THE DEVELOPMENT AND INITIAL EVALUATION OF A WEIGHT-SPECIFIC QUALITY OF LIFE INSTRUMENT

by

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ABSTRACT

SETTING THE SCENE: Obesity can have debilitating effects on a person's health-related quality of life (HRQoL). Participant-reported HRQoL should be assessed in addition to Body Mass Index (BMI) to evaluate the effectiveness of obesity interventions.

AIMS: This programme of work aimed to a) assess the need for a new weight-related quality of life (WRQoL) scale, b) develop a WRQoL scale with input from UK samples and c) conduct the initial psychometric evaluation of the new WRQoL scale.

METHODS:

Assessing the need for a WRQoL scale: A systematic review was undertaken. Medline, EMBASE, CINAHL and PsycINFO were searched for literature published between 1974-2018 detailing the development and psychometric evaluation of adult WRQoL scales. Two independent researchers screened the articles by title, abstract and full text to identify relevant papers. Each scale was evaluated for risk of bias and psychometric properties using the COSMIN checklist. Additionally, cognitive debriefing interviews were conducted to test content/face validity of the current 'gold standard' WRQoL measure.

Developing a WRQoL scale: A qualitative approach was used to conduct and analyse one-to-one interviews over two phases (preliminary interviews and item generation interviews). Adults with experience of weight issues were recruited via opportunity sampling at community locations. All participants had their BMI and waist circumference measured. Findings from the item generation interviews were used to generate items in expert panel meetings. Cognitive interviews assessed the face validity of the new instrument.

Initial evaluation of the new scale: Exploratory factor analysis, internal consistency, known groups comparisons, concurrent validity and test-retest reliability were conducted on the draft scale.

RESULTS:

Assessing the need for a WRQoL scale: The systematic review identified 9886 articles which were screened initially by title, then by abstract (*n = 966*) and finally by full text (*n = 426*). Twenty-eight articles contained information regarding the development or psychometric evaluation of 17 WRQoL scales. No instrument had evidence for all psychometric properties, demonstrating the need for a new WRQoL scale. The cognitive debriefing interviews highlighted issues with the content validity of the most used WRQoL scale.

Developing a WRQoL scale: The preliminary interviews (*n = 10*) enabled the development of an interview schedule for the item generation interviews. Data from the item generation interviews (*n = 48*) were used to draft a 31-item instrument during discussions with an expert panel. The initial items covered six themes identified in the item generation interviews; physical health, mobility, clothing, food, feeling towards themselves and psychosocial experience.

Initial evaluation of the new scale: The final draft scale contained 29 items covering four domains (confidence with self, getting around, feeling valued and weight stigma). Good internal consistency, test-retest reliability, and concurrent validity was shown, and the new scale was able to discriminate between BMI groups.

CONCLUSION: This programme of work has contributed to knowledge by a) providing a detailed evaluation of existing WRQoL scales; b) providing a clear description of the impact of obesity on everyday life, from people who have experienced weight issues; c) developing and preliminary evaluating a WRQoL scale with input from the population it is intended for. After further development and psychometric work, the instrument will be able to describe and measure changes in WRQoL in community and clinical populations.

CONTENTS

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List of Abbreviations

BMI	Body Mass Index
BOMW	Because of my weight
BOSS	Bariatric and obesity-specific survey
BQL	Bariatric Quality of Life
CDC	Centre of Disease Control
COSMIN	Consensus-based standards for the selection of health measurement instruments
CRUK	Cancer Research UK
CTT	Classical Test Theory
EQ-5D	European quality of life scale
FDA	Food and Drug Administration
GP	General Practitioners
HCP	Health care professional
HRQoL	Health-related quality of life
HSP	Health State Preference
ICC	Intraclass correlation coefficient
IRT	Item Response Theory
IWQOL	The Impact of Weight on Quality of Life
IWQOL-Lite	the Impact of Weight on Quality of Life – Lite scale
LBP	Low back pain
MA-QoLQ-II	Moorehead-Ardelt Quality of Life Questionnaire II
MHO	Metabolically Healthy Obesity
MID	Minimal Important Difference
MRI	Magnetic Resonance Imaging
MUO	Metabolically Unhealthy Obesity
NHAMES	National Health and Nutrition Examination Survey
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OA	Osteoarthritis
OECD	Organisation for Economic Co-operation and Development

ORWELL-97	Obesity related wellbeing – 97
ORWELL-R	Obesity related wellbeing – Revised version
OSQOL	Obesity-specific quality of life
OWLQOL	Obesity and Weight Loss Quality of Life
PBOT	Post Bariatric Outcome Tool
PCA	Principal component analysis
PIS	Participant information sheet
PROM	Patient-reported outcome measure
QoL	Quality of life
QOLOD	Quality of Life, Obesity and Dietetics
QOLOS	Quality of Life for Obesity Surgery
RCT	Randomised controlled trial
SEM	Standard error of measurement
SF-36	Medical outcomes Study Short-Form Health Survey
SPSS	Statistical Package for Social Sciences
SW	Slimming World
T2DM	Type II Diabetes Mellitus
UK	United Kingdom
WHO	World Health Organisation
WRQoL	Weight-related quality of life

PRELUDE

SETTING THE SCENE

Obesity can lead to serious health consequences, including increased morbidity and early mortality. Despite this, obesity prevalence in the UK is rising. As the prevalence of obesity rises, the treatment and management of obesity are becoming increasingly community-based comprising of lifestyle interventions, with specialist weight management services and bariatric surgery being offered only in extremely complex cases. When evaluating the treatment of disease, an individual's health-related quality of life (HRQoL) should be assessed. To measure HRQoL in obesity, scales developed specifically for use in overweight and obesity should be used. Disease-specific scales are more sensitive and responsive to changes in HRQoL so may pick up changes that generic measure might miss.

AIMS OF THE THESIS

The purpose of this programme of work was to:

a) *assess the need* for a weight-specific HRQoL scale,

b) *develop* a new weight-specific HRQoL scale with input from a UK population,

c) conduct the *initial evaluation* of the new weight-specific HRQoL scale.

ASSESSING THE NEED FOR A NEW WRQoL SCALE

Chapter 1 provides a background to obesity, indicating its prevalence, the complex nature of its development and consequences, as well as how obesity is managed in the UK. It highlights the important health effects obesity can lead to, along with the psychosocial consequences and their clinical implications (such as further weight gain, eating disorders and depression). The available weight management services are also discussed highlighting the high prevalence of referrals (self-referral and primary care referrals) to

lifestyle interventions, rather than the prescription of anti-obesity medicine or referral to specialist services (such as specialist weight management programmes within hospitals or bariatric surgery). Whilst lifestyle interventions are the treatment of choice (NICE, 2014), the evaluation of these is poor and focuses on weight loss rather than improvements in both physical and psychosocial aspects of obesity or HRQoL.

In Chapter 2, HRQoL is defined, and the measurement of HRQoL in obesity is explored. It argues the need for weight-specific HRQoL scales as these are more relevant to overweight/obesity and are likely to be more sensitive to changes. Previous research describing HRQoL in overweight/obesity shows an impaired HRQoL compared to normal-weight populations. However, research measuring changes in HRQoL with weight loss is inconsistent. It is thought that the inconsistencies are due to problems with the HRQoL measures used. The recommended practices for scale development, including the "art" and "theory" behind scale development are discussed. Finally, Chapter 2 introduces the aims and methodological approach of this programme of work.

Chapter 3 describes the process and results of a systematic review conducted to identify and evaluate the development and psychometric properties of existing WRQoL scales. Seven of the 17 scales identified were explicitly designed for use in bariatric patients, and so these were deemed irrelevant and unsuitable for use in community lifestyle interventions. Of the other ten scales, none had been fully validated for all psychometric properties. The Impact of Weight on Quality of Life – Lite scale (IWQOL-Lite) was identified to have the most published validation papers. Yet, the development of the items did not follow recommended practices and had limited participant involvement. Therefore, the content validity of the IWQOL-Lite was questioned. It was concluded that there was a need for a new WRQoL scale.

Additionally, Chapter 5 and 6 provide further evidence, that the IWQOL-Lite is unsuitable for use in UK populations, as problems were found with its content validity (including missing aspects and irrelevant domains in the scale) and potentially its responsiveness to change. This evaluation further supported the need for a new WRQoL scale.

DEVELOPMENT OF A NEW WRQoL SCALE

Chapter 4 and 5 detail the qualitative methods used in the development of the new WRQoL scale to gain input from the target population as well as input from experts. The aim of chapter 4 was to develop an interview schedule with the help of a UK sample for use in the item generation interviews (detailed in Chapter 5). These chapters describe the lived experiences of individuals with overweight/obesity across weight loss stages. The process and decisions of generating items within the expert panel meetings are described in Chapter 5 before the initial draft scale is presented.

INITIAL EVALUATION OF THE NEW WRQoL SCALE

The new scale was evaluated using both qualitative and quantitative methods. The qualitative approach utilised cognitive interviews to test for face validity and is detailed at the end of chapter 5. The psychometric testing of the draft WRQoL instrument (Chapter 7) involved exploratory factor analysis in deciding its structure and in informing item reduction. It was conducted on 160 participants and led to a 29-item scale covering four domains; confidence with self, getting around, feeling valued, and weight stigma. The internal consistency, known-groups validity, concurrent validity and test-retest reliability of the scale were tested, showing it to be reliable and valid. However, the analysis highlighted that the weight stigma domain could be improved.

CONCLUSION

Chapter 8 concludes the thesis by detailing the contribution to knowledge this programme of work has achieved. It also contains a critical evaluation of the methods used and outlines the future work planned to evaluate the new instrument further.

This programme of work has contributed to knowledge through:

a) The provision of clear information on the strengths and limitations of existing WRQoL scales;
b) A clear description of the impact of overweight/obesity on aspects of daily life from people who have experienced weight issues;
c) The development and preliminary evaluation of a new WRQoL scale using input from those who the measure is intended. This instrument will be able to describe and evaluate changes in WRQoL in UK community and clinical samples.

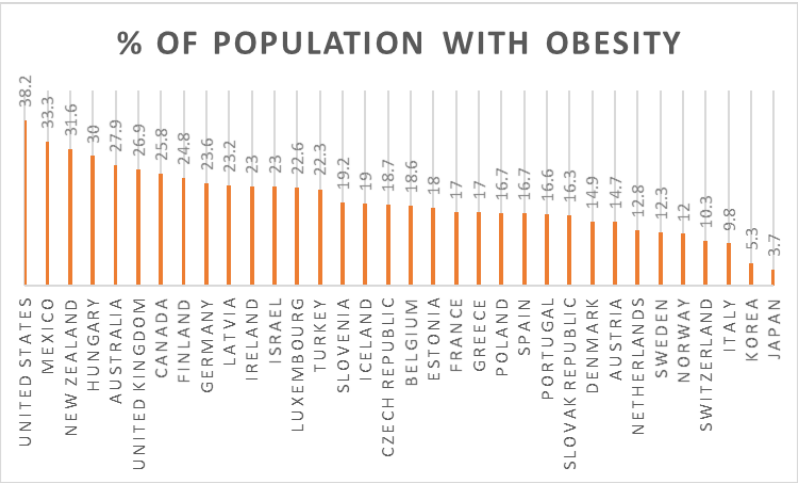
1 OVERVIEW OF OBESITY/OVERWEIGHT

This first chapter sets the scene for the thesis by providing background information surrounding overweight and obesity. It starts by indicating the prevalence of obesity across the world and in the UK, in addition to discussing the ways obesity is defined and measured. The complex nature of its development and the physical and psychosocial consequences of carrying excess weight are then considered, before outlining how obesity is managed within the UK.

1.1 PREVALENCE

Obesity is classed as a worldwide epidemic, with 13% of the worlds adult population classed as having obesity in 2016 (World Health Organisation, 2018). Alongside this, 39% of the world's adult population were overweight. The obesity rates differ from country to country and tend to be higher in developed countries rather than developing countries. Figure 1.1 shows the adult obesity prevalence across the world. The United Kingdom (UK) had the 6th highest incidence of obesity (26.9%) across the countries with data available.

Figure 1.1 Obesity Prevalence across Countries

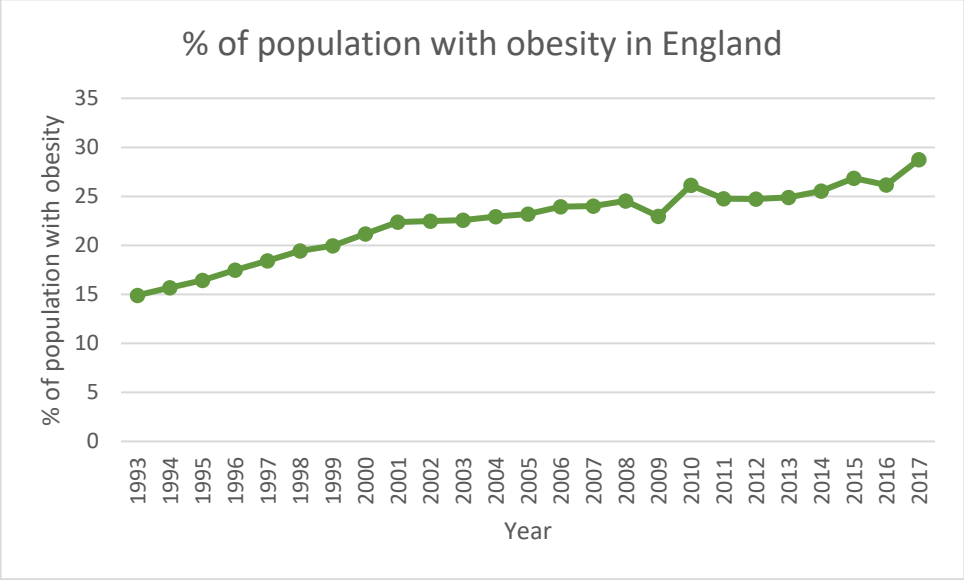


Data from (OECD, 2017), data not available for all countries.

1.1.1 Prevalence of Obesity in England

Obesity rates in England were at a higher level of 29% in 2017 (Conolly & Davies, 2018). This rate has almost doubled since 1993, and currently, a total of 64% of the adult population are overweight or have obesity (Conolly & Davies, 2018). This indicates the scale of obesity as there are more individuals in England at an 'unhealthy' weight than there are at a healthy weight. Figure 1.2 shows the rate of increase in the prevalence of obesity in England from 1993 to 2017.

Figure 1.2 Prevalence of Obesity in England from 1993 to 2017



Data from Health Survey for England (Conolly & Davies, 2018)

If the rate of obesity keeps rising in this manner, over half of the UK population will have obesity by 2050 (Zhang, Kris-Etherton, Hartman et al., 2010). However, the prevalence of obesity seems to have remained stable since 2010, fluctuating slightly year to year. This does not mean that the issue has been solved as less than half the population are a "healthy" weight, and the prevalence of adult obesity has risen by 3% in the last year (2016-2017) (Conolly & Davies, 2018).

The prevalence of obesity varies between males and females, 27.4% and 30% respectively. It also varies with age. The highest incidence of obesity was seen in males aged 45 to 74 and in females aged 45 to 85. Obesity prevalence also varies with levels of area deprivation, but only for females, as prevalence rises to 38% in women in the most deprived areas (Conolly & Davies, 2018).

1.2 DEFINITION OF OVERWEIGHT & OBESITY

Obesity is defined as abnormal or excessive fat accumulation that may impair health (World Health Organisation, 2000). Being overweight is seen as a precursor to obesity or pre-obesity. They are both considered to be preventable multi-faceted conditions caused by the excess storage of fat. There are numerous consequences that excess fat can lead to (these are discussed further from section 1.5). Consequences include early mortality (Peeters, Barendregt, Willekens et al., 2003) and serious morbidity (Calle, Rodriguez, Walker-Thurmond & Thun, 2003; Feller, Boeing & Pischon, 2010; Hu, 2003), along with psychosocial consequences. Due to the impacts on health, accurately measuring overweight and obesity is essential.

1.3 MEASURING OVERWEIGHT AND OBESITY

1.3.1 Body mass index

Body mass index (BMI) is the most commonly and easily used method to determine weight status. BMI equals weight in kilograms divided by height in meters, squared (Roehling, 1999). This is a person's weight to height ratio and is compared to a chart with defined categories and classifications. The classifications have slightly different labels depending on the organisation or country the measurement is taking place in, but they tend to have the same numerical reference points. BMI can be used to classify people into the following categories: Underweight (<18.5kgm2), Normal weight (18.5-24.9kgm2),

Overweight (Pre-obesity) (25-29.9kgm2), Obesity class I (30-34.9kgm2), Obesity Class II (35-39.9kgm2) and Obesity Class III (>39.9kgm2) (NICE, 2014). Whilst BMI is an easy and practical measurement tool for classifying overweight/obesity, it is not the most accurate measure. It cannot determine whether excess weight is down to increased body fat or fat-free mass. Based on the World Health Organisations (WHO, 2000) definition of obesity, the amount of fat someone has is the important factor, rather than just weight alone. Although BMI is not the most accurate measure of obesity/overweight, it is used internationally and is understood by clinicians and researchers.

1.3.2 Body Fat Percentage

Whilst BMI can estimate the amount of body fat someone has, body fat percentage can be measured more directly via skinfold callipers. Skinfold callipers measure the thickness of skin folds at various specific points on the body to calculate a person's body fat percentage (McLannahan & Clifton, 2008). To gain an accurate measure of fat accumulation at each site, the skin is pinched in a way that separates the fat from the muscle. Skinfold callipers typically have an upper measurement limit of 45-55mm, and so the use of them is restricted to moderately overweight or thinner individuals (Duren, Sherwood, Czerwinski et al., 2008). The callipers that can provide larger measurements can be impractical as holding onto a large skinfold while reading the measurement is difficult (Duren et al., 2008). This could allow for small measurement errors that would equate to significant errors in the final calculation of fat percentage. Therefore, using skinfold callipers can lead to inaccuracies if the individuals using them are not proficient or are inexperienced in using them.

1.3.3 Fat Distribution

Body fat can also be measured using magnetic resonance imaging (MRI) which gives an accurate view of fat amount and distribution (McLannahan & Clifton, 2008). This is important as the risks associated with obesity differ depending on where excess fat is distributed. For example, abdominal fat (central obesity) is a higher risk factor for metabolic complications associated with obesity (Aronne, 2002). However, MRI scans are very costly and so are rarely used in this manner. Due to the disadvantages of skinfold callipers and the cost of MRI, obesity is widely measured using BMI alongside waist circumference.

Measuring waist circumference is a relatively simple way to measure abdominal fat. Waist circumference is classified as low, high or very high, indicating the level of risk for health complications (NICE, 2014). *Table 1.1* shows the cut off points/classifications of waist circumference for men and women. Janssen, Katzmarzyk and Ross (2004) found waist circumference to be a more accurate measure of fatness and a better predictor of obesity-related health risks than BMI. The National Institute for Health and Care Excellence (NICE, 2014) agrees that waist circumference is the most useful measure to determine health risks associated with central obesity, compared with BMI and waist to hip ratio (another measure of central obesity). Therefore, waist circumference is generally measured alongside BMI as a practical indicator of visceral abdominal fat and the related health risks (Aronne, 2002). It is also a useful tool, as changes in waist circumference can show improvements in body fat distribution, even when BMI has not changed.

Table 1.1 Waist circumference classifications

	Low	High	Very High
Men	<94cm	94-101.9cm	>101.9cm
Women	<80cm	80-87.9cm	>87.9cm

Information adapted from NICE (2014)

1.4 CAUSES OF OBESITY/OVERWEIGHT

1.4.1 Energy Imbalance

Obesity occurs when an undesirable positive energy balance leads to weight gain (World Health Organisation, 2000). This positive energy balance happens when the calories consumed (food and drink) are higher than those expended (bodily functions and physical activity). When an energy surplus is created, the body stores this excess energy as triglycerides[1] within fat cells. This causes fat cells to increase in size (hypertrophy). It can also cause an increase in the number of fat cells (hyperplasia) in severe obesity. The energy imbalance is increasingly being seen to be a result of profound social and economic changes as levels beyond the control of any single person (Hruby & Hu, 2015). In other words, economic growth, increased availability of inexpensive and nutrient-poor food, industrialisation, mechanised transport, and urbanisation are contributing to an obesogenic environment. High calorific convenience food is more accessible, and there is less need to be physically active. However, these environmental changes do not have the same effect on everyone's weight, indicating that other factors are affecting weight gain.

[1] Triglycerides are fats that are stored within fat cells and released into the blood when the body needs energy between meals or during exercise.

1.4.2 Genetics

To explain why some people are affected by the obesogenic environment, and some are not, the role of genetics in obesity development has been investigated. Over 60 relatively common genetic markers have been found to increase an individual's susceptibility to obesity (Ramos, Sethupathy, Junkins et al., 2009; Speliotes, Willer, Berndt et al., 2010). However, the 32 most common genetic variants only account for less than 1.5% of the overall inter-individual variation in BMI. Therefore, it is generally agreed that there is a gene-environment interaction in which genetic risk predisposes individuals to either adverse or beneficial effects of behavioural and environmental exposures, such as diet and exercise. This is supported by Kilpelainin, Qi, Brage and colleagues (2011) as they found a gene allele that increased the odds of obesity by 23% per allele which can be modified by physical activity in adults. These findings indicate that while genetics have been found to have some effect on an individual's risk of developing obesity, personal behaviours in response to obesogenic environments play a vital role in preventing (and possibly reversing) obesity (Hruby & Hu, 2015).

1.5 PHYSICAL CONSEQUENCES OF OBESITY

1.5.1 Health

Individuals with obesity/overweight are at an increased risk of serious health issues (Finer, 2015). A high BMI and waist circumference is associated with an increased risk of developing cardiovascular disease (Hu, 2003), type II diabetes mellitus (T2DM; Feller et al., 2010), cancer (Calle et al., 2003) and lowers life expectancy by up to six years (Peeters et al., 2003). Overweight and obesity even makes the treatment of these conditions more difficult and can lead to greater treatment failure and complications (Al-Refaie, Parsons, Henderson et al., 2010; Healy, Ryan, Sutton et al., 2010; Wong, Gao, Merrick et al., 2009). As excess abdominal fat leads to a higher risk of health issues,

disease risk associated with obesity is classified by BMI and waist circumference (NICE, 2014). This indicates the importance of using waist circumference alongside BMI to identify disease risk in overweight/obesity. *Table 1.2* displays the classifications of cardiovascular and metabolic disease risk by waist circumference in the overweight and obesity I BMI groups.

Table 1.2 Classification of cardiovascular and metabolic disease risk by waist circumference (W/C) relative to normal weight.

Body Mass Index*	**Low W/C**	**High W/C**	**Very high W/C**
Overweight (BMI 25-29.9)	No Increased Risk	Increased Risk	High Risk
Obesity I (BMI 30-34.9)	Increased Risk	High Risk	Very High Risk

Information adapted from NICE (2014); *People with BMI of 35kg/m^2 or above are at very high risk, regardless of waist circumference.

1.5.2 Metabolic Syndrome

Metabolic syndrome refers to a group of risk factors that occur together and increase the risk of developing heart disease, T2DM, and strokes (Wolin & Petrelli, 2009). These risk factors include high blood lipids (triglycerides), insulin resistance, high blood pressure, elevated fasting blood sugar and high waist circumference (Soverini, Moscatiello, Villanova et al., 2010). If an individual presents with at least three of the health indicators mentioned above, they would be diagnosed with metabolic syndrome.

Individuals with obesity are at risk of metabolic syndrome. This is because the factors included in metabolic syndrome occur most commonly in obesity (Grundy, 2016). Individuals with obesity where excess adipose tissue is mainly located on their upper body, are at a higher risk than those with mostly lower body located adipose tissue (Kelley, Thaete, Troost, Huwe & Goodpaster, 2000). The development of metabolic

syndrome depends on adult weight gain with body fat accumulation, and also a predisposition to store fat in intra-abdominal areas including abnormal fat stores in the liver, pancreas, and heart (Han & Lean, 2016). This indicates that the location of excess fat is an important factor in the risk of metabolic syndrome. However, research has also found that excess calorie intake is an important driver of metabolic syndrome, as calorie restriction can reverse most metabolic risk factors even with the presence of obesity (Grundy, 2016).

There is an ongoing debate as to whether obesity is the primary driver of metabolic syndrome. This is because research has identified a subset of individuals with obesity who have healthier metabolic profiles and decreased health risks compared to other individuals with obesity (Robson, Costa, Hamer & Johnson, 2018). This finding has led to the concept of metabolically healthy obesity (MHO) and metabolically unhealthy obesity (MUO). MHO is classed as obesity without metabolic abnormalities associated with metabolic syndrome. The prevalence of MHO varies between studies due to the use of differing populations. Across studies, MHO has been found to occur in around 10-48% of persons with obesity (Ortega, Lee, Katzmarzyk et al., 2013; Pajunen, Kotronen, Korpi-Hyövälti et al., 2011; van Vliet-Ostaptchouk, Nuotio, Slagter et al., 2014), with MHO being more prevalent in women than men (van Vliet-Ostaptchouk et al., 2014).

It is not fully understood why some individuals with obesity develop metabolic syndrome, and some do not. Research has explored various explanations cross-sectionally such as smoking (Gutiérrez-Repiso, Soriguer, Rojo-Martínez et al., 2013), higher physical activity, lower sedentary time (De Rooij, Van Der Berg, Van Der Kallen et al., 2016), and fitness levels (Barry, Baruth, Beets et al., 2014; Ortega et al., 2013). Ortega and colleagues (2013) investigated the role of fitness on MHO and MUO and found that

individuals with MHO had better fitness than individuals with MUO. They also found, when adjusting for fitness, that individuals with MHO had a 30-50% lower risk (similar to metabolically healthy normal-weight individuals) of all-cause mortality, non-fatal and fatal cardiovascular disease and cancer mortality than those with MUO phenotypes. While these may be important differences between MHO and MUO, the cross-sectional nature of the research and lack of longitudinal studies on these phenotypes does not explain the cause of MHO as opposed to MUO.

One aspect that has been investigated longitudinally is whether MHO is a permanent or temporary state. Despite being metabolically healthy, meta-analyses of prospective cohort studies have found individuals with MHO to be at four times the risk of developing T2DM (Bell, Hamer, van Hees et al., 2015) and cardiovascular disease (Kramer, Zinman & Retnakaran, 2013) than metabolically healthy normal-weight individuals. Research has also discovered a high rate of transitioning from MHO to MUO which increases with longer follow up periods (Hamer, Bell, Sabia, Batty & Kivimäki, 2015; Hwang, Hayashi, Fujimoto et al., 2015; Heianza, Kato, Kodama et al., 2014). This suggests that MHO is a transient state rather than a stable condition that is immune to the development of metabolic syndrome. Therefore, identifying at-risk individuals such as those with overweight and obesity is essential to help prevent the development of metabolic syndrome.

As with MHO, physical activity and good levels of fitness are important for reducing the risk of MUO and other health complications. Weight loss surgery, physical activity and calorie restriction are effective in reducing health indicators of metabolic syndrome (Han & Lean, 2016; Ikramuddin & Buchwald, 2011). However, very low-calorie diets are not the preferred method as the fast weight loss resulting from them is not long term and

weight regain is highly likely, undoing the beneficial effects (Grundy, 2016). Behavioural modification is needed alongside calorie restriction to enable long term benefits of the weight loss on metabolic abnormalities. Long term prevention and treatment of metabolic syndrome using lifestyle changes (such as healthy diet and increased exercise) or through weight loss surgery can reduce the risk of further health complications associated with obesity and metabolic syndrome (such as cardiovascular disease, cancer, and T2DM).

1.5.3 Type II Diabetes Mellitus

Diabetes is a condition where an individual's blood glucose levels are higher than they should be. It is a metabolic condition where the body does not produce sufficient amounts of insulin to regulate blood glucose levels. There are two types of diabetes: type I diabetes mellitus and T2DM. Type I diabetes is an autoimmune condition that is not associated with obesity and so will not be discussed further. T2DM accounts for 90% of diabetes cases and is associated with obesity, metabolic syndrome, and unhealthy lifestyles (Feller et al., 2010; Gatineau, Hancock, Holman et al., 2014). T2DM occurs when the body becomes resistant to the insulin produced in the body or when the body does not produce enough insulin to lower blood glucose sufficiently. Individuals with T2DM must regularly monitor their blood glucose levels, regulate their diet, and in more severe cases, take tablets or inject insulin to control it. This is because if glucose levels remain high for a prolonged period, it will lead to other serious health conditions such as cardiovascular diseases.

The rise in obesity is thought to be linked to the increase in the prevalence of T2DM (Eckel, Kahn, Ferrannini et al., 2011). In the UK, 90% of adults with T2DM also had a BMI of over 30kg/m^2 in the latest available statistics provided by Public Health England (Gatineau et al., 2014). Due to this, having obesity is an established risk factor for

developing T2DM, and the main modifiable risk factor. As with other conditions associated with obesity, T2DM risk is determined by the location of fat accumulation. In particular, increased abdominal fat is related to the development of metabolic syndrome, T2DM and cardiovascular disease (Eckel et al., 2011), thus showing the importance of waist circumference in assessing the risk of comorbidities.

Despite the high prevalence of obesity in individuals with T2DM, the prevalence of T2DM in individuals with obesity is low. Only 12% of individuals with obesity and 7% of overweight individuals have T2DM in the UK (Conolly & Craig, 2019). This indicates that not all individuals with obesity go on to develop T2DM. However, the risk of developing T2DM is five times higher in adults with obesity than with healthy weight adults, indicating considerable risk. The mechanisms linking obesity and T2DM are unclear. Physiologists and researchers have explored various avenues, and it is accepted that both insulin resistance and pancreatic β-cell dysfunction[2] must occur together for T2DM to develop (Al-Goblan, Al-Alfi & Khan, 2014; Eckel et al., 2011). Insulin resistance is thought to occur from obesity-induced nutrient excess within cells that trigger an inflammatory response. In contrast, β-cell dysfunction is thought to occur due to a genetic predisposition that is triggered by stress caused by excess nutrients in the cells. When insulin resistance occurs, the β-cells will release more insulin to attempt to lower blood glucose levels. Still, if the β-cells are dysfunctional, they cannot release as much insulin and so are unable to regulate glucose levels sufficiently, leading to T2DM (Al-Goblan et al., 2014; Eckel et al., 2011).

[2] The pancreas is made up of alpha and beta cells which help to control blood glucose levels. Beta cells are responsible for releasing insulin when blood glucose levels rise. Dysfunctional beta cells may not produce sufficient insulin to reduce glucose levels back to normal and so blood glucose remains high.

There is accumulating evidence suggesting that glycaemic control can be improved with modest weight reduction, which in turn reduces the risk of diabetes (Singla, Murthy, Singla & Gupta, 2019; Lean, Leslie, Barnes et al., 2018; Eckel et al., 2011). Weight loss can occur through lifestyle/behavioural modification, weight loss medication and through surgical intervention to reap these benefits. However, some methods have differing evidence for their long-term success. Bariatric surgery produces substantial and sustained weight loss with evidence suggesting a resolution of comorbidities, including T2DM. Whereas, lifestyle and behavioural interventions have varying success mainly due to the differing approaches and intensity. For example, individual or group counselling interventions aimed at behaviour change are successful at obtaining the desired 5-10% weight loss. However, these are only successful for 12 months before weight is regained (Eckel et al., 2011). More extended term programmes with sustained intervention can lead to more sustainable weight loss, with long term success being predicted by the extent of weight loss in the first 3-6 months (Wing, 2010; Knowler, Barrett-Connor, Fowler et al., 2002).

Anti-obesity medications have also been found to reduce weight and subsequently, T2DM risk (Choussein, Makri, Frangos, Petridou & Daskalopoulou, 2009). The percentage of weight loss due to medication varies from 2 to 8% greater than a placebo. However, long term inferences in sustained weight loss cannot be made as trials tend to last 6-12 months. There are also high dropout rates of up to 50% in anti-obesity drug trials, limiting data analysis to those who complete the trial (Wilding, 2018; Eckel et al., 2011; Choussein et al., 2009). This can amplify the drug's benefits and limit generalisability as it is likely that those who complete the trial have found success with the drug. Despite the limited evidence of the most effective treatment, it is clear that weight loss can reverse and prevent T2DM health indicators, especially in newly diagnosed individuals and those

with metabolic syndrome (or prediabetes). Thus, showing the importance of preventing and treating obesity in relation to T2DM.

1.5.4 Cancer

Obesity has also been found to increase an individual's risk of developing cancer (Cancer Research UK, 2019; Brown, Rumgay, Dunlop et al., 2018). Cancer is a group of diseases characterised by the uncontrolled division and spreading of abnormal cells (McLannahan & Clifton, 2008). Cancer occurs when cells undergo a series of genetic changes as a result of genetic or environmental causes (Tannock, Hill, Bristow & Harrington, 2013). These genetic mutations affect the cells ability to respond normally to signals controlling cell growth, differentiation and death. The uncontrollable growth of cells leads to a mass of cells or tumours. Cells can break off from the tumour to spread through either blood vessels or the lymphatic system to start the cycle of uncontrollable cell growth in a different part of the body (Tannock et al., 2013). If the growth and spread of cancer is not controlled or stopped, it can interfere with vital organ function and eventually lead to death.

In the UK, cancer is the biggest cause of death, when grouping all types (Public Health England, 2018), and caused 163,444 deaths in 2016 (CRUK, 2019). However, four in 10 cases of cancer can be preventable, with obesity being the second largest preventable cause in the UK (CRUK, 2019). It is estimated that rising obesity levels will lead to 670,000 extra cases of cancer by 2035 (CRUK, 2019). Individuals with obesity are likely to take part in unhealthy behaviours, such as decreased physical activity, consumption of high-calorie dense food, high dietary fat intake, low fibre intake and may have oxidative stress. These behaviours are also considered risk factors for cancer (Kaidar-Person, Bar-Sela & Person, 2011). Alongside this, adipose tissue functions as endocrine tissue

producing hormones associated with the occurrence of cancer (such as leptin and insulin-like growth factor 1).

The duration and severity of overweight during adulthood has also been found to play a role in the risk of developing cancer. Arnold, Jiang, Stefanick et al. (2016) conducted a large cohort study of women who were cancer-free at baseline. Twelve years after baseline, they found that longer durations of overweight and greater severity of overweight was associated with the incidence of all obesity-related cancer types. Obesity is also associated with increased mortality from all cancers (Calle et al., 2003) and lower levels of cancer survival (Parekh, Chandran & Bandera, 2012). Furthermore, obesity has been found to increase the risk of developing 13 different types of cancer (Brown et al., 2018). Here endometrial cancer and oesophagus cancer will be used as a case study. Still, it is important to note that these are not the only cancer types associated with overweight/obesity. Among women, overweight/obesity puts them at an increased risk of endometrial cancer, higher than the risk for all other cancer types (Brown et al., 2018; Onstad, Schmandt & Lu, 2016). A similar increased obesity-related risk is seen in men for developing oesophagus cancer (Brown et al., 2018), with large cohort studies indicating that 34-50% of endometrial and 31-50% of oesophagus cancer cases can be attributable to overweight and obesity (Brown et al., 2018; Reeves, Pirie, Beral et al., 2007).

Despite the increased risk of cancer for individuals with obesity, recent research has indicated that individuals may not be aware of their cancer risk (Wilkinson, Murphy, Sinclair et al., 2020). Wilkinson et al. (2020) examined the attitudes of women, with a current or previous diagnosis of endometrial cancer, towards obesity as a disease risk for cancer. They found that 53% believed obesity could cause cancer, but only 35.5%

believed that obesity was a risk factor for endometrial cancer. This suggests that the awareness of obesity-related endometrial cancer risk is lower than the awareness of general obesity-related cancer risk and that there is a lack of awareness among women with overweight/obesity regarding the increased risk of specific cancers that obesity leads to. However, these women had, or previously had, a diagnosis of endometrial cancer and this lack of awareness could represent an internalised guilt or obesity bias that resulted in them answering untruthfully. There is evidence of internalised weight bias in individuals with overweight/obesity, and this will be discussed further in Section 1.6.1.

Low awareness of obesity-related cancer risk is quite alarming, given that weight loss can lower this risk and potentially reverse the pathology (Luo, Hendryx, Manson et al., 2019; MacKintosh, Derbyshire, McVey et al., 2019). Luo et al. (2019) conducted a large cohort study to investigate intentional weight loss and obesity-related cancer risk. It was found that intentional weight loss was associated with a lower overall risk of obesity-related cancers. The largest reduction in risk through intentional weight loss was for endometrial cancer. Similar results were found with waist circumference reduction, which would be expected as it is a better indicator of obesity-related health risk (NICE, 2014; Janssen et al., 2004). Colorectal cancer risk was lower with waist circumference reduction but not weight loss. Race/ethnicity, baseline BMI, smoking status and prior hormone use was controlled for, but physical activity levels and diet were not.

The research investigating the relationship between obesity and health risks/disease tend to use observational cohort studies. As these studies are observational rather than experimental, causality cannot be inferred. Furthermore, many of the studies do not control for other aspects which are linked to increased risk such as physical activity, dietary behaviour, and alcohol consumption. These aspects could play a mediating role

in obesity-related cancer, metabolic syndrome and T2DM risk. Also, the majority of studies measure body adiposity levels through BMI, which is not the most accurate measure of body fat, as discussed earlier. Self-reported BMI is often used, which tends to be both under and over reported depending on actual BMI. However, the vast amount of research linking and attributing obesity to physical health conditions cannot be ignored, and future research needs to continue to investigate the causal links.

1.5.5 Pain and Mobility

Along with the increased risk of disease, obesity can also lead to issues with mobility which can lead to pain (McLannahan & Clifton, 2008). Pain is increasingly being associated with overweight/obesity. The relationship between increasing weight and pain conditions such as low back pain (LBP) and Osteoarthritis (OA) has been investigated many times (Janke, Collins & Kozak, 2007). In terms of LBP, despite the large number of studies investigating the link with weight, the relationship is unclear. It is thought to be mediated by other factors such as lifestyle. However, evidence for the connection between increasing weight and OA is much more reliable. It is consistently shown that being overweight is a risk factor of OA in the knees, hips, and hands. Even being only slightly overweight puts an individual at an increased risk of developing knee OA.

Explanations for the relationship between pain and overweight/obesity include mechanical/structural factors, metabolic factors, and behavioural factors (Janke et al., 2007). First, mechanical/structural factors explain the development of pain conditions through changes to posture. Carrying excess weight can cause severe changes to a person’s posture. Individuals with obesity tend to carry their weight towards the front of their feet due to the abnormal distribution of body fat in the abdominal area. This leads to an altered walking pattern where the knee's ability to rotate under force (e.g. when

walking) is restricted. This is thought to be a mechanism to maintain skeletal health in the short term, but as it affects the loading on individual joints, over time, it has adverse effects on bones and joints (Forhan & Gill, 2013).

Second, metabolic factors attempt to explain the development of pain within overweight/obesity due to their increased risk of metabolic disorders. The increased risk of metabolic disorders leads to an increased vulnerability to nerve damage (neuropathy) associated with diseases such as diabetes (Janke et al., 2007). Symptoms of nerve damage include pain. Finally, behavioural explanations for the development of pain look at lifestyle and psychosocial factors. It is thought that specific lifestyle and psychosocial factors can all provide shared pathways to explain the development of both pain and obesity. This is because experiencing pain can be a risk factor for weight gain as it can lead to decreased physical activity. Out of these three explanations, all likely contribute to the development of pain in those with overweight/obesity. Whilst pain may not be as serious as the more life-threatening health conditions associated with obesity; it can still have a debilitating effect on an individual's life, including psychological and social wellbeing.

1.6 PSYCHOSOCIAL CONSEQUENCES OF OBESITY

The World Health Organisation defined health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity" (WHO, 2014). This indicates that the psychological and social wellbeing are important aspects of a person's health. The physical and clinical effects of obesity are very important. They can be very debilitating, but there are other, salient consequences of obesity that can be just as debilitating on an individual's life. For example, increasing body mass is associated with poorer wellbeing (Jorm, Korten, Christensen et al., 2003), poorer perceived health

(Sullivan, Karlsson, Sjostrom et al., 1993) and higher levels of body dissatisfaction (Wardle & Cooke, 2005). Evidence of an anti-fat (or weight) bias and stigma also exists where individuals with obesity are seen as lazy, to have low competence and trigger feelings of disgust (Levine & Schweitzer, 2015; O'Brien, Daníelsdóttir, Ólafsson et al., 2013).

1.6.1 Stigma towards overweight and obesity

Weight bias is thought to exist where individuals have negative attitudes and beliefs about others due to their weight. These negative attitudes and beliefs include stereotypes and engrained prejudice towards people with overweight/obesity. They lead individuals with obesity to be wrongly labelled as lazy, stupid, ugly, unhappy, socially isolated and lacking self-confidence (Levine et al., 2015; O'Brien et al., 2013). Stigma towards overweight and obesity also exists. Stigma is defined as an attribute that is deeply discrediting to its possessor and reduces the individual "from a whole person to a tainted, discounted one" (Goffman, 1963, pg 12). Stigmas tend to be widespread across social existence, and stigmatising conditions can lead to rejection of individuals due to the 'disgrace' associated with the condition (Link & Phelan, 2001). As more knowledge is gained and public acceptance of conditions change, the negative reactions towards deviant conditions improve (Crocker, Cornwell & Major, 1993). Therefore, stigma arises from others' reactions to conditions rather than from the stigmatising condition itself (Crocker et al., 1993).

Stigma towards being overweight is thought to be the most deliberating (Crocker et al., 1993). This is due to the visibility of the condition making weight-related bias inescapable (Palmeira, Pinto-Gouveia & Cunha, 2016). Other seriously stigmatised conditions such as HIV, are generally only known by the individual themselves as they can choose to

conceal this from others. However, overweight/obesity is immediately visible and has the potential to affect most social interactions and can lead to exclusion, marginalisation and subsequently inequalities. Research has highlighted this as individuals with obesity are perceived to be less attractive than normal-weight individuals (Puhl & Heuer, 2009; Harris, 1990). People make more favourable assumptions about attractive individuals and assume they are more able and have good social skills compared to individuals perceived to be unattractive (Cross, Kiefner-Burmeister, Rossi et al., 2017).

Another reason obesity is stigmatised is that individuals with obesity are generally seen as responsible for the condition. Many popular narratives of obesity oversimplify the causes and the potential solution. The narrative of 'eat less, move more' and the vast amount of 'diet' protocols circulating the media (such as 5:10, intermittent fasting, Atkinson's diet to name a few) implies that there is a quick and easy solution to achieve sustainable weight loss. The tendency to focus on the individual's behaviour, such as eating and physical activity habits, fails to account for all other factors known to contribute to the complexity of overweight/obesity, such as biological, social, and environmental factors. This leads to the general population, along with persons with obesity, developing unrealistic expectations for weight loss and ignores the challenges faced when attempting to change behaviour. Social acceptability of weight bias is reinforced by the media as they portray stereotypical images and videos of people living with obesity. For example, Puhl and Latner (2008) highlight the way the media frames obesity, by emphasising individual responsibility, can contribute to a culture of weight bias and stigma. These over-simplistic beliefs about the cause of obesity can influence stigmatising attitudes in both the general population and even within people with obesity.

