loss to follow up					
Reason for losses					

**OUTCOME DATA EXTRACTION**  
Replicate the tables required for different outcomes

COMPARISON		
INTERVENTION A:	INTERVENTION B:	
WA	SET / SET - FR.	
DICHOTOMOUS DATA		
Outcome:	Improved walking dist max. SET + SET + FR	
	INTERVENTION A	INTERVENTION B
Timing/sub-group	e.g. 23/104	e.g. 34/98
Medium	?	280 → 620
Max walking dist.		240 → 580

COMPARISON						
INTERVENTION A:			INTERVENTION B:			
CONTINUOUS DATA						
Outcome:						
	INTERVENTION A			INTERVENTION B		
Timing/sub-group	N=	Mean	SE	N=	Mean	SE

The table asks for mean and SE. Make it clear if these have not been used.

COMPARISON						
INTERVENTION A:			INTERVENTION B:			
CHANGE FROM BASELINE DATA						
Outcome:						
	INTERVENTION A			INTERVENTION B		
Timing/sub-group	N=	Mean	SD	N=	Mean	SD

## Appendix B: Pilot study phase I successful ethics approval LREC



**Health Research Authority**  
**National Research Ethics Service**

### **NRES Committee North West - Lancaster**

Barlow House  
3rd Floor  
4 Minshull Street  
Manchester

18 April 2012

Ms Alison Dewhurst  
Specialist Physiotherapist  
Lancashire Care NHS  
Ribbleton Clinic  
Langden Drive, Off Pope Lane  
Ribbleton, Preston  
PR2 6HT

Dear Ms Dewhurst

**Study title:** **The effect of feedback of outcome data on patient involvement and progression in the treatment of Shoulder Impingement Syndrome (SIS) in physiotherapy, an exploratory study.**

**REC reference:** **12/NW/0229**

The Research Ethics Committee reviewed the above application at the meeting held on 12 April 2012. Thank you for attending to discuss the study.

#### **Ethical opinion**

The Chair welcomed you and Beverley French to the REC and thanked you for attending to discuss the study. The Committee told you that this is a well written application.

The Committee asked for clarification of how the participants are referred to the assessment clinic. You explained that they are referred by their GPs and go onto a waiting list. They will be contacted within 18 weeks and offered the first available place. If appropriate they are referred on to the class. There are up to 10 people in a class. It is a circuit class, with 2 minutes per station and a warm up and cool down.

The Committee asked whether all participants will be on the study and you said that some may not be. It is a rolling programme so they can join at any time. Everyone gets the same treatment and if they are not in the programme they will do another 2 minutes of exercise instead of the 2 minute feedback station. In addition, all patients do home exercise.

The Committee asked whether the interview is optional and you confirmed that it is. If the participant does not want to do the interview you will keep recruiting until you have 20 who do wish to be interviewed.

The Committee asked that the Participant Information Sheet be revised to state that they may be recalled for interview but that it will be optional and that if they withdraw their healthcare will not be affected, and that the letter be revised to include that it is an educational project.

The Committee advised that a copy of the interview schedule should be provided. You had brought one to the meeting which the Chair read out to the members.

The Committee asked whether participants would be given the transcripts to read or just the summary. You stated it would just be the summary as you feel the transcripts would be too complicated and too time consuming to expect participants to read.

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.

### **Ethical review of research sites**

#### **NHS Sites**

The favourable opinion applies to all NHS sites 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).

### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

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*

### **Further Conditions specified by the REC:**

- a. The Committee would like to see the Participant Information Sheet revised to
  - i) Change the last sentence of "What will happen if I take part?" to "At the end of the treatment you may be recalled to an interview by a researcher, but this will be optional"
  - ii) Include under "what will happen if I don't want to carry on with the study?" "If you decide to withdraw it will have no effect on your treatment"

b. The Committee would like to see the Letter of Invitation revised to include the sentence “This project is being done as part of an educational study for a PhD for Alison Dewhurst”

**It is 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).**

**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. Confirmation should also be provided to host organisations together with relevant documentation**

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		08 March 2012
Evidence of insurance or indemnity		
Interview Schedules/Topic Guides		
Investigator CV	Alison Dewhurst	
Investigator CV	Beverley French	
Investigator CV	Michael John Leathley	
Investigator CV	Lois Thomas	
Letter of invitation to participant	1.6	22 February 2012
Participant Consent Form: Participant consent form- Interviews	1.7	08 March 2012
Protocol	1	08 March 2012
REC application	3.4	09 March 2012

### **Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **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.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

**12/NW/0229**

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Lisa Booth**  
**Chair**

Email: carol.ebenezer@northwest.nhs.uk

*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"*

*Copy to: Dr Robert Walsh  
Beverly Lowe, Lancashire Care NHS Trust*  
**NRES Committee North West -  
Lancaster**

**Attendance at Committee meeting on 12 April  
2012**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Brenda Ashcroft	Lecturer	No	
Mr David Barber	Pharmacist	No	
Dr Lisa Booth	Senior Lecturer	Yes	

Mr James Burns	Retired Lay Member	Yes	
Dr Nigel Calvert	Associate Director of Public Health	Yes	
Mrs Andrina Lawrence	Lay Member	No	
Dr Brenda Leese	Lay Member	Yes	
Dr Anas Olabi	Consultant Paediatrician	Yes	
Susan Page	Senior Clinical Tutor	Yes	
Mrs Gillian Rimington	Paralegal	No	
Dr John Shakespeare	Retired GP	Yes	
Mrs Valerie Skinner	Nurse (Retired)	Yes	
Professor Jois Stansfield	Professor of Speech Pathology	Yes	
Dr Gary Whittle	Consultant in Dental Public Health (retired)	No	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Carol Ebenezer	Committee Co-ordinator

**Written comments received from:**

<i>Name</i>	<i>Position</i>
Dr Brenda Ashcroft	Lecturer

## Appendix C: Pilot study phase I NHS R&D letter of approval

Lancashire Care   
NHS Foundation Trust

Lancashire Care NHS Foundation Trust Research and Development Sceptre Point

Sceptre Way

Walton Summit Preston PR5 6AW

Tel: 01772 773602

beverley.lowe@lancashirecare.nhs.uk

1st May 2012

Mrs Alison Dewhurst  
Specialist Physiotherapist  
Lancashire Care NHS Foundation Trust  
Ribbleton Clinic  
Langden Drive, Off Pope Lane  
Ribbleton Preston PR2 6HT

Dear Mrs Dewhurst,

**Re: NHS Trust Permission to Proceed**

**Project Reference: 12/11**

**Project Title: The effect of feedback on outcome data on patient involvement and progression in the treatment of Shoulder Impingement Syndrome (SIS) in physiotherapy, an exploratory study**

I am pleased to inform you that the above project has received research governance permission. Please take the time to read through this letter carefully and contact me if you would like any further information. You will need this letter as proof of your permission.

Trust R&D permission covers all locations within the Trust; however, you must ensure you have liaised with and obtained the agreement of individual service/ward managers. You must also contact the relevant service/ward managers prior to accessing the service to make an appointment to visit before you can commence your study in the trust.

### **Honorary Research contracts (HRC)**

All researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that directly affects the quality of their care, should hold Honorary Research NHS contracts. Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners or when they are employed by an independent practitioner (Research Governance Framework for Health and Social Care, 2005). If a researcher does not require an HRC, they would require a Letter of Access (LoA). For more information on whether you or any of your research team will require an HRC or LoA please liaise with this office. It is your responsibility to inform us if any of your team do not hold Honorary Research NHS contracts/Letters of Access.

### **Research Governance**

The Research Governance Sponsor for this study is The University of Central Lancashire. Whilst conducting this study you must fully comply with the Research Governance Framework. This can be accessed at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4108962&chk=Wde1Tv](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv)

For further information or guidance concerning your responsibilities, please contact your research governance sponsor or your local R&D office.

### **Risk and Incident Reporting**

Much effort goes into designing and planning high quality research which reduces risk; however untoward incidents or unexpected events (i.e. not noted in the protocol) may occur in any research project. Where these events take place on trust premises, or involve trust service users, carers or staff, you must report the incident within 48 hours via the Trust incident reporting system. If you are in any doubt whatsoever whether an incident should be reported, please contact us for support and guidance. Regardless of who your employer is when undertaking the research within Lancashire Care NHS Foundation Trust you must adhere to trust policies and procedures at all times.

### **Confidentiality and Information Governance**

All personnel working on this project are bound by a duty of confidentiality. All material accessed in the trust must be treated in accordance with the Data Protection Act (1998) For good practice guidance on information governance contact us.

### **Protocol / Substantial Amendments**

You must ensure that the approved protocol is followed at all times. Should you need to amend the protocol, please follow the Research Ethics Committee procedures and inform all NHS organisations participating in your research.

### **Monitoring / Participant Recruitment Details**

If your study duration is less than one year, you will be required to complete an end of study feedback report on completion. However if your study duration is more than one year, you will be required to complete a short electronic progress report annually and an end of study report on completion. As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum; however, if you fail to supply the information requested, the trust may withdraw permission.

### **Recruitment**

If your study has been included on the UKCRN Clinical Research Portfolio it is important that you ensure your monthly recruitment figures are uploaded onto the UKCRN Portfolio and recorded as Lancashire Care participants, where applicable.

### **Final reports**

At the end of your research study, we will request a final summary report so that your findings are made available to local NHS staff. The details from this report may be published on the NHS Trust internet site to ensure findings are disseminated as widely as possible to stakeholders. On behalf of this Trust, may I wish you every success with your research. Please do not hesitate to contact us for further information or guidance.

Yours sincerely,

Louise Worrell

Quality & Research Lead

On Behalf of the Research Governance Sub-Committee

Cc: [clare.lucas@lancashirecare.nhs.uk](mailto:clare.lucas@lancashirecare.nhs.uk) [rwwalsh@uclan.ac.uk](mailto:rwwalsh@uclan.ac.uk) [keith.mills@lancashirecare.nhs.uk](mailto:keith.mills@lancashirecare.nhs.uk)  
[Helen.hatcher@lancashirecare.nhs.uk](mailto:Helen.hatcher@lancashirecare.nhs.uk)

## Appendix D: Pilot study phase I UCLan ethics approval letter



27<sup>th</sup> June 2012

Bev French & Alison Dewhurst  
School of Health  
University of Central Lancashire

Dear Bev & Alison

**Re: BuSH Ethics Committee Application**  
**Unique reference Number: BuSH 076**

The BuSH ethics committee has granted approval of your proposal application 'The effect of feedback of outcome data on patient involvement and progression in the treatment of Shoulder Impingement Syndrome (SIS) in physiotherapy, an exploratory study.' Phase 1 only.

Please note that approval is granted up to the end of project date or for 5 years, whichever is the longer. This is on the assumption that the project does not significantly change in which case, you should check whether further ethical clearance is required.

We shall e-mail you a copy of the end-of-project report form to complete within a month of the anticipated date of project completion you specified on your application form. This should be completed, within 3 months, to complete the ethics governance procedures or, alternatively, an amended end-of-project date forwarded to [roffice@uclan.ac.uk](mailto:roffice@uclan.ac.uk) together with reason for the extension.

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely

Denise Forshaw  
Chair  
**BuSH Ethics Committee**

## Appendix E: Main study phase II successful ethics approval LREC



West of Scotland REC 5  
Ground Floor - Tennent Building  
Western Infirmary  
38 Church Street  
Glasgow  
G11 6NT

Date 03 July 2014  
Direct line 0141 211 2102

E-mail WoSREC5@ggc.scot.nhs.uk

## WoSRES

West of Scotland Research Ethics Service

Ms Alison Dewhurst  
Specialist Physiotherapist  
Lancashire Care NHS Foundation Trust Ribbleton Clinic, Langden Drive, Off Pope Lane  
Ribbleton  
Preston  
PR2 6HT

Dear Ms Dewhurst

**Study title:** Exploration of the impact of feedback of the QuickDASH outcome measure to physiotherapy patients with shoulder impingement syndrome: a qualitative study.  
**REC reference:** 14/WS/1038  
**IRAS project ID:** 138955

The Proportionate Review Sub-committee of the West of Scotland 5 reviewed the above application on 02 July 2014.

We plan to publish your research summary wording for the above study on the NRES 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 make a request to postpone publication, please contact the REC Manager Mrs Sharon Macgregor, WoSREC5@ggc.scot.nhs.co.uk.

## **Ethical opinion**

On behalf of the Committee, the sub-committee 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.

1. In the “Who has reviewed this study?” section, the name of the REC should be changed to “West of Scotland Research Ethics Committee 5”.

**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 the IRAS filter page) must be registered on a publicly 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).

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](mailto: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**

The favourable opinion applies to all NHS sites 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”).

### **Summary of discussion at the meeting**

#### **Ethical issues raised, noted and resolved in discussion:**

#### **Social or scientific value: scientific design and conduct of the study**

The protocol mentions the use of linear regression. The value of this in such a small sample size is questionable. The Committee suggest that you consult a professional statistician but this is not a condition of approval.

#### **Other general comments**

It was noted that A6-2 summaries the whole study and doesn’t concentrate on the ethical issues. It was also an overly complex protocol submission.

### **Approved documents**

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCLan indemnity insurance]		16 August 2013
Interview schedules or topic guides for participants [Interview schedules patient participants and Physiotherapists (2 separate schedules in the same document)]	1.1	16 June 2014
Letters of invitation to participant [Physiotherapist letter of invitation and PIS]	1.1	16 June 2014
Other [Private physiotherapy insurance certificate]		
Other [3rd supervisor CV]		22 June 2014
Other [Physiotherapist participation consent form]	1.1	15 June 2014
Other [Second supervisor CV]		22 June 2014
Participant consent form [Patient participant consent form]	1.1	15 June 2014
Participant information sheet (PIS) [Patient PIS]	1.1	16 June 2014
REC Application Form [REC_Form_24062014]		24 June 2014
Research protocol or project proposal [Phase II plan]	1.2	16 June 2014
Summary CV for Chief Investigator (CI) [CV Alison Dewhurst Chief Investigator]		15 May 2014
Summary CV for supervisor (student research) [Supervisor CV]		22 June 2014

## Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## 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 HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website

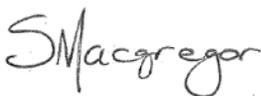
<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

<b>14/WS/1038</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

Yours sincerely



for  
**Dr Greg Ofili**  
**Chair**

Enclosures: List of names and professions of members who took part in the review  
“After ethical review – guidance for researchers”  
Copy to: Denise Forshaw, The University of Central Lancashire  
Ms Beverley Lowe, Lancashire Care NHS Foundation NHS Trust

**West of  
Scotland 5**

**Attendance at PRS Sub-Committee of the REC meeting on 02  
July 2014**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Stewart Campbell (VICE-CHAIR)	Consultant Physician & Gastroenterologist	Yes	
Canon Matt McManus	Parish Priest	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Sharon Macgregor	Co-ordinator

## Appendix F: Main study phase II NHS R&D letter of approval



Lancashire Care NHS Foundation Trust Research and Development

The Lantern Centre Vicarage Lane

Fulwood

Preston

PR2 8DW Tel: 01772 773498

R&I@lancashirecare.nhs.uk

26th August 2014

Mrs Alison Dewhurst  
Senior Musculoskeletal Physiotherapist Lancashire Care NHS Foundation Trust Ribbleton Clinic  
Langden Drive, Off Pope Lane  
Ribbleton  
Preston  
PR2 6HT  
Dear Mrs Dewhurst,

### **Re: NHS Trust Permission to Proceed**

#### **Project Reference: 14/16**

#### **Project Title: Exploration of the impact of feedback of the QuickDASH outcome measure to physiotherapy patients with shoulder impingement syndrome: a qualitative study**

I am pleased to inform you that the above project has received research governance permission. Please take the time to read through this letter carefully and contact me if you would like any further information. You will need this letter as proof of your permission. Trust R&D permission covers all locations within the Trust; however you will only be allowed to recruit from the sites/services you have indicated in section 3 of the SSI application form. If you would like to expand recruitment into other services in the Trust that are not on the original SSI then you must contact the R&D department immediately to discuss this before doing so.

You also must ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing recruitment in that service and you must contact the relevant service/ward managers prior to accessing the service to make an appointment to visit before you can commence your study in the trust.

Please make sure that you take your Trust permission letter with you when accessing Trust premises and please include the Trust reference number on any correspondence/emails so that the services are assured permission has been granted.

### **Honorary Research contracts (HRC)**

All researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that directly affects the quality of their care, should hold Honorary Research NHS contracts. Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners or when they are employed by an independent practitioner (Research Governance Framework for Health and Social Care, 2005). If a researcher does not require an HRC, they would require a Letter of Access (LoA). For more information on whether you or any of your research team will require an HRC or LoA please liaise with this office. It is your responsibility to inform us if any of your team do not hold Honorary Research NHS contracts/Letters of Access.

Staff involved in research in NHS organisations may frequently change during the course of a research project. Any changes to the research team or any changes in the circumstances of researchers that may have an impact on their suitability to conduct research MUST be notified to the Trust immediately by the Principal Investigator (or nominated person) so that the necessary arrangements can be put in place

### **Research Governance**

The Research Governance Sponsor for this study is University of Central Lancashire. Whilst conducting this study you must fully comply with the Research Governance Framework. This can be accessed at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4108962&chk=Wde1Tv](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv) For further information or guidance concerning your responsibilities, please contact your research governance sponsor or your local R&D office.

### **Good Clinical Practice (GCP)**

GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. It is the responsibility of all researchers who are carrying out a research project involving NHS patients and carers to complete GCP training and to update this every 2 years. All training certificates must be forwarded to the R&D department to comply with Trust permission. Please note that student projects are exempt from this process.

### **Risk and Incident Reporting**

Much effort goes into designing and planning high quality research which reduces risk; however untoward incidents or unexpected events (i.e. not noted in the protocol) may occur in any research project. Where these events take place on trust premises, or involve trust service users, carers or staff, you must report the incident within 48 hours via the Trust incident reporting system. If you are

in any doubt whatsoever whether an incident should be reported, please contact us for support and guidance. Regardless of who your employer is when undertaking the research within Lancashire Care NHS Foundation Trust you must adhere to trust policies and procedures at all times.

### **Confidentiality and Information Governance**

All personnel working on this project are bound by a duty of confidentiality. All material accessed in the trust must be treated in accordance with the Data Protection Act (1998) For good practice guidance on information governance contact us.

### **Protocol / Substantial Amendments**

You must ensure that the approved protocol is followed at all times. Should you need to amend the protocol, please follow the Research Ethics Committee procedures and inform all NHS organisations participating in your research.

### **Monitoring / Participant Recruitment Details**

If your study duration is less than one year, you will be required to complete an end of study feedback report on completion. However if your study duration is more than one year, you will be required to complete a short electronic progress report annually and an end of study report on completion. As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum; however, if you fail to supply the information requested, the trust may withdraw permission.

### **Recruitment**

Please provide the trust details of your recruitment numbers when requested. If you have any concerns with recruitment please contact the R&D team immediately for assistance.

### **Final Reports**

At the end of your research study, we will request a final summary report so that your findings are made available to local NHS staff. The details from this report may be published on the NHS Trust internet site to ensure findings are disseminated as widely as possible to stakeholders. You may also be invited to present your findings to the Trust at an event or meeting.

On behalf of this Trust, may I wish you every success with your research. Please do not hesitate to contact us for further information or guidance.

Yours sincerely,

Professor Jenny Shaw

R&D Director

On Behalf of the Research Governance Sub-Committee

Cc: DForshaw@uclan.ac.uk

## Appendix G: Main study phase II UCLan ethics approval letter



3<sup>rd</sup> October 2014

Lois Thomas and Alison Dewhurst  
School of Health  
University of Central Lancashire

Dear Lois & Alison

**Re: STEMH Ethics Committee Application**

**Unique reference Number: STEMH 275**

The STEMH ethics committee has granted approval of your proposal application 'The impact of outcome feedback in physiotherapy'. Approval is granted up to the end of project date\* or for 5 years from the date of this letter, whichever is the longer. It is your responsibility to ensure that

- the project is carried out in line with the information provided in the forms you have submitted. You regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify [roffice@uclan.ac.uk](mailto:roffice@uclan.ac.uk) if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use [e-Ethics Closure Report Proforma](#)).

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Tal Simmons', written over a light grey rectangular background.

Tal Simmons, Chair, **STEMH Ethics Committee**

\* for research degree students this will be the final lapse date

*NB - Ethical approval is contingent on any health and safety checklists having been completed, and necessary approvals as a result of gained.*

THE *QuickDASH*

OUTCOME MEASURE

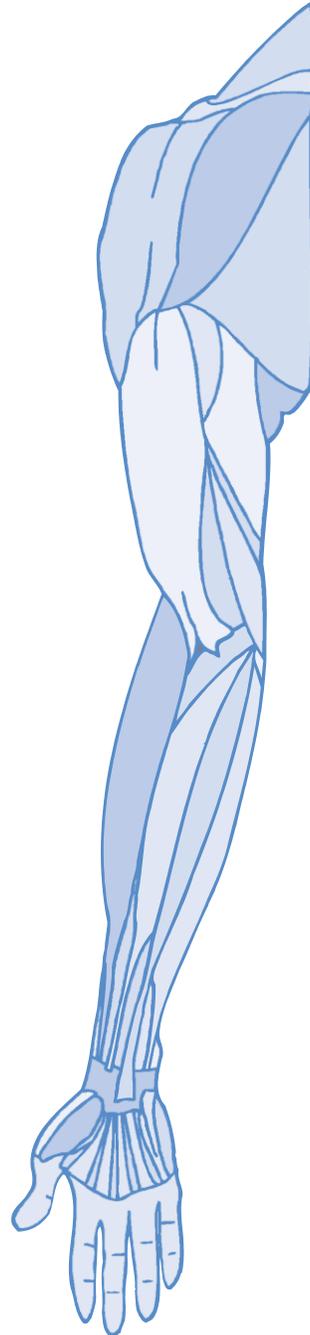
**INSTRUCTIONS**

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



# QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, <i>to what extent</i> has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. (circle number)

	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)	1	2	3	4	5

$$\text{QuickDASH DISABILITY/SYMPTOM SCORE} = \left[ \frac{\text{(sum of n responses)}}{n} \right] - 1 \times 25$$

where n is equal to the number of responses

## Appendix I: Pilot study phase I patient information sheet and consent form



Date

Dear

### **Letter of invitation for study participation: The effects of outcome feedback in Physiotherapy**

I am writing to ask if you would be willing to take part in a research project. The project is about feeding back outcome assessment scores to patients. The research is an educational project funded by the University of Central Lancashire and supported by Lancashire Care NHS Foundation Trust.

Scores are generated by asking patients to fill in a questionnaire. Results are used for NHS statistics and currently questionnaires are only completed at the start and end of a course of physiotherapy. The project is about exploring responses when a patient is informed of their outcome assessment scores throughout treatment (at every session in their course of physiotherapy).

Taking part in this study is optional. However, you can find out more about the study if you read the enclosed patient information sheet. If you feel you may be interested in taking part you can tell your physiotherapist at your first exercise class.

Please do not hesitate to contact myself, Alison Dewhurst, if you have any questions about the research project:

Email: [acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk)

Tel: 01772 777463

Thank you for your time.

Alison Dewhurst

University of Central Lancashire research student and Specialist Physiotherapist, NHS Central Lancashire

## **The effects of outcome feedback in Physiotherapy**

### **Patient information sheet Part 1**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 of the information sheet gives you more detailed information about the conduct of the study.

### **What is the purpose of the study?**

In physiotherapy we use basic scoring systems to monitor progress. We call these outcome assessments. Scores are created by getting patients to answer a questionnaire. Data about assessments is usually only used for NHS statistics and is only done at the start and end of a course of Physiotherapy. We do not know whether it would benefit patients or not to tell them these scores throughout their treatment.

### **Why have I been invited to take part?**

The patient group selected for taking part in this study are patients with a condition called "Shoulder Impingement Syndrome". On assessment your physiotherapist did a test that confirms this is the problem with your shoulder, and will have informed you of this diagnosis. As you have Shoulder Impingement Syndrome, you are eligible to be a participant. There are many causes of Shoulder Impingement Syndrome, and the most common symptoms in impingement syndrome are pain, weakness and a loss of movement at the affected shoulder.

### **Do I have to take part?**

It is up to you to decide. We will describe the study within this information sheet. We will then ask you to sign consent forms to show you have agreed to take part. There are 2 consent forms we will ask you to sign: one for collecting data at the shoulder class and one to agree to be interviewed. This will be done at a later date when you commence treatment at the Minerva Centre at the shoulder class. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

### **What will happen to me if I decide to take part?**

You will attend 8 sessions of the shoulder class at the Minerva Centre, Preston North End. Each session will last approximately 1 hour. This is the same as your normal NHS treatment.

At each session you will fill in a questionnaire to score your progress. At the same session your progress will be put on a chart and you will discuss how well you are doing with the Physiotherapist. At the end of the treatment you will be asked to be interviewed by a researcher.

### **What will happen at interview?**

We will arrange for the researcher to meet you at a time and place of your choice and will ask questions about how the feedback affected your progress, motivation to get better and if it helped you to achieve your goals. Interviews may last up to 1 hour. The interview will be audiotaped and transcribed. The transcription summary will be returned to you for verification. If you are happy with the transcript summary, the audiotape will be deleted. All audiotapes and documentation is kept in accordance with the Data Protection Act (1998).

### **Will my treatment change if I decide to take part or not?**

If you decide to take part or not, your treatment will continue as normal at the shoulder class, based at the Minerva Centre.

### **What are the possible risks and disadvantages of taking part?**

You are continuing normal treatment, therefore the risks are no higher than normal for injury during exercise. If your scores inform you that you are not progressing as well as you thought, you may become disheartened.

### **What are the possible benefits of taking part?**

We cannot promise the study will help you personally. The information we get from this study will help us to understand the thought processes of physiotherapy patients and whether outcome assessment information is useful to them or not, how and why. Dependent on the results, it may change our current practice to involve patients more in telling them about their progress.

### **What happens when the research study stops?**

If the numbers needed for the study have been reached before you finish your treatment, you will continue your normal NHS treatment pathway until you have completed 8 sessions of the shoulder class as per normal treatment.

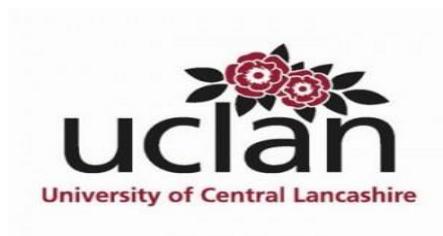
### **What if there is a problem?**

Any complaint about the way you have been dealt with during the study and will be addressed.

### **Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

***If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.***



## **The effects of outcome feedback in Physiotherapy**

### **Patient information sheet Part 2**

#### **What will happen if I don't want to carry on with the study?**

If you withdraw from the study, we will request your consent to use the data collected up to your withdrawal. If you decide to withdraw, your treatment will continue as normal at the shoulder class, based at the Minerva Centre.

#### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions:

[acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk)

Telephone: 01772 777463

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from:

<http://www.lancashirecare.nhs.uk/pals.php>

Telephone: 01282 657837 or 0750785734

You are covered for clinical negligence and other negligent harm to individuals covered by the NHS duty of care, as in normal NHS treatment. The University of Central Lancashire will provide insurance and indemnity for the study.

#### **Will my taking part in this study be kept confidential?**

If you join the study, the data collected for the study will be looked at by the researcher, authorised persons from UCLan and an administrator who will transcribe the interviews. All will have a duty of confidentiality to you as a research participant.

Your data will be coded with a participant number to keep your identity confidential. Outcome assessments will be collected via paper-based questionnaires and stored separately from the participant names and codes.

Interviews will be audio-taped digitally and transcribed to electronic files and stored on an encrypted and password protected drive at UCLan. The transcript summary will be sent to you, and you will be asked to verify it's content. As soon as the transcript summary is verified the audio-tape file will be deleted.

All paperwork will be stored in locked filing cabinets at NHS premises. Paper-based files will be destroyed 5 years after the study is completed.

### **What will happen to the results of the research study?**

The results of the research will be fed back to you in a summary document if you so wish. You will need to state this on your consent form if you would like to receive this or not.

The results will be presented and written to produce an MPhil / PhD thesis. The results will be published on the UCLan website and will be presented at local and national conferences. The results of the study may also be published in UK and International Journals. You will not be identified personally in any report, publication or presentation. Any quotes you make which identify yourself will not be used or will be anonymised for confidentiality purposes.

### **Who is organising and funding the research?**

The research is funded by UCLan and organised by UCLan and Lancashire Care NHS Foundation Trust.

### **Who has reviewed this study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Preston Research Ethics Committee. The School of Health in the University of Central Lancashire also have an Ethics Committee. Both committees have checked on this study and have allowed it to take place.

The NHS Research and Development team at Lancashire Care NHS Foundation Trust have reviewed this study and given a favourable opinion.

### **I still have further questions, who should I ask?**

Please do not hesitate to contact the researcher, Alison Dewhurst on the email or phone number outlined below should you have any further queries:

[acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk)

01772 777463



Participant ID:

Date:

**The effects of outcome feedback in Physiotherapy**

**Participant consent form- general study**

**Please initial box**

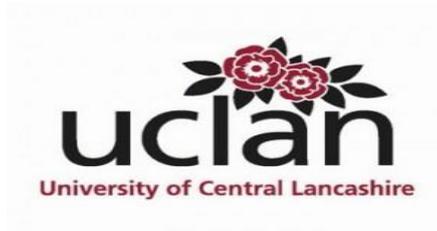
1. I confirm that I have read and understand the information sheet dated 22/2/2012 (version 1.6) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from UCLan, from regulatory authorities or from Lancashire Care NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to take part in this study.	
5. I would like to be informed of the outcome of this study in a summary document.	

Date \_\_\_\_\_ Signature \_\_\_\_\_

Name of participant, printed \_\_\_\_\_

Date \_\_\_\_\_ Signature \_\_\_\_\_

Name of person taking consent, printed \_\_\_\_\_



Participant ID:

Date:

**The effects of outcome feedback in Physiotherapy**

**Participant consent form- interviews**

**Please initial box**

1. I agree to the interview being audio recorded.	
2. I agree to the use of anonymised quotes in publications.	

**Date** \_\_\_\_\_ **Signature** \_\_\_\_\_

**Name of participant, printed** \_\_\_\_\_

**Date** \_\_\_\_\_ **Signature** \_\_\_\_\_

**Name of person taking consent, printed** \_\_\_\_\_

## Appendix J: Main study phase II patient information sheet and consent form



Physiotherapy Department, Ribbleton Clinic,  
Langden Drive, Off Pope Lane,  
Ribbleton, Preston,  
PR2 6HT.

Date

Dear

### **Letter of invitation for study participation: The impact of outcome feedback in Physiotherapy**

I am writing to ask if you would be willing to take part in a research project. The project is about feeding back outcome assessment scores to patients and discussing responses to the feedback of these scores with the patients themselves and their Physiotherapists. This project is being done as the final part of an educational study which contributes towards a doctoral qualification for the researcher.

Scores are generated by asking patients to fill in a questionnaire. Results are used for statistics and questionnaires in the NHS are only completed at the start and end of a course of physiotherapy. This project is the second phase of a study exploring responses when a patient is informed of their outcome assessment scores throughout treatment (at every session in their course of physiotherapy) and additionally the Physiotherapists' opinion on patient responses. It is important to research this issue as it is unknown what responses patients have to feedback of these scores and Physiotherapists opinions on the process.

Taking part in this study is optional. However, you can find out more about the study if you read the enclosed patient information sheet. If you feel you may be interested in taking part you can tell your physiotherapist at your next treatment session.

Please do not hesitate to contact me if you have any questions about the research project and thank you for your time.

Alison Dewhurst

University of Central Lancashire PhD research student and Specialist Physiotherapist, NHS Lancashire Care Foundation Trust and Physiofusion private practice, Lancaster  
Email: [acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk) Tel: 01772 777463



Version 1.3 30/09/2014 REC reference: 14/WS/1038

## **The impact of outcome feedback in Physiotherapy: Patient information sheet Part 1**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 of the information sheet gives you more detailed information about the conduct of the study.

### **What is the purpose of the study?**

In physiotherapy we use basic scoring systems to monitor progress. We call these outcome assessments. Scores are created by getting patients to answer a questionnaire. Data about assessments is usually only used for statistics and is usually only done at the start and end of a course of physiotherapy. We do not know whether it would benefit patients or not to tell them these scores throughout their treatment.

### **Why have I been invited to take part?**

The patient group selected for taking part in this study are patients with a condition called "Shoulder Impingement Syndrome". There are many causes of Shoulder Impingement Syndrome, and the most common symptoms in impingement syndrome are pain, weakness and a loss of movement at the affected shoulder. On assessment your physiotherapist did a test that confirms this is the problem with your shoulder, and will have informed you of this diagnosis. As you have Shoulder Impingement Syndrome, you are eligible to be a participant. To be eligible to take part in this study, you should have either been referred by your GP and be receiving treatment under a Physiotherapist working on a service level agreement with Healthshare provided by Lancashire Care NHS Foundation Trust or have referred yourself to a private Physiotherapist at Physiofusion in Lancaster.

### **Do I have to take part?**

It is up to you to decide. We will describe the study within this information sheet. We will then ask you to sign consent forms to show you have agreed to take part. Taking part in the study for data collection and agreeing to be interviewed are both optional and you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive and you will be able to continue your treatment path as normal in the shoulder class.

### **What will happen to me if I decide to take part?**

You will attend 3 or more sessions of treatment. Each session will last between 20 and 30 minutes. This is the same as your normal treatment. At each session you will fill in a questionnaire to score your progress. At the same session your progress will be put on a chart and you will discuss how well you are doing with the Physiotherapist. At the end of the treatment you may be recalled to an interview by a researcher, but this will be optional.