Individuals who believe that obesity is caused by a lack of will power or self-control tend to hold more stigmatised attitudes toward people with obesity than individuals who believe it is caused by genetics (Hilbert, Rief & Braehler, 2008; Saguy & Riley, 2005; Crandall, Cohen, Hardy et al., 1994; Allon, 1982). There has been much debate about classifying obesity as a disease to help combat the misconceptions mentioned, as well as to help individuals gain appropriate treatment. It is argued that classifying obesity as a disease will reduce stigma. However, Hoyt, Burnette, Auster-Gussman, Blodorn & Major (2017) indicate that defining obesity as a disease to reduce stigma may be counterproductive. Whilst it reduces views of responsibility and blame, it also creates a belief that they have a negative unchanging essence as it is not possible to change someone's genetics.

Ata, Thompson, Boepple, Marek & Heinberg (2018) support this notion as, despite increasing beliefs that obesity is out of a person's control, classifying obesity as a disease did not have a positive effect on weight-based biased attitudes. However, the participants within this study were only exposed to the obesity as a disease rhetoric for a short time. Yet, stigmatising attitudes and stereotypes of obesity are likely to be engrained and will take a long time to change. Future research needs to investigate the impact of this notion on the general public's attitudes towards obesity in a more naturalistic setting and over a long period of time to allow public acceptance of the new knowledge.

1.6.1.1 **Consequences of Stigmatised attitudes**

Stigma towards overweight/obesity has been found to lead to discrimination and biases towards individuals with obesity/overweight. Weight-based discrimination has been found to take place within higher education and work (Grant & Mizzi, 2014; Puhl & Heuer, 2009) in terms of limiting access to further training and wage penalties (Baum &

Ford, 2004) and also within health care settings (Grant & Mizzi, 2014). Roehling (1999) reviews research investigating weight-based discrimination within employment environments. Evidence of discrimination is found at every stage of the employment cycle. This bias is thought to be stronger than any other bias associated with characteristics such as sex, specific disabilities, race etcetera. Overweight individuals are generally perceived as disagreeable and not emotionally well adjusted, and these stereotypes can sometimes affect employers' decisions on hiring and firing (Roehling, 1999). However, clear information regarding successful performance, such as high qualifications may overcome this negative stigma towards overweight individuals. Furthermore, there is substantial literature suggesting that both men and women with obesity are paid less than individuals of an average weight doing the same work (Baum & Ford, 2004; Cawley, 2004; Puhl & Heur, 2009).

Weight discrimination can have a deleterious effect on various aspects of a person's life. In particular, weight bias and discrimination are associated with eating disordered attitudes and behaviours (Durso, 2012), avoidance of physical activity (Faith, Leone, Ayers, Heo & Pietrobelli, 2002), psychopathological symptoms (Puhl & Heuer, 2009), poorer health care, reduced treatment compliance, medical care avoidance (Dovidio & Fiske, 2012; Lillis & Hayes, 2009; Puhl & Heuer, 2010). They have also been found to lead to weight gain (Sutin & Terracciano, 2013) and lack of success in weight loss treatments (Carels, Wott, Young et al., 2010; Puhl & Heuer, 2009). Experiencing weight discrimination can also lead to diminished body image (Grogan, 2006), feelings of embarrassment about weight (Sarwer, Wadden & Foster, 1998) and physical self-consciousness (Myers & Rosen, 1999).

The vast amount of consequences related to weight bias/stigma indicates the potential suffering an individual with overweight/obesity faces. However, more recent research has shown that weight stigma needs to be internalised and not just experienced to have negative impacts on health aspects (Pearl, Puhl, Himmelstein, Pinto & Foster, 2020). Rudman, Feinber and Fairchild (2002) examined weight bias within individuals with obesity and found that some individuals shared societies weight biased attitudes and beliefs that they themselves are lazy, undisciplined and undesirable in some way because of their weight. Self-criticising, in this way, is referred to as weight bias internalisation (Durso & Latner, 2008).

In terms of the individuals who experience weight bias/stigma, internalising this bias can lead to impairments in psychosocial functioning, self-esteem and mental health (Tomiyama, Carr, Granberg et al., 2018; Myers & Rosen, 1999). It can also lead to changes in attribution styles as Crocker and colleagues (1993) found that overweight women tend to attribute negative outcomes to their weight; their weight has caused the negative outcome. This not only indicates that overweight individuals are prejudiced towards themselves, but it also leads to diminished self-esteem and mood. Furthermore, internalising weight bias leads to feelings of guilt and self-blame (Ata, Thompson, Boepple, Marek & Heinberg, 2018; Crocker et al., 1993), along with a deterioration in weight-related quality of life (WRQoL; Walsh, Wadden, Tronieri, Chao & Pearl, 2018).

1.6.2 Body Image

Individuals with obesity are also likely to have an impaired body image. Body image relates to an individual's perceptions, thoughts and feelings towards their body (Grogan, 2017). Much of the research into body image focuses on dissatisfaction with weight and desires to be thinner. However, the construct of body image is thought to be broader than

this and includes body size estimation, evaluation of body attractiveness and emotions towards body shape and size (Grogan, 2017). In general populations, a more favourable body image is seen in men compared to women (Cash, Jakatdar & Fleming, 2004; Feingold Alan & Marzzella Ronald, 1998) and in women with lower BMI's (Cash et al., 2004). Feingold and Mazzella (1998) reported a large increase in the number of women among those with poor body image during the 50 years before their published paper. Poorer body image and body dissatisfaction in women is a normative finding and is hypothesised to be due to societal emphasis on thinness and beauty in females (Grogan, 2017). Therefore, it is not surprising that females with obesity are more dissatisfied with their bodies than are males with obesity (Weinberger, Kersting, Riedel-Heller & Luck-Sikorski, 2017).

Body image has been found to be linked to BMI in women, as women with higher BMI's tend to have a poorer body image than women with lower BMI's (Cash et al., 2004). This was not found in men, suggesting that their body image is less affected by weight. However, there is very little research that investigates the effect of body image in men, so it is uncertain how men are affected. The little research that has been conducted indicates that men and boys increasingly report body dissatisfaction (McCreary & Sasse, 2002) and males are concerned with body image across the life span (McCabe & Ricciardelli, 2004). Despite this, men with obesity seem to be less affected than women with obesity in relation to their body image and body dissatisfaction (Weinberger et al., 2017). It is theorised that societal expectations of muscularity and strength in men could help men with obesity protect themselves by considering themselves as big and strong rather than 'fat' (Grogan, 2017; Weinberger et al., 2017; Schwartz & Brownell, 2004). Further research and investigation into the effect of obesity on body image in males are needed. As there is limited research, qualitative research could help guide this to enable

males to think and consider their experiences of obesity/overweight and its potential impact on their body image and body dissatisfaction.

1.6.2.1 **Implications of body image**

Body image has been found to affect clothing choices and experiences when shopping for clothes in women. Tiggemann & Lacey (2009) found that those with a higher BMI and higher body dissatisfaction were more likely to use clothing to camouflage their bodies and reported a more negative experience of clothes shopping. This is supported by Sarwer, Wadden & Foster (1998). They found that individuals with obesity were significantly more likely than normal-weight individuals to use clothing to camouflage their bodies, change their posture or body movements to disguise weight. They were also more likely to avoid looking at their bodies and become upset when thinking about their appearance. They also experienced moderate to extreme embarrassment in social situations because of their weight on more than half of the days of the month.

Weight and shape concerns have been found to be an important mediator between obesity and impaired psychosocial functioning (Mond, Rodgers, Hay et al., 2007). They are thought to lead to poor emotional wellbeing (Mond, Berg, Boutelle et al., 2011). Body worry has been found to explain the relationship between obesity and excessive negative affect in non-clinical populations (Jansen, Havermans, Nederkoorn & Roefs, 2008). This indicates that experiencing issues with body image could lead to the development of depressive symptoms. Hyde, Mezulis and Abramson (2008) support this as they found a link between body shame and the development of depression. Body shame has also been linked to binge eating, restrictive dieting and self-induced vomiting (Levine & Piran, 2004). In contrast, a more positive body image is associated with higher self-esteem, optimism, and social support in both sexes, as well as less eating disturbance among

women (Cash et al., 2004). Within men, body dissatisfaction is also linked to the use of bodybuilding drugs (Wright, Grogan & Hunter, 2000). This indicates that improving body image could potentially reverse these negative impacts on emotional and psychological health.

Alongside these emotional and psychological effects, body image can also affect the likelihood someone will engage in exercise (Brudzynski & Ebben, 2010). Individuals with poor body image may be too self-conscious about their bodies to be seen in sportswear and in gyms. This is likely to increase an individual's weight if they avoid exercise, having further negative effects on body image. However, unlike stigma and discrimination that has been linked to reduced health behaviours, a certain level of body dissatisfaction could motivate healthy behaviours such as increased physical activity (Heinberg, Thompson & Matzon, 2001). Furthermore, weight loss has been found to improve body image in overweight/obesity (Chao, 2015; Palmeira, Branco, Martins et al., 2010) and this improvement in body image can even help to maintain weight loss (Palmeira et al., 2010; Roberts & Ashley, 1999). However, intervention dropout rates tend to be higher in those whose primary motivation to lose weight is appearance related (Dalle Grave, Calugi, Molinari et al., 2005). Therefore, highlighting issues with body image could identify individuals that may need extra support in terms of starting exercise and trying to lose weight, as well as highlighting those at risk of mental health conditions (such as, depression and eating disturbances).

The vast amount of consequences related to weight bias/stigma and impaired body image indicates the potential suffering an individual with overweight/obesity may face. However, the majority of studies investigating consequences are based on quantitative research which reduces their 'problems' to numbers, and there is minimal research

exploring individual experiences of overweight/obesity. There is also limited research investigating body image within males with obesity. Qualitative research will allow a more in-depth insight into both the physical and psychosocial impact excess weight has from the patient's perspective. It has the potential to discover aspects not previously measured, providing a greater understanding of the impact of obesity. Knowing all the potential consequences and impacts of obesity can help to implement effective treatments or interventions.

1.7 OBESITY TREATMENT

The aim of obesity treatments is the maintenance of a clinically meaningful weight loss (NICE, 2014). A clinically meaningful weight loss is when an individual loses 5-10% of their initial body weight (Wilding, 2018). It is classed as clinically meaningful due to the dramatic reduction of risk factors associated with overweight/obesity (Douketis & Sharma, 2005). As discussed earlier in section 1.5, weight loss can improve health indicators relating to metabolic syndrome, T2DM and cancer, as well as reduce pain and increase mobility and body image. The majority of people who attempt to lose weight are generally successful at achieving a clinically meaningful weight loss (Hill, 2005). However, many people fail when it comes to maintaining that weight loss. To keep the weight off, energy intake and energy expenditure need to be permanently balanced (Hill, 2005).

1.7.1 Management/treatment for overweight/obesity in the UK

In the UK, treatment or management services for overweight/obesity are split into four tiers, representing different levels of services (Public Health England, 2015). Tier 1 refers to universal services aimed at preventing and reversing obesity by providing general awareness and advice about healthy lifestyles. Tier 2 covers lifestyle interventions. Tier

3 refers to specialist weight management services. Finally, tier 4 refers to preoperative assessment for specialised, complex obesity services (for example, bariatric surgery).

1.7.1.1 **Tier 1 services: health promotion to the public**

Tier 1 services include universal behavioural interventions aimed at preventing obesity and reinforcing healthy eating and physical activity messages (Capehorn, 2014). They tend to be public health and national campaigns, providing brief advice. For example, the national campaign Change4Life is regularly broadcasted through media platforms to give dietary and physical activity advice to parents and their children. But tier 1 services also involve health care professionals (HCPs), General Practitioners (GP), nurses and health visitors identifying 'at risk' individuals and providing them with general lifestyle advice.

1.7.1.2 **Tier 2 services: lifestyle weight management interventions**

NICE (2014b) highlight lifestyle interventions (tier 2 services) as the treatment of choice for overweight/obesity. Lifestyle interventions for weight management are programmes that aim to reduce an individual's energy intake and help them to become more physically active through behaviour change (NICE, 2014b). They include weight management programmes, courses or clubs that accept adults through self-referral or referral from primary care. The programmes or courses can be provided by the public, voluntary or private sector, and they can be based in communities, workplaces, primary care or online.

NICE endorse commercial slimming organisations such as Rosemary Conley, Slimming World and Weight Watchers as they have demonstrated effectiveness (5-10% weight loss) at 12 months (Ahern, Wheeler, Aveyard et al., 2017). These organisations attempt to help people with overweight/obesity assess their weight and set realistic goals for weight loss. Commercial slimming organisations are both clinically effective and cost-

effective and are useful early interventions for weight management (Ahern, Wheeler, Aveyard et al., 2017; Fuller, Colagiuri, Schofield et al., 2013; Jebb, Ahern, Olson et al., 2011). However, the effect of these commercial interventions on psychosocial wellbeing or quality of life (QoL) is unknown due to a lack of research.

Tier 2 services also include the prescription of anti-obesity medication. Anti-obesity medication can be prescribed by GPs. The UK currently only has one widely prescribed anti-obesity drug; Orlistat (Wilding, 2018). However, Orlistat has only been found to have modest efficacy in leading to clinically meaningful weight loss (this was not maintained). However, it is associated with unwanted side effects which discourage its use (Douglas, Bhaskaran, Batterham & Smeeth, 2015).

1.7.1.3 **Tier 3 services: specialist weight management**

If an individual has not responded to the previous tier 2 interventions and they have a BMI of 40kg/m^2 or over or a BMI of 35kg/m^2 or over with comorbidities, they would be referred to a tier 3 specialist weight management service. Tier 3 services involve a multidisciplinary team of specialists led by a clinician. The team generally includes a physician, specialist nurse, specialist dietician, psychologist (or psychiatrist) and a physiotherapist (or physical activity specialist) (Wilding, 2018). This service is more individualised to the patient and may address specific circumstances and barriers the individual may have. Tier 3 services have been found to achieve clinically meaningful weight loss in individuals with severe and complex forms of obesity (Brown, O'Malley, Blackshaw et al., 2017). However, there tend to be high dropout rates (Brown et al., 2017; Morrison, Boyle, Morrison et al., 2012) and the provision of tier 3 services is variable across the country with many areas lacking these services (Booth, Prevost & Gulliford,

2015; Wilding, 2018). Tier 3 services allow access to tier 4 services, so without tier 3 services, a patient cannot gain access to tier 4 services.

1.7.1.4 **Tier 4 services: bariatric surgery**

Tier 4 services include bariatric surgery. Obesity surgery is only considered in those with a BMI over 40kg/m^2 or 35kg/m^2 if presenting with one or more comorbidities (like tier 3 services). Recently, recommendations for bariatric surgery have been altered to include those with a BMI of 30-34.9kg/ m^2 with a recent diagnosis of T2DM (NICE, 2014b). However, bariatric surgery is generally only recommended if a person has tried all other services with no success (Wilding, 2018). In the UK, bariatric surgery has been found to be successful at achieving massive weight loss which is sustained for at least four years after surgery (Douglas, Bhaskaran, Batterham & Smeeth, 2015).

There are more people in the UK within these lower obesity/overweight categories than the obesity II category, indicating that lifestyle interventions are more likely to be used to treat obesity and prevent the need for surgery. As tier 2 services are the treatment of choice, these services will be the first port of call for individuals with obesity. It is, therefore, essential that these services are evaluated thoroughly to improve them. If these services are efficient, the need for further tier 3 or 4 services will be minimised. Currently, tier 2 services (and even tier 3 services) have been evaluated in terms of weight loss achieved and maintained, but there has been limited research into the individual's experiences of the interventions concerning their psychological and social wellbeing (Fuller et al., 2013; Jebb et al., 2011). While it is important to assess weight loss and the clinical health improvements gained through weight loss, the psychosocial consequences should also be considered.

1.8 SUMMARY

Overweight and obesity can have deleterious effects on an individual's physical health as well as their psychological and social wellbeing. The treatment of obesity, including weight loss surgery, behaviour modifications, calorie restriction leading to weight loss all lead to reductions in the risk of obesity-related metabolic syndrome, T2DM and cancer. This highlights the importance of treating and preventing obesity. However, it is not fully understood how treatment and prevention of obesity affect the more intrapersonal aspects of a person's life. Interventions aiming to reduce obesity tend to focus on reducing health risk indicators, without acknowledgement of the psychosocial consequences of obesity. If an intervention is not improving the psychological and social consequences of obesity, then unsuccessful weight loss or weight regain could occur. Likewise, improving psychosocial aspects such as body image has the potential to motivate individuals to adhere to their weight management, increasing the success of the intervention (Palmeira et al., 2010). Therefore, it is essential to assess an individual's wellbeing or QoL, in addition to the clinical consequences of obesity.

2 QUALITY OF LIFE AND ITS MEASUREMENT IN OBESITY

Since the WHO broadened the definition of health to include physical, emotional and social wellbeing (World Health Organisation, 2014), research into quality of life (QoL) has become increasingly popular. HRQoL is now considered essential to assess the impact and treatment of disease on the individual as a whole. Chapter one highlighted the debilitating effects carrying excess weight could have on an individual's physical health and functioning along with the psychosocial aspects of life. These biopsychosocial effects are likely to harm QoL (Taylor, Forhan, Vigod, McIntyre & Morrison, 2013). Therefore, HRQoL should be measured in those with overweight/obesity to quantify and evaluate the impact of carrying excess weight and weight loss treatments/interventions on the broader aspects of a person's life. Within this chapter, QoL will be defined, and the different types of QoL measures will be described, the literature that describes QoL in obesity in general and after weight loss will be reviewed. Finally, what constitutes a 'good' weight-related quality of life (WRQoL) scale will be considered, in relation to the art and theory of scale development.

2.1 DEFINING QUALITY OF LIFE

QoL is widely used in assessing the consequences of disease. To measure QoL, it is important to have a definition and or conceptualisation of its components. Initial definitions state that QoL represents the variation between an individuals' subjective view of their current ability and their own internalised standards of what should be possible (Cella & Tulsky, 1990). It is generally agreed that QoL is subjective; however, to measure it, a comprehensive definition encompassing the aspects of a person's life perceived to be important to them is needed. Therefore, it is agreed that QoL includes numerous domains relating to an individual's life. Domains include physical and mental health status, social

relationships, and environmental and economic factors (Fontaine & Barofsky, 2001; Whoqol Group, 1995).

Whilst it is generally agreed that QoL encompasses numerous domains, the term quality of life has been used to refer to various things such as health status, physical functioning, symptoms, psychological adjustment, wellbeing, life satisfaction and happiness (Ferrans, Zerwic, Wilbur & Larson, 2005). It is also defined differently within different disciplines (for example, sociologists, economists, epidemiologists, psychologists, nurses and doctors all approach QoL from their perspectives). Due to this, comparing conclusions drawn from QoL life research is difficult. To help overcome this issue and make the results of research more comparable, the term "health-related quality of life" (HRQoL) was developed. HRQoL differentiates between the general aspects of QoL and the more specific aspects that relate to health (Guyatt, Feeny & Patrick, 1993). For example, employment, housing, schools, and neighbourhoods, although they can influence health, would not be considered an attribute of a person's health. These aspects of a person's life are beyond the scope of the health care system. Therefore, HRQoL is concerned with the impact of disease and treatment on an individual's life. At a minimum, HRQoL includes physical, psychological and social functioning (Guyatt et al., 1993).

2.2 WHY MEASURE QUALITY OF LIFE IN OBESITY?

Obesity is considered a chronic disease as only a small percentage of people ever fully recover to maintain a 'healthy weight'. Even then, those who succeed in losing weight are likely to continue to carry excess weight and are at constant threat of regaining weight. It is this chronic nature of obesity that makes the measurement of WRQoL an important health outcome to consider in its management and treatment. Also, obesity has the potential to negatively affect QoL (Kim, Park, Yang et al., 2015; Taylor et al., 2013).

Therefore, health issues experienced due to obesity must be understood from the patients' perspective. This will allow the understanding and evaluation of the subjective experience of obesity-related symptoms and their impact on QoL. Studies that evaluate patient experiences and perspectives will enable HCPs to better understand the importance of obesity outcomes to the patient.

Using HRQoL measurement in overweight/obesity has the potential to first, allow patients to describe self-reported physical and psychosocial health. Secondly, it will enable researchers and health professionals to quantify and evaluate the impact of being overweight/obese on the salient aspects of the individual's life. Finally, HRQoL can be used as a measurement tool and outcome measure in weight-related community and clinical interventions. Using HRQoL in this way will complement existing clinical measures to provide a more holistic picture and evaluation of weight-related interventions. The outcome will be described in a more meaningful way to both the educational and health professional and the individual. It will provide information that only the individual undertaking the intervention will have experienced, helping to discover any limitations and potentially improve interventions. HRQoL scales may be able to pick up important weight-related changes before changes in BMI are observed.

2.3 TYPES OF HRQoL MEASUREMENT

HRQoL is typically measured using patient-reported questionnaires that ask for information relating to various aspects and issues related to health and illness. There are three different approaches to measuring HRQoL; each has been used within obesity populations. These are generic, specific and utility measures. Each approach has various purposes, as well as differing strengths and limitations.

2.3.1 Generic measures

General HRQoL instruments measure broad aspects of HRQoL. They provide a generalised assessment rather than assessing HRQoL in relation to a specific health condition or disease (Fontaine & Barofsky, 2001). The most commonly used generic measure in obesity is the Medical outcomes Study Short-Form Health Survey (SF-36) (Accardi, Fave, Ronchi et al., 2017; Corica, Corsonello, Apolone et al., 2006; Ware & Sherbourne, 1992). The SF-36 measures HRQoL among eight domains: physical functioning, role limitations owing to physical problems; bodily pain; general health perception; vitality; social functioning; role functioning; role limitations as a result of emotional problems; and mental health.

Generic measures can provide useful information about an individual's QoL. The main advantage of generic measures is that they allow comparisons of HRQoL across various diseases and conditions (Guyatt et al., 1993). They can also be administered to the general public to compare HRQoL across different geographical locations or different economic status'. However, they are not designed to measure condition-specific issues and so are restricted in their usefulness for examining specific diseases in detail (Accardi et al., 2017; Abbott, Webb & Dodd, 1996). For example, an individual who is overweight or has obesity may face issues such as weight-related stigma and body image worries. These issues would not be picked up within generic measures, meaning that the scales are less sensitive than specific scales.

Research has illustrated the issue of sensitivity by explicitly examining the structural validity of the SF-36 within obesity populations (Corica, Corsonello, Apolone et al., 2006). Some of the items of the SF-36 were found to group together in a different way compared to general populations. In particular, items about physical activity were

separated into two groups: vigorous activities/complex movements and all other physical activity. It was concluded that HRQoL in individuals with overweight/obesity is better described with an alternative aggregation of items or by using weight-specific QoL questionnaires to represent the differing degrees of obesity-related impairments and the specific impacts of obesity (Corica et al., 2006b). It is important to acknowledge that not all diseases are equally affected by psychosocial factors and obesity is arguably the most multifaceted disease in terms of the possible biological, behavioural and environmental causes and consequences (Fontaine & Barofsky, 2001; Taylor et al., 2013). Therefore, HRQoL scales designed specifically for use within overweight/obesity will give a more accurate representation of HRQoL in these populations.

2.3.2 Disease-specific measures

Disease-specific measures of HRQoL are specifically designed for use in specific disease populations. The rationale behind specific measures is that because they have been developed to measure the effects of a specific disease on HRQoL, they are likely to be more sensitive and therefore more relevant to clinicians (Fontaine & Barofsky, 2001). Numerous obesity-specific QoL measures have been developed such as the Moorhead-Ardelt QoL instrument (MA-QoLQ-II; Moorehead, Ardelt-Gattinger, Lechner & Oria, 2003), IWQOL (Kolotkin, Head & Brookhart, 1997), IWQOL-Lite (Kolotkin, Crosby, Kosloski & Williams, 2001), and the ORWELL-97 (Mannucci, Ricca, Barciulli et al., 1999). The Impact of Weight on Quality of Life – Lite scale (IWQOL-Lite) is the most commonly used specific questionnaire in obesity research. It is a 31-item measure that assesses the effects of weight along five domains of functioning: physical functioning; self-esteem; sexual health; public distress; and work.

It is generally dependant on the goals of the research whether a disease-specific questionnaire provides a 'better' assessment of HRQoL than generic measures (Fontaine & Barofsky, 2001). However, some studies have shown disease-specific measures to be more sensitive to treatment effects than generic measures (Laupacis, Wong & Churchill, 1991). In terms of obesity, psychological distress has been found to correlate more highly with bodyweight when obesity-specific measures are used rather than generic measures (Klesges, Klem & Klesges, 1992). Therefore, it is generally agreed that generic and specific measures should be used together to provide the most comprehensive evaluation of HRQoL possible (Guyatt et al., 1993). However, using both types of assessments may add to response burden and could create potential problems if there are discrepancies between the scale outcomes (Kolotkin, Head & Brookhart, 1997; Fontaine & Barofsky, 2001).

2.3.3 Utility measures

The utility approach to measuring HRQoL is concerned with decisions about treatment, usually at a policy level (Cella & Tulsky, 1990). Utility measures are usually used within health economy to evaluate treatments in terms of their benefits compared to their costs. They generally give one value which can be used to compare cost-benefits across different interventions to decide on the most cost-effective treatment/intervention. The most commonly used utility measure is the European quality of life scale (EQ-5D). The EQ-5D contains five questions representing different dimensions of health (The EuroQol Group, 1990). These are mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each domain is rated by respondents as 'no problem', 'some problem' or 'extreme problem'. This is a general utility measure meaning it can be used across different diseases. There are currently no adult obesity specific utility measures, but there are obesity-specific utilities for use in children and adolescent populations such

as the WAItE (Oluboyede, Hulme & Hill, 2017) and the AQoL-6D (Keating, Peeters, Swinburn, Magliano & Moodie, 2013).

The main advantage of utility measures is that they tend to be short, so response burden is low. This makes it useful within clinical trials or when patients are in hospital. Also, as they give a single number representing the impact of disease on quantity and quality of life, it tends to be easier to interpret the effectiveness of a treatment in terms of value to the patient. However, utility measures do not allow the examination of the effect of disease on different aspects of HRQoL and therefore, may not be as responsive to change (Guyatt et al., 1993).

2.4 OBESITY AND HRQoL

The empirical evidence investigating the effect of BMI on HRQoL widely supports the notion that individuals with obesity have impaired HRQoL compared to normal-weight individuals (Amiri, Jalali-Farahani, Rezaei et al., 2018; Kim et al., 2015; Kolotkin & Andersen, 2017; Soltoft et al., 2009; Ul-Haq et al., 2013; van Nunen et al., 2007). A selection of these studies are described below, and others are summarised in *Table 2.1*. It was not intended to give an exhaustive review of all published studies, rather to provide a representative sample of studies using a range of instruments.

Table 2.1 Summary of descriptive studies investigating the relationship between weight and QoL

Authors	Study and sample	HRQoL measure	General finding
Hassan et al. (2003)	Cross-sectional data from CDC's Behavioural Risk Factor Surveillance System data of 182,372 US persons aged 18 and above.	Study specific (generic questions)	Obesity associated with more unhealthy days for physical and mental health compared to non-obesity.
Jia et al. (2005)	Cross-section survey data of general population from 13,646 US persons aged 18 and above	SF-12 EQ-5D	Obesity associated with lower HRQoL even without comorbidities linked to obesity.
Van Nunen et al. (2007)	Meta-analysis of 54 article and 100,000 persons	SF-36 IWQOL-Lite	Obesity associated with lower HRQoL, especially for patients with morbid obesity seeking surgical treatment.
Sach et al. (2007)	Cross-sectional survey of 1865 persons from a UK general practice ages 45 and above	Various	Obesity associated with lower HRQoL
De Zwaan et al (2009)	Cross sectional baseline data of German and Austrian persons with obesity in weight loss programme (n = 251), bariatric surgery patients (n = 153), and general population of normal weight (n = 174) and persons with obesity (n = 129)	SF-36	Dose-response association with BMI and degree of physical impairment, not effected by treatment status. No association between BMI and mental HRQoL.
Soltoft et al. (2009)	Cross-sectional data from Health Survey for England of 14,416 persons	EQ-5D	Strong association between BMI above normal (and below normal) and HRQoL.
Kearns et al. (2013)	Cross-sectional survey data, from the South Yorkshire Cohort, of 19,460 persons aged 16-85	EQ-5D	Overweight and obesity associated with impaired HRQoL with strongest association in persons with obesity. BMI between 20 and 24 represents highest HRQoL.
Ulhaq et al. (2013)	Meta-analysis of 8 cross sectional studies	SF-36	Dose effect across BMI with physical HRQoL Mental HRQoL only reduced in Class II obesity (40+kg/m2).
Lopez-Garcia et al. (2017)	Prospective cohort of 6207 Caucasian persons in Spain aged 18 and over.	SF-12	Obesity, regardless of metabolic health, is associated with impaired HRQoL. Overweight with metabolic abnormalities associated with impaired HRQoL.
Apple et al. (2018)	Cross-sectional online survey of 10,133 US persons aged 30-67	PROMIS Global Health instrument	Non-linear association between BMI and HRQOL more pronounced in women and with increasing age.

Based on cross-sectional data from the Centre of Disease Control's (CDC) Behavioural Risk Factor Surveillance System, Hassan, Joshi, Mahavan and Amonkar (2003) found that individuals with obesity and severe obesity experienced more unhealthy days (over a month) affecting both the physical health domain and the mental health domain. They also found that obesity was associated with limitations inactivity due to poor physical or mental health. Impairments in HRQoL were found to be partly moderated by exercise, and dietary controls as regular exercise and reporting being on a diet to lose weight were associated with increased HRQoL. This suggests that being active and changing dietary habits in an attempt to lose weight could help improve HRQoL in persons with obesity. It could be that these individuals had recently lost weight due to their weight loss attempt but were still considered to have obesity. However, as this is based on cross-sectional data, the causal relationship is unknown. Therefore, research needs to investigate the effects of weight loss on HRQoL.

Soltoft, Hammer and Kragh (2009) examined the relationship between BMI and HRQoL in the general population of England. Similar to Hassan et al. (2003), reduced HRQoL was found. HRQoL was reduced in the underweight BMI categories and the overweight and obesity categories. However, the proportion of individuals reporting problems in all five domains of the EQ-5D was increased in men and women in the overweight, obesity and severe obesity BMI categories rather than the underweight category. They also found that HRQoL was more negatively affected in women with BMI's above 27 compared to men, showing that gender had a mediating effect on the relationship between BMI and HRQoL. This gender effect has also been found in other descriptive studies (e.g. Apple, Samuels, Fonnesbeck et al., 2018; de Zwaan, Petersen, Kaerber et al., 2009), indicating that women with overweight/obesity tend to report a greater impairment in HRQoL (especially mental HRQoL) than men with overweight/obesity.

Ul-Haq, Mackay, Fenwick and Pell (2013) conducted a meta-analysis to determine the relationship between BMI and physical and mental HRQoL (from SF-36) across eight studies. They found a dose-effect across all BMI categories for physical HRQoL similar to the previous studies. However, they found that mental HRQoL was only reduced in those with class II obesity (BMI of 40kg/m^2 or above). This finding that mental HRQoL is not associated in the same way as physical HRQoL has been supported by de Zwann et al. (2009), where no association between BMI and HRQoL was found. However, this does not mean that mental HRQoL is unaffected by weight, but rather there could be a methodological difference contributing to the differing findings in mental HRQoL. Both de Zwaan et al. (2009) and Ul-Haq et al. (2013) used the SF-36, whereas studies that did not find a difference used the EQ-5D (Soltoft et al., 2009) or a study-specific scale (Hassan et al., 2003). Therefore, it could be the case that the EQ-5D and Hassan et al.'s (2003) study-specific questionnaire contained more relevant items concerning weight and mental HRQoL. It has already been highlighted that the SF-36 item clustering is different in obesity populations compared to general populations which could be affecting the portrayal of HRQoL in these studies.

There have been relatively few studies using weight-specific HRQoL questionnaires to examine the relationship between overweight/obesity and HRQoL. Despite this, research generally shows impairments in HRQoL in those with obesity compared to those of a normal weight (Amiri, Jalali-Farahani, Rezaei et al., 2018; Kim et al., 2015; Kolotkin & Andersen, 2017; Soltoft et al., 2009; Ul-Haq et al., 2013; van Nunen et al., 2007). Van Nunen and colleagues (2007), conducted a meta-analysis on 54 studies to examine the differences in HRQoL (specific and generic) between those seeking surgical treatment, those seeking non-surgical treatment, non-treatment seeking individuals, general populations with obesity and general populations without obesity. The meta-analysis

looked at the baseline differences in scores on the SF-36 and the IWQOL-Lite and found reduced HRQoL in those with obesity on both measures. However, when the data had been adjusted for BMI, the SF-36 showed that those seeking surgery had the worse HRQoL, whereas the IWQOL-Lite did not. Differences are likely due to the specificity of the measures. Bodyweight is the main determinant of HRQoL when measured by the IWQOL-Lite, but HRQoL, as measured by the SF-36, was not purely being affected by weight in this study.

In summary, empirical evidence indicates that people with obesity report significant impairments in HRQoL, with these impairments becoming increasingly worse with increasing BMI. This association of BMI and HRQoL is seen to be mediated by gender, age and with a lesser agreement, comorbidities. Further research is needed to examine these mediating factors. Research investigating the effects of weight loss on HRQoL is also important.

2.4.1 Impact of weight loss on HRQoL

Whilst it is important to use HRQoL measures to describe the relationship with obesity/overweight, it is also important to measure the change in HRQoL with treatment/weight loss or weight gain. A selection of studies investigating weight change and HRQoL are critically discussed below, and others are detailed in *Table 2.2*. It was not intended to give an exhaustive list but rather to provide a representative sample of studies using a variety of behavioural and combined interventions and HRQoL measures.

Table 2.2 Summary of research investigating the effect of weight loss on HRQoL

Authors	Sample	Intervention	Weight loss	Follow-up	HRQoL measure	Effect on HRQoL
Arrebola, Gomez-Candela, Fernandez-Fernandez, Loria & Munoz (2011)	N = 27 (71% female) 18-50years BMI 27-39.9kg/m^2 50% dropout	Lifestyle Modification Programme that included nutrition education, physical activity recommendations and psychological support. 11 sessions, one every 2weeks. No control group.	Average weight loss = 7% of initial weight (moderate weight reduction)	6 months	SF-36	Improvement in both metal and physical composite scores.
Wright, Boyle, Baxter, Gilchrist et al (2012)	N = 199 Mean age = 50 years BMI > 30 with comorbidities BMI > 35	Lifestyle intervention including 9 fortnightly sessions providing lifestyle advice (diet and exercise) and behaviour change strategies. No control group.	Mean weight loss = 5.1kg of initial weight	18 weeks	IWQOL-Lite	Improvement in HRQoL was found. Improvement due to weight loss when 5+kg losses was achieved. Improvements due to reduction in depression when <5kg was lost.
Rothberg, McEwen, Kraftson, Neshewat et al (2013)	N = 188 BMI ≥ 32 with comorbidities and ≥ 35 20% dropout	Intervention included very low-calorie diets, physical activity, and intensive behavioural counselling. No control group.	Mean BMI reduction = 7 points	6 months	EQ-5D	Improvement in HRQoL from baseline to follow up. Improvement associated with lower baseline BMI, greater reduction in BMI at follow up, fewer comorbidities and lower HRQoL at baseline.
Kolotkin, Smolarz, Meincke & Fujioka (2018)	Prediabetes with BMI ≥ 30 or BMI ≥ 27 with hypertension or dyslipidaemia Liraglutide n = 661 Control n = 249 Dropout = 50%	2 Groups: 1. Liraglutide 2. Placebo Both groups received lifestyle diet and exercise advice/ recommendations	15% WL = 11% vs 3% placebo 10-14.9% = 14% vs 7% 5-9.9% = 25% vs 14% 0-<5% = 35 vs 37% Weight gained in 15% liraglutide vs 19% placebo	3 years	IWQOL-Lite; SF-36	At 3 years mean change from baseline in IWQOL-Lite total score and each of its subscale was significantly higher for liraglutide compared to placebo. The PCS on the SF-36 increased in both groups during the first 28 weeks and remained stable after that. MCS scores remained relatively unchanged.

						Greater improvements in IWQOL-Lite total score and PCS scores associated with higher weight loss. No relationship between MSC scores and weight loss
Pearl, Wadden, Tromeri Berkowitz & Chao (2018)	N = 112 (86% female) Phase 1: Mean BMI 41kg/m^2 Mean age = 46 years Phase 2: participants who had lost ≥ 5% of initial weight in phase 1 included. 19% dropout	Two phase intervention: 1: 14 week non randomised intensive lifestyle intervention 2: 52 week double blind RCT of drug lorcaserin with weight loss maintenance counselling	Phase 1 achieved a mean of 9.3% weight loss Phase 2: No further weight loss; weight loss maintained in both groups	Baseline (phase 1), Week 14 (end of phase 1), and Week 66 (end of phase 2)	IWQOL-Lite	End of phase 1: Improvement in total score, Physical functioning, self-esteem, sexual life and work sub-scales but not public distress subscale. End of phase 2: No further improvements on subscales except for public distress. More benefits in HRQoL seen ≥ 10% weight loss
Chao, Wadden, Walsh et al. (2019)	N = 150 (79% female) Mean age = 48 years Mean BMI = 38.4kg/m^2 9% dropout	Three conditions: 1. Intensive behavioural therapy (IBT) alone 2. IBT & liraglutide 3. IBT, liraglutide & low-calorie diet	Average weight loss: 1. 6.1% 2. 11.5% 3. 11.8%	Baseline, Week 24, Week 52	IWQOL-Lite; SF36	IBT: Clinically meaningful improvements in PCS score, IWQOL-Lite total score, physical functioning, self-esteem and sexual life subscale. Liraglutide groups: 2.4X more likely to achieve clinically meaningful improvements in IWQOL-Lite total score than IBT-alone. Greater increases on the SF-36 MCS score than IBT-alone Independent of group, greater weight loss associated with improvements in several domains of both SF-36 and all domains and total score of IWQOL-Lite

Hageman, Mroz, Yoerger & Pullen, (2019)	N = 219 females Age 40-69 years Mean BMI = 34.5kg/m^2 23% dropout	Women weigh-in for wellness clinical trial Lifestyle modification for initial weight loss (baseline to 6 months); then guided web-based weight loss maintenance (6 months to 18 months)	Average weight loss = 4.06kg (4.45% initial body weight)	18 months	PROMIS -29 v1.0	Weight loss associated with improved HRQoL in depression, physical function, pain interference, fatigue and satisfaction with role function but not sleep disturbance and anxiety. Women with ≥10% weight loss at 18 months more likely to report a substantial improvement in HRQoL than those with <5kg weight loss.

Weight loss has been found to produce improvements in HRQoL, with greater improvements being shown in bariatric surgery patients (Kolotkin & Andersen, 2017; Kolotkin, Crosby & Wang, 2017) and when 10% or more of an individual's initial body weight is lost regardless of the method used to lose weight (Pearl, Wadden, Tronieri et al., 2018). Lifestyle based interventions producing moderate levels of weight loss have led to improvements in both mental and physical HRQoL on generic scales (Hageman, Mroz, Yoerger & Pullen, 2019; Rothberg, McEwen, Kraftson et al., 2014; Arrebola, Gomez-Candela, Fernandez-Fernandez et al., 2011) and on weight-specific QoL scales (Chao, Wadden, Walsh et al., 2019; Wright, Boyle, Baxter et al., 2013). These lifestyle interventions involved education/advice on diet, nutrition and physical activity along with either psychological support (Rothberg et al., 2014; Arrebola et al., 2011) or behaviour change strategies (Wright et al., 2013). This indicates that lifestyle interventions containing these aspects have the potential to improve HRQoL in individuals with overweight or obesity. However, there are limitations to this research which mean caution must be taken when making generalisations. The limitations include small sample sizes (*n = 27 – 219*), high dropout rates (20 – 50%), and the absence of control groups.

In an attempt to overcome and control for these issues, systematic reviews and meta-analyses have been conducted. Meta-analyses and systematic reviews of randomised controlled trials (RCTs) and weight-loss interventions have found inconsistencies in HRQoL improvements after non-surgical weight loss (Kolotkin & Andersen, 2017; Maciejewski, Patrick & Williamson, 2005; Warkentin, Das, Majumdar, Johnson & Padwal, 2014). This indicates that the relationship between weight loss and HRQoL is still poorly understood. Within chapter one, the ability to produce weight loss, along with improvements in health indicators through lifestyle/behavioural modification, anti-obesity medication and bariatric surgery was highlighted. Yet within the research

investigating the effect of weight change from different weight loss interventions of HRQoL, the weight loss is not always translating into meaningful improvements in QoL. Research indicates that losing 10% or more of initial body weight, regardless of the method used, is associated with more substantial improvements in HRQoL. However, other factors such as depression, baseline BMI and number of comorbidities, have been found to account for changes in HRQoL when weight loss is below 10% of initial weight.

Attempts to explain inconsistencies in findings include variations in the quality of data reporting, variations in the HRQoL measures used, variations in study populations and variations in weight loss interventions being studied (Kolotkin & Andersen, 2017; Maciejewski et al., 2005; Warkentin et al., 2014). Inconsistencies in non-surgical interventions are also thought to be due to the variation in follow up periods (Elbe, Elsborg, Dandanell & Helge, 2018). Elbe and colleagues (2017) investigated the relationship between weight loss (due to an intensive residential intervention) and obesity-specific QoL (using the IWQOL-Lite). They measure HRQoL up to seven years after the weight loss intervention and conducted regression analyses to determine the predictors of HRQoL. They found that weight loss occurring after the end of the intervention predicted HRQoL, but not weight loss that occurred during the intervention. This could suggest that HRQoL takes time after weight loss to show improvements. However, as this was a cross-sectional study, the cause and effect of the relationship cannot be inferred.

Despite the increasing use of HRQoL measures in obesity weight loss interventions and treatments, meta-analysis studies have indicated many problems. As these measures (both generic and specific) are generally used as secondary outcomes in RCTs, the reporting of data tends to be poor for HRQoL outcomes (Warkentin et al., 2014; Maciejewski et al.,

2005). For example, some RCTs measure HRQoL but do not report the data or specify the results on HRQoL (Fuller et al., 2013; Jebb et al., 2011). Whilst some RCTs report significant improvements in HRQoL (both generic and specific) this is not translated to clinically meaningful results (for example, specifying minimal important differences; MIDs). Changes in scores on an HRQoL scale must be understood and represent an important or meaningful change to the population being measured. This allows any significant differences reported to be compared to the MID and be interpreted in terms of meaningful improvements (or deteriorations) in HRQoL.