### **What will happen at interview?**

We will arrange for the researcher to meet you at a time and place of your choice and will ask questions about how the feedback affected your progress, motivation to get better and if it helped you to achieve your goals. Interviews may last up to 1 hour. The interview will be audiotaped and transcribed. The transcription summary will be returned to you for verification. If you are happy with the transcript summary, the audiotape will be deleted. All audiotapes and documentation is kept in accordance with the Data Protection Act (1998).

### **Will my treatment change if I decide to take part or not?**

If you decide to take part or not, your treatment will continue as normal with your chosen Physiotherapist.

### **What are the possible risks and disadvantages of taking part?**

You are continuing normal treatment, therefore the risks are no higher than normal for injury during exercise. If your scores inform you that you are not progressing as well as you thought, you may become disheartened.

### **What are the possible benefits of taking part?**

We cannot promise the study will help you personally. The information we get from this study will help us to understand the thought processes of physiotherapy patients and whether outcome assessment information is useful to them or not, how and why. Dependent on the results, it may change our current practice to involve patients more in telling them about their progress.

### **What happens when the research study stops?**

If the numbers needed for the study have been reached before you finish your treatment, you will continue your normal treatment pathway.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study and will be addressed.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

***If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.***

## The impact of outcome feedback in Physiotherapy

### Patient information sheet Part 2

#### What will happen if I don't want to carry on with the study?

If you withdraw from the study, we will request your consent to use the data collected up to your withdrawal. If you decide to withdraw, your treatment will continue as normal and it will have no effect on your treatment pathway.

#### What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (01772 777463 [acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk)). If you would like to speak to another member of the research team please contact Dr Lois Thomas (01772 893643) or the Dean and Head of School, Mr Nigel Harrison (01772 893701).

The University of Central Lancashire will provide insurance and indemnity for the study.

If you remain unhappy and wish to complain formally, you can do this through your physiotherapy provider:

- NHS Complaints: You are covered for clinical negligence and other negligent harm to individuals covered by the NHS duty of care, as in normal NHS treatment. Complaints procedure details can be obtained from: <http://www.lancashirecare.nhs.uk/pals.php>

Telephone: 01282 657837 or 0750785734

- Physiofusion Lancaster: <http://www.physiofusion.co.uk/> Telephone: 01524 874649

#### Will my taking part in this study be kept confidential?

If you join the study, the data collected for the study will be looked at by the researcher, authorised persons from the University of Central Lancashire and an administrator who will transcribe the interviews. All will have a duty of confidentiality to you as a research participant. Your data will be coded with a participant number to keep your identity confidential. Outcome assessments will be collected via paper-based questionnaires and stored separately from the participant names and codes.

Interviews will be audio-taped digitally and transcribed to electronic files and stored on an encrypted and password protected drive. The transcript summary will be sent to you, and you will be asked to verify it's content. As soon as the transcript summary is verified the audio-tape file will be deleted.

All paperwork will be stored in locked filing cabinets at NHS premises. Paper-based files will be destroyed 5 years after the study is completed.

### **What will happen to the results of the research study?**

The results of the research will be fed back to you in a summary document if you so wish. You will need to state this on your consent form if you would like to receive this or not.

The results will be presented and written to produce a PhD thesis. The results will be published on the UCLan website and will be presented at local and national conferences. The results of the study may also be published in UK and International Journals. You will not be identified personally in any report, publication or presentation. Any quotes you make which identify yourself will not be used or will be anonymised for confidentiality purposes.

### **Who is organising and funding the research?**

The research is funded by UCLan and organised by UCLan, Lancashire Care NHS Foundation Trust and Physiofusion.

### **Who has reviewed this study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the West of Scotland Research Ethics Committee 5. The School of Health in the University of Central Lancashire also have an Ethics Committee. Both committees have checked on this study and have allowed it to take place. The NHS Research and Development team at Lancashire Care NHS Foundation Trust have reviewed this study and given a favourable opinion.

### **I still have further questions, who should I ask?**

Please do not hesitate to contact the researcher, Alison Dewhurst on the email or phone number outlined below should you have any further queries: [acdewhurst@uclan.ac.uk](mailto:acdewhurst@uclan.ac.uk)  
Tel: 01772 777463

Version 1.3 30/09/2014 REC reference: 14/WS/1038

Participant ID:

Date:

**Title of the study: The impact of outcome feedback in physiotherapy**

Participant consent form: Agreement for participation in the study, receiving feedback of outcome measures within physiotherapy treatment and participation in an interview to discuss responses to the feedback of these measures.

**Please initial box**

<p>1. I confirm that I have read and understand the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.</p>	
<p>2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.</p>	
<p>3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Central Lancashire, from regulatory authorities or from Lancashire Care NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.</p>	
<p>4. I agree to the interview being audio recorded.</p>	
<p>5. I agree to the use of anonymised quotes in publications.</p>	
<p>6. I agree to take part in this study.</p>	
<p>7. I would like to be informed of the outcome of this study in a summary document.</p>	

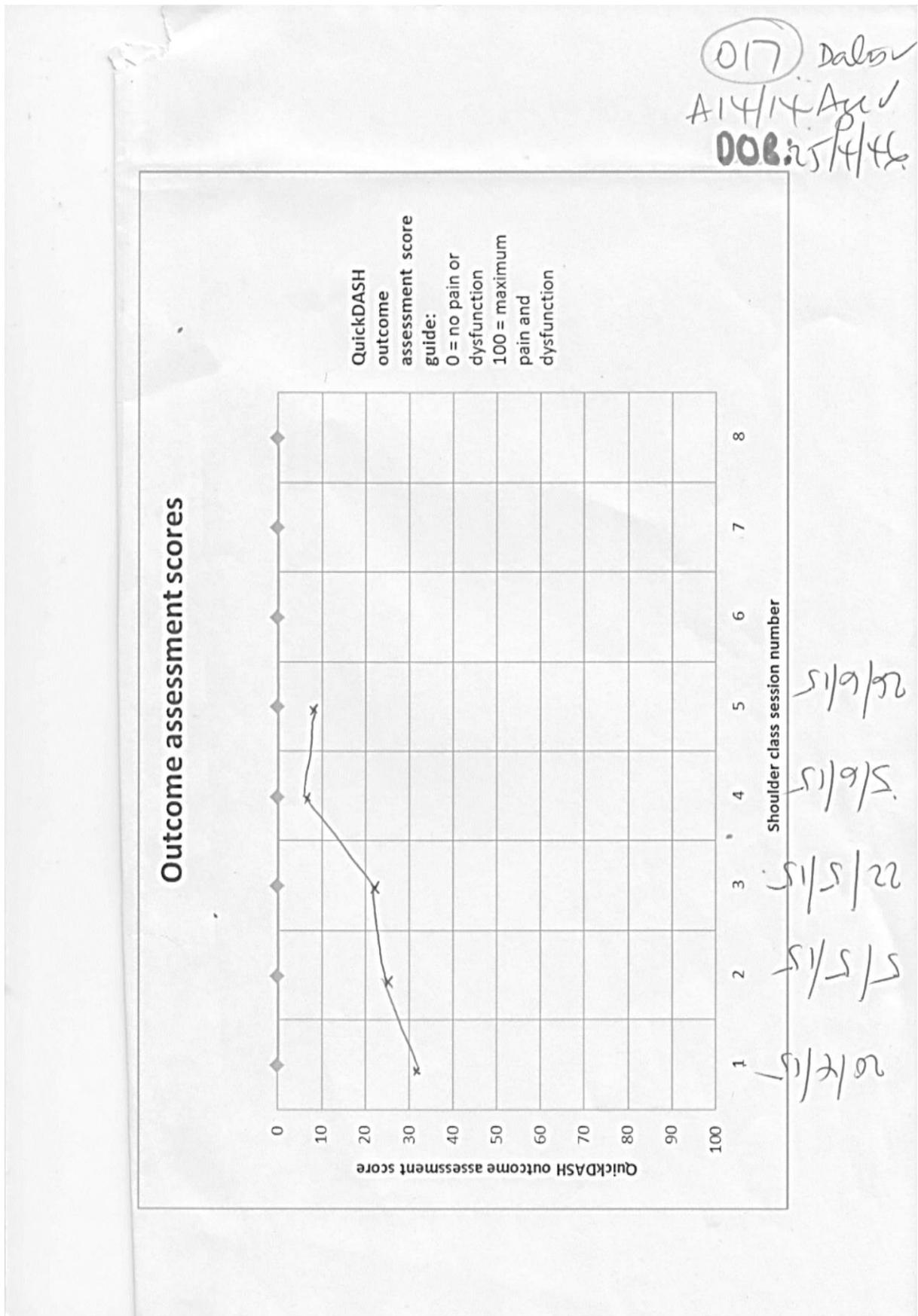
Date \_\_\_\_\_ Signature \_\_\_\_\_

Name of participant, printed \_\_\_\_\_

Date \_\_\_\_\_ Signature \_\_\_\_\_

Name of person taking consent, printed \_\_\_\_\_

Appendix K: QuickDASH completed example graph (participant 17)



## Appendix L: Pilot study interview schedule with written notes

- 1) When you started the class, how serious was the shoulder problem to you in daily life? What couldn't you do? What were the consequences of that for you?
- 2) What do you think caused the problem? What actions were you taking on your own to deal with it and try to make it better? What previous treatment had you had?
- 3) Did you have a goal you wanted to achieve? What did you want to be able to do? What is it important for you to be able to do in your daily life?
- 4) When you started, how far off that goal were you? What was your shoulder like at the beginning? Where are you now in relation to your goal?
- 5) Did you have an idea of how long it would take you to get better – what sort of progress you wanted? Has it gone as you thought it would? Have you had any setbacks? Has anything been better than you thought it would be?
- 6) Where are you now in relation to your goal? Are you happy with that, or not? What else do you want to do?
- 7) Has there been anything that has influenced your progress?
- 8) How has filling in the questionnaire been? You have to do it every time you come – how is that? Do you think it was asking the right questions for you? Do you think the scores were an accurate reflection of where you were at the beginning – was it a surprise? Did it seem to be too low, too high or just right? Why – what was the difference between what it said and how you felt?
- 9) Let's have a look at the pattern... do you think that is right – did you have (comment on line up, down, etc) Why was that? Each week you seem to improve a little bit – what do you put that down to? On that week, you didn't improve – is that an accurate reflection? Why?
- 10) How was it, getting these scores every week? What was it like? How did it make you feel when ...things went up, down, stayed the same? Were the scores ever a surprise? Was it always what you expected? Did you want to get scores every week, or not? Were they of any use to you? Would it have made any difference if you hadn't had them? What sort of difference?
- 11) Do you think you did anything differently because of the scores? Did it change how you felt? Did it change how you thought? Did it change what you did? You knew that someone would be looking at the scores each week – how did that feel? Did it impact on what you did or not?
- 12) How do you think you compare to the other people in the class? Do you think other people might feel differently?
- 13) How do these scores relate to your goal that you told me about at the beginning – to...

Checklist

Attitudes

Goals.

Types of feedback.

Acceptance - why - accuracy  
- relevancy

Use of FB - confirmation, <sup>-use</sup> working harder  
changing behaviour.

## Appendix M: Interview summary example sent to participant for comment

Ian

- Retired
- Enjoys going caravanning with his wife and dog
- Away as much as possible around the country travelling
- Ripped and damaged tendons in the shoulder by tripping and hitting shoulder on the car
- Previous shoulder injury, and also shoulder injury to the right side also so previous experience of the healing process
- He knew already what damage he had done
- Tried without physio. Still painful so then decided to get referred
- Severe at the start
- Had to wait 3 weeks for treatment
- Had a no pain, no gain attitude to treatment
- Used feedback of activities such as washing hair to determine if was improving
- Goal at end of treatment for arm to just get stronger
- Pain shows still a problem although also works through pain in exercising (no pain no gain) as doesn't hurt after exercise. Uses pain as a feedback to if he is improving
- Heat helps and cold makes it worse
- Complies with all treatment and in control of progression
- Perseveres and goes through the pain
- The scoring sheet (graph) he completed to help the therapist but didn't necessarily use it for himself
- Scores went up and down due to circumstances and increased activity
- Monitoring didn't change action
- He has a goal to get better and healed as much as possible but knows he will never be 100%
- Important to still be able to do all caravanning activities which make him happy
- Attributes some change to the help and guidance of the therapist
- 80% improved at end of treatment
- Action plan to continue exercising as working well

Appendix N: Two examples of combined participant storyboard analysis

**Understanding of variation**  
 + scores  
 + compensating factors 005 + 002  
 "My balance is out of action at the moment, I think that probably didn't help last week"  
 "It went down due to circumstances" 007.

**How to patients gauge accuracy?**

Perceived status vs actual  
 SAME: 006 002 008  
 005 007  
 004 (but didn't use)  
 Diff: 003  
 UNKNOWN: 001, ~~002~~

subjective nature of PROMs  
 pt knowledge of PROMs + accuracy 001.  
 Handedly both awareness (001)  
 or incorrect awareness (003)  
 "I felt I was + being totally honest in what I was writing down"  
 "The scoring system may look a bit but (004)

**Outcome scores**  
 Relevance of questioning  
 YES: 002, 004, 005, 007, 008  
 NO: 003  
 UNKNOWN: 001, 006.  
 awareness related to arm/  
 dominant arm (003)  
 Relevance of ques on daily activities - walk (004) (008).  
 Ambiguous questioning 006

**How do patients gauge RELEVANCE?**

Is it relevant to them as a person?  
 "I don't think I would have got as far... without knowing the scores" 002  
 "Daily tasks and stuff, that's what really looked at whether it was relevant" 007.

**Knowledge**  
 Telling the patient / making them aware of something they didn't know / progress that couldn't be felt (001, 006).  
 Therapist knowledge: "If I hadn't had the session you wouldn't know what could have happened and she (the therapist) wouldn't know" 007.  
 Behaviour activation / change  
 Trying harder (002, 005)

**How to patients gauge something to be USEFUL?**

Help to those / others  
 useful to us as therapists + patient helping to help others (002)  
 Common goals  
 common end point 005  
 "something to look for", "Aim for"  
 -ve relevance  
 004 feels using physio + scores is "reducing on ex."  
 008 "well after that exercise + everything, it just helped me. But going back to work again, I'm daunted"

Measurement of control linked to camp what they are told!

"If you don't adhere to what they ask you to do then you can expect problems" 002

(knowledge/exe) "It's up to you if you use it or not - you know! I think you're stupid if you don't use it" 001

balance on ex

My main goal is getting back 2 my main not playing too much on my physio study" 007

How do they? MESSUCE

"I think it's knowledge base about control & knowledge" 007

"I knew it just wasn't going to get better and if it was going to get it back I would need to take exe" 001

"my horse got to put their heart sound into what they are doing & make something know what they're doing about it" 008

"I think you get frightened of trying it" 002 "I am frightened of it starting again"

"I'm going to be even worse pain because of my job" 008

Controlling by way of making around a problem.

"I can do these extra tasks when I can't do them" 003

"I can do these extra tasks when I can't do them" 003

"I can do these extra tasks when I can't do them" 003

Talking about control

00 state of normality

"It wasn't actually stopped, I've done nothing" 005

"I think I'd go to the bus as the one at home was 2x or 3x as fast... I didn't know if there's something else other than muscle" 008

"I've had scans and there's not much showing up... and I mean I go to the gym and do you think I could go further?" 007

Medical intervention

Loss of control

"Does it need an injection?" 003

"I would love to get both 2 work but can't do that against the evidence" 004

"I thought it would be about control & knowledge" 004

"I think with myself I know exactly how I feel about the situation" 004

"I didn't know whether it was going to rhyme or not" 006

"I thought I'd have a lot" 006

"I'll always have that knowledge I can use again & again" 006

"The exercise is what I've gained + I've learned I can use" 007

The 6 illness "situations"

001 Nearly better

Still affecting heavy APLS + bubbles received physio by dawn + supping.

002 Near full recovery

not affecting many activities. Using only physio as "back up"

003 Phys. Affecting

APLS + work but not taking any time off

004 Much improved not @ free yet - still off work

005 Slightly improved.

1 year H2O problem continuing activities as is a cder

006 Near full recovery

improvements nearly @ function!

007 No real improvement

of scores improved in total + @ reported pt.

008 No impact of scores

improvement in strength with main ass factor.

Attitude beliefs about themselves:

"It's who I am, I have to do the exe I just go and do the exe" 001

"I haven't got an attitude for doing things" 002

"I am an optimist that I will get better" 003

"I was just being honest" 008

Achievement

"I think I have achieved" 002

Attribution

- how do people talk about themselves?

Talk about themselves as better (less severely affected)

001, 005 (Lawrence), 006, 007

Attribution

- See attitude

"I know to get that I would + stick to a gym, what I will go swimming" 005

"I had that more determined to me!" 005

Like to tell you about @

activity + compliance

"I go to the gym 5 times a week anyway" 001

"complaint right in the start" 001 "my motivation didn't need changing" 001

"I was quite happy to do what I was asked to do and I know what they told me to do" 002

"I would improve it" 002

"I'm a patient + I know it's helped a lot" 007



	Statement	001	002	003	004	005	006	007	008
Monitoring and feedback: Internal and external feedback mechanisms	Pain (as a guide to closeness to recovery)	✓	✓	✓	✓		✓	✓	✓
	Functional measures	✓	✓	✓	✓		✓	✓	
	Pain was used as a negative measure that problem was not resolving/severe		✓	✓	✓	✓		✓	✓
	Pain used positively to gauge effort or increased activity	✓						✓	
	Use of generalised "feelings"	✓	✓	✓	✓	✓	✓	✓	
	Viewing themselves as better than the other class patients	✓						✓	✗
	Awareness of the scores made patients work harder towards their goals		✓			✓			
	Perceived status vs actual status (confirmation)		✓				✓	✓	✓
	Mention of dissonance of actual scores and perceived scores					✓			
	Interest in outcome assessment scores.	✓							✓
Actions	Scores useful to participant when no dissonance (actual and perceived status)					✓			
	Modification of action	✓	✓	✗	✗	✓	✓	✓	✗
Acceptance		✓	✓	✗	✗	✓		✓	✓

	001	002	003	004	005	006	007	008	
<b>Feedback Comparison against others</b>	<p><i>Rating Quote</i> Strong I am at the top end and there are some people right at the bottom.</p> <p><i>Narrative</i> He views himself as less affected.</p>	<p><i>Weak</i> (No data)</p> <p><i>Strong</i> I don't think I would have got as far... without following any scores.</p>	<p><i>Weak</i> (No data)</p> <p><i>Weak</i> I am right handed... so I fell I was going forward in what I was writing down.</p>	<p><i>Weak</i> I think I have been looking at other people.</p> <p><i>Medium</i> Comparing against others but is unsure of his status against theirs.</p>	<p><i>Strong</i> There were lots of people doing things and a lot more problems than I did.</p> <p><i>Medium</i> Did not consider her problem to be of a serious nature and already felt improvement, prior to starting the process.</p>	<p><i>Strong</i> I did know there were other people doing things... I think I was doing alright actually.</p> <p><i>Medium</i> Compared against others and considered to be doing better despite low scores.</p>	<p><i>Weak</i> No, not really. I was just concentrating on mine.</p> <p><i>Medium</i> Chores (ie used/fitness), it did whether he was progressing, but I felt a bit good to know where you were each week.</p>	<p><i>Weak</i> She doesn't compare against others to determine her status.</p>	
<b>Feedback Outcome scores</b>	<p><i>Medium</i> It's interesting to see how you perform.</p>	<p><i>Strong</i> He viewed the monitoring process as one that may help him get more attention from therapists. He enjoyed the attention and the improvement that followed.</p>	<p><i>Weak</i> I am right handed... so I fell I was going forward in what I was writing down.</p> <p><i>Medium</i> Could do all activities on the PROM with the right hand so answered incorrectly with scores to show own external feedback more accurate than QuickDASH therefore scores were dismissed. Action was to use own feedback mechanism to over-ride outcome score.</p>	<p><i>Medium</i> Feedback of the scores gives a monitoring effect into the self-regulation cycle.</p>	<p><i>Strong</i> When you see the graph... I tried to be top of the score sheet and know made me feel a bit like a fraud can see how it's improving each week.</p>	<p><i>Medium</i> I think I'd be top of the score sheet and know made me feel a bit like a fraud can see how it's improving each week.</p>	<p><i>Medium</i> I think I'd be top of the score sheet and know made me feel a bit like a fraud can see how it's improving each week.</p>	<p><i>Medium</i> I think I'd be top of the score sheet and know made me feel a bit like a fraud can see how it's improving each week.</p>	<p><i>Medium</i> I think I'd be top of the score sheet and know made me feel a bit like a fraud can see how it's improving each week.</p>
<b>Feedback Pain</b>	<p><i>Medium</i> I just thought... is it actually fixed?</p> <p><i>Medium</i> I just thought... is it actually fixed?</p>	<p><i>Strong</i> I may not be able to go any further, I am very pleased in how I'm going on.</p> <p><i>Medium</i> He is pleased with his progress as the therapists are happy with his status and one goal is to please the therapists.</p>	<p><i>Strong</i> It doesn't seem to really be improving, it doesn't seem to be going right really.</p> <p><i>Medium</i> Using feeling as scores not indicative of actual status and hasn't valued the feedback as it hasn't been useful due to inaccuracy and consequence with mechanisms.</p>	<p><i>Strong</i> (Scoring) would be angry for someone to know exactly how I feel about the situation.</p> <p><i>Medium</i> He feels he knows better than the QuickDASH scores and he can monitor it himself.</p>	<p><i>Strong</i> I repair my situation as being pretty good.</p> <p><i>Medium</i> Initially compares against others and feels better in comparison also feels in control of the illness situation.</p>	<p><i>Strong</i> I get frustrated, I think my GOI before, I'm happier from where I started from, I think I was doing not too bad to be honest.</p> <p><i>Medium</i> Contrasting beliefs of improvement and improved GOI, but also still frustrated with the condition.</p>	<p><i>Strong</i> I'm not getting any better... I feel and that's what it is.</p> <p><i>Medium</i> Feels in a generalised way.</p>	<p><i>Strong</i> I'm not getting any better... I feel and that's what it is.</p> <p><i>Medium</i> Feels in a generalised way.</p>	<p><i>Strong</i> I'm not getting any better... I feel and that's what it is.</p> <p><i>Medium</i> Feels in a generalised way.</p>
<b>Feedback Generalised feelings</b>	<p><i>Narrative</i> Knew why pain was evident and believes without causing symptoms. I wouldn't have changed.</p>	<p><i>Strong</i> Focus on pain, fighting symptoms. Fighting of condition worsening. Considers pain to be sign of severity.</p>	<p><i>Strong</i> Relyance upon external feedback recovery, using pain as a feedback mechanism to show it is still not "right".</p>	<p><i>Strong</i> He is using pain as a feedback mechanism.</p>	<p><i>Strong</i> Used to determine level of improvement and awareness of using the wrong muscles in shoulder movements. Led to reasoning, knowledge and understanding of condition.</p>	<p><i>Strong</i> Used to determine level of improvement and awareness of using the wrong muscles in shoulder movements. Led to reasoning, knowledge and understanding of condition.</p>	<p><i>Strong</i> Used to determine level of improvement and awareness of using the wrong muscles in shoulder movements. Led to reasoning, knowledge and understanding of condition.</p>	<p><i>Strong</i> Used to determine level of improvement and awareness of using the wrong muscles in shoulder movements. Led to reasoning, knowledge and understanding of condition.</p>	<p><i>Strong</i> Used to determine level of improvement and awareness of using the wrong muscles in shoulder movements. Led to reasoning, knowledge and understanding of condition.</p>
<b>Feedback Function</b>	<p><i>Strong / medium</i> I can't carry anything heavy.</p> <p><i>Strong / medium</i> I can't carry anything heavy.</p>	<p><i>Strong</i> I can't carry anything heavy.</p> <p><i>Medium</i> I go dancing as well and it can affect that sometimes.</p>	<p><i>Strong</i> I go dancing as well and it can affect that sometimes.</p> <p><i>Medium</i> Affecting hobbies but not all the time.</p>	<p><i>Strong</i> May have the wrong conclusion really because the biggest part of it is getting back my flexibility.</p> <p><i>Medium</i> Views functionality as a strong feedback mechanism.</p>	<p><i>Strong</i> I can't carry anything heavy on that arm, I couldn't pick up my grandchildren.</p> <p><i>Medium</i> Affected everyday function therefore strong mechanism.</p>	<p><i>Strong</i> I can't carry anything heavy on that arm, I couldn't pick up my grandchildren.</p> <p><i>Medium</i> Affected everyday function therefore strong mechanism.</p>	<p><i>Strong</i> I can't carry anything heavy on that arm, I couldn't pick up my grandchildren.</p> <p><i>Medium</i> Affected everyday function therefore strong mechanism.</p>	<p><i>Strong</i> I can't carry anything heavy on that arm, I couldn't pick up my grandchildren.</p> <p><i>Medium</i> Affected everyday function therefore strong mechanism.</p>	<p><i>Strong</i> I can't carry anything heavy on that arm, I couldn't pick up my grandchildren.</p> <p><i>Medium</i> Affected everyday function therefore strong mechanism.</p>

	001	002	003	004	005	006	007	008
	Strong Quote Goal related to the pain that just passed everywhere	Medium Narrative He has achieved (my goal)	Strong Quote Getting back to work	Strong Quote Getting to work for to have a lot more movement and my arm a bit more free	Strong Quote I think they are accurate to a point (the QuickDASH questions)	Strong Quote I think they seemed alright (the QuickDASH questions)	Strong Quote I felt that the questions were appropriate; I think they were quite positive	Strong Quote I could lift my hand and not have pain
Goals	Narrative Pain related goal as pain caused reduced function affected hobbies	Narrative His action now he has reached his goal and his is to have his arm so it doesn't aggravate the pain e.g. limited lifting. Acceptance of his condition and reduced motivation to try harder at this point.	Strong Quote Pain related goal and pre-set personal norms wanted it to be normal	Strong Quote She preferred the graph to verbal feedback as it's clearer. The scores were that the feedback increased attention to the scores and made her realise she was closer and closer to achieving her goal and she enjoyed the feedback of the scores.	Strong Quote Her goal was split: ideal goal was to live and work normally and she was unsure of whether she could reach this, so added 'or minimise it'. She was not definite on where her end-point of improvement may be. She was monitoring herself in closeness to goal achievement.	Strong Quote Contrasting goal quotes from small to large fitness, health and realistic goals mentioned.	Strong Quote Measurable and non-measurable goals were used	
Feedback process with QuickDASH	Medium Quote It just confirmed things	Strong Quote I didn't mind at all (filling in the paperwork)	Weak Quote It doesn't matter which arm you use answering	Medium Quote He finds the monitoring process challenging	Medium Quote I found that the steeper one with the weights, that was hard work, but I persevered	Medium Quote She is taking action by adhering to the exercise and realises she will always have to do some exercises to prevent flare-ups. She takes in control of the situation and has an 'armoury' of exercises to lessen the pain	Medium Quote I thought what the questions were asking were appropriate; I think they were quite positive	Medium Quote Of course (in response to a question if it was useful) Yes (in response to if relevant to you) Yes (in response to if actually says useful) but did not actually use it for feedback in any way other than to confirm status
Acceptance of	Medium Narrative Without the exercises it wouldn't have changed; it still needs to be stronger	Strong Quote He is happy to help the person as he is consistent with all requests	Strong Quote I have tried because I do want it to be right.	Weak Quote (no data)	Medium Quote She is taking action by adhering to the exercise and realises she will always have to do some exercises to prevent flare-ups. She takes in control of the situation and has an 'armoury' of exercises to lessen the pain	Medium Quote I am trying to build it into everyday exercises	Medium Quote I found that the steeper one with the weights, that was hard work, but I persevered	Medium Quote Hot water bottle, cream and painkillers (in response to self-treatment pre physio)
actions and	Strong Narrative Determining status and deciding on actions to change status	Strong Quote He will do what he is advised by a health professional but without advice he only does 'a bit' of exercise at home.	Strong Quote I am an optimist that it will get better; My main goal is getting back to physiotherapy	Strong Quote I know I wouldn't stick to them (the exercises); I will go swimming	Strong Quote She uses this in a sense of constant monitoring and if she is falling short of her normal standard she will increase her effort. She feels with the knowledge she has gained if she releases she can improve independently	Strong Quote Keen to show she had learned knowledge and is equipped to lessen the pain with the exercises	Strong Quote Keen to show she had learned knowledge and is equipped to lessen the pain with the exercises	Strong Quote Non-exercise based actions. She is not regular with exercise.
Self-regulation	Strong Quote It's who I am, if I have to do the exercises, I just do them. I was doing me any good, but it did. It taught me a lot	Strong Quote I have a positive attitude; I have got an attitude for doing things	Strong Quote I am an optimist that it will get better; My main goal is getting back to physiotherapy	Strong Quote I know I wouldn't stick to them (the exercises); I will go swimming	Strong Quote I can do these extras to lessen the pain; if I do release I can bring myself back up	Strong Quote If I can't use the exercises then I kind of goes back to back. I'm a quite active person	Strong Quote If I can't use the exercises then I kind of goes back to back. I'm a quite active person	Strong Quote Knowledge and self-efficiency. Keen to show activity pre-class with Yoga and Pilates.
monitoring	Strong Quote Intentions to self-regulate by actions at gym / home and maintenance of goal and further monitoring	Strong Quote He prides himself on his adherence of attending every week and arriving early. He is keen to monitor his progress and enjoys it. He is not necessarily self-efficient	Strong Quote I am an optimist that it will get better; My main goal is getting back to physiotherapy	Strong Quote I know I wouldn't stick to them (the exercises); I will go swimming	Strong Quote I can do these extras to lessen the pain; if I do release I can bring myself back up	Strong Quote If I can't use the exercises then I kind of goes back to back. I'm a quite active person	Strong Quote Knowledge and self-efficiency. Keen to show activity pre-class with Yoga and Pilates.	Strong Quote Knowledge and self-efficiency. Keen to show activity pre-class with Yoga and Pilates.



## **Appendix Q: Main phase II patient and physiotherapist interview schedules**

### **Interview questions for patient participants**

#### **Background**

- 1) Tell me a bit about yourself....
  - What you like to do
  - Where you work
  - A bit about your homelife
- 2) Can you tell me a bit about your shoulder problem
  - How it started
  - How long you've had it
  - How things have progressed
- 3) When you started treatment, how did you feel attending physiotherapy? What was it like?
  - How serious was the shoulder problem to you in daily life?
  - Did the problem restrict you at all? In what way?
  - Were there things you believed you couldn't do? Were there things you avoided or feared trying? What were the consequences of that for you?
- 4) What do you think caused the problem?
- 5) What previous treatment had you had?
- 6) Were you happy with the way your Physiotherapist delivered your questionnaire scores to you? Sensitive? Private?

#### **Goals**

- 7) Did you have a goal you wanted to achieve at the start of treatment?
  - What did you want to be able to do? What is it important for you to be able to do?
  - When you started, how far off that goal were you?
  - Where are you now in relation to your goal?
  - Why was it important to you to be able to reach this goal?

Did you have any other goals that you wanted to achieve? (repeat above questions)

#### **QuickDASH scores**

- 8) Did you have an idea of how long it would take you to get better?
  - What sort of progress you wanted?
  - What actions were you taking on your own to deal with it and try to make it better?
  - Has your recovery gone as you thought it would?
  - Have you had any setbacks?
  - Has anything gone better than you thought it would?
- 9) Where are you now in relation to your goal(s)?

Are you happy with where you are now, or not?

What else do you want to do?

10) Has there been anything that has influenced your progress?

11) How has filling in the questionnaire been?

You have to do it every time you come – how is that?

Do you think it was asking the right questions for you? (relevancy)

Do you think the scores were an accurate reflection of where you were at the beginning – was it a surprise?

Did it seem to be too low, too high or just right? (accuracy)

Why – what was the difference between what it said and how you felt?

(prompt did they feel better than the score said / worse than the score said and did it change at different time points?)

Do you think the scores at the end of treatment were an accurate reflection of where you were?

12) How involved in your treatment did you feel?

13) How did you use the scores and the graph?

Did it affect your progress? Why did it affect it that way?

Let's have a look at the pattern...

How would you describe it? (prompt good / poor / average)

Do you think that is right – did you have an idea that you were improving / staying the same / worsening (comment on line up, down, no change)

Why was that? Each week you seem to improve a little bit – what do you put that down to? On that week, you didn't improve – is that an accurate reflection? Why?

What could you have changed to make it different?

14) How was it, getting these scores every week?

What was it like? How did it make you feel when ...things went up, down, stayed the same? Did you want to get scores every week, or not?

Were they of any use to you? Did the scores change your involvement or commitment to the treatment? Would it have made any difference if you hadn't had them? What sort of difference?

15) Do you think you did anything differently because of the scores?

Have you changed anything you were doing because of the scores / since starting treatment?

How has knowing how well you are doing with the scores made you feel? (Prompt increased focus / goal focus / indifferent / involvement in treatment)

Did it change how you thought?

Did it change what you did?

You knew that someone would be looking at the scores each week – how did that feel?

Do you have any explanations for your scores? Did it impact on what you did or not?

16) Did you compare yourself to other people? Or talk to other people with shoulder problems?

What did they say / do and how did it make you feel?

17) How do these scores relate to your goal that you told me about at the beginning .....

18) You have scores that are going up/down/in a line....

Why do you think that is?

How do you feel this line would have been without the feedback of the scores?

### **Dissonance**

19) Did you use any other information to gauge how well you were doing?

Prompts: Pain, general feelings of improvement, functional changes, comparison against other people. What was the most important piece of information you have used to gauge your progress?

### **Causal attributions**

20) Did you feel you had control over your condition?

21) Some people feel their conditions are relatively new to them (acute) and curable and some think they have had theirs so long it is chronic and will never resolve, Would you consider yourself acute or chronic?

22) Are there any home or work issues that have affected you?

23) Have you changed how you are dealing with your condition? (consider mechanisms)

Gym? Self-treatment?

Home exercises?

24) Did you comply with the treatment the physiotherapist gave you?

25) How did the time passing affect your condition?