Research attempting to describe and understand the association of BMI, weight loss and HRQoL has used utility measures, generic measures, and specific measures. It is clear that disease-specific HRQoL scales are more sensitive to changes than generic measures. However, many studies and RCTs continue to use generic measures. This could be due to obesity-specific scales, not meeting the Food and Drug Administration's (FDA) guidelines for patient-reported outcome measure (PROM) use (FDA & HHS, 2009). In order to make labelling claims about drugs or dieting products (for example, "obesity drug improves HRQoL"), the PROM used must follow certain guidelines to ensure it has evidence of good psychometric properties. In particular, the FDA requires PROMs to be developed using an iterative process with detailed evidence of its development and content validity.

2.5 DEVELOPING AND EVALUATING QOL INSTRUMENTS

Investigating and treating the physical and psychosocial effects of obesity is the primary interest of researchers and HCPs. With limited time and resources, it is easy to discount the importance of measurement. However, research and health care rely on measurement instruments to evaluate interventions and treatments. With the increasing interest on the

impact of obesity on QoL, measurement is becoming increasingly important. Measurement instruments are used within research and health care to draw conclusions and inferences about treatments. Therefore, ensuring the measurement scales used are of high quality and validity is a necessity. A lack of time or resources to invest in choosing (or even developing) a suitable scale could jeopardise the credibility of conclusions drawn from research. Data is not protected from the limitations and inappropriateness of their sources, so the understanding of concepts, such as WRQoL, depends on the quality of its assessment.

There are numerous obesity-specific QoL measures that have been developed, and although they have been shown to have greater sensitivity in obesity populations over general measures, it is still questionable whether these scales can map changes across the whole weight/BMI spectrum. To allow useful evaluation of weight-related interventions, a WRQoL scale must be relevant to both clinical and community populations and must have been developed in a way that meets the FDA guidelines. This is to ensure the scale is relevant to the target population, measures the concept it is supposed to and is sensitive to the issues faced by those who have lost (or gained) weight and moved along the weight-spectrum.

2.5.1 Instrument Development

Scale development involves complex and systematic processes that require theoretical and methodological rigour (Morgado, Meireles, Neves, Amaral & Ferreira, 2017). The literature surrounding instrument development describes the many steps involved (Boateng, Adams, Odei Boateng, Luginaah & Taabazuing, 2017; DeVellis, 2017; Morgado et al., 2017; FDA & HHS, 2009). Some describe steps in differing orders to

others. However, there seems to be a consensus on the phases involved. These phases include:

1) Item generation
2) Theoretical analysis: establishing content validity
3) Establishing psychometric properties

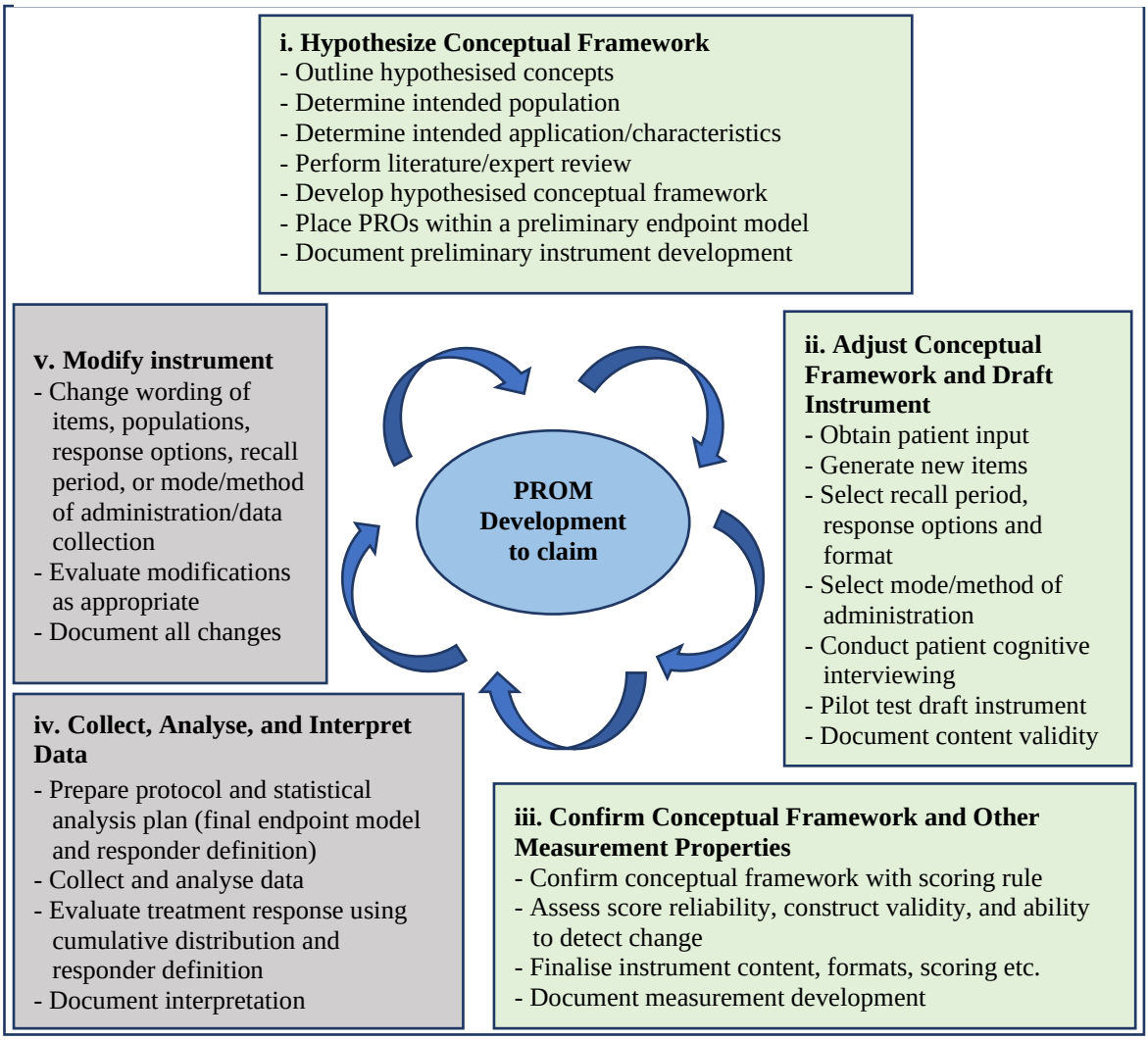
Each stage of development contains its own methods. However, instrument development is an iterative process, and so steps are likely to be revisited to ensure the instrument is valid and reliable. For example, any changes to the wording, the instructions or recall periods need further input from the target population to ensure understanding and relevance is maintained (Terwee, Prinsen, Chiarotto et al., 2018; DeVellis, 2017; FDA & HHS, 2009;). Therefore, it is expected that throughout instrument development, there will be a need to go back and forth to the target population. The iterative nature of PROM development is highlighted as important by the FDA especially when PROMs are being used to make claims about medications and food products (FDA & HHS, 2009). *Figure 2.1* displays the iterative stages of scale development proposed by the FDA. The stages of development are discussed in the following sections starting with assessing the need for a new scale before going into the theoretical framework, item generation, theoretical analysis, and finally psychometric evaluation. These discussions then pave the way for the aims and methods of this thesis.

2.5.2 Hypothesised Conceptual/Theoretical framework of HRQoL

Understanding and defining the concept of interest is the first step to developing a measurement scale. Having a detailed knowledge of the concept lends itself to a less problematic item generation and content validation phase, as relevant (and irrelevant) items will be easier to identify and include (or not include). Earlier in this chapter, QoL and HRQoL were defined. These definitions are quite vague and attempting to measure

QoL or HRQoL based on these definitions would be fraught with issues, if not almost impossible. The subjective nature of QoL and HRQoL makes it challenging to define and conceptualise. Despite these difficulties, attempts have been made to develop theoretical models of HRQoL to aid understanding and measurement.

Figure 2.1 Development of a PROM: An Iterative Process



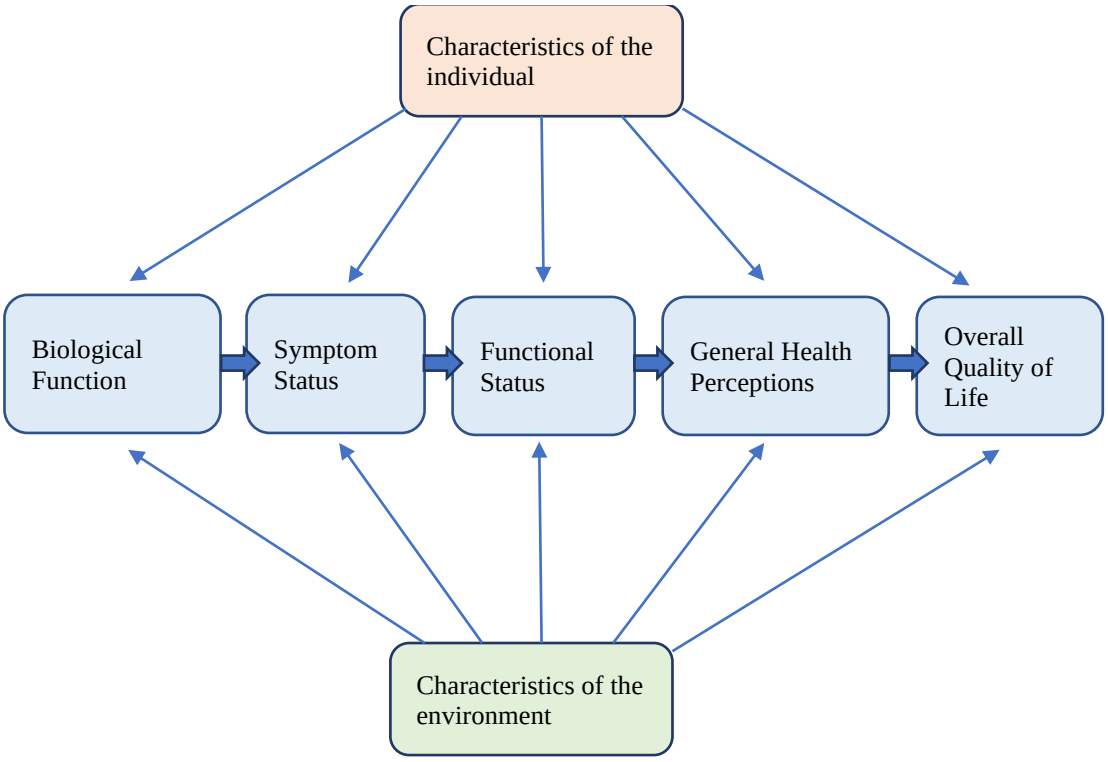
*Information adapted from FDA & HSS (2009)

*Green boxes represent aspects completed within the development of the new WRQoL instrument outlined in this thesis.

*Grey boxes represent future stages which are not development stages but rather further research to allow the PROM to be used to make claims. These stages are beyond the scope of this PhD Programme and future research will be needed to address them. Whilst they are not development stages, they still involve modifying the scale and the input of the target population, especially if changes are made to the wording of items, response options, recall periods or instructions

The Wilson-Cleary model is frequently used to explain QoL (Ferrans et al., 2005; Wilson & Cleary, 1995). The model has been empirically tested by several studies which indicate that the model can inform HCPs and researchers of the factors and pathways that form QoL (Ojelabi, Graham, Haighton & Ling, 2017; Bakas, McLennon, Carpenter et al., 2012). Wilson and Clearly (1995) proposed a conceptual model of patient outcomes with different measures of health outcomes classified into five levels. These levels are biological factors, symptoms, functioning, general health perceptions, and overall QoL. *Figure 2.2* illustrates the model moving outwards from biological factors to psychosocial factors incorporated into HRQoL.

Figure 2.2 Wilson-Cleary Model of Quality of Life



*Information adapted from Ferrans, Zerwic, Wilbur & Larson (2005) and Wilson & Cleary (1995)
The arrows represent the dominant causal relationship rather than the absence of a reciprocal relationship.

According to the model, biological function includes molecular, cellular and organ level processes that support life (Ferrans et al., 2005; Wilson & Cleary, 1995). Biological

function is measured using traditional methods and indicators such as laboratory test, physical assessments, and medical diagnoses. It is described as a continuum ranging from ideal function to life-threatening pathological functioning (Ferrans et al., 2005). Optimising biological functioning is the main focus in treating disease as changes in functioning can affect all components of health in the model, both directly and indirectly. However, changes in the other components of health, such as general health perceptions and overall QoL cannot be measured using traditional laboratory tests.

Moving from biological functioning to symptoms involves a shift in focus from the cellular level to an individual or person level (Wilson & Cleary, 1995). Symptoms refer to the individuals perceived abnormal physical, emotional, and cognitive symptoms due to their health status. The symptoms experienced are usually the reason a person seeks medical care. Measurement at this level focuses on symptom intensity which includes pain scales and disease-specific symptom measures. The intensity and experience of symptoms is an important modifier for functional status and ability. For example, an individual with obesity experiencing knee or back pain could start to avoid physical activity. This pain interferes with their day to day activities, causing them to become sedentary and physically deconditioned, representing a decline in functional status. Functional status refers to an individual's ability to perform physical, social, and psychological tasks. Existing physical functional tests include measures of aerobic capacity, functional capacity for walking and skeletal muscle strength assessments. The SF-36 Health Survey also contains two scales measuring physical and social functioning (Ware & Sherbourne, 1992).

General Health Perceptions refer to the perceived impact of disease on health. This is subjective and according to the model is an accumulation of the severity and intensity of

symptoms and the degree of functional limitations experienced by the individual (Ferrans et al., 2005; Wilson & Cleary, 1995). The final component of the model, overall QoL, depends on the severity of disease in relation to the physiology, the number and severity of symptoms experienced, the effect of these symptoms on functioning and the individual's perception of overall health. As it moves towards the psychosocial factors, the concepts become increasingly challenging to define and measure, and there is an increasing number of mediating variables (Wilson & Cleary, 1995). The mediating variables relate to the characteristics of the individual and the environment.

Characteristics of the individual include intrapersonal influences that can affect health outcomes. These include biological factors, demographics, development status and psychological factors (Ferrans et al., 2005). Examples of biological factors that can affect health outcomes are BMI and family history of genetic risk factors for disease. As discussed in Chapter 1, a high BMI and waist circumference increases the risk of diseases such as T2DM and cancer. An individual's demographics, such as sex, age, marital status, and ethnicity, are unchangeable but can be useful for targeting obesity interventions. For example, if obesity rates are worse in a certain demographic population, interventions can be tailored to that population. An individual's development status relates to the stage of life they are in. Whilst this is static, it also cannot be changed (Ferrans et al., 2005). When developing interventions, the development stage of the individuals they target need to be considered. For example, women or men with young children and little time would probably benefit more from lifestyle interventions that provide ways to enhance their activity levels at home rather than providing them with a structured exercise programme.

The final characteristics of the individual that can affect health outcomes proposed by Ferrans and colleagues (2005) are psychological factors. Psychological factors are

dynamic, modifiable and can respond to interventions (Ferrans et al., 2005). They include cognitive appraisals: attitudes, knowledge and beliefs towards illness, treatment, or behaviour; affective responses: the emotion evoked such as fear, anxiety, sadness or happiness; and motivation: whether an individual is intrinsically or extrinsically motivated to change. These psychological factors can influence each other to affect health outcomes further. For example, someone who has been overweight all their life may remember humiliating experiences when forced to participate in physical activity during high school. If they are advised to exercise this thought process of remembering can lead to anxiety (emotional response) and a lack of motivation to change. Whereas another individual with overweight or obesity could believe walking or cycling is within their physical capabilities, giving them the initial motivation to change.

Characteristics of the environment are classified as social or physical. Social, environmental aspects include the influence of family, friends, and health care providers (Ferrans et al., 2005). Whereas physical characteristics of the environment relate to setting such as the home, town, or city lived in, and workplace that can positively or negatively affect health outcomes. These aspects are useful for intervention developers to consider and could help to design and target interventions to individuals in certain areas. Things to consider would include how to improve social support and how to gain access to relevant resources.

2.5.3 Assessing the need for a new scale

Before venturing onto the development of a new measurement instrument, existing scales measuring the concept should be sought (DeVellis, 2017; FDA & HSS, 2009). Existing scales should be assessed for the target population used, the development process followed and the evaluation of its psychometric properties. There are many existing QoL

and HRQoL scales as well as some weight-specific QoL scales. It has already been established that weight-specific QoL scales exist and are more sensitive to issues faced by individuals with obesity. However, what is not certain is the validity of these scales. As these scales have been used in research to draw conclusions, these scales must be evaluated in terms of their psychometric properties.

The FDA has developed guidance to those selecting and developing PROMs (FDA & HHS, 2009). The FDA attempt to protect public health by ensuring the safety, efficacy and security of human drugs. They regulate the marketing of food and drugs to ensure all claims made regarding the efficacy/outcomes of taking them are substantiated. Therefore, if a company wants to claim that a food or drug used to treat obesity helps to improve QoL, this needs to have been measured within high-quality clinical trials using a QoL measure that has been developed thoroughly and has good psychometric properties. These guidelines have been developed to ensure both the development and validation of PROMs are accurate, of good methodological quality, and the PROM measures the concept proposed. An initial stage in the guidelines is to ensure there is a need for a new scale. If a scale already exists, its properties should be checked to establish if it is appropriate and psychometrically sound. In this way, these guidelines can also help researchers decide on a suitable PROM/HRQoL scale.

2.5.4 Item generation

Once the concept of interest has been defined, its components identified, and no existing scales serve the same purpose, item generation can begin (Boateng et al., 2018). Methods used to generate items can be classified as deductive, inductive or a combination of the two (Boateng et al., 2018; DeVellis, 2017; Kingsley, Frca, Patel & Bmedsci, 2017; Morgado et al., 2017). *Deductive* methods involve the use of extensive literature review

and pre-existing scales to generate items. In contrast, *inductive* methods rely on qualitative information about the concept obtained from responses from the target population. Domain items can be obtained inductively through the collection of qualitative data from the target population, in the form of direct observations and exploratory research methods, such as individual interviews and focus groups (Boateng et al., 2018; DeVellis, 2017; Kingsley & Patel, 2017; Morgado et al., 2017; Mahoney, Thombs & Howe, 1995).

The most common method of item generation is through deductive methods that do not involve the input of the target population (Boateng et al., 2018; Morgado et al., 2017). However, patients and individuals within the target population can provide extremely important insight in the concept of interest, especially when the concept is subjective like HRQoL (DeVellis, 2017; FDA & HSS, 2009). Deductive methods are likely to miss important elements of HRQoL concerning the lived experiences of the target population. Furthermore, if items are generated based on existing scales that have been poorly developed and evaluated, the concept can be incorrectly operationalised, potentially leading to the inclusion of irrelevant items, and missing important items. Once questionnaires have been generated no amount of statistical manipulation can account for poorly chosen questions, such as irrelevant, ambiguous and badly worded questions or even questions that are not present that should be. Therefore, inductive, and qualitative methods for generating items should not be overlooked, nor should they have lesser importance placed on them than deductive methods.

It is recommended that items generated should represent a broader and more comprehensive representation of the concept than its theoretical definition or model (Boateng et al., 2018). Items that do not fully represent the concept or domain will be

eliminated later in the development process. However, being too stringent on the items generated can lead to neglecting important aspects of the concept. When generating items, regardless of the methods used, the form of the items, the wording of items, response options and recall period should be considered (Boateng et al., 2018; DeVellis, 2017; FDA & HSS, 2009). The items must capture the lived experiences of the concept from the target populations perspective, and so using their own words in the items is preferable. This is thought to aid understanding of the items. Questions should be worded simply and unambiguously and should not offend the target population or be biased in terms of gender, religion, ethnicity, race, economic status, or sexual orientation. (Boateng et al., 2018).

2.5.5 Theoretical analysis: establishing content validity

Content validity concerns the development of the PROM, and whether the content (items) accurately reflects the construct, it claims to measure. It includes face validity; do the items look as though they reflect the construct being measured? The items generated need to be relevant, representative, comprehensive and comprehensible (Terwee et al., 2018). Therefore, the next stage is to establish the content validity of the items, otherwise known as theoretical analysis. This phase involves the input of experts who are highly knowledgeable about the concept of interest or in scale development. The expert's role is to evaluate the items in relation to the concept (do the items reflect the concept?) and with regard to the item and instruction wording (are they understandable?). Experts facilitate the selection of items by providing their expert knowledge about the phenomenon or scale development. The inclusion of experts is especially important within health measurement scales to establish the clinical value of the items and domains.

Target population judges can also be used to establish content validity. Target population judges are potential users of the scale and are experts at evaluating the face validity of the questionnaire (Boateng et al., 2018). Cognitive interviews with the target population are recommended to pre-test the questions and to evaluate face/content validity (Boateng et al., 2018). This is because they allow information to be gathered regarding the face validity of the questionnaire in addition to how well the instructions, recall period, items and response options are understood (Boateng et al., 2018; DeVellis, 2017).

In terms of evaluating the content validity of existing scales, there is no specific test. However, validity is assumed when items on a PROM have been developed using good methodological quality and have employed patients/individuals from the population the PROM is intended for. When evaluating content validity, the relevance, comprehensiveness and comprehensibility of the items should be assessed. The intended population should help inform the items via cognitive interviews or focus groups, to gauge their understanding of the items and to ensure the scale is relevant and comprehensive (Terwee et al., 2018; Blair & Conrad, 2011). If items are deleted through the process of validation and evaluation, patient feedback should again be sought. This process of patient involvement ensures no meaning is lost, and the PROM measures the intended construct in a way that is relevant to the target population. The process of item development and deletion should be described in a clear and detailed way to aid the evaluation of content validity (FDA & HSS, 2009).

When assessing the content validity, the FDA and COSMIN checklist recommend evaluating the evidence from qualitative studies to see whether the items and domains included are appropriate and comprehensive. This is in terms of the intended concept, intended population and intended use. In the COSMIN checklist, content validity,

including the methodological quality of PROM development, is the first measurement property to be evaluated. It is seen as the most crucial measurement property, and problems with content validity cannot be rectified by other measurement properties (Terwee, Prinsen, Chiarotto et al., 2018). Any failure to assess all relevant dimensions may lead to an inability to detect the impact of treatment on QoL or to record no difference where one exists (O'Connor, 2004).

There is great consensus on the inclusion of individuals from the target population when generating or selecting items for a questionnaire (Terwee et al., 2018; Streiner, Norman & Cairney, 2015; Machin & Fayers, 2013; Patrick, Burke, Gwaltney et al., 2011; O'Connor, 2004). This is especially true when questionnaires attempt to measure subjective concepts, such as QoL where the individual is considered the expert of their own QoL. Despite this consensus, the majority of existing scales confirm theoretical analysis or content validity using only experts of the concept. Cognitive interviews with the target population are often neglected or perceived to be too time-consuming. This is problematic for scales measuring subjective concepts like WRQoL, as experts are likely to have expert knowledge on the outward manifestations of a condition or disease but not necessarily the intrapersonal effects perceived as important to the individual. Therefore, utilising the target population along with experts when evaluating the content validity of an instrument would be beneficial.

2.5.6 Establishing psychometric properties

After confirming content validity, the draft items need to be assessed psychometrically. This requires moving from qualitative or the 'art' of item generation to the 'science' or theory that underpins scale development. The traditional test theory for scale development is Classical Test Theory (CTT). CTT's primary goal is to obtain functional items. It is

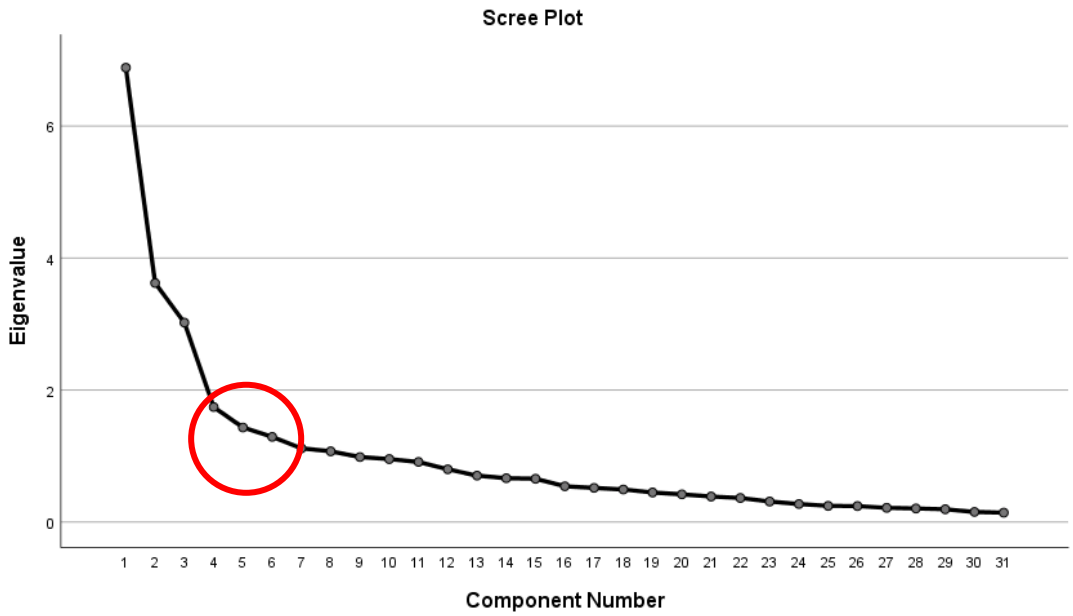
useful when the scale being developed is multidimensional as it allows the *identification* and *evaluations of domains* (DeVellis, 2017; Prieto, Alonso & Lamarca, 2003). This is opposed to Rasch Analysis, where the goal is to develop a unidimensional scale. As HRQoL is a multidimensional concept, having subscale scores is useful to enable researchers and HCPs to identify the specific aspects of WRQoL that are improving (or not improving). Therefore, CTT is the most appropriate theory to underpin scale development within this thesis.

The first step of CTT is to extract the factors or domains within the draft scale (otherwise known as factor extraction). The purpose of this is to explain the data produced by the instrument (Floyd & Widaman, 1995). The statistical technique used to extract factors is Exploratory Factor Analysis. A scale designed to measure a concept such as WRQoL is factor-analysed to identify separable domains. These domains represent theoretical constructs within the concept being assessed. The domains identified through factor analysis then serve as subscales for the instrument. Exploratory factor analysis analyses the correlations or covariances among the items to identify the domains that explain the covariance between the items. Theoretically, these domains are the underlying causes of the measured variables (items).

Factor analysis extracts factors based on eigenvalues above one (Floyd & Widaman, 1995). Eigenvalues indicate the importance of each factor in explaining the variability and correlations within the data. However, as it is exploratory, judgment is needed on the part of the researchers to decide on the number of factors to retain. The scree plot test is frequently used when deciding on the number of factors to retain (Yong & Pearce, 2013; Floyd & Widaman, 1995). The scree test plots the eigenvalues of the factors identified as a line graph. The slope of the line connecting the eigenvalues is examined, and the ‘elbow’

of the slope is normally used as a point of reference to retain factors. For instance, in *Figure 2.3,* the scree plot drops steeply until around component 4, 5 and 6, where it starts to level out. This represents the 'elbow' and would be used to determine the number of factors to retain.

Figure 2.3 Example Scree Plot



This scree plot is from Chapter 7 where exploratory factor analysis is conducted on the draft WRQoL scale. The red circle represents the 'elbow' or the subjective cut-off point where Eigenvalues of the factors begin to level out.

Deciding on the cut-off point on the scree plot is subjective, so investigators need to examine various cut-off points near to the 'elbow' (Floyd & Widaman, 1995). On the scree plot in *Figure 2.3,* the red circle identifies an approximate location for the cut-off point. Components 4, 5 and 6 are within this, and so a factor structure should be explored for each of these in this case. This involves interpreting where the items fit, which items may have to be removed (if factor loadings for the item are low across all factors) and how these structures compare to theoretical knowledge of the concept. The factors are identified by the factor loadings of the items. Factor loadings are regression weights for predicting which items are measuring aspects of the same domain. Factor loadings

represent the contribution the variable (item) has on a factor; higher factor loadings indicate that the variables explain the variance in that factor better than items with low factor loadings (Yong & Pearce, 2013). It is generally agreed that items with a factor loading of 0.3 and above represent a good fit to the factor it loads onto. However, the sample size should be considered when deciding the factor loading cut-off point. It is recommended that with smaller sample sizes ($n < 300$), higher factor loadings should be considered. Items should be deleted if they do not reach the factor loading cut-off unless there is a good reason not to (such as clinical/patient importance). This aspect of scale development uses both art and science as it combines the use of statistical variance with judgement based on the theoretical knowledge of the concept to decide on the subscales of an instrument.

2.5.7 Psychometric properties of a measure

Once the subscales of an instrument have been extracted, the psychometric properties should be evaluated to determine whether further changes to items are needed. Psychometric properties include validity, reliability, and sensitivity/responsiveness. These are discussed in the following sections.

2.5.7.1 **Validity**

Validity is the extent to which a scale measures what it intends to measure. The FDA considers both content and construct validity when reviewing a PROM to be used in clinical trials and interventions. The COSMIN checklist also suggests evaluating content and construct validity, but they also encourage the evaluation of criterion validity and suggest evidence for structural validity and hypothesis testing for construct validity. Content validity concerns the development of an instrument and its theoretical analysis. These have previously been discussed in sections *2.5.4* and *2.5.5*.

Construct validity represents how well an instrument measures the construct it is supposed to. It examines the relationships between the items in a scale as well as the expected relationships hypothesised between the measure and the characteristics of the target population/patients (Guyatt et al., 1993). Comparisons are also made between other scales of similar constructs. There are three aspects of construct validity: structural validity, hypothesis testing (including known groups, convergent and discriminant validity) and cross-cultural validity.

A reliable and valid scale should be able to detect differences between groups of individuals who are known to differ in the construct of interest. In terms of WRQoL, this could be differences between BMI groups. To evaluate this, *hypothesis testing* is required. These hypotheses can either pertain to group differences (otherwise known as known-groups validity) and by testing the subscales of the questionnaire against scales which are thought to measure similar constructs (otherwise known as convergent validity). The questionnaire/subscales can also be tested against scales which are not likely to be related (otherwise known as discriminant validity). These types of validity have been grouped by the COSMIN checklist as they all provide evidence for construct validity in the form of hypothesis testing.

When a scale has subscales, the items on these scales or subscales should be related to each other and should contribute to the overall scale score in different ways (Floyd & Widaman, 1995). As HRQoL encompasses numerous domains (such as physical, psychological and social functioning), WRQoL scales will likely contain subscales, and these subscales will relate to each other. Therefore, *structural validity* should be evaluated to provide evidence for the subscales. The FDA guidelines do not include recommendations for structural validity and only contain information for construct

validity in terms of convergent, discriminant and known-groups validity (FDA & HHS, 2009). However, the COSMIN checklist recommends testing for structural validity using factor analysis or Item Response Theory (IRT)/Rasch analyses. This will assess how well the items fit the scale and whether any items should be excluded if they do not fit. These tests should be used as evidence for structural validity only when used on the *final scale,* and not when they are used for development or refinement of the PROM.

Furthermore, *criterion validity* is how well a scale correlates to a gold standard measure of the same construct. In the past, a well-used scale measuring the same construct would be used to compare to a new scale. For example, the IWQOL-Lite being used as a gold standard to be compared to a new instrument measuring WRQoL. However, the COSMIN panel has recently changed its criteria for assessing criterion validity (Prinsen et al., 2018). They have deleted the guidance on deciding whether a gold standard used for evaluating the criterion validity of a PROM can be considered a reasonable gold standard. It is now believed that there are no gold standard instruments for PROMs unless a shortened version of a scale is compared to a longer version of the same scale. In this situation, the original, long version of the scale will be considered the gold standard. Therefore, if a study compares the scores of a new instrument to a widely used and well-known instrument, this would be regarded as evidence for construct validity (hypothesis testing) and not criterion validity.

A final aspect of validity is *cross-cultural validity*. Cross-cultural validity is needed when a PROM created in one country/culture is used in another. It is needed to ensure the patients in the new country understand the items in the same way and to ensure the items are relevant. Multi-level factor analysis should be used to compare the factor structures of the scale and the translated scale. If the factor structures are different, it indicates that

the PROMs are being understood differently by the two countries. Therefore, to show cross-cultural validity, the factor structures should be similar (it is unlikely that the factor loadings would be exactly the same within two different populations, but they should be similar).

2.5.7.2 **Reliability**

To assess the reliability of a measure, internal consistency, reliability (typically test-retest reliability) and measurement error are measured. *Internal consistency* measures the interrelatedness of the items. Items that are thought to be measuring the same concept (whether it is a unidimensional scale or items within a subscale) should be related to each other. The FDA guidelines recommend calculating the Cronbach's alpha coefficient for each summary score within a scale. The COSMIN manual agrees as it states the criteria for good internal consistency is for each subscale to have a Cronbach's alpha coefficient of at least 0.70. However, to have good internal consistency, there must be at least some evidence of scale domains or the unidimensionality of the instrument (Prinsen, Vohra, Rose et al., 2016).

External reliability looks at the extent to which scores on a PROM are the same for repeated measurement (for example, for patients whose health/weight have not changed). It is the extent to which measurements are repeatable (Nunnally, 1978). Test-retest can be conducted on a PROM to test for external reliability. This is where the PROM is completed at two-time points, and these are compared to make sure the scores stay stable over that time. The scores are only expected to remain stable if the patient's condition also stayed stable (for example, weight remained the same). The FDA guidance recommends the time between the first and second completion of the PROM to be an appropriate length where patients cannot remember their answers, yet their condition has

remained stable. Intraclass correlation coefficients (ICCs) are the statistical method of choice rather than Pearson's and Spearman's correlation coefficients. This is because ICCs take into account systematic error and look at each data point for agreement at the two-time points. Whereas, correlation looks at the data set as a whole to see whether they are related and does not give information on agreement within participants.

When measuring change, variations due to real change and variations due to random error must be distinguished. *Measurement error* refers to the systematic and random error of a person's score that is not attributed to true changes in the construct being measured. In order to calculate the degree of error, standard error of measurement (SEM) is used. SEM is an estimate of the expected variation in a set of stable scores where it can be assumed that no real change has occurred (Beninato & Portney, 2011). It is calculated using the standard deviation in a set of stable scores and the ICCs from test-retest. For a scale to be reliable, there should only be slight measurement error (Nunnally, 1978). High reliability is necessary to achieve high validity. However, high reliability does not necessarily equate to high validity (Prinsen et al., 2016).

2.5.8 Sensitivity and responsiveness

The terms sensitivity and responsiveness are often used interchangeably in psychometrics as they are similar concepts. However, they are not identical. *Sensitivity* refers to an instruments ability to detect differences between patients or groups of patients. *Responsiveness* is a scales ability to detect change within patients such as improvements or deterioration of HRQoL. Responsiveness is sometimes referred to as sensitivity to change or ability to detect change. An instrument should be equally sensitive to gains and losses in the measurement concept (FDA & HHS, 2009). If there is evidence that the patient's experiences concerning the concept being measured have changed, but scores

on the instrument have not, the instruments ability to detect change or its validity should be questioned. If an instrument is lacking in responsiveness, it is likely to have floor or ceiling effects (O'Connor, 2004). *Floor effects* indicate a failure to detect a worsening state in patients who already have a poor QoL. *Ceiling effects* represent a failure to detect an improvement in patients who already have a relatively high QoL (Higginson & Carr, 2001).

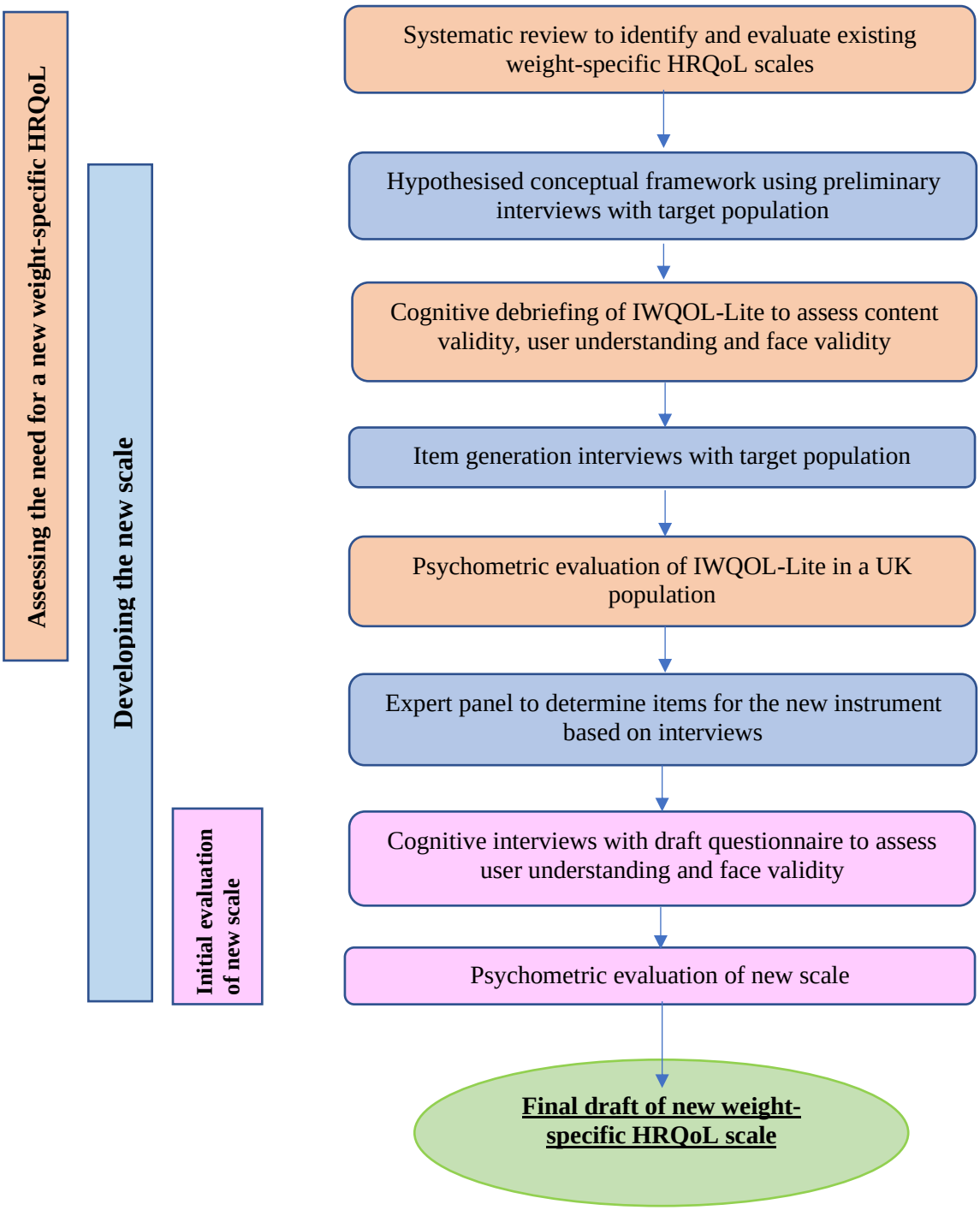
2.6 THESIS AIMS & METHODOLOGY

The purpose of this PhD programme of work was to:

d) *assess the need* for a weight-specific HRQoL scale,
e) *develop* a new weight-specific HRQoL scale with input from a UK population,
f) conduct the *initial evaluation* of the new weight-specific HRQoL scale.

Based on the stages of development, along with the limitations discussed, the methodology related to each aim is outlined within the following sections. *Figure 2.4* shows the stages followed from assessing the need for a new scale, developing a hypothesised conceptual framework of WRQoL, item generation for the new scale and finally, the initial evaluation of its psychometric properties.

Figure 2.4 Methodology Followed to Achieve the Thesis Aims



The flow chart indicates the three aims of the PhD programme on the left. The steps that contributed knowledge towards each aim are shown on the right. The boxes are colour coded to indicate which aim they best relate to. The boxes on the left illustrate each aim and the colour that represents it.

2.6.1 Assessing the need for a new WRQoL scale

Assessing the need for a new scale is important to avoid unnecessary development of new scales. Many of the existing obesity-specific HRQoL scales enlisted the help of health professionals in the development of the items rather than individuals and patients within the target population. Health professionals have been shown to underestimate their patients HRQoL (Srikrishna, Robinson, Cardozo & Gonzalez, 2009), highlighting that health professionals' may not be the best judge of an individuals' QoL. Therefore, as HRQoL is a purely subjective concept, the development of items should be based on information derived from individuals within the target population (FDA & HHS, 2009). Some of the scales are focused on extreme/severe obesity or on patients that have undergone bariatric surgery (such as the MA-QoLQ-II). These scales may not be sensitive or relevant for when the patients have lost weight and are no longer classed as having obesity or severe obesity. If this is the case, these scales will fail to evaluate how weight loss has affected the individuals weight-related QoL.

The most thoroughly tested instrument is the IWQOL-Lite (Kolotkin et al., 2001). The IWQOL-lite has become the most commonly used obesity-specific measure of HRQoL in the US and other English-speaking countries and has shown to be reliable and valid in clinical, (Kolotkin, Crosby, Williams, Hartley et al., 2001) and community populations (Kolotkin & Crosby, 2002). The IWQOL-Lite was developed based on the IWQOL using purely quantitative methods to delete many of its items. Whilst the IWQOL-Lite has been shown to be a valid measure of HRQoL in both clinical and community samples, the IWQOL was developed using a clinical population of moderately to morbidly obese patients seeking treatment for obesity. Community populations were not involved in identifying weight-related issues affecting HRQoL, nor were overweight individuals or individuals not seeking treatment for their weight issue. Due to the increasing prevalence

of overweight and obesity, interventions tackling overweight/obesity will likely become increasingly community based to reduce costs on the nation, so the HRQoL measures used to evaluate these future interventions must be representative and relevant for the community and across the weight-spectrum. Therefore, existing weight-related QoL scales must be identified and evaluated for their suitability across the weight-spectrum and in terms of methodological quality.

There is a lack of collated information regarding the evaluation of obesity-specific HRQoL scales and the appropriateness of these scales in different populations (for example, surgery populations or community interventions). This means it may be time-consuming for researchers to discover the most appropriate specific scale and so may use generic scales in clinical trials to save time. Researchers and HCP's also need the knowledge to identify suitable scales in relation to how the scale has been developed and validated. Systematic reviews that evaluate existing scales can help HCP's and researchers to decide on a suitable scale.

Systematic reviews should evaluate existing scales in relation to the FDA recommendations to ensure they are suitable for use in clinical trials. In addition to the FDA guidelines, a checklist providing consensus-based standards for the selection of health measurement instruments (COSMIN) was developed in an international Delphi study to enable the standardised assessment for evidence-based instrument selection (Mokkink, Terwee, Patrick et al., 2010). The evidence-based HRQoL instrument selection is based on the evaluation of the methodological quality of the studies conducted to develop, evaluate and validate the measurement properties of PROMs. The COSMIN Risk of Bias checklist has been developed to limit non-comparable study results by assisting the researcher in selecting appropriate measurement instruments that are of high

quality (Mokkink, de Vet, Prinsen et al., 2018; Prinsen, Mokkink, Bouter et al., 2018). It takes users through a series of steps to evaluate the methodological quality of studies on measurement properties. Evaluating the methodological quality of studies allows the assessment of the risk of bias on the results of the studies. It leads to the assessment of the overall quality of a measurement instrument.

Standards are provided for PROM development and the nine measurement properties of content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypothesis testing for construct validity and responsiveness. The COSMIN checklist also guides on assessing the methodological quality of the studies evaluating the psychometric properties of existing scales. Assessing the methodological quality of studies is essential as poor-quality studies can lead to inaccurate results and untrustworthy conclusions (Mokkink et al., 2017; Prinsen et al., 2017) and could lead researchers or HCPs to select an inappropriate measure. After assessing the methodological quality of the studies reporting measurement properties, the outcomes are compared and rated against the Criteria for Good Measurement Properties (Prinsen et al., 2016; Terwee et al., 2007).

The Criteria for Good Measurement Properties allows the rating of measurement properties of health status questionnaires to check their quality. They were derived through consensus among a group of experts in measurement properties and by adapting existing guidelines for assessing the methodological quality of clinical trials (Terwee et al., 2007). The purpose of the criteria is to allow meaningful comparisons of PROM measurement properties. They were originally developed to be used within systematic reviews of PROMs to detect any limitations and gaps in knowledge. However, they can

also be used to help developers of PROMs to design validation studies to ensure they report the appropriate statistics.

Initially, these criteria were developed through consensus of under ten experts, and so it was unknown whether these criteria were accepted and agreed with across institutions and countries. Therefore, this did not help in the ability to compare across studies and scales. However, since the criteria were first developed, they have been updated within a Delphi study with over 400 experts in the field of measurement properties (Prinsen et al., 2016; see section *3.4.3.1* for the Criteria for Good Measurement Properties). This has led to more accepted criteria and if used to design validation studies and alongside the COSMIN checklist within systematic reviews will lead to more comparable results. Subsequently, this will aid the selection of appropriate PROMs for research, clinical trials and within health care settings.

In order to identify and evaluate existing WRQoL scales, a systematic review was conducted. The identified scales were evaluated in terms of their development, content validity and psychometric properties using the COSMIN Checklist for systematic reviews. In this systematic review, the COSMIN Risk of Bias Checklist served as a tool to aid the evaluation of the methodological quality of the development of PROMs and the evaluation of their measurement properties. The systematic review methodology and results are outlined and discussed in Chapter 3. To further assess the need for a new scale, the most commonly used obesity-specific scale, within lifestyle and behavioural interventions, was further evaluated. The systematic review highlighted issues with the psychometric properties of the IWQOL-Lite, but the most concerning issue was the content validity of the scale. Therefore, cognitive debriefing interviews were conducted using the IWQOL-Lite to assess its content validity, user understanding and face validity

within a UK overweight and obesity population (see Chapter 5, section 5.4 for methods and section 5.5.10 for results of these interviews). Psychometric evaluation of the IWQOL-Lite in a UK general population was also conducted as it had not been evaluated in a UK population previously (see Chapter 6). It was concluded that the IWQOL-Lite was inappropriate and needed further evidence for its content validity and psychometric properties. This led to the next aim: to develop a WRQoL scale.

2.6.2 Developing a new scale

Developing a PROM is time-consuming as it involves an iterative process whereby stages are repeated to ensure content validity. However, gaining input from the target population helps to ensure content validity. Therefore, gaining input from the target population was considered to be of utmost importance for the development of the new WRQoL scale. This is because the concept of WRQoL has not been thoroughly explored and existing scales fail to discuss and outline the areas of importance found in the item generation stages through patient interviews (see Chapter 3 for more information).

The Wilson-Cleary model serves as an important model to understand the factors and pathways forming HRQoL. Yet, to fully understand HRQoL specific to a population with overweight and obesity, further information is needed. As stated earlier, the psychosocial aspects of HRQoL are difficult to define and measure. Also, there are many ways that obesity can impact an individual's physical and psychosocial wellbeing (as highlighted in Chapter 1 section 1.5 and 1.6). Therefore, a detailed understanding of this, from the individual's perspective, is needed to grasp the subjective nature of HRQoL. Therefore, inductive methods were most appropriate to develop a hypothesised conceptual framework of WRQoL and for item generation. Inductive methods were also important as existing scales were developed using narrow and small samples.

Establishing content validity early on in scale development will ensure the items reflect the concept of interest from the patient's perspective, maintaining the patient-centred nature of the PROM. To create and generate items that are relevant and meaningful to the target population and represent aspects of WRQoL, an understanding of the concept is needed. Therefore, before item generation occurred exploratory pilot interviews were conducted to identify areas of importance to individuals who had or previously had overweight or obesity (see Chapter 4 for the outline and discussion of the pilot interview methods and results). The findings from these pilot interviews form the initial hypothesised conceptual framework of the new WRQoL scale. This framework was then used to develop a relevant and targeted interview schedule from which item generation interviews were conducted. The item generation interviews were used to clarify further the hypothesised conceptual framework developed in the pilot interviews and to generate items based on this (see Chapter 5).

To ensure items represented the hypothesised conceptual framework of WRQoL, an expert panel aided the selection of items for the draft scale. A specialist obesity nurse, an expert in scale development and the researchers who analysed the item generation interviews made up the expert panel. This gave a diverse and complementary expertise to the clinical and subjective aspects of WRQoL in addition to expert knowledge on how items were likely to perform within quantitative analysis (see Chapter 5 for the expert panel).

2.6.3 Initial Evaluation of the new scale

The new scale was evaluated using both qualitative and quantitative methods. The qualitative method used was cognitive interviews to test for face validity and is detailed at the end of chapter 5. Whilst this is traditionally included in the 'theoretical analysis'

phase of scale development, it is included within this aim as it serves to evaluate the content validity of the draft scale. The psychometric testing of the draft WRQoL instrument (Chapter 7) involved exploratory factor analysis in deciding its structure and in informing item reduction. It was conducted on 160 participants which is deemed as adequate for factor analysis, as it is recommended to include a sample size that is *five times* the number of items on the scale (Terwee et al., 2018). Once the structure of the scale was identified, the psychometric properties of internal consistency, construct validity, and test-retest reliability was evaluated. The results of the psychometric analysis along with the other aspects of scale development and evaluation of IWQOL-Lite are discussed in Chapter 8. The strengths and limitations of the research conducted in addition to future research to evaluate the new WRQoL instrument are also discussed in Chapter 8.

3 A SYSTEMATIC REVIEW OF EXISTING WRQOL SCALES

The first line of treatment for individuals with overweight/obesity is lifestyle advice or a lifestyle intervention. To prevent the need of further treatment (tier 3 bariatric surgery), the interventions/programmes offered must be effective at reducing weight and improving health indicators. It is also important that the detrimental effects of excess weight on HRQoL are either reduced or improved. The measurement of weight loss and physical health indicators are well established; however, the measurement of HRQoL in obesity is not. In order to assess the effectiveness of behaviour change interventions/programmes, HRQoL should be assessed. However, the measure of HRQoL used needs to be appropriate and valid. Having established in the previous chapter the importance of measuring HRQoL in disease-specific populations and the steps taken to develop a measurement scale, the next logical step is to seek the disease-specific QoL instruments for overweight/obesity populations and evaluate them. Doing this will help to assess the need for a new WRQoL for use in overweight/obesity lifestyle interventions.

3.1 ASSESSING METHODOLOGICAL RIGOR AND QUALITY

Before using an existing HRQoL scale within research, it is important to select the most appropriate, relevant and psychometrically sound instrument. There are established ways to check whether a scale is appropriate and psychometrically sound. These include:

(1) FDA guidance (FDA & HHS, 2009)

(2) COSMIN checklist (Mokkink, Terwee, Patrick et al., 2010)

(3) Criteria for Good Measurement Properties (Prinsen et al., 2016; Terwee et al., 2007)

These resources can help to assess the overall quality of existing scales by evaluating the methodological quality of the studies evaluating scales psychometric properties, and the

scales summed psychometric properties. For a PROM to be used in clinical research, how it was developed, along with evidence of the psychometric properties (discussed from section 2.5.3 onwards) need to be considered. Evaluating every available scale, before selecting the most suitable for the scope of research is likely to be time-consuming. It requires an in-depth knowledge of scale development and psychometric properties. Using the COSMIN manual and checklist alongside the FDA guidelines and criteria for good measurement properties can help lessen the time taken and expertise required. Also, existing reviews on PROM's can help the selection of suitable scales. Having information on scale development and psychometric properties of available PROMs in one place allows researchers to assess the information on existing scales far quicker than having to retrieve all validation papers and evaluate them.

3.2 PREVIOUS REVIEWS ON OBESITY-SPECIFIC QOL MEASURES

To the knowledge of the author, there have been two reviews conducted which aim to evaluate existing obesity QoL scales. The first review was conducted by Duval, Marceau, Perusse & Lacasse (2006) and a second by De Vries, Kalff, Prinsen and colleagues (2018). These reviews will be discussed separately.

3.2.1 Duval, Marceau, Pérusse & Lacasse, 2006

3.2.1.1 **Overview**

Duval et al. (2006) searched the literature from 1976 to 2005 to identify disease-specific instruments measuring QoL in obesity. Eleven obesity-specific QoL measures (three being specific to bariatric obesity) were identified and reviewed. The instruments identified were classified according to their domain(s) of interest (for example, somatic sensation, physical function, emotional state and social interaction) and their psychometric properties were described. The psychometric properties described for each

instrument were validity (face and construct), reliability (test-retest and internal consistency), responsiveness and interpretability. It was found that only three scales had studied construct validity using appropriate methods, only two demonstrated responsiveness and only three provided information on how to interpret the scores. Therefore, the review highlighted the need for future research to validate existing questionnaires further and to give definitions of their interpretability. The authors also recommended that areas of QoL most affected by obesity should be identified before developing new questionnaires.

3.2.1.2 **Critical analysis of Duval et al.'s review**

This was the first article to identify and review existing WRQoL instruments and was useful in highlighting to HCPs and researchers the available scales, the potential uses of each scale and their psychometric properties. However, there are several limitations of this review (discussed below), which indicate a need for an updated review. At the time the review was conducted, there were no accepted/standardised methods for the evaluation of PROM's. As a result, the review is lacking an in-depth evaluation of the scales and their psychometric properties. The FDA guidelines and the COSMIN Checklist have since been developed and so the properties evaluated within Duval's review differ from those recommended (Mokkink et al., 2018; Prinsen et al., 2018; Mokkink, Terwee, Knol et al., 2010; FDA & HHS, 2009). These differences include the evaluation of PROM development, the assessment of the methodological quality of the studies assessing psychometric properties, and the assessment of evidence for structural validity and content validity.

Regarding PROM development and content validity, Duval et al. (2006) presented the demographics of participants included in the item development. They also included a

table to illustrate the QoL domains each scale assessed. However, no information or evaluation was given concerning the instruments' development (including item generation) or whether further content validity studies were conducted. Therefore, the review leaves it to the HCP and researcher to decide on the most suitable scale in terms of content validity, without essential information on the development of the scales. This is a crucial aspect of a PROM to assure that the instrument is measuring what it is supposed to (Terwee et al., 2018). Evaluating content validity ensures that the questionnaire content is relevant to the target population, and to the concept, it is trying to measure.

Another psychometric property not assessed by Duval et al.'s (2006) review is structural validity. Structural validity is a relatively new name for a measurement property and has been separated from construct validity. The structure of a scale is typically assessed as construct validity. Structural validity and construct validity are thought to be separate aspects of an instrument. It pertains to how well the items of a scale (or subscale) relate to the other items within that scale (or subscale) and how each item contributes to the overall scale (or subscale) score. Whereas, construct validity represents how well an instrument measures the construct it is supposed to. As these are separate measurement properties, they are assessed in different ways (as discussed earlier in section 2.5.7). Duval et al.'s review does not assess structural validity making it unclear as to whether the instruments included have sufficient evidence for their subscale/domain structures.

Duval et al.'s (2006) review did not evaluate the methodological quality of the studies used to develop and evaluate the measures. The review took a more traditional approach in terms of evaluating the data provided by, or outcomes of, the PROMs and not the methodological quality of the studies reporting their psychometric properties. Evaluating

methodological quality is important as poor-quality studies are more likely to produce errors which can bias the results and make them difficult to interpret (Mokkink et al., 2018; Prinsen et al., 2018). Studies with methodological flaws or inappropriate statistical analyses could indicate a PROM has good psychometric properties when it does not. This is problematic as it can lead HCP's and researchers to select a scale that is not psychometrically sound. As the review does not assess methodological quality, the risk of bias of the results presented is unknown. Therefore, making decisions on suitable WRQoL instruments from this review could lead to the selection of a scale that lacks reliability and validity. This, in turn, could lead to biased research results.

Although it is not stated, it is assumed that Duval et al. (2006) were assessing the need for a new QoL scale specific to morbid/extreme obesity. This is assumed as they specifically point out that there are only three scales developed specifically for morbid obesity, and Duval et al. have since developed the Laval; a morbid obesity specific QoL scale (Therrien, Marceau, Turgeon et al., 2011). Whilst this is not a problem, it indicates that the review focused on whether the scales were suitable for use within a morbid obesity population (BMI > 40kg/m^2), rather than suitability along the different weight loss stages. Therefore, WRQoL scales need to be assessed for suitability for use in community weight-loss interventions and with individuals at differing weight loss stages.

3.2.1.3 **Summary**

Duval and colleagues (2006) were the first to review WRQoL measures, giving HCP's and researchers an overview of available instruments and their psychometric properties. However, the review lacks an in-depth evaluation of the WRQoL instruments and the quality of the studies leading to their validation. Therefore, this review leads HCPs and researchers to make decisions without knowing the full extent of a measure's

psychometric properties, suitability for a certain population and its risk of bias. These factors, along with the fact the review was conducted 13 years ago, indicate that there is a need for an updated systematic review to identify and evaluate existing weight/obesity specific QoL instruments.

3.2.2 De Vries, Kalff, Prinsen and colleagues (2018)

3.2.2.1 **Overview**

The most recent review of obesity-specific QoL measures was published in 2018. De Vries and colleagues (2018) systematically assessed the quality of existing PROMs developed and validated for QoL measurement in bariatric surgery and body contouring surgery. They used the COSMIN checklist to evaluate the methodological quality of the validation studies for each identified scale and the measurement properties of the scales. These evaluations led to recommendations for each scale. Their recommendations were based on three criteria. These criteria were 'truth' (includes face, content, construct and criterion validity), 'discrimination' (includes reliability and sensitivity to change) and 'feasibility' (easy application and interpretation).

Twenty-four scales were identified (both weight specific and generic scales), and none of these met all the requirements. However, seven of the scales were seen to have the potential to be recommended depending on future validation studies. De Vries and colleagues recognised the BODY-Q as having the strongest evidence of content validity in bariatric surgery and body contouring surgery (Klassen et al., 2014; 2016). Interestingly, the IWQOL-Lite was not recommended for use in this population as it was minimally validated. It was rated as poor for the three measurement properties reported in its validation paper (internal consistency, content validity and hypothesis testing for construct validity).

3.2.2.2 **Critical analysis of De Vries et al.'s review**

As the systematic review followed the COSMIN guidelines, it is assumed that recommendations made are valid and based on good evidence. However, the review is focused on PROM use within bariatric surgery and body contouring surgery. These patient populations are likely to have more specific impairments in QoL than obesity patients within non-surgical weight loss programmes and interventions. For instance, massive weight loss resulting from bariatric surgery has been found to lead to excess skin (Aldaqal, Makhdoum, Turki et al., 2013; Fotopoulos, Kehagias & Kalfarentzos, 2000; Kitzinger, Abayev, Pittermann et al., 2012; NICE, 2014). The formation of excess skin in post-bariatric patients can lead to impairments of both an aesthetic and physical nature (Aldaqal et al., 2013; Kitzinger et al., 2012). These impairments affect the QoL of these individuals further (Pecori, Cervetti, Marinari, Migliori & Adami, 2007), which will ultimately act against the improvements in QoL gained from initial weight loss. Both men and women affected by impairments due to excess skin are more likely to have a desire for body contouring surgery (Aldaqal et al., 2013; Kitzinger et al., 2012).

Bariatric and body contouring QoL scales need to include these specific aspects relating to QoL in order to fully represents the effects of massive weight loss from bariatric surgery. Whereas, QoL measures specific for use in non-surgical interventions do not need to include these aspects as they are unlikely to be relevant to the population. Weight loss from behavioural interventions happens at a slower rate than that of bariatric surgery. It is the sudden change in BMI that results in excess loose skin because skin tone is lost, and the excess soft tissue (skin) is unable to retract (Grindel & Grindel, 2006). It is unlikely that non-surgical measure will lead to such massive weight loss. As the patient population is different from the current focus, De Vries and colleague's recommendations may not be applicable for use in behavioural/community interventions. Therefore, there

is a gap for a systematic review of obesity specific QoL scales to evaluate their suitability for use across the weight- and BMI-spectrum.

3.3 PURPOSE OF THE CURRENT REVIEW

It is already clear that WRQoL measures exist. However, there may be scales measuring WRQoL that the author is not aware of. If the existing scales are valid and relevant, then there would be no need to create a new scale. It would be useful to systematically evaluate these measures in terms of suitability across the weight-spectrum and in terms of their development and psychometric properties. This would help researchers and HCPs to choose the most appropriate scale for obesity research. Therefore, the systematic review aimed to:

(1) Identify WRQoL measurement scales and their target population

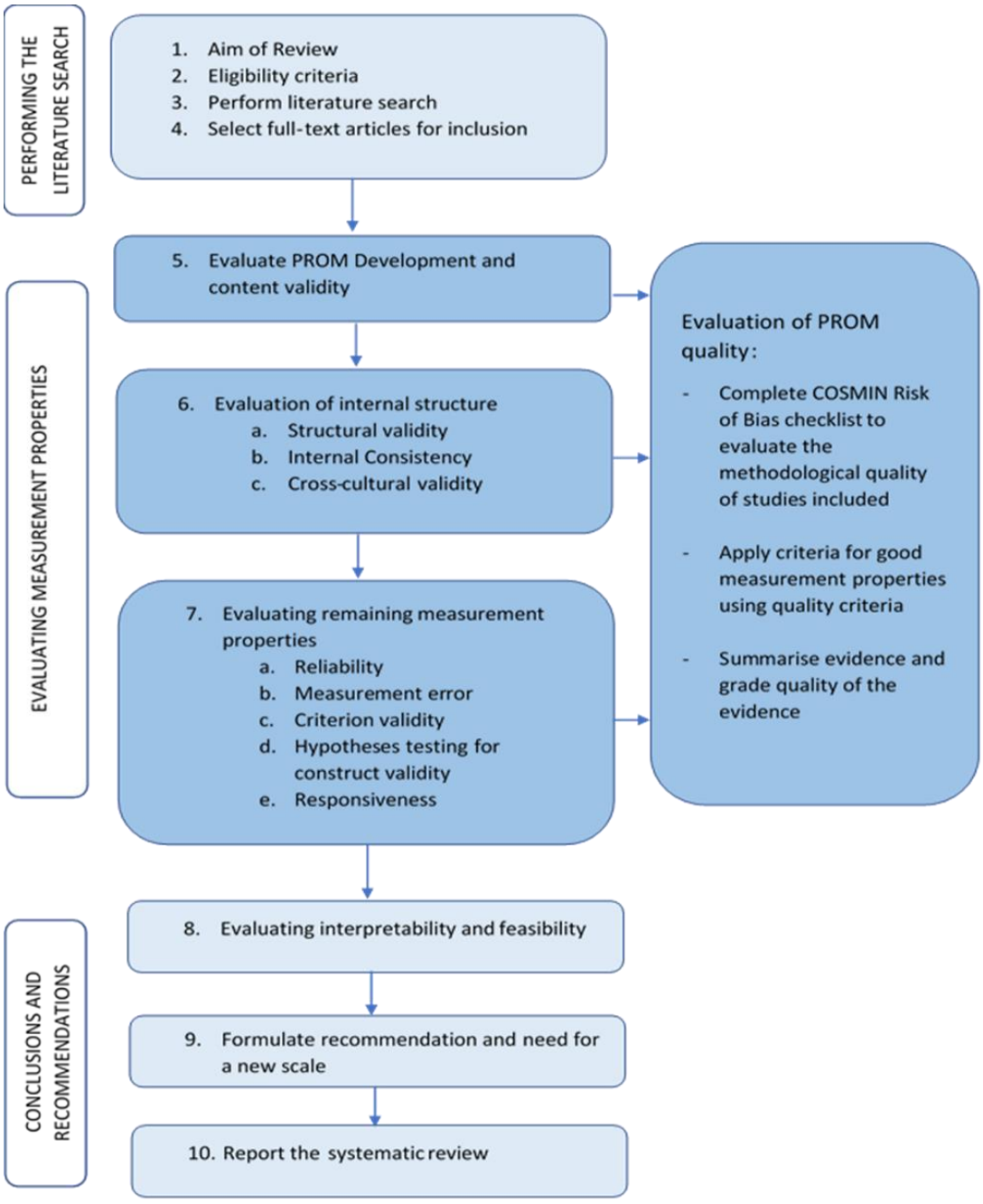
(2) Assess the psychometric rigour and risk of bias of the measures

(3) Ascertain whether a WRQoL currently exists that is suitable for use in community and non-surgical weight loss interventions

3.4 METHODS

This systematic review of WRQoL instruments was conducted following the methodology recommended within the COSMIN manual for the systematic review of PROMs (Prinsen et al., 2017; Mokkink et al., 2017). *Figure 3.1* illustrates this process as a flow chart. This process will be described in more detail in the following sections.

Figure 3.1 Flow chart of Systematic Review Process



*Information adapted from Mokkink et al. (2018)

3.4.1 Performing the literature review

3.4.1.1 **Eligibility criteria**

Papers included in the systematic review process (from abstract screening) met the following criteria:

a) aimed to measure QoL in relation to weight, obesity and/or bariatric patients
b) study concerned PROMs
c) aim of the study is the evaluation of one or more measurement properties recommended by the FDA and COSMIN checklist.

3.4.1.2 **Exclusion criteria**

Studies were excluded if:

a) full-text articles were not accessible
b) articles were not in English
c) PROM was used only as an outcome assessment
d) PROM did not measure weight-specific QoL.

3.4.1.3 **Search Methods for Identification of Studies**

Medline, EMBASE, CINAHL, Psychinfo, were searched for relevant literature published between 1974 and 2018. The search strategy was created using a comprehensive collection of search terms for the following elements:

a) **the construct** (quality of life, health-related quality of life, health status and wellbeing etc.)
b) **the population** (adults with overweight/obesity)
c) **the type of instruments** (PROMs, questionnaires)
d) **development and validation measurement properties**

Search terms for the development and validation measurement properties were initially obtained from the PROM measurement properties filter created by COSMIN (see Appendices 1 for search strategy).

3.4.1.4 **Data collection**

Once each database was searched, the results were pooled. Duplicates were removed, so only unique records remained. These unique records were then screened via title for relevance. Articles deemed not relevant (did not meet the eligibility criteria or met the exclusion criteria) were not included in subsequent steps. Those regarded as relevant were included in the abstract screening. After the abstract screening, full texts were gained for articles deemed relevant. Three researchers independently assessed the list of citations, abstracts and full-text articles for relevance. Articles were progressed to the next stage if there were any disagreement in the relevance of an article. To ensure no relevant papers were missed from the database searches, the references of all included articles were screened for relevance and eligibility.

3.4.2 Data extraction

Data were extracted from each article and collated into purposely created summary tables as recommended by the COSMIN checklist. Data were extracted by two independent researchers, and the tables were compared. In the case of disagreement in the data extracted, discussions were made with a third researcher until an agreement was made. Data extracted included demographic and clinical data (age, gender, BMI and population type (for example, patient and community populations)), information on the description and feasibility of the instruments (country of origin, access to scale, purpose, number of items, domains, response scale), and their development and user understanding (item

development, including the involvement of whole weight spectrum users, and cognitive interviews), and their psychometric properties.

3.4.3 Assessing methodological rigour and quality

In order to evaluate the identified scales steps, 5-8 of the COSMIN recommended methodology were followed (as shown earlier in Figure 3.1). These include:

(1) Assessing the methodological quality of the studies reporting the measurement properties of each scale using the COSMIN Risk of Bias checklist (Mokkink et al., 2010);

(2) Rating the results of the studies on each measurement property against the updated criteria for good measurement properties (Prinsen et al., 2016);

(3) Grading the quality of evidence using the modified GRADE approach (Prinsen et al., 2018)

The studies investigating the measurement properties of PROM development, content validity, structural validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity and responsiveness were evaluated in terms of their methodological quality. Criterion validity was not assessed as there is no gold standard measure of WRQoL. Studies claiming to measure criterion validity were evaluated as hypothesis testing for construct validity. Methodological quality was evaluated per measurement property for each study on the 4-point COSMIN rating scale ("very good", "adequate", "doubtful", "inadequate") (Terwee et al., 2018).

The development and content validity studies for each PROM were evaluated first using the specific COSMIN manual for content validity (Terwee, Prinsen, Chiarotto et al., 2018). These criteria relate to the relevance, comprehensiveness and comprehensibility

of the instruments for the construct (QoL), target population (individuals with obesity/overweight) and context of use (evaluating community and clinical non-surgical weight loss interventions). Within this systematic review, the target population was people with obesity/overweight, and the context of use for PROMs was to evaluate both community and non-surgical clinical weight-loss interventions. Therefore, to have good content validity, a PROM needs to be relevant to individuals across the weight spectrum and varying weight loss stages.

The remaining measurement properties were evaluated in terms of methodological quality in the order stated above (again in relation to the target population and context of use in the review). The COSMIN checklist consists of a set of questions for each measurement property pertaining to the appropriateness of the statistical analysis used and the quality of the study design. Each aspect is rated on the 4-point scale. The worst score counts principle (Terwee et al., 2012) was used to report the overall methodological quality rating for each measurement property. For example, if a study on internal consistency was rated as adequate for one question on the COSMIN checklist and inadequate on another, the overall methodological quality for internal consistency in that study would be inadequate.

3.4.3.1 **Apply criteria for good measurement properties**

Once the methodological quality was assessed, each measurement property was then evaluated using the criteria for good measurement properties presented in *Table 3.1* (Prinsen et al., 2016; Terwee et al., 2007). Evidence was graded as sufficient (+) [reaches accepted standards], conflicting (+/-), insufficient (-) [does not reach accepted standard] or indeterminate (?) [results are difficult to define]. Where there was more than one study assessing the same measurement property of the same PROM, the results and study

quality were assessed separately in the first instance. This evidence was then qualitatively summarised and then rated against the criteria for good measurement properties.

Table 3.1 Criteria for good measurement properties

Property	Definition	Rating*	Quality Criteria
Content Validity	The degree to which the content of a measurement instrument is an adequate reflection of the construct to be measured	+	All items refer to relevant aspects of the construct to be measured AND are relevant for the target population AND are relevant for the context of use AND together comprehensively reflect the construct to be measured
		?	Not all information for '+' reported
		-	Criteria for '+' not met
		NR	No information found on target population involvement
Structural validity	The degree to which the scores of a measurement instrument are an adequate reflection of the dimensionality of the construct to be measured	+	CTT: Unidimensionality: EFA: First factor accounts for at least 20% of the variability AND ratio of the variance explained by the first to the second factor greater than 4 OR Bi-factor model: Standardized loadings on a common factor >0.30 AND correlation between individual scores under a bi-factor and unidimensional model >0.90 Structural validity: CFI or TLI or comparable measure >0.95 AND RMSEA <0.06 OR SRMR <0.08 Rasch/IRT: At least limited evidence for unidimensionality or positive structural validity AND no evidence for violation of local independence: Rasch: standardized item-person fit residuals between -2.5 and 2.5; OR IRT: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 AND no evidence for violation of monotonicity: adequate looking graphs OR item scalability >0.30 AND adequate model fit: Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > -2 and <2; OR IRT: G2 >0.01
		?	CTT: Not all information for '+' reported IRT: Model fit not reported
		-	Criteria for '+' not met
		NR	No information reported
Internal consistency	The degree of interrelatedness among the items	+	At least limited evidence for unidimensionality or positive structural validity AND Cronbach's alpha(s) ≥ 0.70 and ≤ 0.95

		?	Not all information for '+' reported OR conflicting evidence for unidimensionality or structural validity OR evidence for lack of unidimensionality or negative structural validity
		-	Criteria for '+' not met
		NR	No information reported
Reliability	The degree to which the measurement is free from measurement error	+	ICC or weighted Kappa ≥ 0.70
		?	ICC or weighted Kappa not reported
		-	Criteria for '+' not met
		NR	No information reported
Measurement error	The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured	+	SDC or LoA < MIC
		?	MIC not defined
		-	Criteria for '+' not met
		NR	No information reported
Hypothesis testing	The degree to which the scores of a measurement instrument are consistent with hypotheses based on the assumption that the measurement instrument validly measures the construct to be measured	+	At least 75% of the results are in accordance with the hypotheses
		?	No correlations with instrument(s) measuring related construct(s) AND no differences between relevant groups reported
		-	Criteria for '+' not met
		NR	No information reported
Cross-cultural validity	The degree to which the performance of the items on a translated or culturally adapted measurement instrument is an adequate reflection of the performance of the items of the original version of the measurement instrument	+	No important differences found between language versions in multiple group factor analysis or DIF analysis
		?	Multiple group factor analysis AND DIF analysis not performed
		-	Criteria for '+' not met
		NR	No information reported
Criterion validity	The degree to which the scores of a measurement instrument are an adequate reflection of a "gold standard"	+	Convincing arguments that gold standard is "gold" AND correlation with gold standard ≥ 0.70
		?	Not all information for '+' reported
		-	Criteria for '+' not met
		NR	No information reported
Responsiveness	The ability of a measurement instrument to detect change over time in the construct to be measured	+	At least 75% of the results are in accordance with the hypotheses
		?	No correlations with changes in instrument(s) measuring related construct(s) AND no differences between changes in relevant groups reported
		-	Criteria for '+' not met
		NR	No information reported

Adapted from Prinsen et al (2016) and Terwee et al (2007)

AUC = area under the curve, CFI = comparative fit index, CTT = classical test theory, DIF = differential item functioning, EFA = exploratory factor analysis, ICC = intraclass correlation coefficient, IRT = item response theory, LoA = limits of agreement, MIC = minimal important change, RMSEA = root mean square error of approximation, SEM = Standard Error of Measurement, SDC = smallest detectable change, SRMR = standardized root mean residuals, TLI = Tucker-Lewis index

'+' = sufficient rating, '?' = indeterminate rating, '-' = insufficient rating

3.4.3.2 **Grading the quality of evidence**

The quality of the summarised evidence was then graded in terms of trustworthiness based on the modified Grading Recommendations Assessment, Development and Evaluation (GRADE) approach for systematic reviews of clinical trials. The quality of evidence was rated as 'high', 'moderate', 'low' or 'very low'. *Table 3.2* explains these ratings. The GRADE approach is used to downgrade evidence based on the risk of bias (methodological quality), inconsistency (unexplained inconsistency of results across studies), indirectness (evidence from different populations that the population of interest in the review), and imprecision (total sample size of available studies). The final rating of a PROM has two elements;

(1) The overall quality of a measurement property (sufficient, insufficient, indeterminate, inconsistent).

(2) The level of evidence for the overall quality of each measurement property (high, moderate, low, very low).

Table 3.2 Definitions of quality levels

Quality level	Definition
High	Very confident that the true measurement property lies close to that of the estimate* of the measurement property
Moderate	Moderately confident in the measurement property estimate: the true measurement property is likely to be close to the estimate of the measurement property, but there is a possibility that it is substantially different
Low	Confidence in the measurement property is limited: the true measurement property may be substantially different from the estimate of the measurement property
Very low	Very little confidence in the measurement property: the true measurement property is likely to be substantially different from the estimate of the measurement property

*Estimate of the measurement property refers to the summarised result of the measurement property of a PROM.

These definitions were adapted from the COSMIN checklist (Terwee et al.,2018) and the GRADE approach (Schünemann, Brożek, Guyatt & Oxman, 2013)

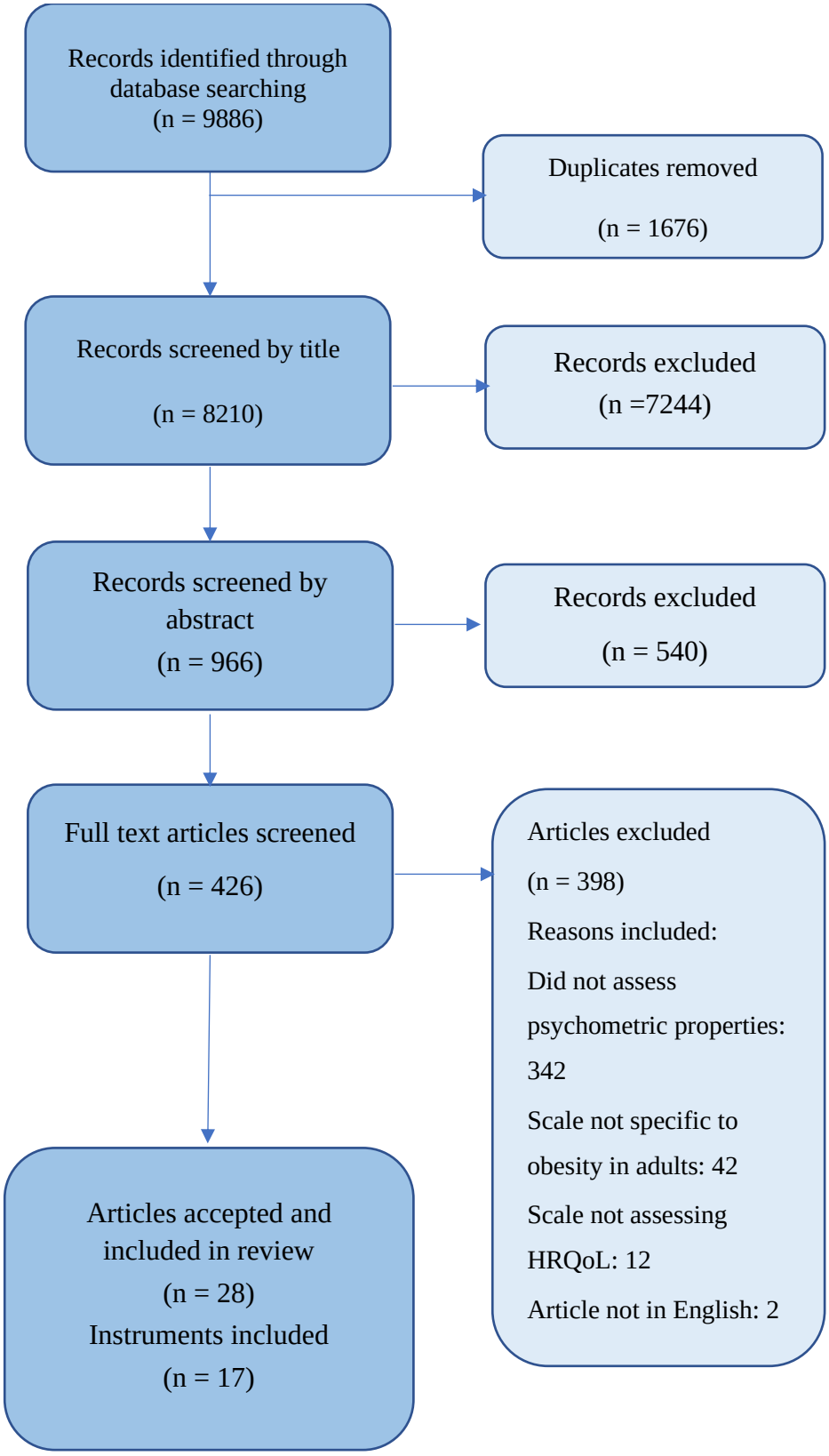
3.4.3.3 **Independent reviewers**

As with data extraction, two researchers independently assessed the methodological quality, applied the criteria for good measurement properties and graded the quality of evidence. Comparisons were made when both researchers had a final rating for each PROM. Any disagreements were discussed until agreement was reached.

3.5 RESULTS

The search produced a large number of potential articles. *Figure 3.2* summarises the process for the identification and selection of the articles. Out of the initial articles, 17 obesity and bariatric specific QoL scales were identified. Seven of the scales were specifically developed for use in bariatric and/or body contouring patients. The overall quality of the scales in relation to the psychometric properties and level of evidence will be discussed separately for the non-bariatric and bariatric instruments scales.

Figure 3.2 Flow chart showing identification and selection of eligible articles



3.5.1 Non-Bariatric Obesity/weight Specific QoL Scales

Ten non-bariatric WRQoL scales were identified from the literature. One of the measures (Impact of Weight on Quality of Life Clinical Trials Version; Kolotkin, Ervin, Meincke, Hojbjerre & Fehnel, 2017) was excluded from the final review as it was still in the developmental stages and was yet to be psychometrically tested. *Table 3.3* provides a description of the included non-bariatric measures, including critical comments on item selection/generation for each scale. *Table 3.4* displays the demographics of participants/patients included in the development and evaluation studies. It has highlighted the lack of diversity in terms of the participants included in the item generation stages of the scale's development (this is further discussed in section 3.6.1). In some instances, further development of measures led to refined or reduced versions of the same scale. In these instances, the results in the tables are presented separately for each version of the scale. At least one article was identified for each scale. The mode of completion for the scales was self-report, except for the LEWIN-TAG of which the HRQoL element was administered by interview. Each psychometric property will be discussed separately.

Table 3.3 Description of the Non-bariatric Obesity-specific QoL measures

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection
1a	The Impact of Weight on Quality of Life (IWQOL) (USA)	Kolotkin et al. (1995)	Individuals being treated for obesity	Self-report	7 (74)	To be used as a descriptive tool and as an outcome measure in clinical research.	The development article reports that the items were derived from approximately 20 patients during clinical interviews and group discussions, but no details regarding methods used to conduct and analyse these interviews are given, nor are the findings of these interviews presented or discussed. No demographic information was provided for the patients included in the interviews. No piloting of the IWQOL was conducted to assess the relevance, comprehensiveness and comprehensibility of the items and instructions in the target population.
1b	The Impact of Weight on Quality of Life – Lite (IWQOL-Lite) (USA)	Kolotkin et al. (2001)	As above	Self-report	5 (31)	As above	The deletion of items on the IWQOL (to form the IWQOL-Lite) were based on statistical methods. Patient input was not included to assess the importance and relevance of the items that were deleted. There was no piloting of the final version of the IWQOL-Lite to assess the relevance, comprehensiveness and comprehensibility of the target population.
2	LEWIN-TAG (USA)	Mathias et al. (1997)	Adults with moderate obesity	Self-report with one part being administered by interview	8 Separate scales (55; 58 at follow up)	To evaluate obesity intervention studies	This battery of test consists of generic existing measures recommended by QoL researchers, clinicians and individuals with obesity. No details on the decisions to include the different non-specific scales are given. The battery also included 6 new obesity specific items; however, it is not apparent how these were developed and whether input from the target population was gained for these. No piloting of the final scales was conducted.

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection
3	Obesity Specific Quality of Life (OSQOL) (France)	Le Pen et al. (1998)	Individuals with obesity.	Self-report	4 (11)	To be used as a descriptive tool to assess the impact of weight on QoL.	The OSQOL items were derived from interviews with six overweight individuals and six individuals with obesity. On review of the domains and number of items in each domain, it is doubtful that the OSQOL is comprehensive enough. This is because the social domain and the psychological domain were only assessed by one item each. Therefore, the scale is likely to be more sensitive to physical QoL than psychosocial aspects of QoL. There was no piloting of the OSQOL to assess relevance, comprehensiveness or comprehensibility of the final version in the target population.
4a	Obesity related wellbeing – 97 (ORWELL-97) (Italy)	Mannucci et al. (1999)	Individuals seeking treatment for obesity.	Self-report	1 (18 pairs)	To be used in clinical practice.	The paper detailing the development of the ORWELL-97 states that items were developed with the involvement of experts and patients with obesity (Mannucci et al., 1999). That is the only detail provided on the development of the items. It is not known how many patients were involved in item generation, the range of demographics of the patients or how they were involved in item generation. The ORWELL-97 has not been piloted on the target population to check for relevance, comprehensiveness and comprehensibility. This is particularly important for this scale as it is novel in terms of its questioning and scoring and so it is important to know whether patients understand the instructions and items in the way intended by the developers.

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection
4b	Obesity-related wellbeing – R (ORWELL-R) (Portugal)	Camolas et al. (2016)	As above	Self-report	3 (21 pairs)	To assess obesity-related QoL in both research and clinical contexts.	The items of the ORWELL-R include those from the ORWELL-97 plus 3 additional pairs of items based on expert input and morbid obesity patients. The inclusion of patients in the new items suggests some content validity. However, details of the number of patients or how they were involved are not reported. The ORWELL-R has not been piloted within the target population to provide evidence for relevance, comprehensiveness and comprehensibility.
5	Obesity and Weight Loss Quality of Life (OWLQOL) (USA/Europe)	Niero et al. (2002)	Individuals with overweight and obesity, both trying to lose weight and not trying to lose weight.	Self-report	1 (17)	To be used alongside other measures in observational studies and to evaluate weight-loss interventions.	The OWLQOL items were generated from interviews and focus groups with individuals from the USA with overweight/obesity. These items were translated for 5 European countries. Piloting of the items in each country led to additional items. Four domains were identified, yet the OWLQOL is scored overall only. Items seem to have been deleted from the development study to the psychometric evaluation study, but there is no mention nor explanation for this in either study. The final version of the OWLQOL had not been piloted within the target population to provide evidence for relevant, comprehensiveness and comprehensibility.

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection
6	Quality of Life, Obesity and Dietetics (QOLOD) (France)	Ziegler et al. (2005)	Obesity patients seeking treatment.	Self-report	5 (36)	Intended to be used in clinical trials in French-speaking countries.	Item selection for the QOLOD initially consisted of the IWQOL items translated into French. These items were added to with original items derived from 31 interviews with obesity patients (no demographics provided). The purpose of this was to create a scale adapted to socio-cultural factors of obesity and dietary weight management in France. Items were reduced from 91 to 36 using statistical analyses. No piloting has been conducted on the final version to ensure relevance, comprehensiveness and comprehensibility of the items and scale instructions.
7	Laval (Canada/French)	Duval et al. (2006)	Patients seeking treatment for morbid obesity	Self-report	6 (44)	To be used as an evaluative tool in clinical trials.	The items of the Laval were generated using numerous sources including; literature review, obesity experts, existing measures and interviews with patients with morbid obesity. All patients included in the item generation were awaiting bariatric surgery and had a BMI of 40 and above. Therefore, items are likely to be relevant for morbid obesity patients seeking bariatric surgery, rather than individuals with overweight or obesity seeking treatment in the community. Items were reduced using statistical methods. No piloting to test for relevance, comprehensiveness or comprehensibility took place on the final scale version in any population.