### **Information and feedback**

26) Is there anything you would like to add?

27) Do you have any questions?

## **Interview questions for physiotherapists**

### **General**

28) How have you found filling in the questionnaire with patients?

### **QuickDASH**

29) You have to ask the patients to do it every time they come for appointments – how is that?

Do you think it was asking the right questions? (relevancy)

How accurately did the scores reflect the patients' conditions and current symptom state?

(accuracy)

Why – what was the difference between what it said and how you felt they were doing?

(prompt better than the score / worse than the score)

How did you find communicating with the patients about their scores?

30) How did telling patients their scores affect patient involvement in treatment?

Interest

Exercises

Adherence

Motivation

31) How did you use the scores and the graph?

32) How did the patients use the scores?

33) How did you find recording the scores every week? And discussing them with patients?

How did it make the patients feel when ...things went up, down, stayed the same? Were the scores ever a surprise to you? Was it always what you expected?

Did you want to give out the scores every week, or not?

Were they of any use to you?

Would it have made any difference if you hadn't had them? What sort of difference?

34) Do you think you did anything differently because of the scores and discussion with patients?

Have you changed anything you were doing with the patients because of the scores?

Have you noticed any increased focus / goal focus / indifference / involvement in treatment?

Did it change how you thought about a patient's current level of recovery?

Did it change what you did or change your focus?

### **Goals**

35) What goals from treatment did patients seem to have?

Pain / function

Specific / non

Realistic or not

36) Did scores help patients work towards or reach their goals?

Identification of dissonance / congruence?

37) How do you feel patients would have done without feedback of the scores?

### **Dissonance**

38) From your experience, what told this group of shoulder patients that they were getting better?

Do you think they used.....

Pain feedback

The score sheet / trajectory/ QuickDASH

How they felt

How they were doing in comparison to others

Function

### **Causal attributions**

39) What kind of shoulder problems did patients have? What things couldn't people do?

Causes

Acute/chronic

In control or not

Serious or not

Previous treatments people had

Issues affecting progress

40) Did they comply with treatment?

Any reasons for this?

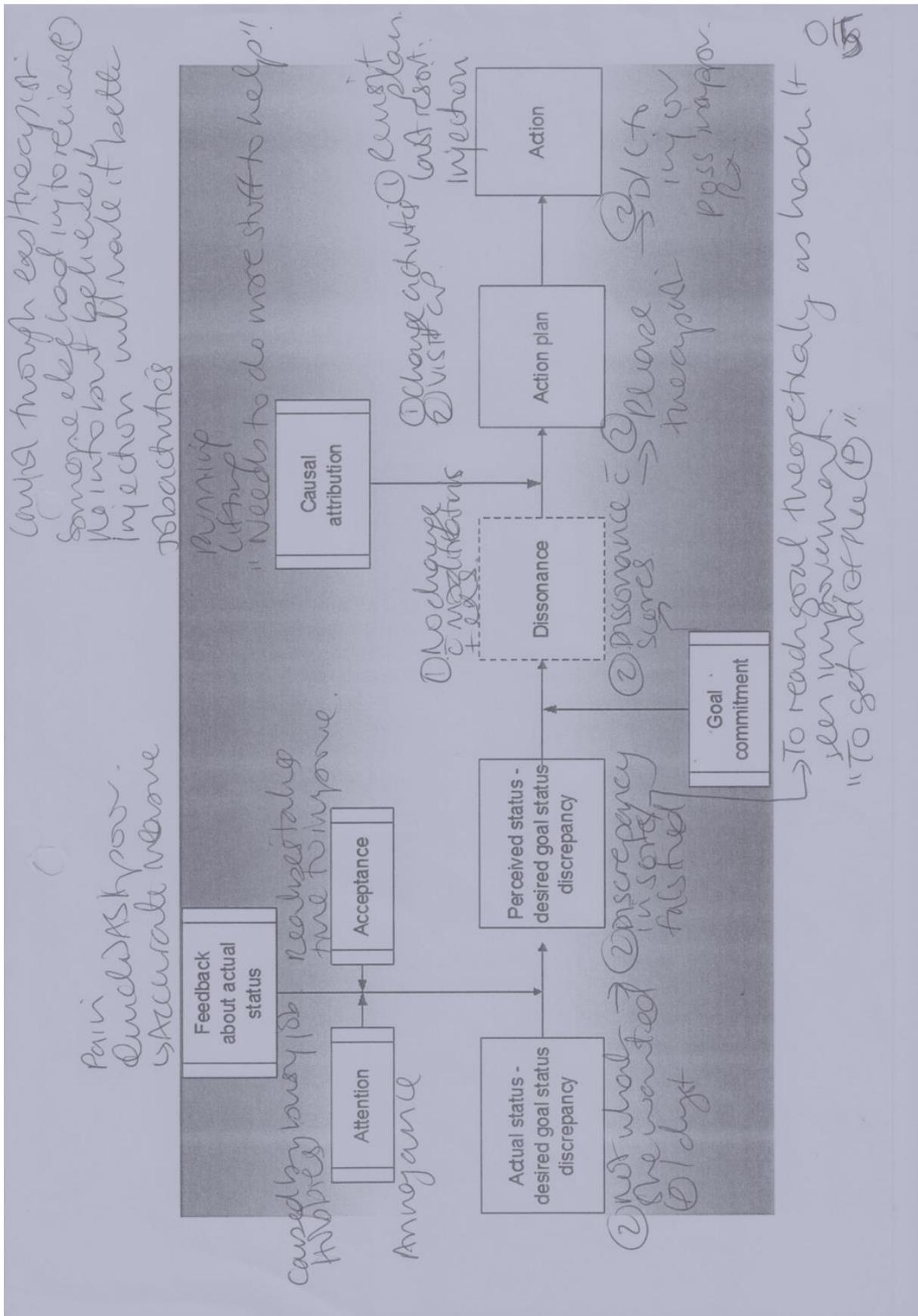
Did they do any self-treatment?

### **Information and feedback**

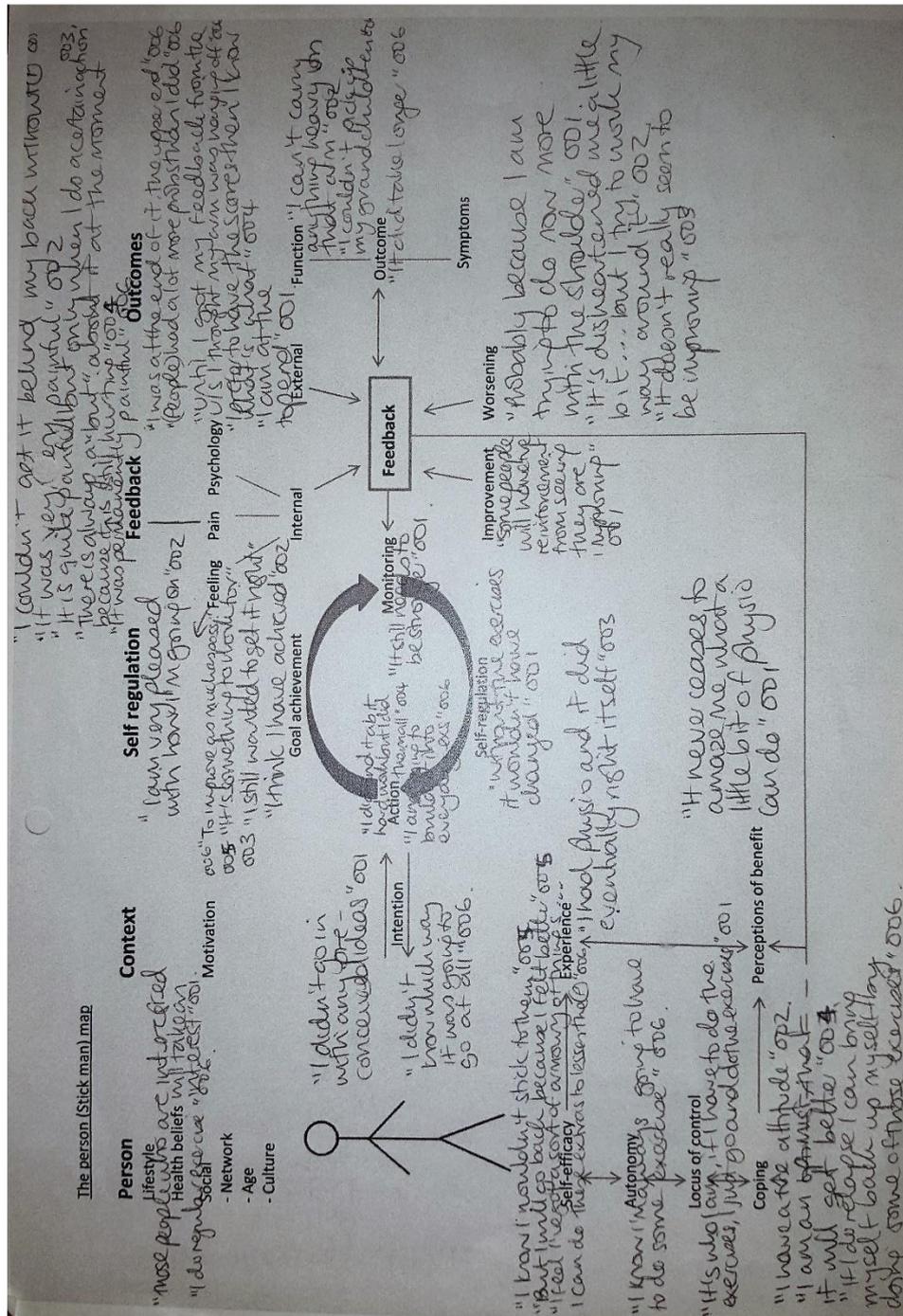
41) Is there anything you would like to add?

42) Do you have any questions?

Appendix R: Mapping participant data against the CFIT participant 15



# Appendix S: Mapping orders of processes with participant data by hand



## Appendix T: Analysis notes for identifying elements of CMOcs

*Resources on*

CONTEXT	INTERVENTION	MECHANISM	OUTCOME
Aches and pains	Feedback	Spreading pain Gauging severity of pain Level of effort dependent on commitment	Pain, acceptance, non-acceptance Stopping activity, carrying on with pain Commitment to exercise Adherence Non-compliance Placement in the spectrum
Trying	Decision to commit/do		
Normality	Feedback	Comparison against normal and where as a patient they sit in the spectrum	
Work	Function feedback on ability to work	Reflection on current status and work levels required <i>investigation construction</i>	Return to work Fear of being off sick for longer / repeatedly Avoidance
Discomfort	Pain score Type of pain	Level of pain How aggravated it is	Severity Irritability Nature of pain
Pain whilst exercising	Feedback	Thinking of why the pain is there Benefit/risk/damage of pain	Exercise should hurt/Exercise is hurting, it is a sign to stop / pain is damaging my shoulder
Group setting	Feedback	Comparison against others	Judgement of what is normal Placement of self within the group (top/middle/bottom)
Age	Degeneration of the shoulder	Thinking of ageing	Everything starting to fail
Feeling	Feedback	Reduction in uncomfortable feeling	Looser
Closeness to goals	Feedback of status	Comparison against standard/goal level <i>(tracking progress)</i>	Progress, achievement No progress, plateau Worsening, failing
Doing stuff	Feedback	Self-monitoring activity Testing function, what can you do	Doing more or less Improved QoL as increased function, ADLs
Time	Memory	Reflecting on chronicity	Disappointment in time taking to get better
Monitoring	Questionnaires Feedback of scores	Self-monitoring Repetition Visibility of progress Reflecting on action External visibility and monitoring by others	Change in behaviour Increased awareness Reflecting, assessment of status and progress Looking at goals, changes to make Judgement

*① Closeness to goal / tracking progress  
② Causal  
③ High / low impact*

# Appendix U: Poster for CARES October 2016



## Patients' views and experiences of outcome data feedback in physiotherapy: A realist evaluation study



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### Introduction

- Feedback is the transmission of evaluative information about an action in comparison to original information given to a person about their status; this can be in the form of outcome data.
- Feeding outcome data back to patients has been shown to increase treatment involvement (compliance) and improve therapeutic relationships, however the effect in physiotherapy has not been tested.

### The Contextualised Feedback Intervention Theory (CFIT) framework (Sapyta, Riemer, & Bickman, 2005)

- The CFIT was used as the middle range theory underpinning the realist evaluation study.
- The CFIT provides a framework to describe a person's actions resulting from changes in their responses due to feedback of information, dependent on their initial beliefs about their status (which in this study concerns their shoulder condition).

### Methods

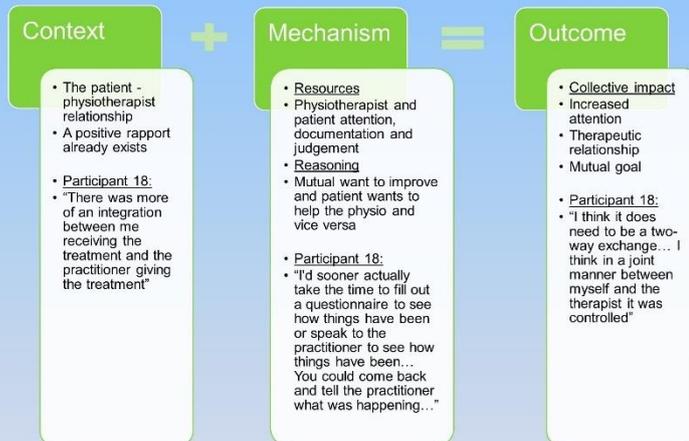
- A realist evaluation study was designed to explore patients' experiences of the feedback of outcome data by physiotherapists.
- Ethical approval was gained from the NHS, local research and university research ethics committees.
- Patients with shoulder impingement were recruited and consent gained in one North West NHS trust. Participants attended between one and eight physiotherapy sessions and completed a shoulder-specific outcome measure (QuickDASH) at each one. The score was plotted onto a graph at each appointment and discussed with the participant.
- 25 semi-structured interviews were conducted with patient participants after completion of treatment. Topics discussed were based on the CFIT (Sapyta, Riemer, & Bickman, 2005).
- Data were then explored using storyboards, narrative analysis and open coding to develop common themes and following this, analysed to test consistency with the CFIT to develop Context, Mechanism and Outcome configurations.

### Findings from qualitative analysis

The 5 emergent themes	Open coding headings within each theme
<b>Control and expectations</b>	Acceptance Attention Chronicity Control Co-problems Longer or shorter than expected to improve Worry about prognosis Frustration
<b>Goals</b>	Type of goal Near recovery Re-evaluation of goal Still improvement to be made Achievement Goal commitment Happy not reaching 100
<b>Feedback of improvement</b>	Symptoms up and down in line with QuickDASH Near recovery Improvement stated although QuickDASH unchanged Exertion to create symptoms as feedback Frequency of symptoms Function Measurable feedback (% of pain score) Pain QuickDASH as feedback General feelings of recovery
<b>Dissonance</b>	Goal closeness Longer or shorter than expected to improve Symptoms up and down not in line with QuickDASH Near recovery Scores different to expected QuickDASH inaccuracy Re-evaluation of goal Improvement but not related to work or hobby
<b>Therapist-patient relationship</b>	Control Compliance with physiotherapy Expectations Knowledge Pleasing therapist Pleasing self not therapist Taking part

### Context Mechanism Outcome configurations (CMOCs)

- Within the study analysis, multiple CMOCs were developed to work through the CFIT process and explore what works for whom, in what circumstances.
- For the purposes of this poster, one CMOC will now be presented to outline a finding a new additional element which is not currently present in the CFIT, specified as 'the collective impact of feedback'. It describes the commitment of both physiotherapist and patient working to a common agenda to tackle the patient's shoulder condition.



### Poster conclusion

- The patient participants who fostered a therapeutic relationship had an outcome of a mutual goal to improve the condition. This was heightened, showing increased attention between the two parties to the feedback of outcome data in terms of the QuickDASH.
- The feedback process also then is able to support an ongoing positive rapport between patient and therapist to repeat the CMOC configuration repeatedly with ongoing feedback of information. Patients were keen to show to the physiotherapist that they were making effort and therefore improving and help the therapist by providing this information. The physiotherapists were also keen to identify improvement to the patients when they had been engaging in treatment and they felt that they had improved with regards to activities such as functional movements, pain or scores on the QuickDASH.
- The patient-physiotherapist relationship needs to be positive for the mechanism to be triggered. The feedback intervention process with the QuickDASH appeared to encourage this relationship to be fostered. A positive relationship would be one where the patient feels they have a connection with the therapist.
- The suggestion following the identification of this CMOC is to modify the CFIT middle range theory to accommodate the element of 'the collective impact of feedback'.

### Contact



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### Reference

Sapyta, J., Riemer, M., & Bickman, L. (2005). Feedback to clinicians: Theory, research, and practice. *Journal of Clinical Psychology*, 61(2), 145-153. Retrieved from Wiley Online Library.