Table 3.4 Demographics of patient included in the non-bariatric QoL scale studies

Measure	First Author and Year	Number of participants in the studies	Female, n (%)	Age, mean (S.D.), years	BMI, mean (S.D.)	Population Validated on
ORWELL-97	Mannucci (1999)	147	99(NR)	45.2(13.4) (15-73)[a]	37.9(6.3) (30-61.3)[a]	Patients
ORWELL-R	Camolas (2016)	Clinical sample = 188 Community sample = 758	157 376	44.38(12.49) 47.55(11.74)	43.94(4.31) 29.26(3.80)	Clinical and community
LEWIN-TAG	Mathias (1997)	Normal Weight Gym = 75 Normal Weight Shopping Mall = 67 Obesity = 242 Morbid obesity = 33	NR(66.7) NR(47.8) NR(79.7) NR(78.8)	NR NR NR NR	NR NR NR NR	Clinical and community Obesity and normal weight
IWQOL	Kolotkin (1995)	Item Generation = 20* Validation = 181	NR 117	NR 48.7(13.7)	NR 38.3(10.2)	Obesity outpatients
	Kolotkin (1997)	394	243	F=46(14.96) M=49(12.98)	F=35.90(9.38) M=42.37(10.74)	Patients
IWQOL-Lite	Kolotkin (2001)	1987	1372	F=45.9(14.3) M=47.3(14.1)	F=36.6(9.4) M=37.2(10.8)	Clinical Community
	Kolotkin (2002)	494	341(69.0)	F=37.6(13.4) (18-90)[a] M=38.6(13.1) (18-74)[a]	27.4(7.1) (18.6-73.0)[a]	Community
OWLQOL	Niero (2002)	Initial Phase = 68	33(49)	52(10.5)	33.4(4.1)	n/a
		Cognitive Debriefing = 35	-	-	-	n/a
		Final Stage = 50	-	-	-	n/a
	Patrick (2004)	Initial Validation = 340	204(60)	45.4(11.6)	36.3(5.3)	US Obesity
		U.S. Clinical Trial = 1282	1048(81.7)	44.5(10.7)	37.3(5.2)	Clinical Trial Obesity
		U.S. Community = 1478	590(39.9)	51.1(13.3)	32.9(4.7)	U.S. Community Obesity
		European Community = 3007	1825(60.7)	47.8(13.6)	33.6(4.9)	EU Community Obesity
OSQOL	Le Pen (1998)	Qualitative Interviews = 12	-	-	-	Household Survey
		Obesity Quantitative = 391	NR(42)	-	-	
		Non-Obesity = 462	NR(42)	-	-	(Continued)

Measure	First Author and Year	Number of participants in the studies	Female, n (%)	Age, mean (S.D.), years	BMI, mean (S.D.)	Population Validated on
Laval	Duval (2006)	Item Generation = 25	23	44(10)	51(6.9)	
		Item Reduction = 100	68	42(10)	51.5(8.7)	
	Therrien (2011)	Treatment Group = 67	51(79)	45.0(10.2)	52.6(8.5)	French Surgery Patients
		Control Group = 45	33(73)	43.6(11.6)	54.4(9.7)	
QOLOD	Ziegler (2005)	Qualitative = 31	-	-	-	
		Validation 1 = 128	NR(83.8)	42.5(12.1)	34.5(2.8)	Patients
		Validation 2 = 210	NR(77.7)	43.3(12.2)	35.8(7.5)	
		Validation 3 = 75	NR(73.3)	44.8(12.5)	34.1(3.0)	

*IWQOL item generation participant number reported as approximate; [a] range; F: female; M: male; n/a: not applicable; NS: not stated; NW: normal weight

3.5.1.1 **Overall quality**

None of the scales had high-quality evidence for any measurement property. *Table 3.5* presents the overall quality ratings of the measures and the ratings for each quality criteria. The evidence quality ratings ranged from moderate quality to very low. The IWQOL-Lite and the OWLQOL had evidence for all measurement properties except for measurement error and floor/ceiling effects. The table of ratings for each single study on the measurement properties of the non-bariatric scales can be found in Appendices 1.

Table 3.5 Overall result of the summarised evidence for each measurement property per non-bariatric scale

Scale	Content Validity	Structural validity	Internal consistency	Reliability	ME	Hypothesis testing	Responsiveness
IWQOL	? Very low	0	? Low	? Very low	0	? Moderate	0
IWQOL-LITE	? Very low	? Very low	? Moderate	? Moderate	0	+ Moderate	? Very low
OSQOL	? Low	? Very low	? Very Low	0	0	0	0
LEWIN-TAG	? Very low	0	0	- Low	0	+ Low	? Very Low
ORWELL-97	? Very low	- Low	? Very low	? Very low	0	? Very low	0
ORWELL-R	? Very Low	- Moderate	? Very Low	? Very Low	0	? Very low	0
OWLQOL	? Low	+ Very low	? Low	+ Low	0	+ Low	? Low
QOLOD	? Very low	? Very low	? Low	+ Very low	0	+ Very low	0
Laval	? Low	0	? Low	+ Low	0	+ Moderate	- Very low

ME: Measurement error;
0: No evidence found; ?: indeterminate rating, +: sufficient rating; -: insufficient rating
Quality of evidence ratings (GRADE approach): High, Moderate, Low, Very Low

3.5.1.2 **Content validity**

None of the measures achieved a sufficient rating for content validity. No scale provided a definition or conceptual framework of QoL of which the items and domains of the scales were based on. Two of the measures (OWLQOL and the Laval) had an article dedicated to the item generation/development of the measure. The remaining measures included a brief paragraph within the validation paper. All of the scales included some level of patient involvement in item generation/selection. However, only two of the scales (OWLQOL and the Laval) explained how patients were involved in item selection, with the rest merely stating that there was patient input. Only two scales provided demographic information of the patients involved within the item generation studies, and none of the studies provided the range of BMI's included in these. These were the OWLQOL and the Laval. Seven of the nine scales included only individuals from clinical populations. None of the scales indicate the ethnicity of the participants included in item generation, although within the IWQOL development paper it was stated that patients at the inpatient facility in which qualitative interviews took place were mainly Caucasian. No scale has been evaluated in its final form for relevance, comprehensiveness, and comprehensibility to its target population or for use within clinical and community weight-loss interventions. Due to these issues, all measures received an indeterminate rating of low to very low quality.

3.5.1.3 **Structural validity**

One measure (OWLQOL) achieved a sufficient rating for structural validity; however, this was of very low-quality evidence. Two of the scales (IWQOL and LEWIN-TAG) have no information on the structural validity of the scale. However, as the QoL aspect of the LEWIN-TAG is a single item interview, it is not possible to test structural validity. The IWQOL has

multiple domains, but these have not been confirmed through statistical analysis. The remaining six scales have studies on structural validity but are all of doubtful or poor methodological quality (IWQOL-Lite, OSQOL, ORWELL-97, ORWELL-R, QOLOD, Laval) or have not met the criteria for good measurement properties (IWQOL-Lite, OSQOL, ORWELL-97, ORWELL-R, QOLOD).

3.5.1.4 **Internal consistency**

None of the measures met the criteria for good internal consistency. All measures provided uninterpretable results for internal consistency due to having inadequate evidence for the structural validity of the scale. Internal consistency does not apply to the LEWIN-TAG as the QoL component is only one item. The studies assessing the internal consistency of the OSQOL, ORWELL-97 and ORWELL-R provided Cronbach's alphas for the scales total score despite being scored by subscale. The remaining scales reported the Cronbach's alphas appropriately for the way the scale was scored.

3.5.1.5 **Reliability**

Three measures (OWLQOL, QOLOD and Laval) provide sufficient evidence for test-retest reliability. However, the quality of this evidence was low (OWLQOL and Laval) to very low (QOLOD) due to small sample sizes and scores for the final version of the scale being computed from the longer draft version. One measure (OSQOL) has not been tested for reliability, and the remaining measures had issues with the methodological quality of the test-retest studies. Six of the scales had no measure of stability in the construct, or HRQoL or weight over the period between the first and second completion of the scales (OWLQOL, Laval, IWQOL-Lite, LEWIN-TAG, ORWELL-97, ORWELL-R). Two scales had an

inappropriate time period between questionnaire completion (ORWELL-R, IWQOL). Two scales used insufficient statistical analysis (for example, the IWQOL and ORWELL-97 used correlation instead of intraclass correlation coefficient).

3.5.1.6 **Measurement error**

None of the studies calculated the scales measurement error.

3.5.1.7 **Hypothesis testing for construct validity**

Five of the nine scales provided sufficient evidence for hypothesis testing for construct validity (IWQOL-Lite, LEWIN-TAG, OWLQOL, QOLOD and Laval). The Laval and IWQOL-Lite provided evidence of a moderate quality level, while the LEWIN-TAG and the OWLQOL provided a low quality of evidence, and the QOLOD provided a very low-quality level. This indicated that the true construct validity of these scales might be different from the evidence provided. There was a lack of specified hypotheses within all the studies which made it difficult to interpret the results. No studies assessing the construct validity of the OSQOL were found.

3.5.1.8 **Floor/ceiling effects**

Only the OWLQOL and the QOLOD psychometric evaluation papers mentioned floor and ceiling effects. The OWLQOL indicated that items demonstrating floor or ceiling effects were removed. The QOLOD deleted 14 items due to them demonstrating floor effects. The sex domain of the QOLOD demonstrated a ceiling effect of 19.7%. None of the other non-bariatric scales mentioned or presented data for floor or ceiling effects.

3.5.1.9 **Responsiveness**

None of the measures provide sufficient evidence for its responsiveness. Five scales have not been tested for responsiveness (IWQOL, OSQOL, ORWELL-97, ORWELL-R and QOLOD). The scales that did assess responsiveness were of low to very low-quality evidence with mostly indeterminate results (except the Laval which received an insufficient rating). This is due to the methodological quality (risk of bias) of the studies as the effectiveness of the treatment being received within the study was not specified, or a stable control group was not used. Similar to the studies of construct validity, there was a lack of hypotheses stated within the papers; therefore, it was difficult to interpret the results of these studies. The Laval had insufficient evidence of responsiveness as only 50% of the hypotheses were met (75% should be met to meet standard).

3.5.2 Bariatric-specific QoL Scales

Seven QoL scale were found that were specific to bariatric and body contouring surgery populations. One scale was excluded from the review as only psychometric data was available from a conference abstract: the Moorehead-Ardelt Questionnaire. However, the second version of this scale (M-A QoLQ II) was included as it has been psychometrically tested. The BodyQ consists of separate unidimensional scales with five of the scales being related to HRQoL. *Table 3.6* shows a description of the scales evaluated in this review and includes critical comments on the item selection/generation methods used in each scale. *Table 3.7* displays the demographics of participants/patients included in the development and evaluation studies.

Table 3.6 Description of the Bariatric and Body-contouring surgery specific QoL measures

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection /PROM development
8	Moorehead-Ardelt Quality of life questionnaire II (M-A QoLQ II)	Moorehead, Ardelt-Gattinger, Lechner & Oria (2003)	Bariatric surgery patients	Self-report	6 (6)	To be used for pre- and post-intervention assessment	This scale was developed to measure self-perceived QoL in patients with obesity, before and after bariatric surgery. It is a very basic questionnaire with very few items. This allows quick completion of the scale, which is important when patients are in hospital/just out of surgery. However, the scale was developed from expert opinions rather than from patient input, and the items are not specific to weight. Patients are not even asked to think about their weight while completing the scale. While this scale is good for use after surgery, it is unlikely to be sensitive enough for use along the whole weight spectrum, for different treatment/management types or within interventions where repeated measures are required.
9	Bariatric Quality of life (BQL)	Weiner, Sauerland, Fein, Blanco, Pomhoff & Weiner (2005)	Bariatric surgery patients	Self-report	5 (19)	To be used as a clinical tool for research purposes or quality assurance in bariatric surgery	This scale was developed based on feedback from the completion of SF-36 and BAROS (includes MA-QoLQ) by 50 patients. Items were generated based on this feedback and comments from surgeons on face validity. The BQL aims to measure QoL in relation to weight, weight-related co-morbidities and surgery-related gastrointestinal side effects. The methodology or characteristics of the participants involved in item generation or concept rationale are not detailed. It is also stated that the initial items were tested on 110 patients to reduce the items to 19 from 30. However, what the testing was or included is not detailed.

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection /PROM development
10	Body Q	Klassen, Cano, Scott, Tsangaris & Pusic (2014)	Bariatric and body contouring surgery patients	Self-report	6 separate scales (49)	To be used to support patient advocacy, patient education and within clinical research.	Klassen et al. (2014; 2012) describe and explain their process of item generation and selection in detail. Items were generated using qualitative interviews with 63 participants who had either received body contouring surgery or were waiting for it. Items were based on the conceptual framework developed from the interviews, which consisted of 3 major themes: appearance, HRQoL and process of care. Item selection/reduction was performed using cognitive interviews with 25 bariatric patients over two rounds. Items are therefore very specific to pre- and post-bariatric and body contouring surgery.
11	Bariatric and Obesity-specific Survey (BOSS)	Tayyem, Atkinson & Martin (2014)	Bariatric surgery patients	Self-report	6 (42)	To be used in clinical practice and research settings pre- and post-bariatric surgery.	Item generation for the BOSS used a literature review, other generic and disease-specific scales, patient involvement and suggestions and discussions with HCPs. However, how patients were involved in the initial item generation or the characteristics of the patients is not explained and is unclear. Further items were generated from feedback from 12 bariatric surgery patients, but again the demographics and characteristics were not detailed.
12	Post Bariatric Outcome Tool (PBOT)	Al-Hadithy, Welbourn, Aditya, Stewart & Soldin (2014)	Post-bariatric surgery patients and pre and post body contouring patients	GP report, self-report and photograph	6 (77)	To be used as part of a referral pathway to identify patients that meet national guidelines of MWL body contouring surgery.	The measure was developed based on an existing measure for patient outcomes of hand/arm surgery (Cano, Browne, Lamping, Roberts, McGrouther & Black, 2004). The paper describes interviews with hand/arm surgery patients for item development. The items seem to have been adapted from this hand/arm surgery outcome measure to be more appropriate to massive weight loss patients who desire body contouring surgery. There is a lack of information and clarity regarding how this was done and whether any interviews were conducted with massive weight loss patients to inform the items of the PROM.

	Name	Author(s)	Target Population	Mode of Completion	Number of domains (items)	Purpose of the measure	Comments on item selection /PROM development
13	Body Shape Related Quality of Life (BodyQoL)	Danilla, Dominguez, Cuevas, Calderon et al. (2014)	Pre and post body contouring patients	Self-report	4 (20)	To be used by plastic surgeons, researchers and patients to measure the impact and effectiveness of body-contouring procedures.	Items were developed from reviewing the literature and existing scales, as well as input from experts and in-depth qualitative interviews with pre- and post-body contouring patients. The Body QoL measures satisfaction after body contouring procedures (Danilla, Cuevas, Aedo et al., 2016; Danilla, Dominguez, Cuevas et al., 2014). While this is a body shape related QoL instrument, it has not been developed to measure change in QoL due to weight loss or gain. Therefore, it is unlikely to be relevant to the whole weight spectrum. However, the qualitative aspect of item generation and the selection was very thorough and methodologically sound for the scales target population.
14	Quality of Life for Obesity Surgery Questionnaire (QOLOS)	Muller, Crosby, Selle et al. (2017)	Bariatric surgery patients	Self-report	7 (32)	Authors suggest it could be used as an outcome measure in clinical research and as a tool to facilitate HCP's and patient's awareness for improvements and deteriorations following bariatric surgery.	Items were developed from interviews and focus group interviews with 19 post-operative bariatric surgery patients. Details of the interviews are limited in Muller et al.'s (2017) article as the interviews are detailed in a doctoral student's thesis, which is not accessible to the author. Items were rated by a further 101 patients and 69 experts in terms of their importance. This scale likely has good content/face validity in the target population it was developed for. However, as items were derived through input from postoperative bariatric patients only, they are specific to bariatric surgery and not relevant to individuals within the lower obesity and overweight BMI ranges.

Table 3.7 Demographics of patient included in the bariatric QoL scale studies

Measure	First Author and year	No. of participants in studies	Female, n (%)	Age, mean (S.D.), years	BMI, mean (S.D.)	Population Validated on
M-A QoLQ II	Moorehead (2003)	Validation = 110	90 (81)	42 [19-65][a]	50 [32-92][a]	Surgery Patients
BQL Index	Weiner (2005)	Development:				Surgery Patients
		Phase 1 – n = 50	NR	NR	NR	Clinical control
		Phase 2 – n = 110	NR	NR	NR	Healthy control
		Validation:				
		Bariatric Patients – n = 133	108 (81)	39 (11)	47.2 (8)	
		Healthy volunteers – n = 220	138 (63)	36 [17-72][a]	23.3	
		General surgery patients – n = 40	NR	50	24.4	
BODY-Q		Development:				Bariatric Surgery - pre & post patients
	Klassen (2012)	Item generation – n = 49	60 (95)	48 (12)	NR	Body contouring - pre & post patients
	Klassen (2014)	Cognitive interviews 1 – n = 19	16 (84)	47 (11)	NR	Nonsurgical body contouring patients
		Cognitive interviews 2 – n = 3	3 (100)	42 (3)	NR	
	Klassen (2016)	Validation:				
		US – n = 185	171 (94)	43 (10)	25.2 (3.6)	
		Canada – n = 412	354 (86)	47 (10)	37.8 (10.7)	
		UK – n = 271	119 (87)	48 (9)	29.3 (5.8)	
BOSS	Tayyem (2014)	Validation:				Pre- and post-bariatric patients
		Pre-bariatric surgery – n = 83	(77)	45 (11)	48.4 (9.2)	Healthy volunteers
		Post-bariatric surgery – n = 68	(78)	44 (10)	39.0 (7.8)	
		Volunteers – n = 85	(64)	44 (11)	29.6 (6.3)	
PBOT	Al-Hadithy (2014)	Validation:				Bariatric surgery patients
		Non-obese – n = 10	6 (60)	48 [31-68][a]	22.6 [18-26][a]	Post body contouring patients
		Massive weight loss – n = 10	6 (60)	45 [31-67][a]	30.2 [23-41][a]	Healthy control
		Post body contouring – n = 10	6 (60)	48 [24-67][a]	29.1 [20-50][a]	

Body-QoL	Danilla (2014)	Development:				General Population
		Item generation – n = 16	15	40 (9)	NR	Pre & post body contouring surgery
		Pilot testing – n = 29	25	37 (11)	NR	
	Danilla (2016)	Validation:	737 (71)	31 (10)	23.7 (3.8)	
		General population – n = 1029	140 (82)	38 (9)	25.3 (1.9)	
		Surgery population – n = 171				
QOLOS	Muller (2017)	Development:				Preoperative bariatric surgery patients
		Item generation – n = 19	NR	NR	NR	Post-operative bariatric surgery patients
		Pilot testing – n = 101	NR	NR	NR	
		Validation				
		Preoperative patients – n = 220	159 (72)	41 (11)	48.1 (7.4)	
		Post-operative patients – n = 219	170 (78)	44 (11)	35.3 (8.3)	

[a] range; F: female; M: male; n/a: not applicable; NS: not stated; NW: normal weight

3.5.2.1 **Overall quality**

None of the scales had high-quality evidence for any measurement property. *Table 3.8* presents the overall quality ratings of the measures and the ratings for each quality criteria. The evidence quality ratings ranged from moderate quality to very low. The BQL and Body-QoL had evidence for all measurement properties except for measurement error. The table of ratings for each single study on the measurement properties of the bariatric scales can be found in Appendices 1.

Table 3.8 Overall result of the summarised evidence for each measurement property per bariatric scale

Scale	Content Validity	Structural validity	Internal consistency	Reliability	ME	Hypothesis testing	Responsiveness
MA-QoLQ-II	? Very Low	0	? Low	+ Low	0	? Very Low	0
BQL	? Very Low	+ Low	? Very Low	? Very Low	0	? Very Low	? Very Low
Body-Q	? High	? Moderate	? Moderate	+/- Low	0	0	+/- Low
BOSS	? Low	? Low	? Low	+ Low	0	+ Low	0
PBOT	? Very Low	0	? Very Low	? Very Low	0	+ Very Low	0
Body-QoL	? High	? Low	? Moderate	+ Low	0	+ Moderate	+ Low
QOLOS	? Low	+ Low	+ Low	0	0	+ Low	0

ME: Measurement error;
0: No evidence found; ?: indeterminate rating, +: sufficient rating; - : insufficient rating
*The BODY-Q scored +/- in terms of the evidence found for reliability and responsiveness as one scale out of the 5 HRQoL scales did not meet the criteria for good measurement properties. This will be further explained in the reliability and responsiveness sections below (3.5.2.5 and 3.5.2.9)
Quality of evidence ratings (GRADE approach): High, Moderate, Low, Very Low

3.5.2.2 **Content Validity**

All the bariatric scales included some information regarding their development. The scales were developed with input from bariatric surgery patients and or massive weight

loss patients seeking body contouring patients. However, only three scales (BODYQ, BodyQoL and QOLOS) provided detailed information regarding participant numbers and characteristics involved in item generation interviews, with the BODYQ and BodyQoL having an article dedicated to development. All scales were rated as indeterminate due to the specificity to surgery patients. Content validity of the scales was not tested in a range of BMIs or individuals not seeking bariatric surgery. As the target population for this systematic review is individuals seeking weight loss through community/non-surgical interventions, it is likely that the bariatric and body contouring QoL scales are too specific to surgery populations and will contain irrelevant items and subscales to the target population. It should be noted that these scales were developed for use in bariatric surgery populations and or body contouring populations, and the authors did not intend for them to be used within lifestyle and non-surgical interventions. Therefore, the ratings received for content validity will be different if rated in terms of a bariatric or body contouring surgery target population.

3.5.2.3 **Structural Validity**

One of the seven scales achieved a sufficient rating for structural validity (QOLOS) as it met the criteria for structural validity. However, this evidence was of low quality as there was only one study for structural validity, and this was of doubtful quality, indicating a risk of bias. Three of the scales (BODYQ, BOSS, BodyQoL) had indeterminate results for structural validity. The results were rated as indeterminate as the statistics required to compare to the criteria were not reported in the articles. The BQL received an insufficient rating for structural validity as factor analysis found three factors, yet the scale is scored as a unidimensional scale. No evidence for unidimensionality of the BQL was found. Two of the scales (MA-QoLQ-II and BOSS) had no information on structural validity.

3.5.2.4 **Internal consistency**

All the scales had been evaluated for internal consistency. Only one scale received a sufficient rating for internal consistency (QOLOS); however, this was of low quality due to having only one study of doubtful quality. The remaining scales had uninterpretable results for internal consistency due to either having no evidence of structural validity (MA-QoLQ-II and BOSS) and having uninterpretable results for structural validity (BODYQ, BOSS and BodyQoL).

3.5.2.5 **Reliability**

Six of the seven scales had been tested for reliability. The QOLOS had not been tested for reliability. The evidence for reliability met the criteria (ICC > 0.70) in four scales (MA-QoLQ-II, BOSS, BodyQoL and the BODYQ). The BODYQ had sufficient evidence for reliability for four of its five scales relating to HRQoL. However, the physical scale did not meet the criteria for reliability. The PBOT and the BQL used inappropriate statistical analyses for test-retest reliability, and the PBOT included only 10 participants. In all the test-retest analyses, stability in the construct, and in participants weight, was assumed and not measured. The timeframe between tests ranged from 48 hours to 2 weeks.

3.5.2.6 **Measurement error**

None of the measures had been tested for measurement error.

3.5.2.7 **Hypothesis testing for construct validity**

Six of the seven scales had evidence evaluating the construct validity through hypothesis testing. The BODYQ had no evidence to test this. Four scales (BOSS, PBOT, BodyQoL and QOLOS) had sufficient evidence for construct validity. The PBOT had very low-

quality evidence for hypothesis testing as a very small sample size was used (*n = 10*). The BOSS had low-quality evidence for construct validity as the reporting of the methods and data was unclear. The domains of the scales used as a comparison were not outlined, and the data was not provided in the article. The BOSS final 42 item scale was also computed from the draft 81 item version. Two of the scales had indeterminate evidence for construct validity (MA-QoLQ-II and BQL).

3.5.2.8 **Floor and Ceiling effects**

Only the BODY Q presented statistics for floor or ceiling effects. Floor effects ranged from 4 – 23% across the items, and ceiling effects ranged from 0 – 16% of the items. None of the remaining bariatric scales mentions how items or domains with floor or ceiling effects were handled nor were any statistics presented.

3.5.2.9 **Responsiveness**

Three of the seven scales had been evaluated for responsiveness (BQL, BODYQ, BodyQoL). The BODYQ had sufficient evidence of responsiveness for four of the five HRQoL scales, and the remaining scale (sexual life) showed no improvement with weight loss. The BodyQoL also has sufficient evidence of responsiveness, but the sample size used within the responsiveness study was very small (*n = 17*). The methodological quality (risk of bias) of the studies was doubtful as they did not specify the effectiveness of the treatment being received within the study or they did not use a stable control group and there was a lack of hypotheses being stated within the papers. So it was difficult to interpret the results of these studies. These studies were indirect in terms of populations used compared to the population of interest in the review.

3.6 DISCUSSION

Measuring QoL provides information on the impact of carrying excess weight on functioning and well-being. It is also useful to evaluate the effects of pharmacological treatments and lifestyle interventions and may provide useful information to help improve treatments/interventions. In order to accurately measure QoL, researchers and HCP's must have access to valid and psychometrically sound instruments. Therefore, the purpose of this review was to a) identify existing weight/obesity-specific QoL scales and their target population; b) assess the psychometric rigour and risk of bias of the measures and c) to conclude whether a suitable scale exists for use in community and non-surgical weight-loss interventions. The review identified 17 WRQoL scales, of which seven scales were specific to bariatric/body contouring surgery and 10 were weight/obesity (non-bariatric) HRQoL scales. Three scales not previously reviewed by Duval et al. (2006) and De Vries et al. (2018) were identified. These were the ORWELL-R (a revised version of the ORWELL 97), the QOLOD and the IWQOL-Lite Clinical Trials version. The clinical trials version of the IWQOL-Lite was not evaluated as it was still being developed, had not yet been evaluated, and only one qualitative article was available.

All identified measures have gaps in their validation supporting De Vries et al.'s (2018) findings. None of the scales provided evidence for measurement error, nor did they estimate a MID. However, this is typically evaluated after the scale has been found to have good psychometric properties. The measurement of sensitivity to change and evaluating the MID is usually a separate comprehensive piece of work. For the measurement properties that had been measured, the methodological quality was lacking. Therefore, the review further supports De Vries et al.'s (2018) review by highlighting the need for further evaluation of existing WRQoL scales. This review also highlights

important issues with the development and subsequent content validity of existing WRQoL scales.

3.6.1 Strengths and limitations of existing scales

In relation to content validity, most, but not all scales, had developed items using patient interviews; a necessity to ensure content validity (FDA & HHS, 2009; Terwee et al., 2018). However, the review highlights some issues with these existing scales. Firstly, they incorporate different aspects and issues that excess weight may cause/affect. There was consensus on some domains (for example, all scales included a physical domain/question) but even then, items within the domains covered slightly different aspects. Some scales included domains that others did not (for example, sexual life and work life). This indicates that there were different findings in the item generation phases of the scale's development in terms of which aspects of life were affected by weight. However, very few of the scales provided details or discussions of the qualitative element of item generation making it difficult to infer the importance of the different content in each measure (for example, (Camolas et al., 2016; Duval et al., 2006; Weiner et al., 2005; Ziegler et al., 2005; Mannucci et al., 1999; Le Pen et al., 1998; Kolotkin et al., 1995). A lack of reporting also makes it difficult to explain the differences.

Possible explanations for differences in domains and item content could be due to differing methodology used for item generation, the inclusion of different populations (for example, BMI range, age groups, country) and/or because scales were developed in different decades and countries/cultures. Firstly, the differing methodology could account for the varying domains/content found as differences in participant numbers and interview questioning could have affected the depth and variety of information gained from the item generation interviews. Comparisons in the methodology used in existing

scales cannot be made due to a lack of details on the item generation. However, none of the WRQoL scales intended for non-bariatric populations was developed using an iterative process involving repeated input from the target populations.

Including the target population within the item generation process is important, as discussed in Chapter 2, section 2.5.4. Qualitative methods used to generate items include one to one interview or focus groups to identify the aspects of WRQoL important to the individual rather than solely relying on an expert's opinion. Once items have been generated, an iterative process must be used to go back and forth to the target population to clarify item relevance, understanding and comprehensiveness. As the non-bariatric scales and the majority of the bariatric scales did not use an iterative process, they would not meet the FDA guidelines. Therefore, the FDA would not accept label claims for obesity treatments to be made if these scales had been used in clinical trials.

In terms of the populations used within the item generation phases of the scales' development, there are differences in the severity of obesity and the age of individuals included in the qualitative phases, as well as the country they were developed in. As previously stated, the reporting of participant demographics across the scales' is poor as only four of the non-bariatric, and bariatric scales reported demographic information of the participants involved in item generation interviews. None of the scales provided a BMI range of the participants interviewed, so the suitability of the scale across the weight spectrum is unknown. The scales identified were developed via involvement with morbid obesity patients (before weight loss) and experts. This is problematic as it is difficult to distinguish the population the scales are designed for and could lead to them being used within an inappropriate population.

It is recommended that item generation should involve input from individuals with varying degrees of condition severity and with varying population characteristics (FDA & HHS, 2009). To be able to detect changes as BMI reduces into the lower obesity and overweight categories (or increases to higher BMI categories), scales should be developed using people with a range of BMIs. It should include individuals of varying weight loss stages to capture any changes in QoL fully. However, this was not the case for all measures, and consequently, the content validity in relation to WRQoL across the BMI spectrum and weight loss stages in the existing scales should be questioned.

On the other hand, the newest bariatric and body contouring scales were better in terms of providing sufficient details of patient involvement. Two of the most recently developed scales within this category provide more relevant and detailed information regarding the demographics and characteristics of the patients involved in the content validity studies (item generation interviews, cognitive debriefing interviews). More specifically, the Body Q (Klassen et al., 2016) and the BodyQoL (Danilla et al., 2014) provided high-quality evidence for their content validity. The development of these scales is detailed in separate articles to the validation papers and is described in detail. The Body Q items were based around a conceptual framework which had been hypothesised based on interviews with participants (Klassen et al., 2016). Developing a conceptual framework to base the items of a PROM on is an important step of scale development, especially if the scale is to be accepted by the FDA for use in clinical trials (FDA & HSS, 2009). The FDA requires the developmental history of a scale, including the evolution of the conceptual framework, which is the basis of the concept, domains and the items and how they all relate. Having a conceptual framework allows for better interpretation of scores produced from completing the instrument.

Both the BodyQ and BodyQoL were developed using phases of qualitative interviews establishing their content validity within their target population. Initial phases of item generation consisted of qualitative interviews with patients from the target population, individuals seeking body contouring surgery or those who had received body contouring surgery after massive weight loss. The next phase of interviews involved cognitive debriefing interviews where different participants from the same target population were asked about the items generated in the previous interviews. This enabled them to gain information on the relevance of the items, how well the items were understood and whether there was any aspect affecting QoL missing from the items. The detailed reporting of the qualitative aspects and the comprehensive qualitative elements used in item generation and deletion has led to the rating of high-quality evidence for content validity. However, as these scales are specific to changes in QoL due to body contouring procedures (procedures to reduce or remove loose skin that has resulted from massive weight loss), they do not measure WRQoL generally, or changes in QoL due to weight loss/gain. What they do show is an improvement in item generation and content validity methods used to develop PROMs and the reporting of these methods.

Furthermore, several issues were highlighted in this review regarding the methodological quality of the studies that measured the psychometric properties of the identified instruments. Firstly, for many of the psychometric analyses, the scores for the final version of the scales had been computed from a longer draft version. In fact, the Laval was the only scale that had conducted analyses on the final scale rather than computing scores from the draft version. Using the draft version of a scale is normally done when the final scale has not been finalised, and it is still in the developmental stages. Psychometric analyses in this stage can give an indication of the psychometric properties of the final scale. However, these analyses should be repeated in a separate sample using

the final scale as changes in question orders, and content can change the way it is interpreted by the patient or participant.

Across all evaluation studies, there was a lack of consistency in the reporting of statistics and measurement properties leading to indeterminate ratings as the results of studies could not be compared/rated against the Criteria for Good Measurement Properties. This supports DeVries et al.'s (2018) findings and recommendations that further evaluation of these measures is needed before they are used within clinical trials and future research. But it also adds to this, as the scales have now been evaluated in relation to the overweight and obesity spectrum and the suitability to be used within clinical and community lifestyle interventions. Responsiveness studies were also difficult to interpret as the studies did not state the effectiveness of the treatment being used to assess responsiveness. There were also no stable control groups included to compare changes in scale scores, and there was a lack of hypotheses regarding the expected changes after the intervention or with weight loss or overtime. Therefore, it is unknown whether these scales can detect change due to interventions/weight loss.

Due to these issues, it is uncertain whether all important aspects of QoL that weight effects are included within these scales. Therefore, a detailed understanding of how carrying excess weight affects QoL is needed. Within the UK there is likely to be an increase in a variety of obesity interventions, due to these being the initial and preferred treatment of overweight/obesity, combined with the fact that over 60% of the UK's adult population are overweight or have obesity. Valid and reliable outcomes are required to measure their effectiveness, of which patient-reported outcome and QoL measurement is essential.

3.6.2 The IWQOL and IWQOL-Lite

The review highlights the IWQOL-Lite as the most validated scale; however, the studies on its measurement properties are of a low quality. It is also the most commonly used non-bariatric obesity scale. The IWQOL-Lite deleted 43 of the original 74 IWQOL items, including the whole comfort with food domain. This deletion was based solely on using statistical methods. These items and domains were developed using qualitative interviews and were perceived to be important in terms of impacting the QoL of these individuals. No demographic information was provided of the participants that took part in the qualitative item generation interviews except for the statement that they were inpatients at a diet and exercise facility and were mainly Caucasian. Therefore, it is unknown who the items are relevant to. The new shortened scale (IWQOL-Lite) was not subject to content validity checks within the population it was intended for (such as cognitive interviews) but has subsequently been used in research as a measure of WRQoL (Aasprang et al., 2013; Engel et al., 2003; Palmeira et al., 2009). This indicates that there could be important elements of QoL missing from this scale, and so might not show the full picture when measuring WRQoL.

Additionally, although the review highlights the IWQOL-Lite as the most validated scale, its studies are of poor methodological quality, and it was developed over 20 years ago. In the 20 years since the IWQOL was developed, rates of obesity have risen (Conolly & Davies, 2018), and the ability to correctly identify yourself or someone else as having obesity has decreased (Public Health England, 2015; Robinson & Kersbergen, 2016). This could indicate that carrying excess weight is becoming more normal, and the effects on QoL are evolving. There may be additional aspects of QoL which are affected. Therefore, the effects of excess weight on cognitions, behaviours and emotions need to be reassessed across the whole weight-spectrum, and weight loss stages and the scales

need to be updated, as necessary. The content validity and psychometric properties of IWQOL-Lite need evaluating within a UK population.

3.7 CONCLUSION

To conclude, this systematic review highlights the limitations in the development of existing WRQoL, along with the gaps in the evaluation of their psychometric properties. Limitations in item generation in addition to the lack of cognitive interviews with individuals with overweight and obesity indicate missing evidence for the content validity of existing scales. It is recommended that content validity studies of existing scales are conducted before further use in research, to ensure they are relevant, comprehendible, and comprehensive to patients with overweight and obesity. Furthermore, none of the existing scales was developed with input from patients with varying degrees of overweight and obesity or with individuals at different stages of weight loss. Therefore, there is a need for a new WRQoL scale that is suitable for populations with overweight and obesity to allow the evaluation of lifestyle and behavioural interventions.

4 A PRELIMINARY QUALITATIVE EXPLORATION OF WEIGHT-RELATED QUALITY OF LIFE

Content validity (ensuring that the items in a scale are clear, relevant and meaningful) is arguably the most important aspect of a PROM (Terwee et al., 2018) and WRQoL measurement is no exception. To ensure content validity, input from the PROMs intended population is a must (FDA & HHS, 2009). This is especially true when PROMs are measuring subjective concepts such as QoL. To explore subjective concepts, in-depth qualitative research methods should be used as they allow more open research questions and are more focused on individual experiences (Willig, 2013).

Chapter 3 highlighted issues with content validity in the most commonly used obesity-specific QoL scale; the IWQOL-Lite. The IWQOL-Lite was developed in the USA over 20 years ago. However, obesity is likely experienced differently in the UK (due to lower prevalence and free health care). It is also likely that obesity is experienced differently now as opposed to 20 years ago, due to increasing prevalence. Also, within the UK, there is likely to be a greater variety of obesity interventions due to the tiered approach of obesity management in the NHS. Valid and reliable outcomes are required to measure the effectiveness of these treatments/interventions, of which participant-reported outcome is essential. It is uncertain whether the IWQOL-Lite includes all important and relevant aspects of obesity-related HRQoL. Therefore, a detailed understanding of the effects of carrying excess weight on HRQoL is needed.

4.1 PURPOSE OF THIS CHAPTER

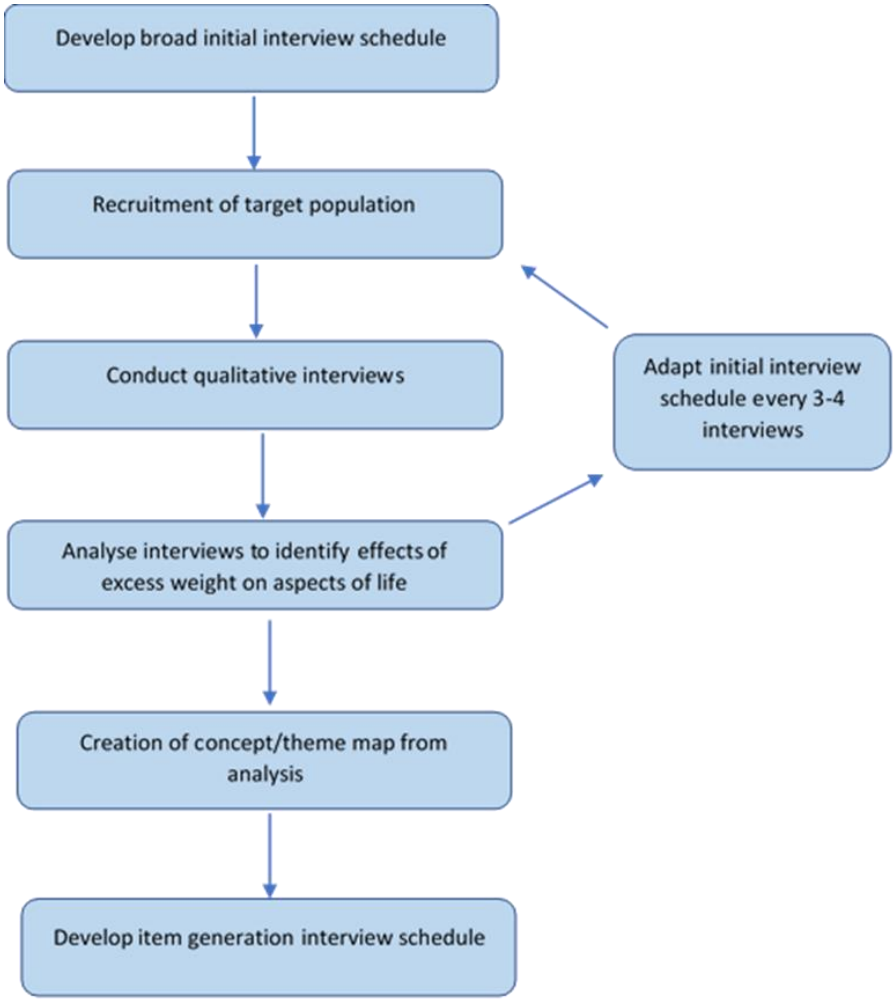
The purpose of this qualitative work was to identify the aspects of life that are affected by carrying excess weight and, to explore how weight affects the emotions, cognitions

and behaviours of individuals with overweight or obesity using one to one interviews. The study used an inductive approach due to the explorative nature of the interviews and to reduce the influence of existing WRQOL scales on the outcomes of this study. If the interviews were based on existing WRQoL scales, it might bias the interviews by focusing on the aspects which are already measured. It could prevent any unknown effects of obesity on QoL from being discovered. The results would inform the subsequent development of an interview schedule to be used within the item generation phase of a potential new instrument.

4.1.1 Developing an Interview Schedule for Item Generation

To generate the most meaningful information on the impact of weight on everyday life, the interview schedule itself needed to be informed by those it was intended for. Therefore, the results of these pilot interviews informed the interview schedule for the item generation interviews. *Figure 4.1* shows the process followed to develop the interview schedule for item generation.

Figure 4.1 The process of developing a meaningful interview schedule for item generation of a potential new WRQoL instrument



4.2 METHODS

4.2.1 Research Design

As established in Chapter 2 and 3, when measuring a subjective concept, gaining the target populations' experiences is important for the understanding of the concept. Therefore, a cross-sectional, exploratory, qualitative approach was taken to explore the effects of excess weight, and weight loss on the aspects of life thought to be important to the individual. Semi-structured, one to one interviews were conducted and analysed using thematic analysis. One to one interviews rather than focus groups were used to allow each participant to express their views without the influence of others. Also, one to one

interviews should help participants feel more comfortable sharing personal and possibly embarrassing experiences.

4.2.2 Ethics and Consent

The study was approved by the PSYSOC Ethics committee at UCLan before data collection (see Appendices 2). Potential participants were given all the details of the research, including information about their right to withdraw and the contact details of the researcher, director of studies and the officer for ethics, in the form of a participant information sheet (PIS) (see Appendices 2). The PIS was either emailed or handed to those who expressed an interest in participating in the research. Written consent was gained from all participants via Consent form version 1 (see Appendices 2). Participants were asked to read each section of the consent form and initial in the boxes to indicate they were happy with each section. They were asked to print and sign their name at the bottom of the consent form. After the interviews, a debrief sheet was given to all participants to reiterate the information from the PIS, to thank them and to allow them to indicate their interest to receive a summary of the results once available (see Appendices 2). The debrief sheet signposted participants to the NHS website for advice on weight loss and psychological advice in case individuals wanted guidance on this. All paper documents were stored in a locked filing cabinet only accessible to the research student. The interview recordings were downloaded onto the research student's password-protected computer at UCLan.