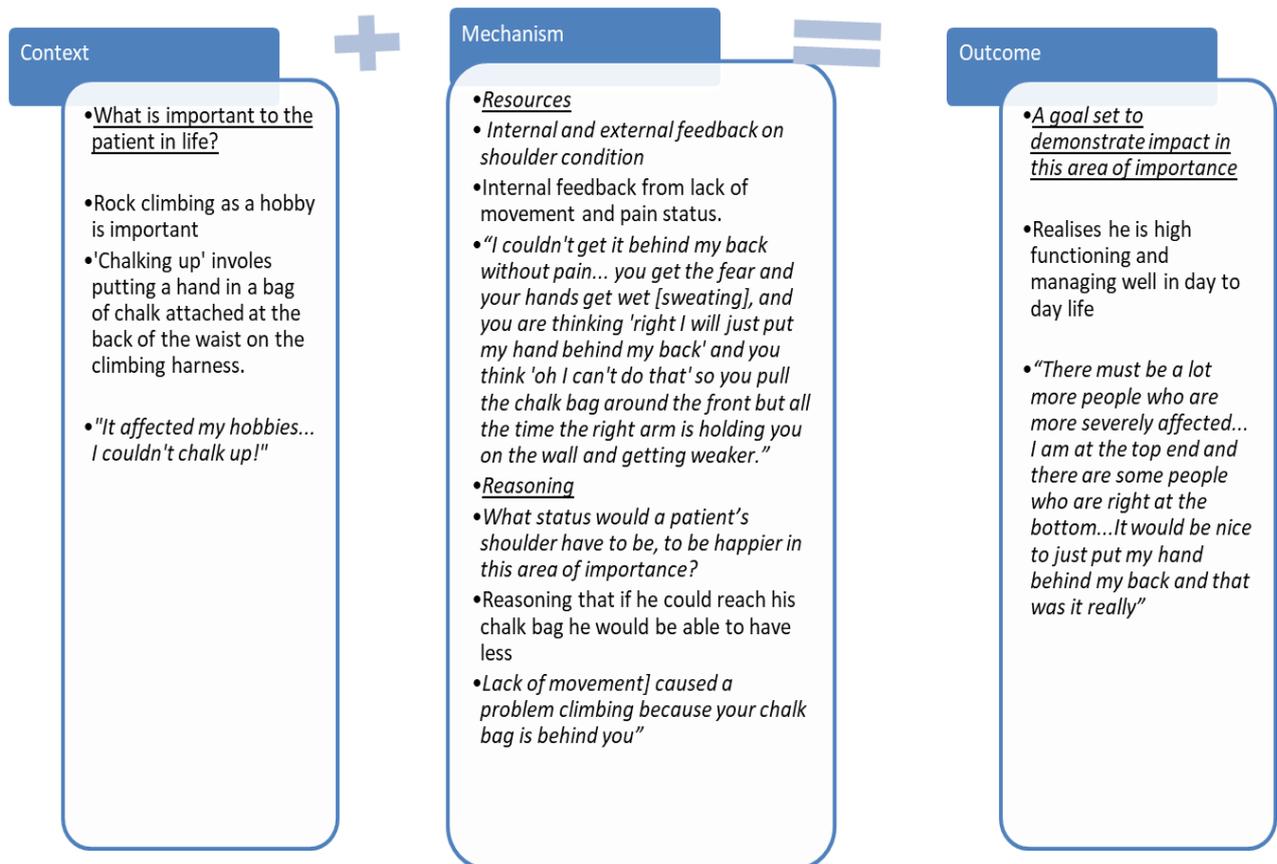
**Appendix V: Starting QuickDASH score for each patient participant and category of severity**

	Start score (0 high, 100 low)	Severity of start score based on (Fan et al., 2008)	End score	Change score - for improved + For worsened	Change score categorisation
01	12.5	Mild	6.8	- 05.70	No change
02	57.5	Severe	11.4	- 46.10	Very much improved
03	13.6	Mild	11.4	- 02.20	No change
04	75	Severe	23	- 52.00	Very much improved
05	40.9	Severe	27.3	- 13.60	Minimally improved
06	9.1	Mild	-----	00.00	No change
07	63.6	Severe	62.5	- 01.10	No change
08	68.18	Severe	59.09	- 02.09	No change
09	34.09	Severe	27.3	- 06.79	No change
10	40.00	Severe	20.45	- 19.55	Much improved
11	32.5	Severe	18.18	- 14.32	Minimally improved
12	23.3	Moderate	15.91	- 07.39	No change
13	29.5	Moderate	6.8	- 22.70	Much improved
14	36.4	Severe	15.9	- 20.50	Much improved
15	61.4	Severe	50.0	- 11.40	Very much improved
16	54.5	Severe	61.4	+ 06.90	No change (worsened)
17	32.5	Severe	9.09	- 23.41	Much improved
18	68.1	Severe	59.1	- 09.00	No change
19	30	Moderate	5.0	- 25.00	Much improved
20	Drop out / no data				
21	27.5	Moderate	7.5	- 20.00	Much improved
22	68.2	Severe	18.2	- 50.00	Very much improved
23	29.5	Moderate	11.4	- 18.10	Much improved
24	25	Moderate	25	00.00	No change
25	Drop out / no data				
26	31.8	Severe	6.82	- 24.98	Much improved
27	72.72	Severe	61.4	- 11.32	No change

## Appendix W: Examples of individual CMOcs

### CMOc 1: Goal Choice

Participant 01 was a retired man. He was previously a business analyst in the aerospace industry with a high-level statistical analysis role. He felt *"a bit time loose"*, and since retiring he had increased his time participating in hobbies and physical training. He started concentrating on running and had worked up to a high functioning level, commenting, *"I have been out and done a ten-mile run"*. He also concentrated on fitness at the gym *"five times a week"* and through his hobby of rock climbing. Since retiring, his hobbies featured in his day to day life more than when he was employed and subsequently were important to him on a day to day basis (context). He talked about his hobbies at length and had noticed from his internal feedback mechanisms that he was struggling with pain and specific movements limiting him being able to carry out his hobbies at the level he had trained to. He had already managed to achieve improvement with his running: *"I have been out and done a ten-mile run and normally at the end of that my shoulder would have been aching and it wasn't"*, and improvement at the gym: *"now I have got some more strength in the shoulders I have been doing some more exercises."* The only hobby still being affected in his day to day life was rock climbing, reasoning he needed his movement to improve and his pain to reduce to be able to function in the way he would be happy with whilst rock climbing (mechanism). His goal (outcome) was therefore very specific, focused on a limited movement, putting his hand behind his back to put his hand into his chalk bag, which had direct consequences on him being able to enjoy his rock climbing and functionally being able carry out his hobby.

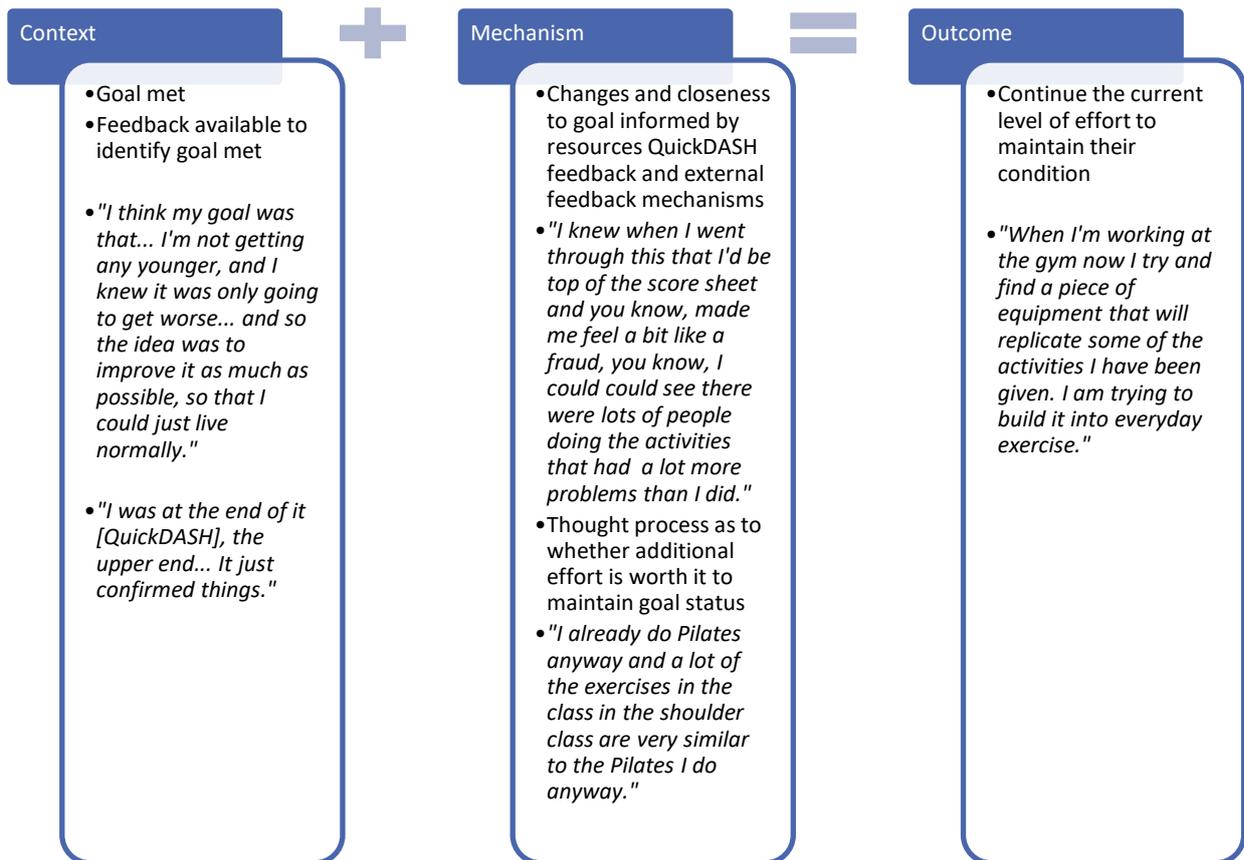


Participant 01 demonstrating CMOc 1 in choice of goal

### CMOc 2: Tracking progress and closeness to goal

#### When a goal is met

06 only completed one QuickDASH measure as she felt she had reached her full potential which she could attain through physiotherapy. She describes her goal of living a 'normal' life in terms of activity, which was met and confirmed by her external QuickDASH feedback (context) in addition to her own internal feedback mechanisms which consolidated her feelings of improvement (mechanism), thus finishing treatment voluntarily and continuing shoulder exercises independently of physiotherapy treatment (outcome).



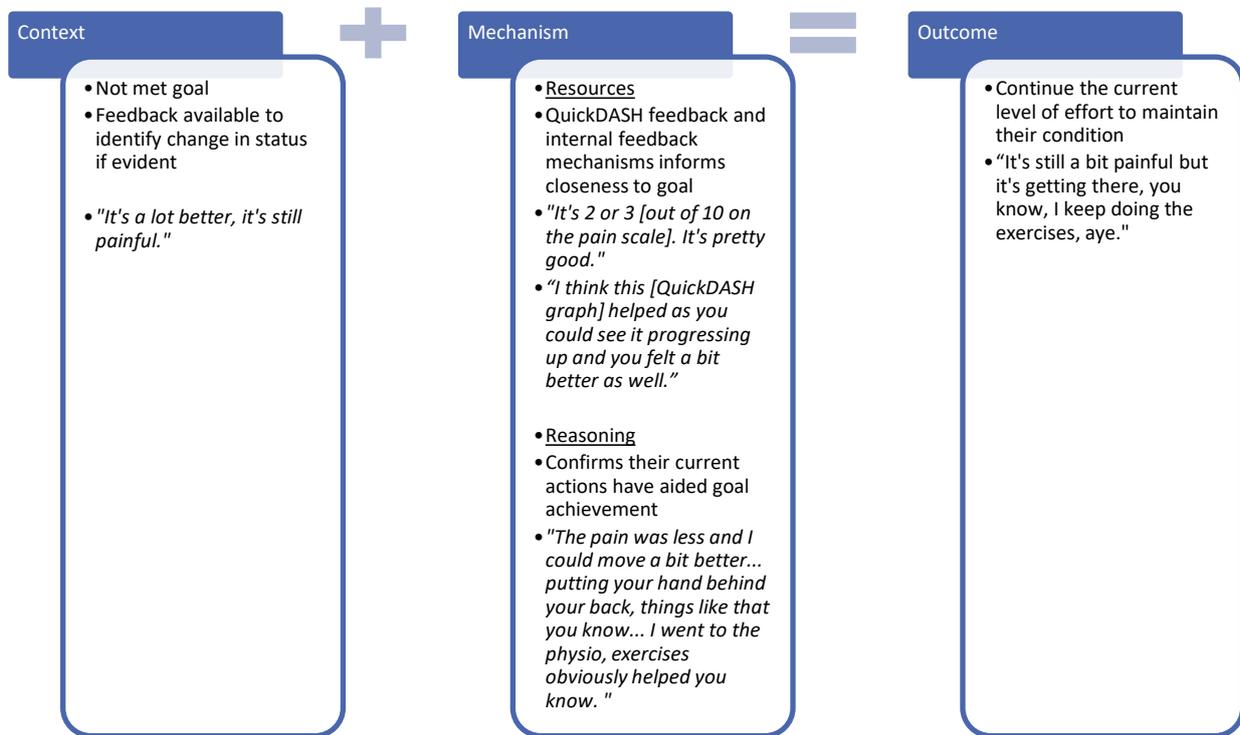
CMOc example for participant 06 outlining when a goal is met

### Additional effort

Participant 26 declared a goal of wanting to "get back to normal". She was a busy retired lady who was caring for her husband who was recovering from bowel cancer, and cared for another elderly person by preparing meals and helping with their shopping. She attended three sessions of physiotherapy and progressed positively on the QuickDASH score each week. She commented on her improvement but that she had not achieved her goal yet (context): "You know, it's a lot better, it's still painful but it's not half as bad as what it was, it's a lot better."

She had felt the benefit of the exercises, which had been visually shown by the feedback (mechanism). As she had not fully achieved her goal she had to decide whether to put in additional

effort or accept not reaching her goal status, or change her plan of action. As she had shown improvement from external and internal feedback (the QuickDASH scores and reduction in pain, respectively) with her current treatment approach of home exercises given by the physiotherapist, she decided to continue with additional effort (outcome), aiming to improve further.



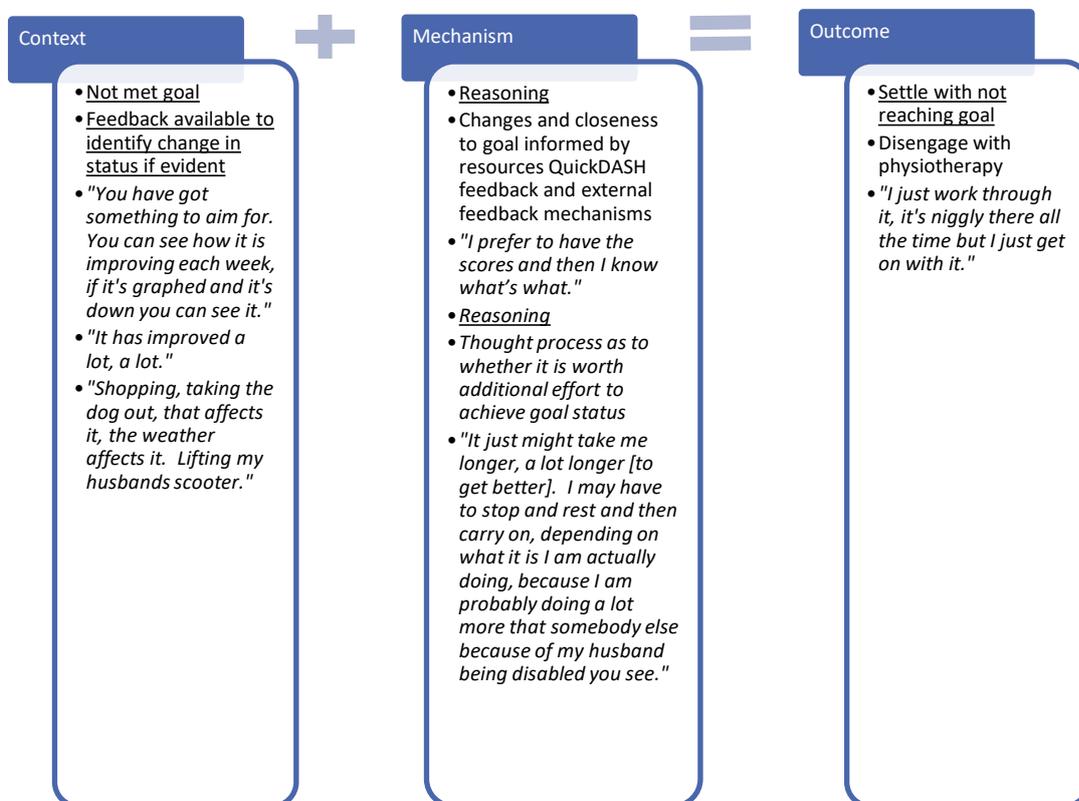
*CMOc example for participant 26 outlining tracking changes and closeness to goal with an outcome of continued effort*