The interviewer had previous experience conducting qualitative interviews as part of her undergraduate and master's degree education and had attended a training course on conducting qualitative interviews. The training provided guidance on effective questioning (for example, avoiding leading questions and closed questions) and on ways

to deal with sensitive or distressing topics. As there was a potential for the topic to be sensitive and upsetting for some individuals who were, or had been, severely affected by their weight, it was important to minimise any distress and signpost participants for support where appropriate. If a participant became upset or distressed, they were asked if they would like a break from the interview. The voice recorder was then paused until they felt happy to continue. They were offered the choice to continue or to end the interview. No participants wanted to end the interview as a result of becoming upset or distressed. To ensure participants were not distressed or upset at the end of the interview, a summary was provided focusing on the positive aspects mentioned in the interview. Finally, to help integrate them back into their day, they were asked general questions about the rest of their day/week.

4.2.3 Participants

4.2.3.1 **Recruitment**

The recruitment of participants took place via convenience and opportunity sampling at numerous community locations and from the University of Central Lancashire using a research poster. The research poster provided necessary details of the interviews and the contact number and email of the researcher, enabling potential participants to get in contact (see Appendices 2 for research poster). *Table 4.1* displays the community locations recruitment took place from and how permission was gained. Permission to display the research poster was obtained at all locations and varied from email exchanges or face to face meetings with facility managers/coordinators.

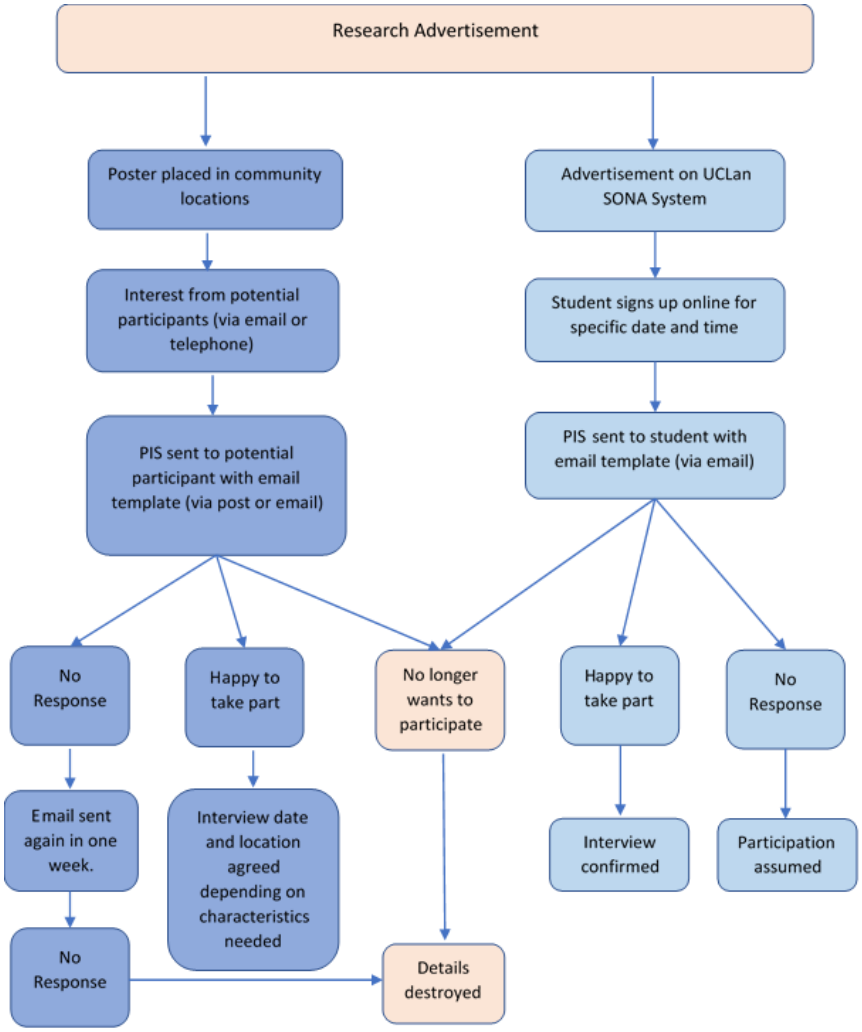
Table 4.1 Location and method of gaining permission for poster display

Location of Poster Display	Permission gained via	Length
TESCO - 3 different stores around Lancashire	Customer service desk	2 weeks per store
Gyms/Leisure centres - 3 different centres around Lancashire	Email exchange and meetings with centre managers	Full duration of recruitment period
Community Centre	Meeting with centre manager	Full duration of recruitment period
Burnley, Pendle & Rossendale Council for Voluntary Service (BPRCVS)	Meeting with centre coordinator	Email newsletter for December 2016
Library	Meeting with centre manager	Full duration of recruitment period
Park community boards - all parks around Burnley	Email exchange with park officer	Full duration of recruitment period
UCLan Campus	Permission not required for student notice boards	Full duration of recruitment period
UCLan SONA System*	Moderator approval	Full duration of recruitment period

*UCLan SONA system is an online area where research can be advertised to students. Students receive points when they participate in research, which allows them to use the system to recruit for their third-year project.

The research poster also contained eligibility criteria to ensure only people with or people who have had obesity were recruited. The eligibility criteria are discussed in detail in section 4.2.3. Individuals who responded to the research posters were emailed the participant information sheet (see Appendices 2 for email template). The email template asked for some demographic information based on the four key variables (see section 4.2.3 below) to aid the screening of participants. If no response was received after two weeks, the individual was contacted once more to check if they were interested in taking part. They were not contacted again if they did not respond for a second time or if they did not want to take part. *Figure 4.2* illustrates the recruitment process followed.

Figure 4.2 Self-selection recruitment process



Individuals residing in the UK, aged 18 and over, and had been overweight or were currently classed as overweight or obese according to BMI, were eligible for the study. To ensure a representative sample of participants were recruited, four key variables were represented in the sample. These were:

a) **Body mass index** (BMI; at the time of the interview); normal weight, overweight, obesity I, obesity II, obesity III (NICE, 2014).

b) **Weight loss status**; as WRQoL scales are used before, during and after weight loss, input from individuals at different stages of their weight loss journey is important. Therefore, one of the key variables covered in the pilot interviews

(and the item generation interviews) is weight loss status. This includes no attempts, unsuccessful attempts, successful attempts, and individuals who had regained weight previously lost. Weight loss status was self-reported.

c) **Gender**; as the majority of existing WRQoL scales interviewed mainly females to generate items, it is important to include both males and females and highlight any differences that may be present. Therefore, males and females were sought.

d) **Age;** as the research is exploring WRQoL in adults the age groups of 18-29 years, 30-49 years, 50+ years were represented to ensure a range of ages were included.

As these interviews were exploratory pilot interviews, and a further phase of interviews was planned, a sample size of around 10 participants was considered sufficient. The aim was to have at least one individual representing each of the key variables to gain knowledge of their experiences with weight. Exclusion criteria included individuals who had never been overweight, were pregnant, diagnosed as terminally ill, seeing a doctor for an eating disorder or a chronic disorder which has resulted in their weight gain, and individuals who were unable to stand unassisted. Individuals who were unable to stand unassisted were not included to avoid their discomfort when it came to having height measured. These exclusion criteria were detailed at the bottom of the research poster and on the PIS (see Appendices 2 for pilot interview research poster and PIS).

4.2.3.2 **Participants recruited**

Ten individuals who were either classed as overweight, obese, according to BMI or had previously been classed as overweight or obese (self-reported) were interviewed. Qualitative data were collected at three geographical locations across the North West of

England (Preston, Burnley, and Rossendale) over two months (November 2016 – January 2017). The ages of participants recruited ranged from 19 to 68 years (*mean = 46.1*). All participants self-identified as white/Caucasian. Five participants reported successful weight loss; one participant reported an unsuccessful weight loss and three participants reported regaining weight following weight loss. BMI ranged from 20 to 49kg/m^2 (*mean = 32.4*) and weight circumference ranged from 73 to 126cm (*mean = 102cm*). Individual participant characteristics and demographics are presented in *Table 4.2*.

Table 4.2 Participant number, gender, age, race, weight loss status, BMI and waist circumference

Participant	Gender	Age	Race	Weight loss status	BMI (kg/m^2)	Waist Circumference (cm)
1	Female	21	White/ Caucasian	Unsuccessful	Overweight (28.6)	Very high (105.0)
2	Male	46	White/ Caucasian	Successful	Obesity I (30.3)	Very high (111.0)
3	Female	38	White/ Caucasian	Successful	Normal (20.0)	Normal (73.0)
4	Female	56	White/ Caucasian	Regained	Obesity II (37.0)	Very high (114.5)
5	Female	55	White/ Caucasian	Regained	Obesity I (33.0)	Very high (106.5)
6	Female	40	White/ Caucasian	Regained	Obesity III (48.5)	Very high (126.0)
7	Female	68	White/ Caucasian	Unsuccessful	Obesity III (44.1)	Very high (121.0)
8	Female	52	White/ Caucasian	Successful	Normal (23.4)	Normal (78.0)
9	Male	66	White/ Caucasian	Successful	Overweight (25.5)	High (99.0)
10	Male	19	White/ Caucasian	Successful	Normal (23.9)	Normal (86.0)

Participants were recruited from a variety of the locations outlined earlier in section 4.2.3.1, with one participant being recruited via referral from a previous participant

(snowball sampling). The number of participants recruited from each poster location is displayed in *Table 4.3*. However, no individuals responded to the research poster from the TESCO locations indication that these locations were unsuccessful and ineffective places of recruitment.

Table 4.3 Number of participants recruited at each location

Place of recruitment	Number recruited
UCLan Staff AU Lookout Newsletter	2
UCLan Campus	1
SONA	2
Riverside Health Club, Rawtenstall	1
BPRCVS NL	2
Park Notice Boards	1
Referral from participant	1

4.2.4 Materials

4.2.4.1 **Anthropometric Measurements**

Tanita Digital Medical Scales were used to determine the participant's weight in kilograms to the nearest 0.1g. Participants were weighed without shoes and in light clothing. Participants stood on the scales with equal weight through each foot. A reading was taken once the figure shown had stabilised. A stadiometer was used to measure the participant's height in centimetres to the nearest millimetre. Participants were asked to remove their shoes when having their height measured. Finally, waist circumference was measured on the line of the navel using a standard tailors tape measure to the nearest millimetre. Measurements were taken following the NHAMES Anthropometry protocol (Centres for Disease Control and Prevention, 2007).

4.2.4.2 **Olympus WS-811 Voice Recorder**

A voice recorder was used to record the interviews. The recordings were uploaded in a .WMA file format to a password protected windows computer as soon as possible after the interview and then deleted from the recorder.

4.2.4.3 **Demographic Questionnaire**

The demographic questionnaire was given to participants after the interview to gain characteristics and demographic information (see Appendices 2). The demographic questionnaire asked for the participant's gender, age, ethnicity, weight loss status, level of education, employment status, history of health conditions and marital status.

4.2.4.4 **Initial Interview Schedule**

The initial interview schedule contained broad questions about how weight affected different aspects of life (see *Table 4.4* for interview schedule). The questions were open to allow participants to shape the interview and discuss the important aspects of life which their weight affected and avoid being compromised by assumptions from the researcher (Sbaraini, Carter, Evans & Blinkhorn, 2011). This ensured the openness of the study. No questions were asked that are items on existing WRQoL scales as this could prompt interviewees to answer the way they thought the interviewer wanted them to, rather than giving their own experiences. It could also emphasise aspects that are not as important to the individual. Whereas, having an open and less specific interview schedule allowed an unbiased view on the individual's experiences of weight and its effect on QoL. Therefore, participants were free to shape the interview and emphasise what was important to them. Prompts were also included to keep the interview on the topic of weight and QoL. These prompts included different areas of life and QoL. The interview schedule was adapted

after every 3-4 participants to cover aspects that were arising from these interviews. *Table 4.4* shows the additional prompts and questions added after the initial analysis.

Table 4.4 Questions/Prompts added to interview schedule after initial analyses

Interview Number	Questions included in interview schedule
Initial Questions	What does quality of life mean to you? What is important to ensure you have a good quality of life? What does "overweight" mean to you? How does being overweight differ from being "obese"? Describe your current quality of life Does your weight affect any aspects of your life? - How? - Which aspects? How do you feel about your weight? Have you ever attempted to lose weight? - What were your expectations at the start? - Do you feel that you met these expectations? - Looking back, do you feel these expectations were realistic? - What things did you do to try and lose weight? - How did they make you feel at the time? - Were they successful? - If yes, did this affect your life? - Have you kept the weight off? - Why do you think this is? - How does it make you feel? What do you think your weight and quality of life will be like in the future? Is there anything you thought I would ask but haven't?
After interview 4	How do you think others perceive you? How does your weight affect your physical fitness? Have you experienced any pain? Do you feel in control of your weight? What is your experience of buying clothes?
After interview 7	What are your experiences with health care professionals? What are your experiences with public transport? Has your weight ever effected your relationship with your significant other?

4.2.5 Interview Locations

The interviews took place in various locations. For participants recruited from UCLan (incl. SONA, staff AU Lookout and student email newsletter), the interviews took place in a psychology lab room within the Darwin building on the UCLan Campus. These are available for students to book online and special permission is not necessary. Participants

recruited from all other areas were either interviewed at their home or a convenient location reserved by the researcher. If interviewing participants off-campus, a procedure was followed to ensure the safety of the interviewer (see Appendices 2 for Lone working procedure). Participants were always asked where they would prefer the interview to take place and if they would be comfortable with the interview taking place in their home. If participants indicated that they would prefer the interview to take place at a community location, a convenient location was agreed and then booked by the interviewer. Rooms were hired at Burnley Central Library and Rawtenstall Library. Each organisation was informed of the nature of the room use (one to one interview), and they booked the most suitable room. However, the room used at one location was quite small and was being used as a storage cupboard. This may have affected how comfortable the participant felt and the amount of detail they went into within the interview. It also affected the quality of the recording as it was next to a noisy main road. After this experience, all rooms hired were viewed before booking to ensure they were suitable.

4.2.6 Interview Procedure

Before the interview began, the participant was asked to read and sign the consent form if they were still happy to participate. Once completed, the participant's right to withdraw was reiterated, and they were given an opportunity to ask questions. They were then informed that the voice recorder was being turned on, and the interview began. The interviewer started by using the interview schedule but did not always follow it strictly and was free to ask additional questions and change the order of questions depending on what the interviewee said. At the end of the interview, the voice recorder was turned off. The participant was then asked to fill out the demographic questionnaire. After this, the participant's height weight and waist circumference were measured if they were still happy to be measured. All measurements were noted in the designated section of the

demographic questionnaire. Finally, the debrief sheet was given to participants, and they were thanked for taking part. If participants indicated that they would like a summary of the research results, they gave a preferred method of contact. They were informed that they would receive the summary at the end of the PhD programme in 2019.

4.2.7 Analysis of Data

The analysis started after the first interview was conducted. Immediately after each interview (or as soon as possible after), a summary was written either as a paragraph or bullet points. This allowed the documentation of any initial thoughts about the interview and what should be added to the interview schedule. After every three interviews, the interview recordings were listened to and analysed for aspects of WRQoL not already on the interview schedule. After all the interviews had been conducted, they were transcribed verbatim. The transcripts were analysed using a combination of NVivo 11 and by hand. Braun and Clarke's (2006) thematic analysis was used to analyse the interview data.

Firstly, each transcript was read through so the researcher could re-familiarise themselves with the interview content. After re-familiarisation, initial coding was conducted. This involved summarising the content of each small section (two-three lines) of the interview as concisely as possible without losing any important detail. Initial codes ranged from one word to a sentence to describe what was being spoken about. After this, the initial codes were grouped into themes and subthemes based on comparisons between participant's data and between codes. Themes with enough supporting evidence from the interviews and that related to the research questions were identified and interpreted to answer the research questions. The coding took place within NVivo, and hand-drawn diagrams were used to aid in structuring the themes in the most meaningful way.

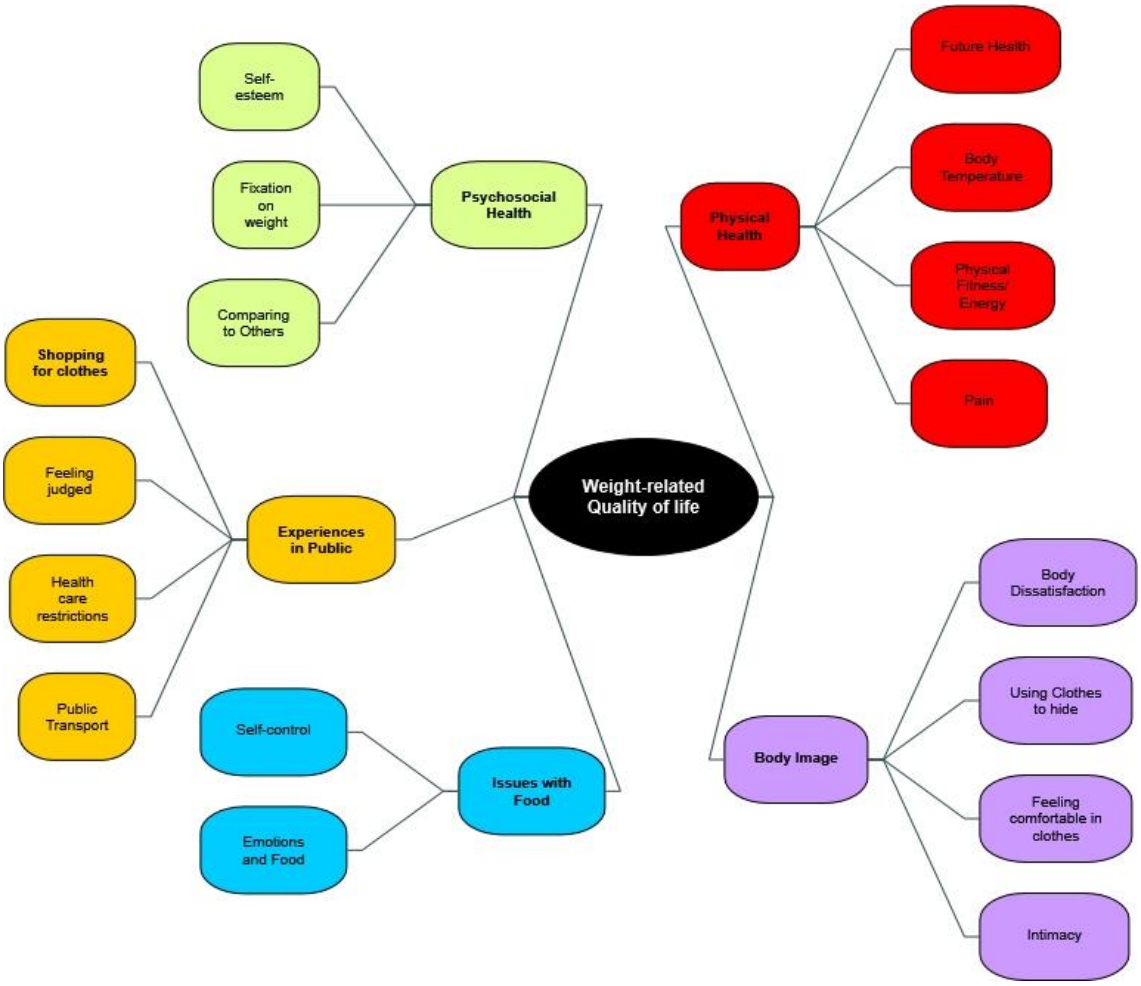
4.2.8 Validity and reliability

To ensure the reliability of the interview analysis, all ten transcripts were analysed separately by a second researcher who had no prior knowledge of WRQoL scales. Discussions on emerging themes occurred half-way through the analysis and at the end of the analysis. In each meeting, emerging themes were compared for similarities and differences. All themes identified were similar, although some were worded slightly differently. The author produced a theme structure, and it was discussed with the second researcher to check for agreements and disagreements. Issues with clothing caused discussion as to whether it should be a separate theme. As elements of clothing represented different aspects of life, such as experiences in public and body image, it was decided that it should not be a separate theme.

4.3 RESULTS/ANALYSIS

From the analysis of the interview transcripts, five themes were identified with subthemes included within each theme. The themes identified were Physical Health, Psychosocial Health, Body Image, Experiences in Public and Issues with Food. All themes represented a part of life which had been affected by carrying excess weight, with subthemes representing specific indicators, behaviours, cognitions, and emotions relating to that aspect of life. *Figure 4.3* provides the themes and subthemes that make up the hypothesised conceptual framework of WRQoL. *Table 4.5* provides example quotes from the data supporting each theme and subtheme.

Figure 4.3 Hypothesised Conceptual Framework of Weight-Related Quality of Life



The main themes and subthemes found in the interview analysis are shown in Figure 4.3. The red boxes represent the physical health theme and subthemes, the purple boxes represent the body image theme and subthemes, the green represents psychosocial health, yellow/orange represents experiences in public, and the blue represents issues with food.

Table 4.5 Themes identified in the preliminary interviews with example quotes

Theme	Sub-theme	Example Quote
Physical Health	Pain	*"My knees… my knees and my back when I lost weight I noticed that I no longer got knee ache and I no longer got back ache"* (P003, F, BMI Overweight)
	Physical Fitness/energy	*"I'm getting out of breath going up stairs I've not got the same energy as I used to have and I know I'm putting that down to to my weight issues because when I have lost weight in the past and it's made me feel so much better"*(P004, F, BMI Obesity III)
	Body Temperature	*"having certainly coming from cold climate and living here which is a difficult climate… having just a little extra fluff and insulation isn't a terribly bad thing"*(P002, M, BMI Obesity I)
		"I'm always cold I know it's probably boiling in here for you but I'm always… I mean I'm warm I am actually warm but generally speaking I am I'm always really really cold I always have been err my fat doesn't work [laughs] you know whatever it is doesn't work it doesn't do all this things they say that people sweat I don't even sweat you know I just don't get that hot and erm I'm always really cold"(P007, F, BMI Obesity III)
	Concern for future health	*"I'm bothered about my body and what's happening to it and your health you know you don't wanna be diabetic or anything like you know these kind of things which is why I always try and eat as healthy as I can cause I don't want any to be worse than I am"* (P007, F, BMI Obesity III)
Psychosocial Health	Self-esteem	*"I don't feel good about myself you know and I know when I had lost I still didn't feel good then I felt better about myself but I were frustrated because I knew I needed to lose more but I couldn't"* (P004, F, BMI Obesity III)
		" I felt really well I felt really good then and I was probably about 18 stone but I felt really confident"(P006, F, BMI Obesity III)
	Comparing to others	*"I do look and think you know I would like to be like that and have that confidence"* (P005, F, Obesity I) *"go for a walk he would be out of puff quite soon erm… and so… I always said to myself I'm not gonna be like that [laughs] so it was my motivation really"*(P009, M, BMI Overweight)
	Fixation on weight	*"once I had my first baby and I put a lot on I became a bit obsessed then after the baby cause I'd put a lot on that's when I started obsessing and doing all the any diet I could do type of thing"*(P005, F, Obesity I)

Body Image	Body Dissatisfaction	*"I was conscious that my body shape was very I was narrower here [upper body – shoulder arms chest] and getting bigger around my legs and my bum and then this way so I felt I probably was critical about myself and thinking that it's not an attractive look"* (P009, M, BMI Overweight)
	Using clothes to hide	*" I don't look at what I look like… cause I just can't bear to look. I never could bare to look. I never could bare to look walking past a mirror."* (P007, F, BMI Obesity III) *"when you've got legs like mine you don't want any of them showing [laughs]. You know you just have to hide them as much as you can that's why I tend to wear trousers"* (P007, F, BMI Obesity III)
	Feeling comfortable in clothes	*"I felt nice in my clothes when I looked in the mirror I thought I don't look I don't look too bad you know for what you imagine someone at 18 well I think what people imagine an 18 [stone] I felt quite good about myself"*(P006, F, BMI Obesity III)
	Intimacy	*"we don't have a [intimate] relationship as such and that's probably my my fault you know 'cause I don't like him seeing me with no clothes on you know cause I'm just I'm just a blob you know"* (P004, F, BMI Obesity III)
Experiences in Public	Possible health care restriction	*"I'm also a little bit nervous that they'll turn 'round and say well you're too heavy and I'm so heavy that it would take like a ridiculous amount to get to something that would be within their I guess but I don't know"*(P006, F, BMI Obesity III)
	Feeling Judged	*I never looked in a well I wouldn't look in a bakers ever or a sweet shop because people would… I'd think that they'd be looking at me thinking "oh well she's fat cause she eats cakes all day"*(P007, F, BMI Obesity III)
	Shopping for Clothes	*"I wouldn't buy gym type looking clothes because I'd be I would think people would be looking and think and saying [laughs] you know she needs them or she shouldn't be wearing them she's too big for them it doesn't look like she goes to the gym type of thing"*(P005, F, BMI Obesity I) *"they tend to show em in thinner girls show pictures of thinner girls wearing what is like size 20 or 22 type of thing and a lot of the time I do think whats the point"(P005, F, BMI Obesity I)* *"nowadays you can't get jeans because they're all skinny legged jeans and even if they are wide at the bottom they're not wide at the top where I am you know"* (P007, F, BMI Obesity III)
	Public Transport	*"I've been conscious about and then the last couple of trips cause we've only been on like Ryanair whether the seat-belt would fit me and that was like a real like panic"* (P006, F, BMI Obesity III)

Issues with Food	Emotions and food	*"I can sit and eat a full pack of cheddars but then feel guilty about it after you know and I'm like sort of in a way hiding the evidence you know I'll put it in the bin"* (P004, F, BMI Obesity III) *"if I felt sad let's get the chocolate biscuits or you know if I'm stressed about something you know when I was at university you know I used to surround myself by chocolate bars you know just to keep me going."* (P008, F, Normal weight)
	Self-control	*I can't leave it alone and it's just like urghh unfortunately I try and think no don't have another but you're just like urhh so I'm better not having any sugar or very little sugar it doesn't suit me it just makes me mad"* (P007, F, BMI Obesity III)

4.3.1 Physical Health

This theme highlights the aspects of physical health associated with carrying excess weight. These aspects/subthemes are:

4.3.1.1 **Pain**

Many of the participants indicated how they were currently experiencing back and knee pain due to their extra weight. Pain/aches were present in both men and women and seemed to be reduced when weight was lost. After losing weight, they noticed that this pain had gone. However, one woman believed her excess weight had done permanent damage as she still experienced knee pain when she exerted herself, despite now being a healthy weight. The pain experienced prevented some interviewees from being more physically active as the pain affected their mobility. The pain was more evident for those with a larger BMI and decreased as people lost weight.

4.3.1.2 **Physical Fitness**

A lack of physical fitness/energy was highlighted by many of the participants. Those in the obesity BMI categories indicated that they would become out of breath quickly when doing everyday tasks such as walking and climbing stairs. When weight was lost, they felt much better and more energetic, and so this lack of physical fitness/energy was put down to their weight. The discomfort and the potential embarrassment and judgement from others due to a lack of physical fitness prevented the women from trying new activities such as Zumba, dancing, and cycling. They felt restricted in what they could do, which led to them avoiding certain activities. Physical fitness and pain were not the only things affecting avoidance behaviours as negative body image and fear of being judged also influenced this. In contrast to the females, the male participants indicated that they would still try an activity despite not being physically fit enough. This indicates that

weight may be a larger barrier to activities, in this context, for females than for males. In fact, most of the men already participated in some form of physical activity. This could explain why they would not avoid new activities as they already had some fitness.

4.3.1.3 **Body Temperature**

A positive of having excess weight was being able to keep warm in winter and in colder climates. This was more apparent for those in the overweight BMI category and in the lower end of the obesity BMI category. However, one woman indicated that she was always cold despite being in the morbid obesity BMI category. Body temperature was only mentioned in the later interviews, and so more information is needed to support this subtheme.

4.3.1.4 **Concern for Future Health**

All participants highlighted differing degrees of concern and worry towards the potential effects of extra weight on their health. For some, it was seeing family members develop health conditions from being overweight, which caused them to worry about having similar problems. Some participants indicated that they already had health issues, and they were worried that being overweight would make these worse. Worry/concern for health seemed to be intensified by age. This is highlighted by a shift in thinking from worrying about body image to concern for health. When this shift happens, there seems to be a sense of urgency towards losing weight to avoid developing health issues. All participants indicated that it was harder to control weight as they get older and so this adds to their concern for health. Both men and women showed concerns for their health, regardless of current weight or BMI status.

4.3.2 Psychosocial Health

This theme highlights the aspects of psychosocial health affected by carrying excess weight. These aspects are:

4.3.2.1 **Self-esteem**

Most of the participants noticed a difference in how they felt about themselves while they were overweight and at times when they lost weight. When they saw themselves as overweight, they reported feeling bad about themselves, having little confidence and feeling as though they were letting themselves down. These feelings led to avoiding social activity as some participants wanted to shut themselves away when they felt like this. After losing weight, their self-esteem and general confidence increased. Two participants indicated that low self-esteem was not an issue for them, and in fact, they could feel good about themselves despite being in the obesity BMI group. They could do this because they did not let their weight define them or think that it changed them in any way; they did not have negative self-thoughts due to their weight.

4.3.2.2 **Comparing to others**

Most of the females indicated that they often saw other women and wished they could be like them. Comparisons were made in terms of being comfortable and looking good in clothing, being confident, being as physical activity as someone else and being attractive to others. These negative comparisons seem to be cognitions that result from having low self-esteem and feeling bad about themselves. The males also compared themselves to others, but in a more positive/constructive way. They saw family members or friends who were more overweight than them and used this as a motivator to lose weight or avoid putting more on. One male even saw someone who was more overweight than himself lose weight and was inspired by this to lose weight. He thought if someone bigger than

him could do it then he could too. Again, the men reported better self-esteem, and so this protected them from these negative comparisons.

4.3.2.3 **Fixation on Weight**

Most women had gone through cycles of dieting and becoming obsessed with losing weight. Weight was a big thing for them and was on their mind all of the time. Even when losing the weight and successfully keeping it off, there was constant monitoring of weight. This fixation seemed to be worse when they felt as though they were not in control of their weight. They did not pay attention to the benefits they had gained from losing a bit of weight, such as fitting into clothes better, improved self-esteem and better mobility. They had a goal weight in mind; they wanted to be thin, so they had to be losing weight or else their efforts were perceived as wasted. On the other hand, two females indicated that they were not bothered about their weight and were just happy that their weight was not physically stopping them from doing what they wanted to. Also, the men did not seem to be fixated on weight and were more relaxed and felt in control. Again, this seemed to link with levels of self-esteem and feeling judged. Those with more negative self-thoughts felt as though they would be judged by others and in turn were fixated on losing weight.

4.3.3 Body Image

This theme represents thoughts the participants had about their appearance, emotions that arose from these thoughts and behaviours that were used to control these emotions. The subthemes identified are:

4.3.3.1 **Body Dissatisfaction**

The majority of participants were or had been, unhappy about their appearance and their body. Some women avoided or did not like, looking at themselves in the mirror. Those

who had lost weight reported feeling more attractive and satisfied with their appearance. This was also apparent in one of the males. They were also unhappy with their body shape and where they stored their fat. Those that were unhappy with body shape indicated that it was because they put weight on their "bums and legs". The other males reported that they would feel dissatisfied with their body if their body shape had been different. However, where their fat was stored now made them feel in proportion, and so they did not feel that they looked overweight. One female reported how she did not want to lose weight because she would not suit it, and so was quite happy in how she looked.

4.3.3.2 **Using clothes to hide**

The women who were dissatisfied with how they looked indicated that they wore baggy and 'frumpy' clothes to try and hide their bodies. Whereas, those who had lost weight stated that they liked to wear tight clothes or more flattering clothes to show off their body shape. It was also apparent that those who were not happy with their body avoided wearing swimwear and that, as they got bigger, they covered more and more of their body up. On the other hand, those who were happy about their body felt comfortable wearing swimwear.

4.3.3.3 **Feeling comfortable in clothes**

The majority of participants indicated that they wanted to wear 'nice' clothes, but they could not. They wanted to look good in the clothes they wore, but some of the participants felt that they did not know what to wear to achieve this. A lot of importance was placed on being able to feel good in the clothes they wore. Some participants indicated that if you felt nice in your clothes, then it makes you feel more confident. Two of the three males indicated that they were not bothered about their clothes or how they looked and so this did not affect them.

4.3.3.4 **Intimacy**

Intimate relationships were affected by how attractive the participants felt. Some felt too conscious about how they looked, and so they no longer had an intimate relationship with their partner. Feeling unattractive also made some participants avoid dating altogether. On the other hand, some participants indicated that their intimate relationships were not affected by their weight because they knew their partner still thought they were attractive.

4.3.4 Experiences in Public

This theme highlights the different public experiences that are exaggerated by carrying excess weight. It consists of the subthemes of:

4.3.4.1 **Feeling Judged**

Many of the participants felt as though people judged them negatively based on their weight. This was generally just the women. It was clear that there was a fixation on what other people were thinking about them, and this was generally negative. This led to avoiding doing things that they wanted to, in some cases in order to avoid being judged and feeling uncomfortable in situations where they felt judged. This decreased as some women lost weight and became more confident, comfortable and happy with themselves. However, the males and one female indicated that they did not care about what other people thought about their weight and so this did not affect them. This is because they had a good level of self-esteem, so they had more positive thoughts about themselves and were not affected by other people's negative thoughts.

4.3.4.2 **Possible Health Care Restrictions**

In the later interviews, some participants highlighted their concern for being judged by HCPs. This concern arose through bad experiences with doctors, where they felt the

doctor had jumped to the conclusion that their weight was the cause of the health issue they had sought advice for. For example, one participant reported having a foot problem which was present when she was a 'healthy' weight. She went to the doctors for help when she was 'overweight', but they told her she needed to lose weight to solve the problem, leaving her feeling frustrated. On another occasion, she had a telephone appointment and was offered a referral, and her weight was not mentioned. She believed that because the doctor could not see her, they did not judge her weight and treated the actual problem. Because of such experiences, many participants were then worried to go to the doctor in case they were told to lose weight before they could be treated. They indicated that not only would this be embarrassing for them, but it would be unlikely that they would be able to lose the amount of weight necessary to meet the 'threshold'. For one of the participants, this led her to think that there was no point in going to the doctors as they would not do anything for her.

4.3.4.3 **Shopping for Clothes**

When shopping for clothes, many of the participants highlighted that they could not tell what the clothes would look like on them due to the model advertising them. The models were thought to be too small to represent bigger clothes sizes. It was also mentioned that bigger sizes were more expensive. This made it difficult and frustrated the participants when shopping for clothes. Most of the participants had an issue with wearing the current fashions. Buying jeans was an issue for both men and women as they struggled to find some that were not skinny or slim fit. Finding pants that fit them was a priority, and quite frustrating for most participants. There seemed to be social 'rules' or norms in some participant's minds that they could not wear certain clothes because of their weight. This links with the 'feeling judged' subtheme as they thought they would be judged if they

wore certain clothes and so avoided wearing them even if they wanted to. Participants felt as though they were being stigmatised for being overweight when shopping for clothes.

4.3.4.4 **Public Transport**

In a small number of participants, there was a concern for their safety on aeroplanes due to their weight. There was also a concern for weight, causing embarrassment on planes. When knowing that they were going on holiday, there was a concern that the seat-belt on the aeroplane would not fit and they would not be able to fly. If this happened, they would feel embarrassed. However, the participant was aware that this was an irrational thought as there have always been seat-belt extenders available when she has flown before. Despite knowing it is an irrational fear, it did not lessen her worry.

4.3.5 Issues with Food

This theme represents the different eating behaviours and the subsequent emotions related to food and eating. Food was mentioned in all interviews. The subthemes are:

4.3.5.1 **Emotions and food**

Many participants described how their emotions affected their eating behaviours and the emergence of guilt after eating. When feeling down and bad about themselves, they indicate that they would eat unhealthy foods to comfort their emotions. However, instead of feeling better, their comfort eating would lead to feelings of guilt. The male participants did not attach feelings of guilt to eating 'bad' food and described their enjoyment for food. One of the males even indicated that he did not mind it when he was overweight as he enjoyed his food so much.

4.3.5.2 **Self-control**

Issues with self-control were seen when it came to food. Participants reported not being able to control their urges to eat 'bad' or 'unhealthy' snacks. When they ate these snacks, they were then likely to binge on them until they were all gone. Again, this was seen mainly in the female participants rather than the males. The males were more relaxed in their view of 'bad' or 'unhealthy' food and would simply enjoy it if they wanted it without attaching emotion to it.

4.4 DISCUSSION

The research aimed to identify areas of life that might be affected by overweight/obesity and to explore how overweight/obesity affected cognitions, emotions and behaviours. Analysis of the interviews identified five main themes representing areas of life that weight affected. Each theme had a differing number of subthemes. The themes of physical health, psychosocial health, body image, experiences in public and issues with food are all measured within existing measures of WRQoL. However, there are elements within some of these themes that are not currently being represented. Also, the IWQOL-Lite removed the Comfort with Food domain from the IWQOL (Kolotkin et al., 2001), and so no longer measures this aspect of QoL. The themes and subthemes that emerged within these interviews were used to construct the main interview schedule. This will ensure the interviews conducted to generate items for a new WRQoL scale will have real meaning for this population.

4.4.1 Physical Health

The theme of physical health represented the presence of pain, lack of or decreased physical fitness/energy, effects on body temperature and concern for health when carrying extra weight. Within the subtheme of pain, individuals were suffering from knee and back

pain which was worse in those with higher BMI's and reduced when weight was lost. This pain affected participation in physical activity. Findings from the literature support this theme as pain is commonly reported in individuals with obesity and has been found to negatively affect HRQoL (Janke et al., 2007). The theme of pain is also supported via existing weight/obesity specific QoL measures as an item measuring pain is normally included in these.

Physical fitness/energy represented the tendency to become out of breath when carrying out daily activities and how this affected women's, but not men's, participation in physical activity. Becoming out of breath quickly suggests a lack of cardio-respiratory fitness. Breathlessness on exertion is a very common symptom in obesity (Gibson, 2000). Previous literature indicates that increasing weight can have a detrimental effect on cardiorespiratory fitness and lung function (Kress, Pohlman, Alverdy & Hall, 1999) and could explain the occurrence of breathlessness on mild exertion within the current study. This breathlessness experienced in women in the current study was preventing them from being physically active due to the potential judgement by others and embarrassment they might encounter about their lack of fitness and their weight.

Avoiding physical activity could have further detrimental effects on their health and mortality but can also negatively affect psychological health (Forhan & Gill, 2013). Individuals with obesity but also a good cardiorespiratory fitness have been found to have similar mortality risks as normal-weight individuals (Barry et al., 2014), so increasing the respiratory health of individuals with overweight/obesity could not only improve HRQoL but their mortality too. Items covering breathlessness are included in WRQoL measures supporting the finding of impaired physical fitness/energy. Pain and physical fitness are important factors to include within a weight-specific QoL measure as patients with

obesity are usually advised by their HCP to be more physically active in order to lose weight and to reduce cardiovascular and metabolic risk. Even though this advice is well intended, individuals who are experiencing pain or mobility dysfunctions may not be able to move around at the intensity or frequency needed to lose weight or even prevent weight gain (Forhan & Gill, 2013). Therefore, including pain on a WRQoL measure can illustrate a need to address this functional mobility/pain problem before advice on physical activity is given.

The subtheme of body temperature represents the effect of excess weight on body temperature. For some, this was seen as positive as they were able to keep warm in the winter. However, there was a contradiction to this as one participant claimed she was always cold. Research into body temperature indicates that individuals with obesity have a suppressed cold response due to the insulative properties of excess adipose tissue and results in persons with overweight/obesity feeling more comfortable in colder environments (Moellering & Smith, 2012). This insulating effect of the excess fat tissue is also thought to make individuals with obesity less comfortable within hot environments (Moellering & Smith, 2012). However, this was not mentioned in these interviews.

While the literature can help to explain this finding of keeping warm, the contradictory case makes it a bit uncertain. It is not known why one person has the opposite experience. It could be possible that this person suffers from hypothyroidism. Hypothyroidism has been closely linked to obesity and is regarded by patients as a cause of their obesity (Sanyal & Raychaudhuri, 2016).[3] This is due to weight gain and difficulty losing weight being symptoms of hypothyroidism (Canaris, Steiner & Ridgway, 1997). Sensitivity to

[3] Whether hypothyroidism does or does not cause obesity is debated in the literature. It is argued that obesity can cause hypothyroidism due to metabolic changes, which can be altered back to near normal with weight loss (Sanyal et al., 2006).

cold is also a symptom of this disorder, and so it could be that this individual has altered levels of thyroid-stimulating hormone, causing her sensitivity to the cold. However, a history of hypothyroidism was not mentioned by the participant, so without clinical tests, this cannot be assumed. Items relating to body temperature are not included within existing scales of WRQoL, therefore, more information is needed on this theme. Body temperature will be explored more within the item generation interviews to decide whether or not it should be included within a WRQoL scale.

As obesity can lead to numerous health conditions, the awareness of this alongside any symptoms individuals may be experiencing (e.g. pain and breathlessness) could result in concerns for their health. Health-related anxieties have been found to be a motivator of initiation of weight loss (Roberts & Ashley, 1999). They, therefore, could help identify people who may be psychologically ready to start losing weight. Concern for health is normally measured within existing WRQoL scales.

4.4.2 Psychosocial Health

Within the theme of psychosocial health were related sub-themes representing the effects of weight on the participant's psychosocial health. Those with low self-esteem tended to compare themselves to others in a way that led to further negative thoughts about themselves. Internalised weight stigma is a common experience within individuals with overweight/obesity and has been found to promote body-related or self-related negative thinking leading to low self-esteem and depression (Jansen et al., 2008; Kasen, Cohen, Chen & Must, 2008). Items relating to self-esteem are included on the IWQOL and IWQOL-Lite. However, this makes up the majority of the psychological items. Fixation on weight is also related to feeling judged, self-esteem and body image as dissatisfaction with appearance and the need to be thin led to cycles of extreme weight loss efforts.

4.4.3 Body Image

Psychosocial health was found to be linked to the theme of body image, particularly self-esteem, comparing to others and body dissatisfaction. Low self-esteem and tendencies to negatively compare themselves to others were always accompanied with body dissatisfaction and using clothes to hide. This supports Mond and colleagues (2007), finding that weight and shape concerns are an important mediator in the relationship between obesity and psychosocial health. Body dissatisfaction was found to be prevalent within the participants, which lessened as weight was lost. It was found that women were more dissatisfied with their bodies and appearance than men. This is supported by the literature as, within the general population, women are more likely to report body shame than males (Else-quest, Higgins, Allison & Morton, 2012).