### **Settle with not meeting goal: disengagement**

Life circumstances can influence a participant's decision to engage with treatment. Participant 05 had slow improvement in her shoulder condition and utilised the feedback process by using the graph as something to track her changes and *"something to aim for."* She was to visually see the external feedback of the slow improvement on the graph as well as her internal feedback, noticing improvements in function in day to day life (mechanism). She was the main carer for her husband, and with him being severely disabled, her role involved most of the physical activities that were required day-to-day (context). She commented that she was required to do all the light and heavy household tasks and also needed to lift her husband's mobility scooter in and out of the car. Despite

her shoulder condition she had continued with doing home improvements herself and liked to be independent: *“Earlier on in the year when I was doing the kitchen, tiling and things like that, you don't realise how much it affects you.”*

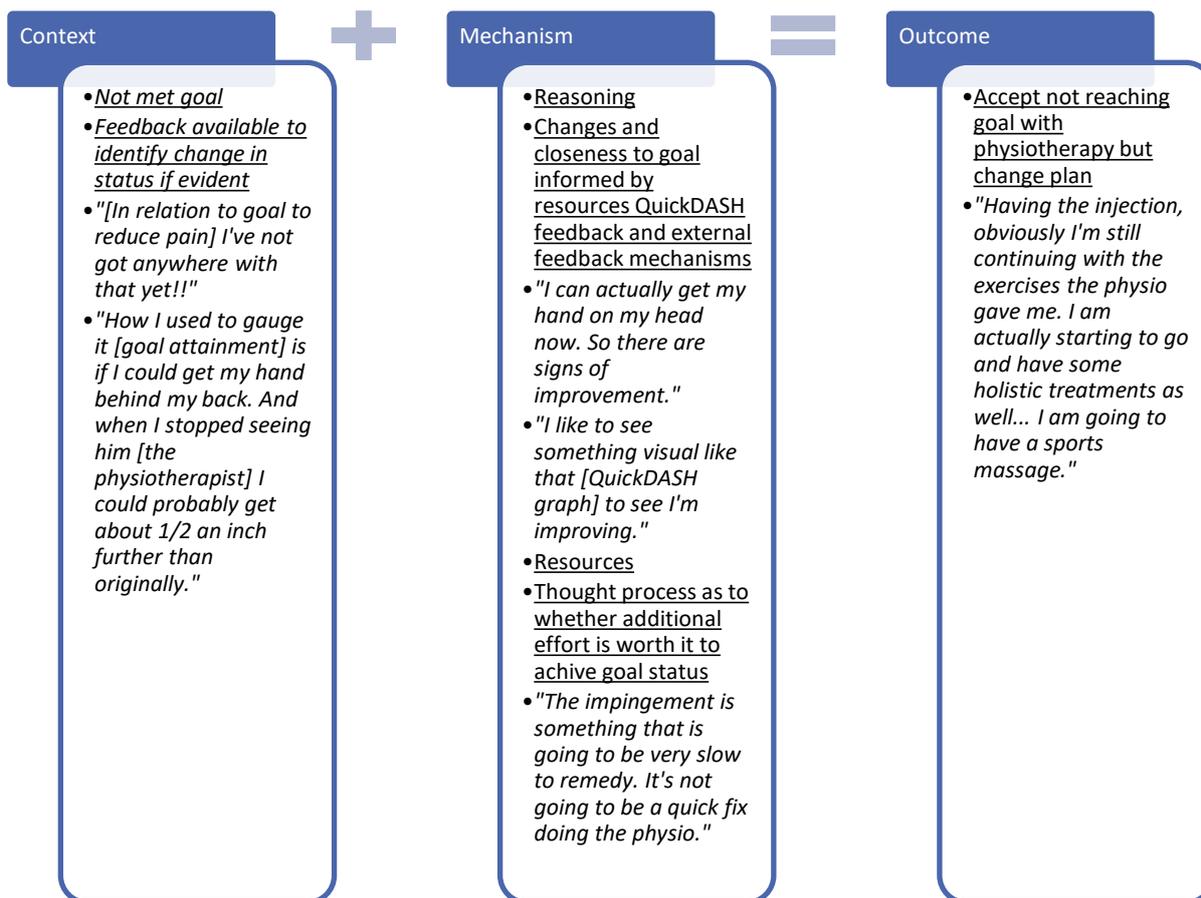
This lady could see improvement from her baseline status at the beginning of the process from her internal and external feedback (context). She could not modify her shoulder activity in-line with suggestions from her physiotherapist and some activities were still painful (context). She speculated from tracking her slow improvement with feedback, that her improvement may take a protracted amount of time (mechanism). Due to the length of time recovery could take, and the possibility that it may not improve further, her decision was to disengage with physiotherapy and live with her current shoulder status as it was (outcome).



*CMOc example for participant 05 outlining tracking changes and closeness to goal with an outcome of continued effort disengaging with treatment*

### **Change treatment plan**

Participant 16 changed her treatment plan after tracking her progress. She expressed two goals she initially set herself: *“Stop having pain in my shoulder! And being able to fasten my bra more than anything.”* When asked how she felt at the time of the interview in relation to her goals she identified that her goals had not been met (context): *“A little bit further on... But some days are better than others.”* She identified that there were improvements with her current treatment regime but not enough to reach her goal (mechanism): *“Some days I can get my hand a bit further up. I can actually get my hand on my head [laughs] but it does cause me discomfort in the shoulder.”* She used her internal feedback of pain status as a resource but also the QuickDASH feedback to confirm her status (mechanism): *“Most of the time it [the QuickDASH score] felt how I actually felt during that period.”* On further, deeper questioning about her plans, she disclosed that the physiotherapy was not a *“quick fix”* and she was going to try alternative treatments to try and relieve her symptoms (outcome).



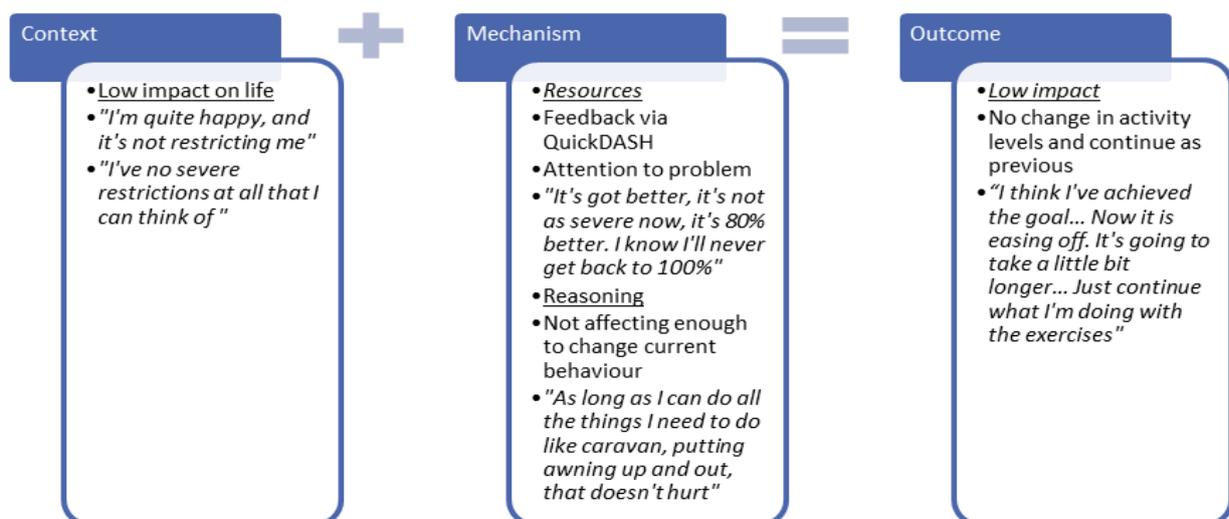
CMOC outlining not reaching a goal, tracking changes and changing treatment plan, participant 16

### CMOc 3: High / Low impact

#### Low impact example

Participant 17 re-evaluated his goal, did not change his current behaviour and withdrew from treatment, exhibiting all three possible outcomes.

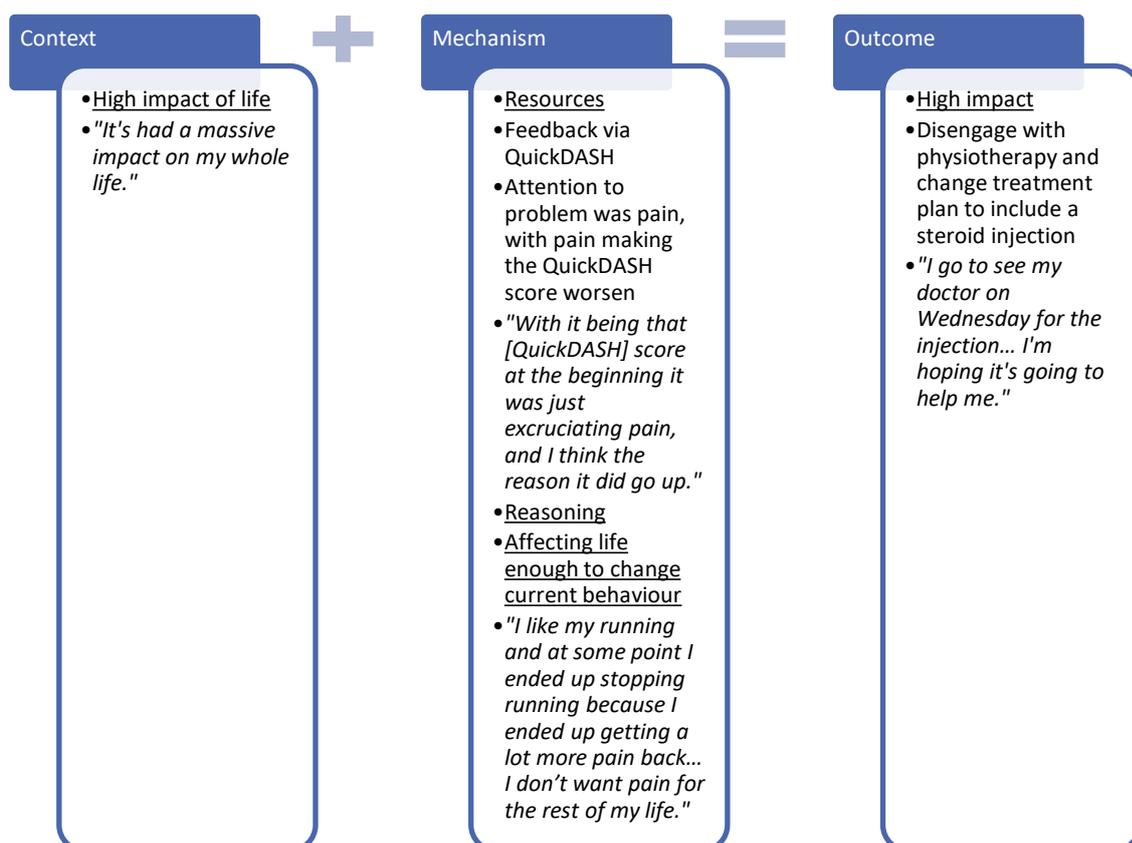
Participant 17 was a retired gentleman with a social life involving caravanning and looking after his small dogs. He improved throughout treatment and was happy with his current status (context), marking himself as “80% better”. He commented that he knew he’d never get to 100%, and he had previously suffered from the same condition on the opposite side, remarking: “I did my other arm in two and a half to three years ago and I knew exactly how long that has taken to heal.” He reasoned that his status was acceptable if he could do all the activities that were important to him, which at the time of interviewing he felt he could (mechanism). He reasoned he had achieved a suitable status (mechanism), commenting, “I think I’ve achieved the goal knowing how long it took to ease the pain in my right arm... 3 years!” (mechanism). He had not reached 100% improvement, but his impact on life was low enough to continue the same exercises at home and withdraw from active treatment (outcomes).



CMOc outlining participant 17, a low impact feedback case

## High impact example

Participant 15 was a busy lady with a job in the media industry where she had to move between sites and lift and carry equipment. She was able to modify her workplace duties: *"It is about changing lifestyle isn't it? When it comes to work... I'll get a trolley. I'll pull all my stuff around. It's got to be done"*. Her impact was mainly high within her hobby of running (context). She had the severity confirmed by the QuickDASH as she started treatment at a severe score of 61.4 and was noticing her continued impact on running and was not back to her goal which was *"Just to get rid of the pain because it was absolutely excruciating"*. She still had a severe score of 50 at the end of treatment on the QuickDASH, and had not met her goal (which she did not want to modify). She was putting full effort into treatment already (mechanism), so changed her approach (outcome). In the case of participant 15, she escalated her treatment to the next level, which was a steroid injection (outcome) to try and reach her goal of getting rid of the pain.



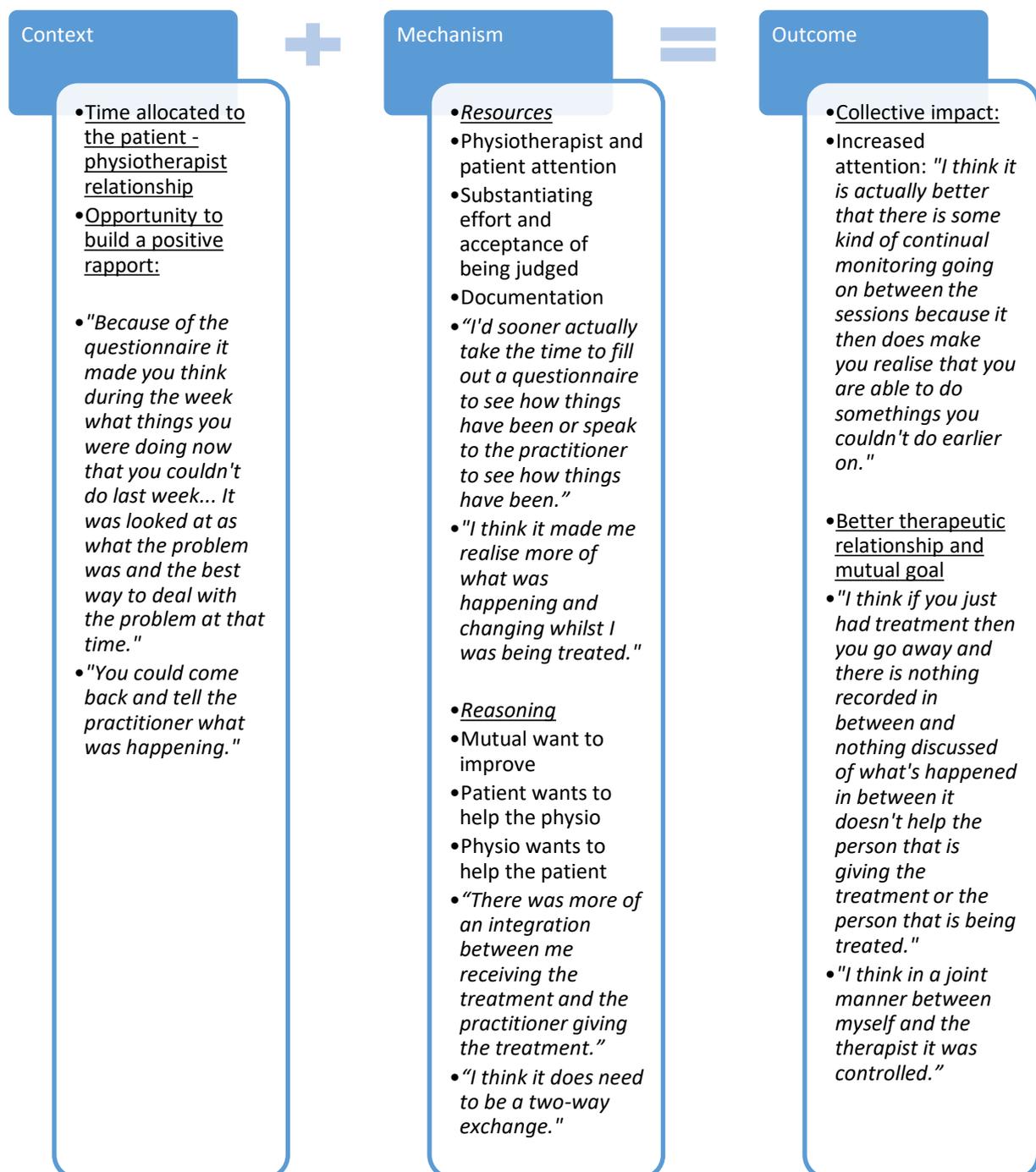
CMOc for participant 15 to outline a high impact of feedback

#### **CMOc 4: Collective impact**

Participant 18 was a retired gentleman who used to work in the military in close protection roles and heavy infantry. The job had entailed excessive physical activity, which he spoke of during his interview: *“Due to the nature of the job which in its own has had permanent effects on my body.”* His previous job role had proceeded to give him early degenerative changes in multiple areas of the body and he presented with compounding health problems, struggling on a daily basis in terms of chronic pain, function and mobility. He had input from different healthcare services for a variety of health problems:

*“I have recently had injections into my lower spine. I'm not sure what they injected, it was a steroid based long painkiller I think. I'm awaiting to have the same things done in my neck in October and I also have quite a lot of medication for pain, muscle relief, that kind of thing.”*

He valued his relationships with health professionals, in this case his physiotherapist. The feedback of the QuickDASH scores provided an integration between him and his therapist via mutual discussion of his status. The outcome was a situation where the therapist-patient relationship was strengthened by the two-way discussion and the gentleman felt his situation was well managed and well controlled, producing an outcome of collective impact where the working together of both patient and therapist produced a better outcome overall for the patient.