Issues with body image are generally worse within individuals with obesity than those without obesity (Sarwer et al., 1998; Schwartz & Brownell, 2004). However, there is not a clear relationship between body image dissatisfaction and BMI (Matz, Foster, Faith & Wadden, 2002; Wilfley, Schwartz, Spurrell & Fairburn, 2000). Body image seems to be related to depressive symptoms and self-esteem independently of BMI (Foster, Wadden, Vogt et al., 1997; Sarwer et al., 1998). This lack of relationship between BMI and body image could explain why one of the women with obesity had quite a good body image compared to the rest as she also had good self-esteem. High self-esteem could be seen as a protective characteristic against body image issues.

Clothing represented issues and behaviours within different aspects of WRQoL. These were body image and experiences when shopping for clothes. Firstly, poor body image led to being unable to feel comfortable in clothes and using clothes to hide their body. Body image affecting the way overweight individuals dress is not a new finding. Sarwer,

Wadden and Foster (1998) found that dissatisfaction with appearance led to individuals with obesity trying to camouflage their body shape with clothing. This dissatisfaction and need to hide, in some cases, led to embarrassment in social situations because of weight and had a negative effect on QoL (Sarwer et al., 1998) and thus supports the current finding and the need for WRQoL scales to represent this aspect of body image. Other qualitative research has found despair at clothes not fitting comfortably (Roberts & Ashley, 1999), the inability to find attractive clothing and clothes being more expensive at larger sizes (Thomas, Moseley, Stallings, Nichols-English & Wagner, 2008), highlighting the potential impact of clothing on WRQoL.

Not only does negative affect about the body and body shame lead to unrealistic weight loss goals (Jung, Spahlholz, Hilbert, Riedel-Heller & Luck-Sikorski, 2017) and unsuccessful weight loss (Roberts & Ashley, 1999), but it also plays an important role in the development of depression (Hyde et al., 2008). Therefore, including body image in a WRQoL scale could help to indicate individuals at risk of developing depression and their likelihood of successful weight loss. This, in turn, can help HCP's recommend suitable interventions and treatments for these individuals. Whilst it is not a new finding that individuals with overweight/obesity experience dissatisfaction with their bodies and appearance, it is not widely measured within WRQoL instruments. The IWQOL-Lite does not measure it. Given the clinical implications of body dissatisfaction, such as its links to depression (Hyde et al., 2008) and weight loss success (Annesi & Whitaker, 2010; Roberts & Ashley, 1999), it should be considered an important aspect of WRQoL that should be measured.

4.4.4 Experiences in Public

Another aspect of WRQoL highlighted by this study is a worry or concern about health care restrictions. Previous literature supports this aspect of WRQoL, as negative attitudes towards individuals with obesity have been found within health care settings, which potentially affects the quality of care received (Phelan, Burgess, Yeazel et al., 2015). Previous experience or the expectation of weight-related judgement from health care providers is likely to lead individuals to avoid seeking health care (Drury & Louis, 2002). Individuals with obesity must seek health care as soon as they need it as they are likely to have numerous health issues (Finer, 2015), and are at a higher risk of complications from treatment (Wong et al., 2009). Health care avoidance represents another important effect of weight which can potentially affect QoL, yet it is not included in WRQoL scales.

Within this theme, being judged by others and worry about using public transport were also found. These aspects of WRQoL are included in existing scales, supporting this finding. The majority of the women reported feeling like they were being judged by others when they were overweight and unhappy about their weight. It is as if they had their own negative connotations about being overweight, and they thought that other people would be thinking the same. Those that did not experience this feeling of being judged tended to feel better about themselves and had better self-esteem. Weight-related stigma and discrimination is a common occurrence and tends to become internalised within individuals with overweight/obesity (Carpenter, Hasin, Allison & Faith, 2000; Crandall et al., 1994; Crocker et al., 1993). This may explain the fear of being judged, as they are already judging themselves. Worries about using public transport seem to stem from a fear of judgements from others and the potential embarrassment that could arise. This could again be due to awareness and internalisation of stigma towards obesity (Crocker et al., 1993).

When shopping for clothes, participants indicated that there was a misrepresentation of size and they felt restricted due to current fashions and clothing norms. This represents a feeling of stigma or bias that these individuals with obesity/overweight are experiencing when shopping for clothes. This experience/feeling of weight stigma led to frustration when trying to buy clothes and avoidance of wearing what they wanted. Restrictions when buying clothes in individuals with obesity/overweight has also been found by Thomas and his colleagues (2008). However, aspects relating to clothing and shopping for clothes are not included within existing WRQoL scales.

4.4.5 Issues with Food

Items regarding food were included within the original IWQOL (Kolotkin et al., 1995). In fact, all the items on the Comfort with Food subscale support the findings within the theme of issues with food. However, this domain had issues in the validation of the IWQOL regarding test-retest and internal consistency of the items. This does not mean that issues with food are not important to individuals with obesity/overweight. It could indicate that these items measure concepts that change frequently and independent of weight loss/gain. Issues with food could also be a separate concept which is influenced or moderated by emotions stemming from obesity/overweight. For example, binge eating has been found to be a coping mechanism to escape negative self-weight-related emotions and cognitions (Crocker et al., 1993; Palmeira et al., 2016). This indicates that negative feelings about weight could trigger binge eating as a way to avoid and push negative feelings away. This does support the current interviews as individuals used food to feel better about themselves, but as soon as they had finished eating, they felt regret or guilt. This was especially true if they had eaten something that they considered bad or if they had eaten a lot (binged). These individuals tended to have low self-esteem. The feelings of low self-control indicate they could not control their urges to eat/binge on the “bad”

food as they needed to do it to push away the negative feelings. However, it was found that the men did not attach as much emotion towards food and their eating behaviour. This could be due to differences in the way they feel about their weight. The male's thoughts and feelings about their weight were not as negative as the women's.

4.4.6 Limitations

This study is not without limitations. Firstly, whilst there is no set sample size required for qualitative interviews, it is important within scale development interviews to gain views and experiences from a range of individuals affected by the condition. While these interviews included a range of experiences from people at differing weight loss stages, BMI's and ages, there was a lack of ethnic diversity within the sample. Therefore, the HCF can only be generalised to people of a white/Caucasian ethnicity. This is similar to the qualitative interviews conducted as part of the existing WRQoL scales item generation, where only white/Caucasian individuals were recruited (Kolotkin et al., 2001). Although, the majority of WRQoL scales did not indicate the ethnicity of patients involved in item generation interviews (Camolas et al., 2016; Duval et al., 2006; Ziegler et al., 2005; Mannucci et al., 1999; Le Pen et al., 1998). However, as the findings from these pilot interviews are further explored within the main interviews, where 48 interviews were conducted, this number of interviews involved a wider range of demographics/characteristics. Therefore, the interview schedule developed from these interviews serves as a good, in-depth starting point for item generation and can be further clarified in relation to a variety of ethnic backgrounds.

Secondly, whilst this study had found aspects of WRQoL that are missing from the IWQOL-Lite, some aspects were not found, that the IWQOL-Lite measures. These aspects include issues relating to public distress and work productivity. As this study

involved individuals across the weight spectrum, this could represent a difference in the occurrence of these aspects for individuals in lower BMI groups. However, the next phase of this research programme incorporated cognitive debriefing interviews, using the IWQOL-Lite that allowed further exploration of these aspects.

4.5 CONCLUSION

The pilot interviews found excess weight to affect physical health, psychosocial health, body image, experiences in public and issues with food. Aspects not currently measured by existing WRQoL measures include experiences when shopping for clothes, using clothes to hide body shape and possible health care restrictions. These aspects have clinical implications, and so it would be beneficial for these aspects to be included within a WRQoL scale. Differences in finding from other scales are thought to be due to the broader range of BMI's used within this study and the different country/culture in which the scales were developed. Within the next chapter, these findings will be further explored to generate items for a new WRQoL scale.

The results of these interviews inform the need for a new WRQoL scale due to themes emerging that are missing from existing scales. They also lead to the development of an interview schedule to be used within the item generation interviews for the new scale. This collaboration with the target population in developing the interview schedule ensures that the subsequent interviews will be meaningful for the participants.

5 DEVELOPMENT OF A WEIGHT-SPECIFIC HRQOL MEASURE

5.1 WHAT HAS BEEN ESTABLISHED SO FAR?

The previous chapters have shown obesity to be a disease that not only affects physical health but QoL as well. Measuring QoL in obesity is essential to provide a more holistic view of the impact of weight on individuals, as well as the evaluation of weight-loss interventions. When measuring HRQoL in a specific disease population, the measure should be specific to that population. This is because diseases can affect QoL in different ways, due to variations in symptoms and stigma related to diseases. Therefore, to measure HRQoL accurately within individuals with obesity, a weight/obesity specific questionnaire should be used.

In chapter three, existing obesity specific HRQoL scales were reviewed and evaluated. The majority of existing scales lacked evidence for the psychometric properties outlined by the COSMIN checklist and FDA guidance. More importantly, the scales lacked evidence for content and face validity. For example, the IWQOL-Lite is the most used WRQoL scale. Yet, the final items have never been tested using cognitive debriefing interviews to evaluate content and face validity or user understanding. It was concluded that there was a need for an obesity specific HRQoL measure, that is sensitive across differing weight loss stages. No other scales have been developed by exploring WRQoL at differing weight loss stages.

Chapter 4 reported the start of the process for the development of a WRQoL scale, using the target population to explore the effects of weight on different aspects of life. This

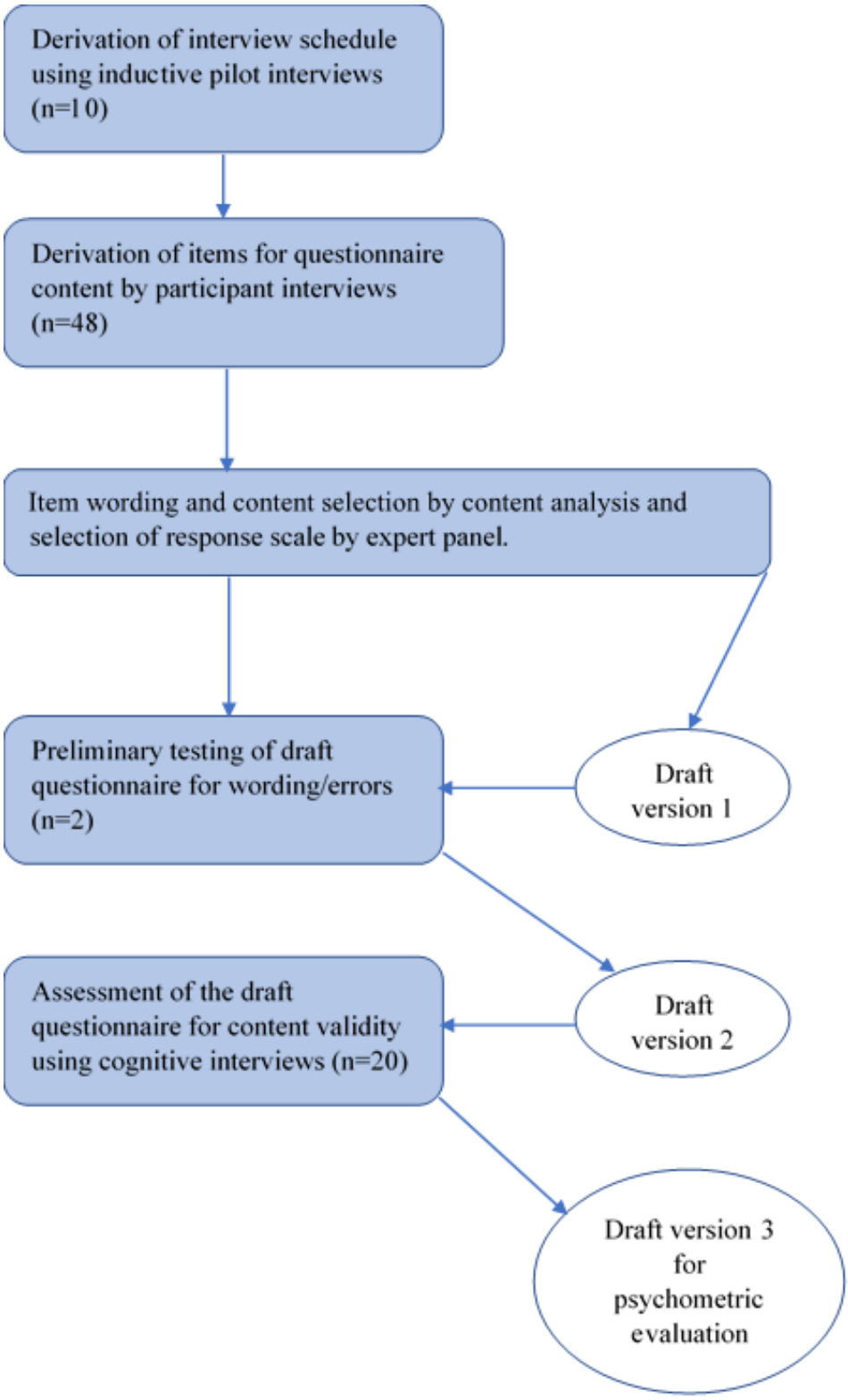
initial exploration led to a hypothesised conceptual framework of WRQoL, which will help to guide the item generation interviews for a new WRQoL scale.

5.2 ITEM GENERATION AND TESTING THE FACE/CONTENT VALIDITY OF THE DRAFT VERSION OF THE NEW SCALE

If the new measure is to be used as a comparative measure from before weight loss to after weight loss attempts, then the way people feel and are affected after losing weight needs to be assessed. These *changes* need to be measurable by the scale: it needs to be sufficiently sensitive to measure meaningful changes, even if they are small. The scale should be able to evaluate longitudinal weight-loss interventions and how these affect WRQoL rather than just how weight negatively affects QoL in cross-sectional work.

In this chapter, the qualitative methodology was continued from chapter 3 to explore further the impact of carrying excess weight on individuals' lives. Subsequently, the analysis of the qualitative data enabled the generation of scale items and ultimately, the development of a quantitative HRQoL questionnaire. The development of the new instrument involved numerous steps, starting with the derivation of the interview schedule for the item generation interviews (see Chapter 4), item generation though interviews and an expert panel, and testing for content validity using cognitive interviews (see Chapter 5). The thesis finishes with the initial evaluation of the draft scale (see Chapter 7 for psychometric evaluation). *Figure 5.1* shows the process of scale development followed to develop the draft WRQoL scale.

Figure 5.1 Process of scale development followed



5.3 AIMS OF THIS CHAPTER

This chapter aims to:

a) Evaluate the content/face validity of the IWQOL-Lite
b) Develop a new WRQoL scale using qualitative interviews with a UK sample and with input from experts
c) Test the face/content validity of the new WRQoL instrument in a UK sample

5.4 METHODS

5.4.1 Research Design

A cross-sectional and qualitative research design was undertaken to generate items for a WRQoL scale, using one-to-one interviews. Cognitive interviews were also conducted to evaluate the content validity of the IWQOL-Lite. Interviews were analysed using thematic analysis.

5.4.2 Ethics and consent

The study was approved by the PSYSOC Ethics committee at UCLan before data collection (see Appendices 3). Potential participants were given all the details of the research, including their right to withdraw, and the contact details of the researcher, director of studies and the officer for ethics, in the form of a PIS (see Appendices 3). The PIS was either handed to or emailed to potential participants. Written consent was gained from all participants via Consent form version 2 (see Appendices 3). Participants were asked to read each section of the consent form and initial in the boxes to indicate they were happy with each section. They were asked to print and sign their name at the bottom of the consent form. A debrief sheet was given to all participants to reiterate the information given in the PIS (see Appendices 3). The procedure for data storage was the same as that used in the pilot interviews (see section 4.2.2). As in the pilot interviews,

there was a potential for the topic to be sensitive and upsetting for participants, so the intervention rules and signposting described in section 4.2.2 were followed.

5.4.3 Participants

5.4.3.1 **Recruitment**

Participants were recruited using convenience and opportunity sampling in the same locations as in the pilot interviews (UCLan and community locations; see *Table 4.1* for how permission was gained at these locations and *Figure 4.2* for the recruitment process). Recruitment also took place via Facebook and at a Slimming World (SW) group. The research poster used in the pilot interviews was used for these interviews also as the content was still relevant. The colour of the poster was changed to represent a separate aspect of research (see Appendices 3).

5.4.3.1.1 Slimming World

Permission was gained to display the research poster in the SW meeting room from the session leader via a volunteer who was responsible for weighing the SW members. The researcher did not attend the SW group meetings as permission was not given for this. The session leader did not want the members to feel pressured into participating. This was despite the assurance that no pressure would be placed on them to participate. Whilst the research poster was displayed in the SW meeting room, only two participants were recruited from this location. This location was not visited by the researcher, so it is unknown how long the poster was displayed for. In future, attendance at the recruitment location would be beneficial to have some presence and allow individuals to ask questions face to face.

5.4.3.1.2 Facebook

The research poster was posted on the following community Facebook groups and pages:

a) Padiham community talk

b) Tottington what's on

c) Tesco Haslingden

d) Fit4Life friends

These locations were chosen as they were areas the researcher could conveniently travel to and contained people from the community. An administrator of each page was contacted to gain permission before posting. Individuals that responded to the research posters were emailed the PIS. If no response was received after two weeks, the individual was contacted once more to check if they were interested in taking part. They were not contacted again if they did not respond or if they indicated that they did not want to take part.

5.4.3.2 Sampling, Eligibility Criteria and Representation

Individuals that were residing in the UK, aged 18 and over and had been overweight or had a BMI of 25kg/m^2 and over, were eligible for the study. To ensure a representative sample of participants, the four key variables included in Chapter 4 (see section 4.2.3) were represented in the sample. These were BMI category (normal weight, overweight, obesity I, obesity II, obesity III), weight loss status (no attempts, unsuccessful, successful, regained), gender (male, female) and age (18-29, 30-49, 50+). The representation of the key variables was checked after 30 interviews to ensure no variables were underrepresented.

Exclusion criteria included individuals who had never been overweight, were pregnant, diagnosed as terminally ill, seeing a doctor for an eating disorder or a chronic disorder which has resulted in their weight gain, and individuals who were unable to stand unassisted. These exclusion criteria were indicated at the bottom of the research poster (see Appendices 3). Despite including the exclusion criteria on the research poster, one participant who had never been overweight was interviewed. They were both sent the PIS with further details of the exclusion criteria, yet they did not inform the researcher that they had never been overweight. In future, participants should be thoroughly screened before interviews take place to ensure all participants are eligible for the research.

5.4.3.3 **Participants recruited**

A total of 68 people expressed an interest in taking part. Of those 68 individuals, 19 were not interviewed (two did not meet criteria, and the rest changed their mind about taking part). Qualitative data were collected at numerous locations across the North West of England over a five-month period (Nov 2017 – March 2018). Given the range of key variables to be explored, 49 participants were interviewed before no new themes or subthemes were emerging. One participant's interview was not included in the analysis as it emerged during the interview that they did not meet the inclusion criteria. Of the remaining 48 participants, 43 (90%) identified themselves as White/Caucasian, and 5 identified themselves as Asian (10%). Thirty-seven participants (77%) had a BMI of 25 and above at the time of the interview. BMI ranged from 21 to 46 (*mean = 32*), and the age of participants ranged from 18 to 70 years (*mean = 41*). The majority of participants reported regaining previously lost weight (63%), with 14% reporting successful weight loss. Participant demographics and characteristics can be seen in *Table 5.1*.

Table 5.1 Participant Demographics and Characteristics

Age – mean (SD)	41 (14.9) [18 – 70]
BMI – mean (SD)	32 (6.2) [21.0 – 46.2]
Waist Circumference – mean (SD)	100 (16.7) [71 -144]
Gender	31 females, 17 males
Ethnicity	
White	43 (90)
Asian	5 (10)
Weight Loss Status – number (%)	
Successful	14 (29)
Unsuccessful	1 (2)
Regained	30 (63)
No Attempts	3 (6)
Employment Status – number (%)	
Employed	28 (58)
Unemployed	4 (8)
Student	10 (21)
Retired	5 (10)
Marital Status – number (%)	
Married	20 (42)
Living with another	7 (15)
Divorced	5 (10)
Single	15 (31)

The majority of participants were recruited from Facebook (56%), and via UCLan's SONA system (31%). The number of participants recruited from each poster location is displayed in *Table 5.2*.

Table 5.2 Place of recruitment

Place of recruitment	Number recruited
Slimming World	2
UCLan SONA	15
Facebook community pages	27
BPRCVS NL	1
Referral from previous participants	4

5.4.4 Materials and Measures

The Olympus Voice Recorder, Tanita Digital Medical Scales, Stadiometer and Measuring tape were all used as in chapter 4 (see section 4.2.4 for details).

5.4.4.1 **IWQOL-Lite Items**

The 31 items from the IWQOL-Lite (Kolotkin et al., 2001) were listed with the response scale as described in (Kolotkin et al., 2001). This scale includes five subscales of physical functioning, self-esteem, public distress, sexual life and work. The questionnaires were not scored but used for cognitive debriefing interviews to evaluate the content validity and the comprehensibility of the scale (see Appendices 3).

5.4.4.2 **Interview Schedule**

The interview schedule for the main interviews was split into two sections (see Appendices 3). Section A contains questions which cover the participants' experience of filling out the IWQOL-Lite items along with their understanding of the items and the relevance of the issues covered in the IWQOL-Lite items. Section B was based on the results of the pilot interviews. There were a series of questions and prompts for each theme identified within the pilot interviews to gain a more in-depth insight into how weight affects these aspects. Sections A and B were counterbalanced, so half of the participants completed the IWQOL-Lite items before the main interview. The other half completed the IWQOL-Lite after the main interview. This was to minimise the effects of the IWQOL-Lite items/concepts on the participants answers regarding the effect of weight on their life.

5.4.5 Procedure

Participants were asked to read and sign the consent form before the interview began. Once completed, the participants right to withdraw was reiterated, and they were given an opportunity to ask questions. The interviews/interview schedule was split into two sections. Section A involved the participant completing the items of the IWQOL-Lite before the interview commenced. Before completing the IWQOL-Lite participants were asked to think about the meaning and relevance of each item. They were told that notes could be made on the questionnaire, and they would be asked questions about their experience of filling out the IWQOL-Lite. The interview schedule for this section contained questions regarding the experience of completing the scale and the issues covered by the IWQOL-Lite. This was to explore the content validity across the weight-spectrum in a UK adult population. Section B was based on the analysis of the pilot interviews and further explored the hypothesised conceptual framework of WRQoL. The schedule for this section was adapted as necessary. Section A and B were alternated to minimise order effects.

For interviews starting with Section A, recording commenced after the participant had completed the IWQOL-Lite items. For interviews starting with Section B, recording commenced once the participant had completed the consent form and had been given a chance to ask questions. The voice recorder was paused while participants completed the IWQOL-Lite items and started again afterwards. At the end of the interview, the interviewer summarised the participant's main points to ensure the correct interpretation. The recording was then stopped, the participants filled out a demographic questionnaire, and their measurements were taken. Measurements were taken in the same way and with the same equipment used in the pilot interviews (see section 4.2.4.1). However, some participants indicated that they would like their measurements taken before the interview

took place, and so measurements were taken after completing the consent form in this scenario. Participants were debriefed and thanked for taking part. If participants indicated that they would like a summary of the research results, they gave a preferred method of contact (email or postal address). They were informed that they would receive the summary at the end of the PhD programme.

5.4.6 Analysis of data

As with the pilot interviews, thematic analysis was used to analyse the item generation interviews (see section 4.2.7). All interviews were audio-recorded, and after each interview, a summary was written as soon as possible. The summary included information about how weight had impacted the participant's life. Interviews were transcribed verbatim by an approved company, in two batches of 30. The recordings were uploaded to the companies secure online site on a private password protected log in. Once the transcripts were ready, they were downloaded from the same password-protected account.

All transcripts were analysed within NVivo 11. As the transcripts were received back, each one was checked for errors or misinterpretations by listening to the recordings, reading the transcript, and checking the researchers notes made during and after each interview. The transcripts were then read and re-read to enhance familiarity with the data. These interviews were analysed separately from the preliminary interviews. Once analysed, the results were compared and combined.

5.4.6.1 **Strategies used to enhance the credibility of findings and data analysis**

To ensure the reliability of the interview analysis, all transcripts were analysed separately by a second researcher, with no previous involvement in the research programme. Discussions on the codes used, emerging themes and the theme structure took place at

three points during the analysis of the interviews. There were no major disagreements in the themes. Differences were generally due to wording of theme names. In this case, the transcripts were referred to in order to use wording close to the language used by the participants.

5.5 RESULTS

Eight themes emerged from the analysis of the interviews. *Figure 5.2* illustrates the theme map from these interviews. The themes identified were Physical Symptoms/Factors, Issues with Mobility, Taking part in Physical Activity, Psychosocial Experience, Feelings towards Themselves, Work, Self-Control with Food, Choosing Clothing, and Support.

In comparison to the preliminary interviews, the theme map from the item generation interviews is more detailed due to the larger sample sizes creating a greater understanding of WRQoL in this sample. The themes and subthemes are labelled slightly differently, but all aspects of the pilot interviews were covered in this phase. Themes represent areas of life affected by carrying excess weight. A brief description of each is given to avoid repetition from the pilot interview. *Table 5.3* provides quotes to support each theme and subtheme with the percentage of participants who had experienced the issue included.

Figure 5.2 Theme map from item generation interviews

Table 5.3 Themes and Quotes from Item generation interviews

Domain	Items	% expressed by p's	Example quotes
Physical Symptoms	Aches and Pains	54	*"I do sometimes have painful joints. My right hip, sometimes I do feel a bit of pain in." (P040, F, BMI Obesity I)* *"...my back starts aching and that's because I'm overweight, I know it is, and my right knee that's always clicking and aching and I'm putting it down to weight because a few years ago I lost about three stone in weight and I felt so much better." (P020, F, BMI Obesity III)*
	Health Conditions/Scares	69	*"I've never had a problem with high cholesterol or blood pressure, but I thought as I'm getting older and my weight was going up and up I thought it was not going to carry on being like that. It would have got worse, I did worry about my health." (P021, F, BMI Obesity II)* *"I knew I wasn't a healthy person, but it didn't dominate my thoughts or anything like that." (P018, M, BMI Obesity I)* *"Well, I'd had three heart attacks beforehand so, yes, it was all done for that." (P026, M, BMI Overweight)*
	Breathlessness going upstairs	50	*"Well, it doesn't look good if I go to a patient who lives in say flats and they're upstairs, by the time I get to the house I'm huffing and puffing." (P015, F, BMI Obesity II)* *"I'm tired walking up a flight of stairs, out of breath and I can't walk as far as... I can walk but I'm out of breath" (P013, F, BMI Obesity II)*
	Energy	58	*"It definitely had an impact with the general lethargy and just feeling [exhale] I can't be bothered." (P012, F, BMI Overweight)* *"But it's the energy levels as well I think. Yes, the energy levels are improved when you're not carrying as much weight really around." (P029, F, BMI Obesity III)*
	Sleep Disturbance	19	*"My neck was 22. I used to stop breathing at night. But that's gone. I used to stop breathing completely." (P026, M, BMI Overweight)*
Limitations in Mobility	Difficulty Walking	35	*"Walking, I used to struggle walking a bit. Come back from walking and I'd be sweating. Go for a walk now and it's just a walk, I could do it ten times a day if I wanted." (P026, M, BMI Overweight)*

			"Yeah, my knees have gone, my hips have gone and I was a walker. I used to walk but I can't walk, I can't do the walking" (P045, F, BMI Obesity II)
	Difficulty Bending down	29	*"I wouldn't have been able to reach my feet, when I was bigger." (P025, F, BMI Overweight)*
	Difficulty getting up from seated	15	*"Occasionally I did have trouble getting up from chairs, but that depended immensely on the chair." (P034, F, BMI Overweight)*
	Fitting into tight spaces	23	*"Actually getting in and out of the car, thinking about parking space. I'm not disabled. I could be registered I think with my legs but I have a Land Rover, I park. I have a Freelander so I have to be sure I can park where I can, because I can't bend this leg and my stomach and make sure I have enough room. So, I consider, really consider, where I park. So I can get in and out." (P029, F, BMI Obesity III)*
	Difficulty Washing	4	*"Do you know what nobody tells you about being fat? It's that you really struggle to wipe your bum." (P025, F, BMI Overweight)* *"It's more awkward. Keeping yourself clean." (P045, F, BMI Obesity II)*
Psychosocial Experience	Feeling self-conscious	100	*"But it is always in the back of your mind that people are watching you thinking, "Oh, well, she's a really slow swimmer because she's so fat." It's like constant things in the back of your mind that put you off." (P013, F, BMI Obesity II)*
	Low self-confidence	75	*"The main effect, I think, was confidence in social encounters." (P034, F, BMI Overweight)*
	Less enjoyment of social activities	52	*The only one I'm going to go to is Christmas one, I do go to the Christmas one, but I can't say I overly enjoy it. Because we have a meal, so then I'm conscious again. (P015, F, BMI Obesity II)* *It doesn't stop me socialising, but I don't enjoy socialising. (P032, F, BMI Obesity II)*
	Limited participation	69	*"There was a lot of downtime to enjoy and the company had laid on these water sports activities but I had to say it wasn't for me and I would've loved to have done it but I just stayed lying around covered up so it affected that." (P012, F, BMI Overweight)* *"Although I did go and do sport and stuff like that, my friends would say they want to go to the swimming pool or stuff like that, in Blackpool they have the sand castles, the waterslide and stuff like that, and I never really wanted to get involved with anything like that because I didn't like taking off my clothes and showing my body." (P019, M, BMI Overweight)*
	Sexual Confidence	48	*"It also has an effect on my sex life. Having the confidence to be more intimate with my husband." (P040, F, Obesity I)*
	Self-esteem	56	*"I hate myself because I'm putting that weight on." (P017, F, BMI Obesity II)*

Feeling towards themselves			*"I realised that a lot of things, like, physically I'm not really impeded by my weight but it's more just how I feel about myself." (P057, F, Obesity I)*
	Body Dissatisfaction	92	*"I didn't like the sight of myself anymore, I looked in the mirror and thought 'that's not nice, why would anybody else want to look at that'. So it was 'do something about it then, get on with it'." (P014, M, Obesity II)*
Issues with Clothing	Hide body shape	83	*"I tend to wear baggy shirts and things so that it's not obvious. So, yes. I try to hide being overweight, I suppose." (P011, M, BMI Obesity I)* *"When I did lose weight it was nice to be able to think I could get a t-shirt that finishes there and it doesn't matter about hiding my stomach if I've got my jeans on or something." (P029, F, BMI Obesity III)*
	Don't look good in clothes	58	*"I'd love to be able to wear some of the clothes but they don't, I can't, I wouldn't look right because I've got tyres popping out all over the show." (P015, F, BMI Obesity II)* *"So, you start thinking like that because 'dress up' things, they don't look as nice when you're a rounder shape and so, you just want to be comfortable most of the time." (P053, F, BMI Obesity I)* *"Before I'd wear ridiculously tight t-shirts because I looked good. I thought I looked... I did look good. I liked the way I looked. Now, everything's baggy, over-sized." (P037, M, BMI Obesity II)*
	Dislike shopping	69	*"choosing clothes and shopping for clothes, I just don't do that while I'm overweight. I just find it too disheartening and too, not that I'm blaming it on anyone else, but it's just not...I don't take any pleasure in it." (P032, F, BMI Obesity II)* *"A special shop, and you walk in and the worst thing in the world is when you're in that cubicle and you try something on and you look at the full-length mirror and you think "God". And I come out... you could ask my wife this like my jackets now are XXXL, my trousers are like 50-inch waist, and I come out and, "I'm never going in that shop again. No, no, I don't want to do that again." (P035, M, BMI Obesity III)* *"It will sound daft. When I lost the weight, when I was getting into 34-inch waist trousers, I thought it was fantastic because I had everything available to me. There was nothing I couldn't wear. I even went as far as skinny jeans." (P011, M, BMI Obesity I)*
Self-Control with Food	Comfort Eating	75	*"I was an emotional eater and I'm an emotional person, so I would just chomp. If I was in and I wasn't going out I would be thinking everyone is out on a Friday night and you know why you're not out, because your fat and then I would eat. Four or five packets of crisps and a couple of chocolate bars." (P031, F, BMI Normal weight)*

	Calorie Restriction	73	*"I stuck to it because I'm really stubborn. But I wasn't happy whilst sticking to it. There was nights where I was eating a bowl of cauliflower rice and chicken curry made from chicken and quark and I'd just cry while I was eating because I just wasn't happy with the food that I was eating and I didn't feel ever satisfied…" (P042, F, BMI Overweight)*
	Food Awareness	29	*"I wouldn't really think about what it was eating through the day or, so even just little things like I used to have scrambled egg on toast every day, I still do have scrambled egg on toast most days, but I have one piece of wholemeal bread with no butter, whereas before it would be like two bits of white bread, butter on the toast, butter in the eggs, full fat milk." (P044, F, BMI Obesity III)*
	Negative thought processes after eating	73	*"I instantly feel guilty and I know that because I'm at work all day I'm not going to get a chance to go to the gym and work that chocolate bar off or that chocolate digestive off." (P040, F, BMI Obesity I)* *""Why didn't I just have ten?" So, then I'll refer to myself, saying, "You fat bastard," and stuff like that. So, you internalise that as guilt and stuff. So, it was regret." (P055, M, BMI Obesity II)*
	Eating in Public	29	*"sometimes we'll go to Asda Café, and I won't have … say I've got sausage, chips and beans, at home I'd have bread, but if we go out, I wouldn't because I feel like people are judging me thinking, "Look at her. Gluttony. Having it all on a sandwich." (P024, F, BMI Obesity I)*
Support	Health Care Professionals	42	*"They sent me to the podiatrist, this woman she said to me, she said to me, she done all these sorts of tests and said I can't give you insoles until you get your BMI down to 25, come back and see me in six months. I went back to see her in six months and of course my BMI is no different because I hadn't lost any weight, so she said the same thing again. Every time I went, I went three times and every time she was really horrible. I cried all the way home every time and I swore I would never ever go to one of them. Really horrible she was" (P021, F, BMI Obesity II)*
	Family and Friends	52	*"She'd say, "How can you eat all that and lose weight?" I said, "I don't know, but it works." And then she'd come in with fish and chips and stuff like that and I thought, "There's something not quite right here." So she was no support whatsoever to be fair" (P023, M, BMI Obesity II)* *"Yeah, I guess, instead of doing the opposite, encouraging me to lose weight, which was the better option, but instead, they do the opposite and just try and be nice I feel like." (P030, M, BMI Normal weight)*
Work	Maintaining a Professional Appearance	21	*"I couldn't do it because then I'm having to find something that looks professional, that looks smart, that I feel comfortable in, and it's dressy clothes. A lot of the time you go for jeans and a floaty top, but you wouldn't be able to wear jeans at work." (P024, F, BMI Obesity I)* *"I do worry sometimes that because I can't dress the way I want to dress to go to work, I sometimes worry that it's affecting the way that other people view me as a professional." (P025, F, BMI Overweight)*

			"So yes, it was a bit difficult trying to maintain a smart appearance at work without ending up looking as though you were in a straightjacket." (P034, F, BMI Overweight)
	Being Taken Seriously	21	*"it's indirectly because where I used to work before, years ago, when I first started there, I was overweight, and it was fine, the job was fine, and nobody was cruel about my weight or anything. But then when I lost my weight I was treated different… I think they took more notice, I felt like, now when I look back I felt like they took me more seriously and I did move on in the company." (P021, F, BMI Obesity II)*
	Productivity	10	*"You're up and down on your knees and stuff like that, so that's quite hard work being big and just things like making a bed in the hospital. You know the beds are quite close together so things like that, you don't really think about it but yeah it does restrict what you're doing in terms of that, so yeah." (P044, F, BMI Obesity III)*

5.5.1 Physical Symptoms/Factors

5.5.1.1 **Aches and Pains**

Twenty-six participants experienced either discomfort, aches or pains due to their weight. This was reported the most in their knees and back but also their joints in general, hips and feet. The pain was more frequent and experienced in more places for those with a higher BMI and non-existent in those who had a normal BMI. Those who had lost weight indicated that the pain they experienced at a higher weight was not as frequent or as bad anymore. This suggests that pain increases with increasing weight and can potentially be improved with weight loss. As in the preliminary interviews, both males and females reported issues with discomfort or pain when overweight.

5.5.1.2 **Health Conditions/Scares**

Individuals who were overweight or had been overweight believed that their weight had caused them to develop a health condition or at least contributed to that. Those whose health had not been affected, along with those that had, expressed concern for their future health if they did not lose weight. Thirty-three participants expressed concern for their health due to their weight. This ranged from a small concern they thought about now and again, to constant worry. Similar to the preliminary interviews, both men and women expressed concern for how their weight was affecting their health.

5.5.1.3 **Breathlessness with little activity**

Half of the participants experienced breathlessness when climbing stairs, this varied with BMI. Those with a higher BMI experienced breathlessness with little physical activity or movement (for example, walking). In contrast, those with lower BMI's (obesity I and overweight) indicated that they would only become breathless when being more physically active, for example, multiple flights of stairs or running. A few participants

with BMI's in the obesity III category reported chest pains with activity along with the breathlessness. This breathlessness was embarrassing for some participants as they could not hold a conversation with their friends, family members or work colleagues when walking. In some cases, this embarrassment of being breathless caused them to avoid physical activity with others. This again was similar to the preliminary interviews with women being more likely than the male participant to report avoiding physical activity or social activities involving physical activity due to the potential embarrassment.

5.5.1.4 **Energy**

Similar to breathlessness, carrying extra weight was seen to be contributing to or causing low energy levels and fatigue. This was the case for 28 participants. In some cases, this led to physical discomfort while exercising, feeling self-conscious when exercising, and in more extreme cases, the avoidance of physical activity due to feeling lethargic. When weight was lost, participants reported feeling more energetic and more motivated to exercise and socialise.

5.5.1.5 **Sleep Disturbance**

Nine participants (four males and five females) indicated that they had trouble sleeping. This was in terms of poor sleep quality, snoring/sleep apnoea and struggling to get to sleep. In some cases, snoring had led them to sleep in separate rooms from their partners as they were disturbing their partner's sleep.

5.5.2 Mobility

Half of the participants indicated that their weight negatively affected their ability to move. Aspects of limited mobility affected their physical activity levels; for example, they can no longer exercise like they used to. The most common problems were bending

down, getting up from a seated position, walking and standing for long periods, breathlessness going upstairs and difficulty with washing.

5.5.2.1 **Difficulty walking**

Eleven females and six males indicated that their weight affected their ease of walking. This was either due to discomfort and pain or becoming breathless. At the extreme end, some participants found it a struggle to stand for long periods and needed to sit down more often when they had been very overweight. Those that had successfully lost weight found it easier and generally less painful to walk since losing weight. Although, some indicated that joint pain that had occurred when they were overweight returned when walking and doing more rigorous physical activity even when they had lost weight. While this suggests that they are still affected from previously carrying excess weight, the pain and ability to walk comfortably had.

5.5.2.2 **Difficulty bending down**

Fourteen participants spoke about struggling to bend down to reach their feet or to pick something up off the floor. Examples of this include struggling to tie or put shoes on due to not being able to reach their feet. This even led to some participants avoiding shoes with laces. Cutting toenails and treating toe conditions was also problematic for some participants, as reaching their feet was difficult and uncomfortable for them. Difficulty bending down occurred in both men and women.

5.5.2.3 **Difficulty getting up from a seated position**

Seven participants indicated that they had difficulty getting up from a seated position. This tended to be those who had knee pain and limited mobility in their legs due to their weight. Trouble getting up from a chair largely depended on the height of the chair; low

chairs being more difficult than higher, more upright chairs. This included getting off the floor and getting off the toilet. Only two males reported an issue with getting up from a seated position.

5.5.2.4 **Fitting into tight spaces**

Eleven participants reported difficulties and worries regarding fitting into tight spaces. These included getting in a bath, getting in/out of a car, aeroplane seats, fairground rides, toilet cubicles and turnstiles. Many of these participants stated that they were conscious and embarrassed about taking up too much space on chairs or "overflowing" onto the next chair.

5.5.2.5 **Difficulty washing**

Two female participants indicated that they had trouble "wiping their behinds" after visiting the toilet when they had been at their largest. They had not got to a point where help was required but believe they would have done if they had put more weight on. This was not mentioned by males or any other participants, but this could be due to the embarrassing nature of the issue.

5.5.3 Psychosocial Experience

5.5.3.1 **Feeling self-conscious**

All male and female participants reported feeling self-conscious about their weight. This was represented by feeling like people are watching them, not wanting people to see them, and worrying what people are thinking about them or that they will be judged due to their weight. This self-consciousness was related to having low self-confidence in social situations and their enjoyment of social activities. Being self-conscious lowered their self-confidence and meant that they could not enjoy social activities. Feeling self-conscious

and lacking self-confidence because of their weight led to some participants avoiding socialising in public with their friends. This was because they were worried people would judge them negatively because of their weight.

5.5.3.2 **Low self-confidence**

Similar to the self-consciousness subtheme nearly all males and females reported lacking confidence and feeling shy in social situations. They found it difficult to meet and talk to new people as they were worried that they would be judged negatively based on their weight and appearance. This also occurred at work where one woman was worried that her new colleagues were *"…going to look and think 'Oh well, she's going to be useless because she's fat'*". Male participants also expressed a belief that they would be judged because of their weight. Most participants reporting these feelings also reported an improvement in confidence when they lost weight as they felt more positive about their appearance.

5.5.3.3 **Less enjoyment of social activities**

Feeling self-consciousness and having low self-confidence affected the enjoyment experienced by participants in social activities, social occasions and on holidays. Some participants looked back on occasions and expressed how they would have been able to do more and enjoy themselves more if they had been a lower weight. Participants could not enjoy social activities as they were too concerned about their appearance, trying to hide themselves to stop people from noticing their weight. Their minds were preoccupied with their weight, appearance and the worry of being judged by others. A lack of physical fitness, experience of pain and lack of mobility because of their weight also meant that did not enjoy or look forward to social occasions the participants would enjoy when they were at a lower weight. A few female participants worried that they were a burden on

their friends and family when they joined them in social activities involving physical activity. Being a burden on their family on friends was not mentioned by male participants. However, ten men did state that their weight affected their social activities through a being preoccupied with their appearance, worrying what others think of them or through being physically uncomfortable due to a lack of fitness.

5.5.3.4 **Limited/restricted participation**

Thirty-three participants expressed how their weight had limited their ability or willingness to take part in social activities. This ranged from the extreme of avoiding social activities altogether due to not wanting to be seen in public, to having to watch their friends or family do activities as they were not physically fit or mobile enough to join in. When weight was lost, and their physical fitness and mobility had improved, they were able to participate in more activities that they would have previously avoided. There was also avoidance of activities that involved having their body on show, for example, going on 'hot' holidays and going swimming as they were self-conscious of their bodies due to their weight. This was reported by both men and women; however, more women indicated that they would avoid social activities because of their weight.