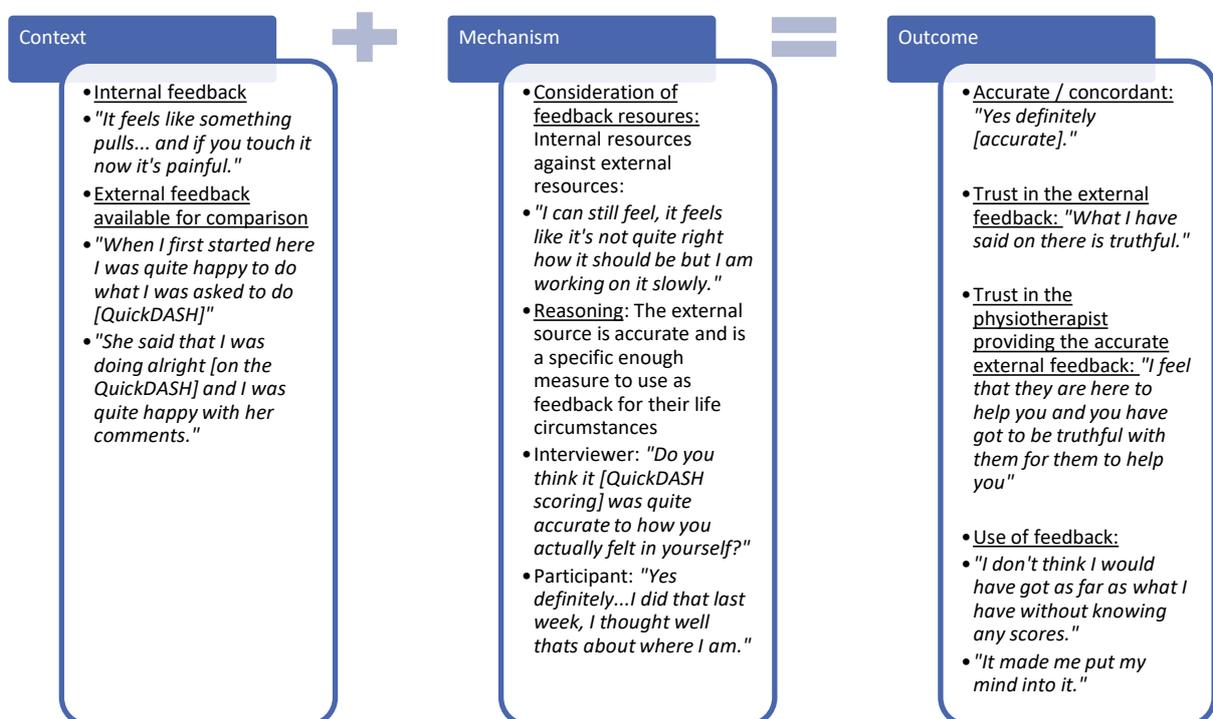
CMOc for participant 18 to outline the collective impact of feedback

## CMOc 5: Dissonance or Consonance

### Consonance

Participant 02 was a 74-year-old retired gentleman who had other contributing health problems.

Over eight sessions of treatment he improved from a severe score of 57.4 to a mild score of 11.4. He had a good rapport with the physiotherapist and appreciation for their help, commenting: *"I think personally they have done a really wonderful job and they do a wonderful job."* He trusted in the external feedback from the physiotherapist and used the QuickDASH feedback (outcome), as he considered his own progress in terms of pain against the scores to be accurate (mechanism) after receiving the QuickDASH feedback plotted on a graph to show his progress each week, which was concordant with his own feelings of improvement (context).

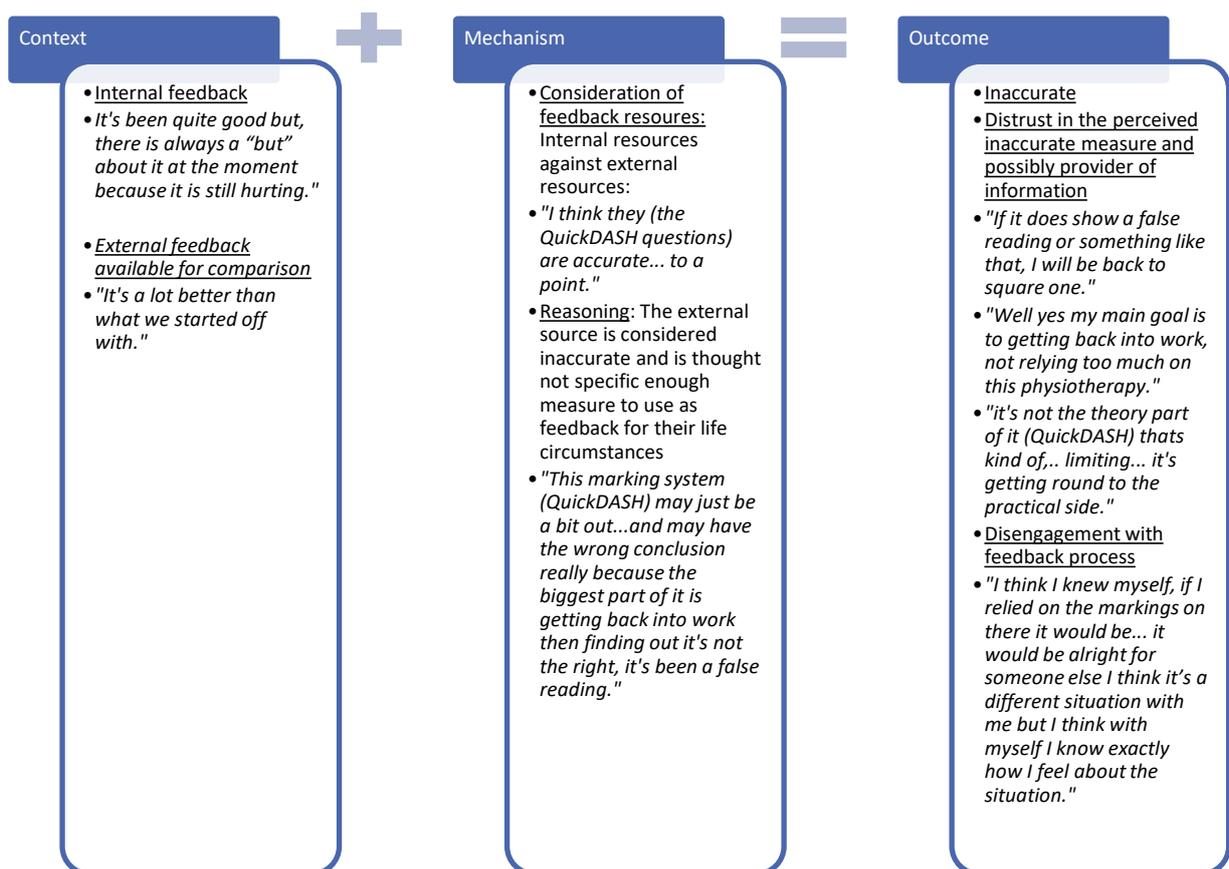


CMOc for participant 02 to outline consonance of feedback

## Dissonance

Participant 04 was a gentleman who had other contributing musculoskeletal problems and was currently unemployed due to his health problems. In reference to the QuickDASH scores provided weekly by his physiotherapist (context), his external feedback exhibited improvement from a score of 75 to 23 on the QuickDASH over eight sessions. Despite his apparent improvement from the QuickDASH as new information, he did not value the scoring system as accurate, reasoning the 'true test' of his shoulder status to be returning to work which he had not completed yet (mechanism). He wanted to disengage with the physiotherapy treatment, not seeing the feedback as useful, or the treatment itself, despite the indication from the external feedback (outcome).

In this instance, the participant valued his own internal feedback of information over the external feedback provided by the physiotherapist, due to the mechanism at play reasoning it to be inaccurate and not able to gauge his readiness for return to work.



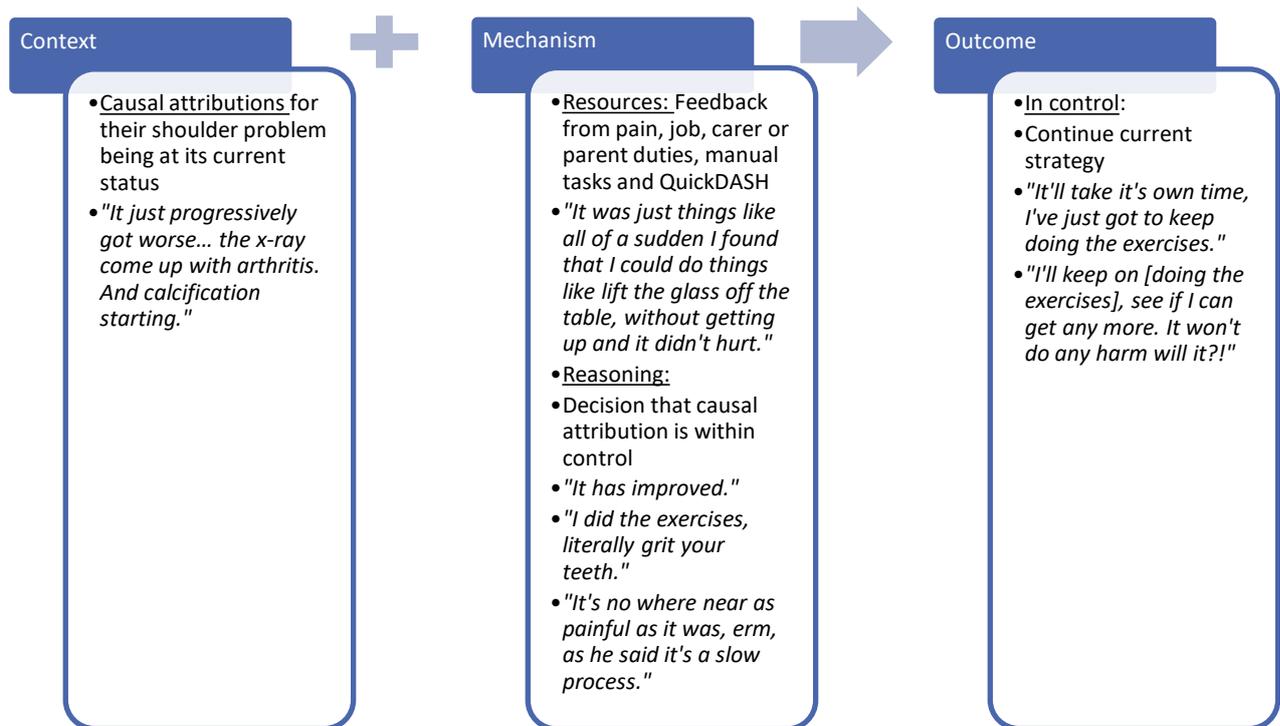
CMOC outlining dissonance with the information feedback process, participant 04

## CMOc 6: Causal attribution

### Control and engagement example

Participant 21 was 62 years old, worked in an administrative role and enjoyed ballroom dancing. She had diagnoses of calcific tendonitis and osteoarthritis and in addition tested positive for shoulder impingement. Calcific tendinitis of the shoulder is a self-limiting condition concerned with deposition of calcium hydroxyapatite crystals within the rotator cuff tendons, most common in people between 30 and 60 years of age, more common in women and those in sedentary jobs (Speed & Hazleman, 1999). Radiologically evident calcification has been reported in 7.5 to 20 percent of adults with no symptoms and in 6.8 percent of those with shoulder pain, so the pain felt by participant 21 could or could not have been attributable to her diagnosis. Calcification of joint tissues contributes to the development of wear and tear which can also be known as 'degeneration' or 'osteoarthritis', and with the presence of changes on x-ray coupled with pain, a patient can be diagnosed with osteoarthritis (Anderson & Loeser, 2010). As osteoarthritis is a permanent physiological change, this could have possibly triggered a mechanism of thinking she could not affect her outcome and disengage with treatment. **Error! Reference source not found.** on page 343 presents her response.

Participant 21 received her diagnosis (context), but instead of disengaging with treatment she continued with the physiotherapist-led exercises, despite them being painful to execute, and received feedback confirming she was improving with regular exercise (mechanism). Due to her improvements, she decided to continue with her actions after discharge to maximise the improvement of her condition (outcome).



CMOc for participant 21 outlining a high level of control and engagement

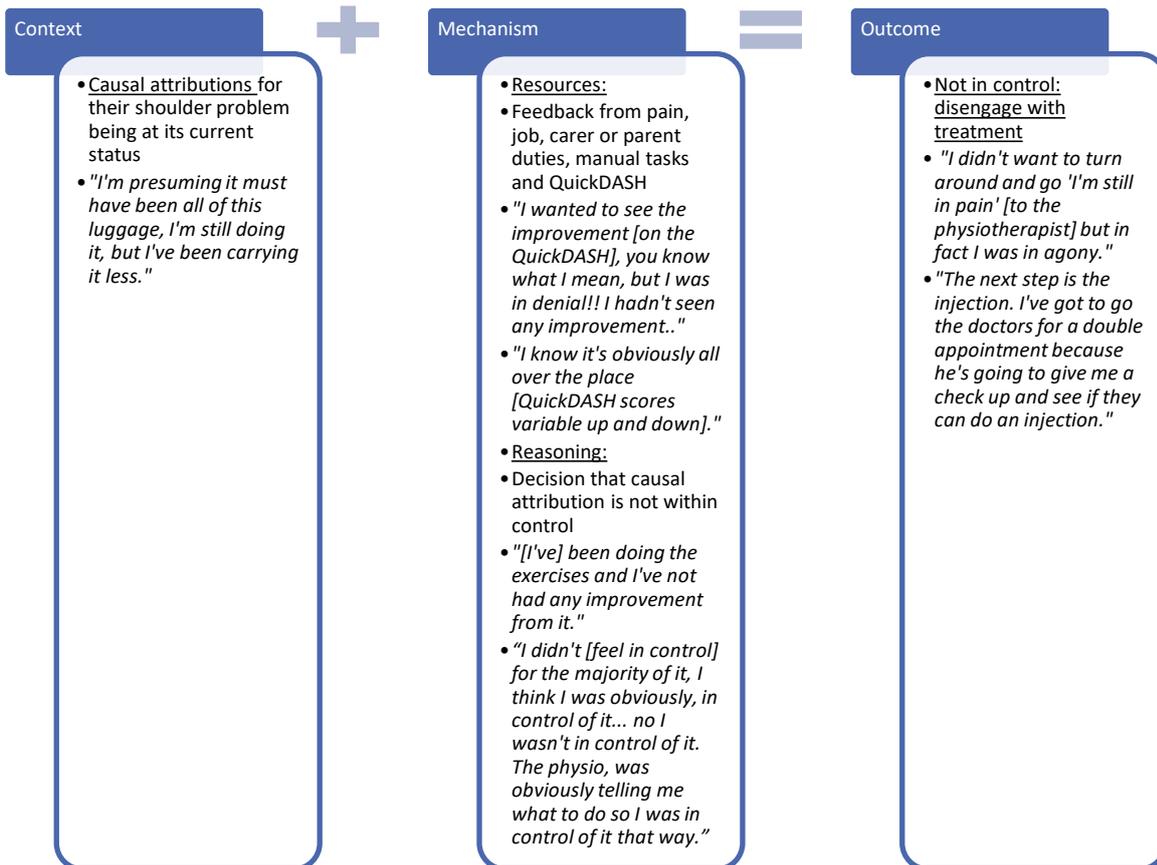
### Lack of control and disengagement example

Participant 15 is an example of an outcome of disengagement due to lack of control. She didn't improve with treatment, having start and end QuickDASH scores which were both classed as severe (61.4 and 50.0 respectively) based on the study reported by Fan et al. (2008). She had attributed her problem to her work duties (context), and although reducing them to lighter duties, was still carrying and lifting. She felt she could not control her situation, describing only partial control as she had a physiotherapist monitoring her (mechanism). She failed to see improvements on the QuickDASH and in day to day life, reasoning that her current treatment plan would not improve her symptoms (mechanism). She disengaged with treatment and the feedback process, to change her plan of action, requesting a steroid injection from the General Practitioner (outcome), knowing this was the next level of intervention.

Participant 15 was unsure as to the benefits and risks associated with the steroid injection procedure she had chosen to pursue following disengagement, commenting:

*"I'm a bit rubbish really when it comes to the data. But I think when it comes down to having this injection I'm hoping that might help but I've not spoken much about the injection and I don't know what it is going to do."*

This exhibits the determination of this participant to achieve her goal *"Just to get rid of the pain,"* even if the outcome from this CMOc is to engage in a treatment option she was not knowledgeable about. This illustrates that CMOcs are not isolated in their occurrence, specifically within this example, that a participant's goal can be related to causal attribution.



CMOC detailing participant 15, exhibiting lack of control and disengagement.

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