5.5.3.5 **Sexual confidence**

Twenty-three participants expressed a lack of sexual confidence. This was more common in those who felt they had put weight on. Feeling unattractive led to them avoiding sexual activity with their partner as they did not want to be seen naked. However, there were different experiences as some participants who were married felt comfortable being naked and taking part in sexual activity with their partners despite their weight. One participant expressed how carrying excess weight meant that she was more creative when it came to sexual activities with her partner. She saw this as a positive and was satisfied with her sex

life despite having obesity. Sexual confidence was spoken about more by female participants (*n = 19*) than male participants. The male participants that spoke about their intimate relationships expressed a lack of confidence when it came to meeting potential romantic partners (*n = 4*). Males who were married indicated that their weight did not affect their sexual confidence with their partners.

5.5.4 Feelings towards themselves

5.5.4.1 **Self-esteem**

For 27 participants, carrying excess weight had affected their self-esteem. This was represented by feeling uncomfortable with themselves, disliking themselves, feeling inadequate and worthless when they were at a higher weight. When weight had been lost, they reported feeling good about themselves and a sense of pride from losing weight. Lowered self-esteem was reported most in female participants than male participants (*n = 7).* However, similar descriptions and experiences of low self-esteem were given by both genders and seemed to be more extreme in the higher BMI categories and improved when they had lost weight.

5.5.4.2 **Body Dissatisfaction**

Forty-four participants had experienced body dissatisfaction when they were unhappy with their weight. This was when their BMI's were in the overweight and obesity categories and occurred in both men (*n = 16*) and women (*n* = 28), unlike the pilot interviews. They reported being unhappy with how they looked, unhappy with their body shape (or specific parts of their body shape). This body dissatisfaction, for some, led to comparing how they looked to others, avoiding having their pictures taken and avoiding looking in mirrors. However, some individuals did not avoid mirrors even though they disliked their appearance, but they would feel uncomfortable and upset when they saw

themselves. The males that expressed dissatisfaction with their appearance indicated that they only realised how “bad” they looked in certain situations. For example, if they saw their reflection or a picture of themselves, or when they were going to take part in an activity like swimming where their “belly” or “man boobs” would be exposed or an activity that involved attracting a potential partner. For women, on the other hand, their dissatisfaction with their appearance seemed to be on their mind a lot more often than males, as they would often compare how they looked and their clothing to other women. This suggests that while body dissatisfaction is present in both males and females with overweight or obesity, females are more aware of this on a daily basis compared to males who become aware once triggered by certain situations.

5.5.5 Issues with clothing/clothes shopping

This theme is closely linked to body image. It includes the subthemes of “hiding body shape”, “do not look good in clothes”, and “dislike shopping” for clothes. It was clear that those with poorer body image had more issues and negative feelings towards clothing and clothes shopping. Poor body image led to a need to hide their body shape (or aspects of their body they disliked) using baggy or dark clothes. It also meant that they did not like how they looked in clothes. Whereas, when they had been at a lower BMI, participants reported feeling and looking good in their clothes and wearing tighter, more revealing clothes. When it came to shopping for clothes, those with poor body image or high BMI's experienced feelings of frustration and despair, these feelings led to avoiding clothes shopping until completely necessary to avoid the discomfort. On the other hand, when weight was lost, there were more positive feelings as there was more availability in the clothes they could buy. Both men and women reported issues with clothing and shopping for clothes.

5.5.6 Self-Control with Food

5.5.6.1 **Comfort Eating**

Over half of the participants (*n = 36*) indicated that they regularly comfort ate. They reported eating when they felt sad, stressed and for some bored, despite wanting/trying to lose weight. While they were aware that they did this, some participants expressed how they felt out of control with this. This reflected comments made in the pilot interviews. Comfort eating was reported more in females (*n = 27)* than males (*n = 9*), but they expressed similar reasons for comfort eating and both indicated the guilt, shame or regret they feel afterwards.

5.5.6.2 **Calorie Restriction**

Thirty-five participants detailed their past experiences of dieting to lose weight. Many indicated that they felt as though they were "*always on a diet"* and yet they felt they "*had got nowhere"* or they "*always break them*". These diets were a form of calorie restriction and led to them not enjoying the food they ate and constantly thinking about food and being hungry. The diets usually ended in comfort eating and feeling out of control. Those who successfully achieved their goal weight through dieting indicated how they were still following the diet to maintain their goal weight. Others expressed how they put the weight back on once they stopped their diet and so ended up "*yo-yo dieting*". Both men and women spoke about being members of slimming clubs and how they felt frustrated or disappointed if they had put weight on at their weekly meeting. This would then lead them to buy unhealthy food or comfort eat afterwards making them feel worse.

5.5.6.3 **Food awareness**

When overweight and not trying to lose weight, participants reported not thinking about what they ate or how much they ate while they were eating. If this occurred in participants

trying to lose weight, this made them feel out of control of their eating and their weight. On the other hand, some individuals who had successfully lost weight reported an increased awareness of their eating and felt more in control of both their eating and their weight.

5.5.6.4 **Negative thought processes after eating**

When individuals had been comfort eating or had a lack of awareness while eating, they experienced negative feelings either directly after eating or the next day. These negative feelings included embarrassment, guilt, feelings of failure and wasted effort and also disappointment with themselves. While this was more common in those who were unhappy with their weight (due to being overweight), it was still present in those that had successfully lost weight and were now happy with their weight. This negative association with food could suggest an unhealthy relationship with food, especially if it does not improve after weight loss. Negative processes after eating were highlighted in 35 participants, and it occurred in both men (*n = 11*) and women (*n = 24*).

5.5.6.5 **Eating in public/social eating**

Participants with higher BMI's (>35kg/m^2; *n = 14*) reported feeling uncomfortable or embarrassed when eating or buying food in public. They believed that they would be judged by others, and in some cases, they had experienced this through being criticised for what they had eaten. This relates to the self-consciousness subtheme of psychosocial experience as they are focused on what other people think of them, which is affecting their enjoyment. Some individuals indicated that they would change what they ate in public to avoid this and one individual avoiding going out for meals altogether. Females seemed to be more affected by this and more conscious about eating in front of others than males as it was reported more by females.

5.5.7 Support

5.5.7.1 **Health Care professionals**

Twenty participants described their negative experiences with HCPs. They felt as though the HCPs did not take them seriously due to their weight and would assume that weight was their problem without considering anything else. For example, one participant reported that they felt as though they were offered no support to help them lose weight. This led to some individuals leaving the doctors upset, angry and annoyed and in some cases meant that they avoided going to the doctors. Also, these participants who were told to lose weight indicated that they were offered no help or guidance to achieve this. This left them feeling hopeless and dismissed. However, being told to lose weight was not taken as a negative by all participants. In some cases, this led to successful weight loss, and others indicated that they wished their doctor had told them that they were overweight. Both men and women reported a similar variety of experiences with HCPs.

5.5.7.2 **Family and friends**

Support from friends and family varied from over supportive to unsupportive. In terms of over supportive friends or family, individuals felt like they were putting too much pressure on them to lose weight by constantly asking if they had lost weight. This led to frustration and annoyance. Some individuals experienced unsupportive friends or family. Examples of this were, friends/family trying to sabotage efforts to eat well, receiving no acknowledgement or praise when weight was lost or family/friends making jokes about their weight. This experience made individuals uncomfortable when talking about weight in front of friends/family and also upset them. Those that indicated that their friends/family were supportive described them as being in similar situations and so were "*in it together*". This led to them being comfortable when talking about their weight to their family/friends. Experiences of support were similar between men and women.

5.5.8 Work

This theme relates to the themes/subthemes of clothing, self-consciousness, mobility, breathlessness with activity and fatigue but is specific to work-related issues.

5.5.8.1 **Maintaining a professional appearance**

Ten female participants felt that they struggled to maintain a professional appearance at work due to their weight. This was because they could not find clothes that fitted right. They worried that people would not take them seriously because of this. However, this was not expressed by male participants in relation to work, but males did express frustration at finding "smart" clothes for special occasions.

5.5.8.2 **Being taken seriously**

Some individuals (*n = 10*) believed that their weight made people assume they were stupid, and in some cases, they had experienced bullying at work. They believed they were bullied because they were overweight. This led to some feeling as though they had to prove themselves more than others. However, the lack of being taken seriously in the workplace was only reported in females. Men did not mention this, yet, all the men expressed a concern that they would be judged about their weight in other settings such as social setting, meeting new people and attracting a romantic partner.

5.5.8.3 **Productivity**

In terms of productivity at work, five individuals believed that their weight made their jobs harder. For example, one participant described her difficulty as a nurse when changing bedding on hospital wards, as this was tiring, and she was conscious that the space between the beds was small. In some cases, they could not get as much done as others, and they were slower than other people or before they put weight on. Another

participant indicated that since losing weight, he was able to go back to work as a window cleaner as he was now able to get up and down ladders safely. This indicates that excess weight can affect how someone performs within their work, especially if the job requires physical exertion.

5.5.9 Summary

These themes show the deliberating effects weight can have on a person's life. But they also show that these aspects can potentially be improved with weight loss. There were a few differences and similarities between men and women that should be noted. Both men and women expressed issues with clothing, shopping for clothes and with body dissatisfaction because of their weight. However, men did not report issues with feeling judged about their weight in relation to eating in public and being taken seriously at work. Despite this, ten men expressed that their weight had caused them to avoid social activities as they were self-conscious about their appearance. Even though they did not report feeling judged in those situations, they were worried that they would be judged when they were overweight. Some males reported avoiding activities that would make them out of breath, where they had to take their tops off (such as swimming) and even to the extreme of avoiding speaking to people they did not know. This was similar to women, although more women reported these issues than men.

Although men reported these issues less frequently than females, these issues were still being discussed and were very real to these participants. It could be that women are more open to speaking about their feelings than men. Males could have felt uncomfortable speaking to a young woman about their issues with confidence and body image, despite the interviewer showing understanding and openness. Furthermore, these themes were discussed in the expert panel meeting to select items (see section 5.6). The participants

also completed the IWQOL-Lite items and answered questions about the relevance and understanding of the items. The results of these cognitive interviews are discussed next, before outlining the expert panel meeting for item selection.

5.5.10 IWQOL-Lite

Out of the 49 participants, 30 indicated that something was missing from the IWQOL-Lite. Issues with clothing was the most mentioned missing aspect, followed by social aspects, and issues with food. *Table 5.4* contains the aspects mentioned by participants when asked if there were any aspects of weight affecting them that were not covered by the IWQOL-Lite. Five participants reported no issues with the IWQOL-Lite (including no missing aspects).

Table 5.4 Aspects of QoL missing from the IWQOL-Lite

Aspect Missing from IWQOL-Lite	Number of Participants	Example Quote
Issues with clothing/shopping for clothes	19	"There's things that I would have expected to be asked about such as going shopping and finding clothes and things like that that weren't on there, which I think is a massive problem" (P042, F, BMI Overweight)
Social aspects/ relationships with others	6	"The social side I think is quite important because you've covered everything, as in your physical, you know, and the going out and stuff but public, you've got very little on public. Social side, because it impacts, and work. You spend half your life at work, the other time is social, you do need something on social." (P015, F, BMI Obesity II)
Eating	5	"They only other thing that it could include is, the relationship with food. Because I think that's a big part. For me, I'm a comfort eater, and I think it's the need to address that issue, and changes in behaviour." (P024, F, BMI Obesity I)
Taking part in exercise	4	"Other thing is probably taking part in exercise. You've got mobility but not exercise. So, for example, if you're overweight, you may not be that keen on going to the pool, even though it's probably good exercise for you. Going to the gym, because you're seeing everybody, beating seven bells out of whatever it happens to be, and you can't." (P011, M, BMI Obesity I)
Depression	3	"So maybe yes, maybe addressing… Your weight can cause you to be depressed and depression can cause you to gain weight." (P013, F, BMI Obesity II)

Cutting toe nails	2	"I think on the physical function, although I don't have trouble tying my shoes particularly, I struggle with things like cutting my toenails" (P021, F, BMI Obesity II)
Sleep	1	"They have for me, sleep. Not just my sleep, but my husbands as well because I snore dreadfully when I have more weight on me and it affects my quality of sleep." (P012, F, BMI Overweight)

Sixteen participants indicated that some part of the questionnaire was irrelevant to them, whether it was one item or a whole domain. The sexual life domain was considered irrelevant to nine participants, as they were not in a relationship and/or for religious reasons. The work domain was also considered irrelevant for seven participants, as they were retired, did not have a strenuous job or were a student and did not work. *Table 5.5* shows the aspects reported as irrelevant to the participants.

Table 5.5 Aspects of IWQOL-Lite reported as not relevant

Irrelevant aspects of IWQOL-Lite	Number of participants	Reason for being irrelevant
Sexual Life domain	9	Not in a relationship Religious reasons
Work Domain	7	Retired Did not have a strenuous job Student
Fitting through turnstiles item	2	Do not go through turnstiles often enough

A lot of participants mention the IWQOL-lite being hard to complete due to the memories and negative emotions being brought up. This could be due to all the items being negatively angled, and no items were positively angled. This could have been priming individuals to feel negative emotions and to score lower when they were overweight and higher when they had lost weight. Items should be neutral or have a balance of positive and negative items. However, it could also be due to the negative effects that weight has had in their lives and could be unavoidable. As well as finding the sexual domain irrelevant, 15 participants indicated that these questions made them uncomfortable when

answering them. *Table 5.6* presents a range of example quotes showing the differing levels of discomfort with the sexual life domain.

Table 5.6 Example quotes from participants that reported sexual life questions as uncomfortable

"I think because sexual life is not something you genuinely openly talk about. So, I think they were harder to answer just because it is more, for most people, it's more of a personal thing that you don't generally discuss, but I still answered them honestly, but I think that's probably the hardest section that was to answer." (P024, F, BMI Obesity I)
"Obviously your sexual life is quite an embarrassment but it does have an impact being overweight because you are like do I look fat and stuff." (P051, F, BMI Overweight)
"I guess the sexual life thing, I wasn't expecting that. Not that it was difficult, but it was like, "oh". But then I thought, "of course it should be there". Do you know what I mean? ... But at first, I don't know why, it's just the usual British kind of stiff upper lip and embarrassment." (P049, F, BMI Obesity II)
"Well, them sex ones but in that department it's never bothered if I'm honest. You just carry on as normal." (P035, M, BMI Obesity III)
"I think the sexual stuff was a bit like…you don't like to admit it." (P032, F, BMI Obesity II)
"I was a little bit 'thingy' about the sexual ones." (P027, F, BMI Normal weight)
"The sexual life ones did a little bit….I just get nervous around things like that, talking to people about things like that." (P022, M, BMI Normal weight)

Furthermore, six participants mentioned issues with the response options. *Table 5.7* provides example quotes from these participants. Some participants found it difficult to decide between the wording of the response options. For example, they could not differentiate between usually and always, or they would prefer different words to those that were offered. It was also suggested that ignoring the words was easier. This could be problematic when interpreting scores if the participants are not sure what the response options refer to and do not answer in the way intended. It would be useful to explore further how individuals interpret the response options on the IWQOL-Lite to make it more appropriate and acceptable.

Table 5.7 Quotes from participants expressing difficulties with the response options and recall period of the IWQOL-Lite

"It's difficult, sometimes, what's the definition between usually and always? Over what period of time? There's a few little bits like that."
"One or two of them I had to think about whether it was sometimes true. Really deciding between two of the points, as we go through. One with trouble using stairs, if I've a lot of stairs to go up, two or three flights, I might feel breathless and ache at the end of it. If it's only a flight of stairs it's absolutely fine. So I did put sometimes true there because it would depend on what I'm climbing."
"I was thinking whether it's how many times is sometimes and how many times is rarely? Is rarely like once a month or once a week or once a day? I wasn't quite sure of what the timescales are, they were relating to."
"No. The only thing is, the actual terms themselves rarely true, never true, sometimes true, I don't know whether it would be best, because in my head I'm going, "Well, occasionally I do", so whether it would be changing the terms of it. Strongly agree, occasionally, no real thoughts on it because some of the questions I didn't really have an opinion on it. The ones with work. I neither agreed nor disagreed, but because I haven't experience it, it wasn't like …"
"For most of the questions it was very logical sometimes I just sort of adding a frequency to something that impacts one part of your life for example, it's difficult because of the way you put it on the scale, that's the only difficulty but just look at the numbers and ignore the words I guess."
"Because of my weight I have trouble crossing my legs. Now it's only just recently but I can actually cross my legs and feel like I'm in a comfortable position, but the weight has always affected the way that I sit and that I can cross my legs if you get what I mean. So I didn't really know… because of my weight I have trouble crossing my legs, not anymore. So… which one should I circle? Because it's not an issue anymore but it was not long ago."

5.6 EXPERT INPUT AND INITIAL DRAFTING OF ITEMS

5.6.1 Generating the items

Once the interviews were analysed by two independent researchers, and the themes had been agreed upon, the actual items that would form the initial questionnaire were debated and worded by an expert panel. The expert panel consisted of the two researchers who had analysed the interview transcripts, a specialist obesity nurse, and an experienced scale developer/psychometrician. Within the expert panel meetings, each theme and subtheme were discussed in terms of relevance to the target population, and in relation to the FDA guidelines for developing PROMs (FDA & HSS, 2009). Once all items had been decided on, the response scale was discussed and developed following FDA guidelines. The

introductory information and instructions for the completion of the new scale were also agreed upon. The following criteria were used by the expert panel to decide whether themes and subthemes should be represented by an item or items:

a. *Each item should be sensitive to change*. In order to be sensitive to change, the concepts found in the analysis of the main interviews need to change with weight loss/gain and in a predictable direction. Therefore, each concept was discussed in terms of the interview data and in relation to the clinical experiences of the Obesity Specialist to ensure change is probable. For example, issues relating to comfort eating may not be subject to change with weight loss as this is not a direct consequence of carrying excess weight.

b. *Items must be general enough to be relevant to the majority of the target population.* As the new instrument will be a general WRQoL scale for overweight and obesity, the concepts measured within the instrument should be present in the majority of demographic groups and patients. For example, concepts present only in female patients would be problematic as they would not be relevant for males.

c. *Items should be easy to understand*. Items should be made as simple as possible and include one concept only to make it simple to understand and answer accurately. Therefore, each item was written as close to the participants own words as possible to ensure content validity and ease of understanding.

d. *Items should not all be angled negatively*. Both positively and negatively angled items should be generated where appropriate to keep the instrument balanced and to avoid priming patients/participants.

These criteria relate to the FDA guidelines for developing a PROM (FDA & HSS, 2009). Each theme and subtheme was discussed until agreement was made on whether an item representing the subtheme would be included or not.

5.6.2 Recall Period

It was decided that every item will assess the current situation of the individual/patient completing the new instrument to adhere to the FDA (2009) guidelines. This will avoid the patient having to rely on memory to recall over a long period of time, compare their current state to an earlier one, or to give an average response over a period of time. As the patient's current state is likely to influence the completion of PRO instruments, assessing, their current state is expected to ensure content validity (FDA & HHS, 2009). Assessing their current state is also vital within interventions with repeated measures as it will give a true representation of how a participant responds at a given time point. Therefore, the new instrument and items need to be worded and angled effectively to assess the current situation of the individual.

5.6.3 Items developed for each theme

A total of 29 items were selected to be included in the scale. Items represented the themes from the item generation interviews and were worded as closely to the participants own words as possible. *Table 5.8* shows the items selected and the themes they relate to. Each theme is discussed further in relation to the decisions made within the expert panel meeting. Some themes were separated due to these discussions.

Table 5.8 Expert Panel Item Selection

Themes	Items Selected
Physical Symptoms	I have aches and pains (for example, in knees, hips, ankles, back, feet and/or joints)
	I worry that my weight will impact my future health
	I am unhealthy
	I have no energy
	I have disturbed sleep
Mobility	I am breathless going upstairs
	I cannot stand for long periods
	Walking is difficult
	Bending down is difficult (e.g. tying shoes, cutting toenails, picking things up from the floor etc.)
	Getting up from a seated position is difficult (e.g. chairs, cars etc.)
Self-Care (personal hygiene)	Washing myself is difficult
Getting into tight spaces	I worry about fitting into seats and public spaces (e.g. aeroplane seats/seatbelts, turnstiles, bus seats, train/bus aisles etc.)
Avoiding Physical Activity	I avoid physical activity
Clothing	I choose clothes that hide my body shape
	I look good in my clothes
	I find clothes shopping pleasurable
	Finding the right clothes for the right occasion is difficult (e.g. wedding, evening, work etc.)
Self-Control with Food	I avoid eating in front of others
	I feel judged when I eat in public
Feelings towards themselves	I feel good about myself
	I am happy about my weight
	I am embarrassed about my appearance
	I am depressed
Psychosocial experience	I avoid social activities (e.g, physical activities, meeting with friends/work colleagues etc)
	I feel confident
	I am teased
	I feel discriminated against
	I am taken seriously (e.g. by HCP, work colleagues etc.)
	I feel valued by others

5.6.3.1 **Physical Symptoms**

A general item on aches and pains was considered sufficient as it covers all possible pain experienced by those who have obesity/overweight. An item covering each type of pain would be problematic and is likely to be subject to floor and ceiling effects. This is because not all types of pain were experienced by the majority of participants. Still, the majority of participants that had suffered from obesity/overweight had experienced at least one type of pain. As physical markers concerning current health conditions are likely to be measured alongside a QoL measure (for example, within clinical trials and intervention studies), it was decided that the presence of current health conditions would not be included in the new instrument. Therefore, an item measuring a general feeling of healthiness and an item measuring worry for future health was considered sufficient to cover this subtheme.

Furthermore, an item measuring energy levels was created to cover this energy subtheme. Shortness of breath was initially included within this subtheme, but it was agreed that it should be included within the mobility subtheme as shortness of breath was only occurring with movement. However, factor analysis will aid in the arrangement of items into subthemes. A general question was generated to measure sleep quality, sleep disturbances (snoring/sleep apnoea) and struggling to get to sleep together, as not all patients will suffer from all these issues but are likely to experience at least one of these.

5.6.3.2 **Mobility**

Five items were generated for the mobility sub-theme and covered bending down, getting up from a seated position, walking, standing for long periods and shortness of breath when climbing stairs. For the more general items (bending down and getting up from a seated

position), examples taken from the interview data were provided in brackets. Getting into tight spaces and personal hygiene was considered separate concepts to mobility.

5.6.3.2.1 Self-Care (Personal Hygiene)

Personal hygiene was considered to be a separate issue to mobility. It was also agreed that this could cause some offence, so the wording was discussed thoroughly. The subtheme heading was changed to self-care, and the term washing was used as it is quite general and would cover a range of personal hygiene matters. While only two participants reported this issue in the interviews, it is possible that it was not mentioned due to the intimate nature of the issue. It could potentially be embarrassing to speak about. Therefore, it was deemed important to include to assess in the cognitive interviews and factor extraction.

5.6.3.2.2 Getting into tight spaces

This item covers the 'tight spaces' aspect of the 'mobility' subtheme. It was decided that while it may be a mobility issue, it is worry related to fitting into tight spaces that was the aspect affecting individuals' QoL rather than the actual ability to fit into tight spaces. The item wording reflected this worry.

5.6.3.2.3 Avoiding physical activity

It was agreed that avoidance of physical activity is likely to be sensitive to change when weight is lost/gained. Avoidance of physical activity was due to both issues with mobility and self-consciousness. Self-consciousness will be covered more specifically in the psychosocial experience domain. An item covering the avoidance of physical activity could also help HCP’s identify individuals who need support with exercise.

5.6.3.3 **Work**

The work domain was removed as aspects within this related to aspects in other domains, and it would cause problems for those completing the new instruments who are not in work. Maintaining a professional appearance was regarding clothing and so is covered in choosing clothes. Being taken seriously relates to concepts within the Psychosocial Experience domain and is now covered in that domain. Finally, productivity relates to mobility and is covered in the items within that domain.

5.6.3.4 **Clothing**

A separate item for each sub-theme within this theme was generated. As these aspects have not been included in previous WRQoL scales, it is unknown how these items would be related and how they would perform in the psychometric analysis. However, issues with clothes were important to the participants.

5.6.3.5 **Self-Control with Food**

The self-control with food theme brought up a few issues in terms of the sensitivity to change in the concepts of comfort-eating, calorie restriction, food awareness and thought processes after eating. It was agreed that while these aspects were commonly mentioned in the interviews, they were not predictable enough to gain any meaningful information in terms of QoL. Social eating was deemed changeable with weight loss, and so avoidance of eating in front of others and feeling judged when eating in public were included as items.

5.6.3.6 **Feelings towards themselves**

A lot of the issues and instances arising from the interviews were symptoms of depression. Therefore, it was decided that a question regarding depression would be added to be evaluated by cognitive interviews and possibly in the factor analysis.

5.6.3.7 **Psychosocial Experience**

Six items were developed to cover the psychosocial experience theme. The obesity expert (JC) noted that, from her experience, patients with a BMI of 40 and above are generally more concerned about the physical problems they experience compared to the psychosocial issues experienced. This does not mean that they do not experience psychosocial issues, but the physical problems are more important and deliberating to them at that point in time. Therefore, it is important to consider this when evaluating the items.

Furthermore, the subtheme of sexual confidence was discussed in detail, and it was decided that items relating to this would be problematic because this domain in the IWQOL-Lite was deemed irrelevant to a quarter of participants and a third of participants feel uncomfortable. This indicates that over half of the participants had an issue with completing the sexual life items. If a domain or item is irrelevant or causes discomfort, it is at risk of not being completed. This would cause issues with the scoring of the scale when being evaluated and when used within research and clinical trials. While it is common for some QoL domains to demonstrate ceiling effects, in previous scale development 38% of responses to intimate relationship items were either reported to be inappropriate, missing or showed ceiling or floor effects (McElhone, Abbott, Shelmerdine et al., 2007). Therefore, items representing sexual functioning or confidence were not included.

5.6.4 Response Scale

It was decided that the response scale would go from 0-9 and would be specific to each individual item. A 10-point scale should allow a spread of responses and be sensitive to changes in weight. The specific wording is only included on the top and bottom of the response scale to allow patients to think about the item rather than having to read the response scale. This should reduce responder burden and avoid any confusion between words such as sometimes and occasionally, as seen in the cognitive interviews with the IWQOL-Lite. Many people have different judgements about what these terms mean and so having two anchors at each extreme should make it easier to decide by eliminating the judgement about similar words. The specific wording was decided after all items were generated.

After the expert panel meetings, the first draft of the WRQoL questionnaire was generated. *Table 5.9* shows the introductory information, response scale and items of the questionnaire. The item generation and selection has followed the recommended and best practices, as highlighted in Chapter 2 (see Section 2.5). The next step was to conduct "theoretical analysis" or test for content validity. This is outlined and discussed in the next section, where cognitive interviews were conducted with the target population.

Table 5.9 The introductory information, items and response scale of the draft version of the new scale

New Weight-Related Quality of Life Instrument

Introductory information

The following questionnaire is designed to find out how your weight/body shape affects your life.

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel today.

Questions start on the next page.

Items	**Response scale**
I have aches and pains (for example, in knees, hips, ankles, back, feet and/or joints)	0 (Not at all) to 9 (All the time)
I worry that my weight will impact my future health	0 (Not at all) to 9 (All the time)
I am healthy	0 (very healthy) to 9 (Very Unhealthy)
I have no energy	0 (No energy) to 9 (Lots of energy)
I have disturbed sleep	0 (Not at all) to 9 (All the time)
I am breathless going upstairs	0 (Not at all) to 9 (All the time)
Standing for long periods is difficult	0 (Not at all) to 9 (All the time)
Walking is difficult	0 (Not at all) to 9 (All the time)
Bending down is difficult (for example, tying shoes, cutting toenails, picking things up from the floor etc.)	0 (Not at all) to 9 (All the time)
Getting up from a seated position is difficult (for example, chairs, cars etc.)	0 (Not at all) to 9 (All the time)
Washing myself is difficult	0 (Not at all) to 9 (All the time)
I avoid physical activity	0 (never) to 9 (always)
I worry about fitting in seats and public spaces (for example, aeroplane seats/seatbelts, turnstiles, bus seats, train/bus aisles etc.)	0 (Not at all) to 9 (All the time)
My eating is under-control	0 (Not at all) to 9 (All the time)
I feel judged when I eat in public	0 (Not at all) to 9 (All the time)
I avoid eating in public	0 (Not at all) to 9 (All the time)
I feel good about myself	0 (Not at all) to 9 (All the time)
I am happy about my weight	0 (Very unhappy) to 9 (Very happy)
I feel confident	0 (Not at all) to 9 (All the time)
I am depressed	0 (Not at all) to 9 (All the time)
I am embarrassed about my appearance	0 (Not at all) to 9 (All the time)
I look good in my clothes	0 (never) to 9 (always)
I choose clothes that hide my body shape	0 (never) to 9 (always)
I enjoy shopping for clothes	0 (never) to 9 (always)
Finding the right clothes for the right occasion is difficult (for example, wedding, evening, work etc.)	0 (Not at all) to 9 (All the time)
I avoid social situations (for example, physical activities, meeting with friends/work colleagues)	0 (never) to 9 (always)
I am teased	0 (Not at all) to 9 (All the time)
I feel discriminated against	0 (Not at all) to 9 (All the time)
I am taken seriously (for example, by health care professionals, work colleagues, etc.)	0 (Not at all) to 9 (All the time)
I feel valued by others	0 (Not at all) to 9 (All the time)

5.7 TESTING THE FACE/CONTENT VALIDITY OF THE DRAFT QUESTIONNAIRE

5.7.1 Preliminary testing for wording/formatting issues

Once the first draft of the questionnaire was developed, the researchers read and completed it to check for any errors or problems. One potential problem was identified relating to the response scale. Originally the response scale was a line with the numbers 0-9 underneath and two anchor points at zero and nine. If the introduction of the questionnaire was not read properly or forgotten, it is likely that respondents will put an X on the line. If the X was between numbers, it would cause issues for scoring. Therefore, it was decided the response scale should include the numbers in a row of boxes. This way, circling the number will be more obvious.

After the response scale was reformatted, two people who were unfamiliar with the project were asked to complete the questionnaire to make sure it was understandable. Both said that they kept forgetting to answer the questions in relation to their weight. Therefore, a reminder to think about weight was added to the top of each page. This has a small limitation as it made the questionnaire two pages longer and could add to response burden. However, this is only the first draft questionnaire, and it is likely that some items will be deleted after the cognitive debriefing interview, and factor analyses have been conducted.

5.7.2 Cognitive Debriefing Interviews

Once the new scale had been drafted, cognitive interviews were conducted to assess user understanding and ease of completing. This was used to decide if any items were problematic or if anything was missing from the scale. The study was cross-sectional and consisted of a structured questionnaire format with a debriefing session.

5.7.2.1 **Participants**

Collection of the data took place over a four-week period. Participants aged 18 and above responded to the research poster placed at the locations described in section 5.4.3.1. The participants who took part in the pilot interviews and item generation interviews were excluded. The aim of the new instrument was explained. They were also informed that their input would help to refine and evaluate the new instrument. Written informed consent was obtained. Twenty participants, recruited from Facebook and the community, consented to take part in this study. The demographics of participants were similar to those included in the item generation interviews. Age ranged from 20 to 75 years (*mean = 52*), BMI ranged from 20 to 42 (*mean = 28.7*) and 95% of participant reported their ethnicity as white/Caucasian. The majority of participants self-identified their weight status as 'regained' indicating that they have regained weight after previously losing weight (50%), with 30% reporting successful weight loss. *Table 5.10* shows the participant demographics and characteristics.

Table 5.10 Participant Demographics for Cognitive Debriefing Interviews

Age – mean (SD)	52 (17.6) [20 - 75]
BMI – mean (SD)	28.7 (4.9) [20.0 – 42.0]
Waist Circumference – mean (SD)	90 (14.2) [69 – 130]
Gender	14 females, 6 males
Ethnicity	
White	19 (95)
Black/African/Caribbean/Black British	1 (5)
Weight Loss Status – number (%)	
Successful	6 (30)
Unsuccessful	1 (5)
Regained	10 (50)
No Attempts	3 (15)
Employment Status – number (%)	
Employed	12 (60)
Unemployed	2 (10)
Student	1 (5)
Retired	5 (25)

Marital Status – number (%)	
Married	8 (40)
Living with another	3 (15)
Divorced	4 (20)
Single	2 (25)
Widowed	2 (10)
Separated	1 (5)

5.7.2.2 **Procedure**

Before the completion of the draft questionnaire, participants were given a brief explanation of the structure of the questionnaire, the nature of the response scale and their role in the scale development process. They were encouraged to write comments or marks if they had any difficulty/ issues with the design, content or structure, whilst they were completing it. Once they had completed the instrument, participants were asked about their experience completing it and their opinions on the content and wording. All participants were asked whether there were any other issues they considered important that were not included in the scale to ensure no important aspects had been excluded. In some cases, the questionnaire content led to further discussion of individual experiences related to weight gain/loss or obesity. Notes containing the participant's comments were made during each interview which were used to refine the draft questionnaire (as well as any notes made by the participants on the questionnaires). After the debriefing session, the interviewer took the participants measurements using the same procedure and apparatus as in the pilot interviews and main interviews (see section 4.2.4.1). The participants were then given the debrief sheet, given a chance to ask any further questions and thanked for their time. As soon as possible after each interview, the notes made were checked, typed up and added to if needed.

5.7.3 Cognitive Interviews Results

The 20 participants reported that the draft questionnaire was easy to understand and answered all the items. They also felt it was relevant and broad enough to measure their

HRQoL in relation to their weight adequately. One participant thought the questionnaire should include a question addressing how someone feels when they are wearing swimwear. Another participant felt that it was missing how weight affects their personal relationships. Three participants commented on the response scale, two on the numbers and one on the wording of the anchor points. Out of the 29 items, eight were commented on. All items were retained, the wording of two items was altered, and one new item was added. *Table 5.11* shows the queries made and the actions taken.

Table 5.11 Queries/comments made during cognitive interviews of the draft instrument and the actions taken

Query type	No. participants	Comments/Queries	Action taken
Item 1	2	They suffered from pain but they did not put this down to weight.	Item instructions changed
Item 5	1	Suffered from disturbed sleep but they did not think this was due to their weight.	Item instructions changed
Item 9	1	Bending down was difficult due to physical activity undertaken, not because of weight. Hard to separate from weight	Item instructions changed
Item 22	1	Not relevant	Item retained
Item 23	2	Shop for their body shape not to hide it.	Item retained
Item 24	1	Does not like clothes shopping regardless of weight	Item retained
Item 27	1	Understanding was different to intended meaning of item	Item wording altered
Item 29	2	Difficulty understanding as they had not experienced it/did not understand the term health care professionals fully	Item wording altered
Missing aspect	1	Wearing swim wear	Item 25 wording altered
Missing aspect	1	Strain on relationships	Item added*
Anchor points	1	Wording suggests over a period of time rather than 'today'	Anchor points retained
Response scale	1	Did not understand the numbers	No action taken
Response scale	1	Too many numbers to choose from	No action taken

**Item added: "There is a strain on my personal relationships."*

Following this process, a revised version of the new instrument containing 30 items was produced, ready for factor extraction and initial psychometric evaluation. The next chapter will further evaluate the psychometric properties of the IWQOL-Lite in a UK community sample before the preliminary testing of the new instrument in Chapter 7.

6 PSYCHOMETRIC EVALUATION OF THE IWQOL-LITE IN A UK COMMUNITY POPULATION

The previous chapter investigated the comprehensiveness and comprehensibility of the IWQOL-Lite in a UK community population. The IWQOL-Lite was found to be missing important issues relating to the impact weight had on an individual's QoL. These included issues with clothing, effects on social aspects of life, taking part in exercise and feelings/symptoms of depression. Chapter 7 details the initial psychometric evaluation of the new instrument. As part of the data, the IWQOL-Lite was given to participants to complete. This chapter details the psychometric evaluation of the IWQOL-Lite in a UK sample.

6.1 FURTHER EVALUATION OF THE IWQOL-LITE

To continue the evaluation of the IWQOL-Lite, psychometric testing was conducted. The IWQOL-Lite has never been psychometrically tested within a UK population, yet it has been used to measure WRQoL in this population (Ahern et al., 2017; Fuller et al., 2013; Jebb et al., 2011). If a PROM is developed in one country and is used in another, it is important to assess its cross-cultural validation. This was started within chapter 5, using cognitive interviews to assess content validity, comprehensiveness and user understanding in a UK community population. The next steps are to assess the psychometric properties of the IWQOL-Lite in a UK population. Therefore, this chapter aimed to:

a) Assess the structural validity of the IWQOL-Lite
b) Assess the internal consistency of the IWQOL-Lite
c) Determine the percentage of missing data and ceiling/floor effects of the IWQOL-Lite

6.2 METHODS

6.2.1 Design

A cross-sectional study was conducted to evaluate specific psychometric properties of the IWQOL-Lite in a UK community population. The factor structure, internal consistency, missing data, and floor/ceiling effects were evaluated.

6.2.2 Recruitment and Data collection

Data collection was carried out between September 2018 and January 2019. The study was approved by the PSYSOC Ethics committee at UCLan prior to data collection (Appendices 3). Verbal consent was gained from all participants as the completion and handing in of the questionnaire was sufficient evidence of consent. Their right to withdraw was detailed in the PIS and was reiterated within the debrief sheet. It informed them that if they did not want their questionnaire data to be used, they could withdraw at any time during the completion of the questionnaire up until they left the research location as the questionnaires were anonymised. Completed questionnaires were kept in a locked filing cabinet accessible only to the research student.

A larger sample size was required within this study compared to the sample sizes of the previous qualitative studies. This is because factor analysis was conducted. In order to gain reliable relationships between items from factor analysis, it is recommended to have a sample size that is at least *five times* the number of items of the instrument being evaluated (Mokkink et al., 2010; Yong & Pearce, 2013). Therefore, the study aimed to recruit at least 155 participants (31 items times five). To recruit a higher sample size, the eligibility and exclusion criteria were relaxed by not specifying participants should have been overweight at some point in their life. Individuals recruited were adults aged 18 and over, recruited from community locations.

A separate research poster was used to provide the differing details for the study (see Appendices 4 for the research advert). For example, details included, the maximum amount of time it would take, the new eligibility criteria, and completion of a questionnaire. Despite the relaxed exclusion criteria, participants were asked on the PIS to inform the researcher if they had never been overweight, if they had existing health problems, and if they could not stand to have their measurements taken. Places of recruitment and the processes of recruitment continued from the previous studies (see sections 4.2.3.1 and 5.4.3.1). Furthermore, new places of recruitment were included in this aspect of research due to the number of participants needed. These were WalkerFire and BoulderUK.

6.2.2.1 **WalkerFire**

WalkerFire is a company that installs fire alarms for their clients. Their employees include office workers and engineers. Its office where their employees are based was at a convenient location to the researcher, so convenience sampling was used at this location. To access this location, the research emailed the head office with details of the research. The operations manager expressed their interest in the research and arranged a private room for the researcher to take measurements from. They circulated the research poster and PIS to their employees before the date of data collection. A date was arranged, and the questionnaire packs were given to the employees willing to take part, to fill in at their work desks. Once finished, participants came to the researcher's room one by one to have their measurements taken and to be debriefed. Participants were informed they could speak to the researcher at any point if they had any questions about the questionnaire pack or the research in general.

6.2.2.2 **BoulderUK**

BoulderUK is a climbing gym with a café/spectator area. Convenience sampling was used in this location, as there was a variety of individuals with differing demographics and characteristics. The centre manager was approached in person and informed of the research, what the research involved, and permission was gained to display the research poster and to approach their customers. Individuals in the café/spectator area were approached, told the details of the research, and asked if they would like to take part. Individuals were not specifically targeted because of their weight. Everyone within the area was informed of the research either individually or by addressing the whole table. Those happy to take part completed the questionnaire before having their measurement taken in a private area. Data collection took place here on four occasions.

6.2.3 Participant characteristics

The IWQOL-Lite was completed by 160 participants. Male participants' (*n = 63*) had an average BMI of 27.0kg/m^2, an average waist circumference of 91.5cm and an average age of 40. Female participants' (*n* = 97) had an average BMI of 28kg/m^2, an average waist circumference of 84.7cm and an average age of 40. *Table 6.1* shows the participant demographics and characteristics used in the psychometric testing of both the IWQOL-Lite and the new instrument (results for the new instrument are detailed in Chapter 7).

6.2.4 Materials

6.2.4.1 **Questionnaire pack**

A questionnaire pack was given to participants at time-one as part of the initial evaluation of the new WRQoL instrument (Chapter 7). This questionnaire pack contained the demographics questionnaire, the new WRQoL instrument (results are reported in Chapter 7) and the IWQOL-Lite items and response scale (Kolotkin et al., 2001). The time-one

questionnaire pack is displayed in Appendices 4. For this study, the IWQOL-Lite was analysed. The IWQOL-Lite contains 31 items covering five domains: Physical Functioning (11 items), Self-esteem (7 items), Sexual life (4 items), public distress (5 items) and work (4 items). Items for each of these domains are summed and transformed into a scale; 0 per cent (poor QoL) to 100 (good QoL). High scores on the IWQOL-Lite domains represent a better QoL, and lower scores represent a worse QoL.

Table 6.1 Participant demographics and characteristics

Age – mean (SD)	39.9 (17.0) [18 – 84]
BMI – mean (SD)	27.6 (5.8) [18.0 – 46.3]
Waist Circumference – mean (SD)	87.3(14.4) [61.0 – 139.0]
Gender	97 females, 63 males
Ethnicity – number (%)	
White	141 (88)
Asian	13 (8)
Other	6 (4)
Weight Loss Status – number (%)	
Successful	27 (17)
Unsuccessful	5 (2)
Regained	78 (49)
No Attempts	50 (31)
Employment Status – number (%)	
Employed	111 (69)
Unemployed	5 (3)
Student	23 (14)
Retired	21 (13)
Marital Status – number (%)	
Married	67 (42)
In a relationship	41 (26)
Divorced/separated	11 (7)
Single	39 (24)

6.2.5 Procedure

Participants either responded to the research poster, were approached by the researcher, or booked an appointment directly through the UCLan SONA system. Participants were given the questionnaire pack and were asked to read through the PIS. After this,

participants were given a chance to ask questions before starting the questionnaires. No information was withheld from the participants. Once they had completed the questions, participants had their weight, height, and waist circumference measured. This was done in the same way as in the pilot and main interviews (see section 4.2.4.1). After taking their measurements participants were given the debrief sheet to read through.

6.2.6 Statistical methods

SPSS (Statistical Package for Social Sciences) version 25 was used to conduct the statistical analysis. As there are no published UK psychometric data evaluating the IWQOL-Lite, its structural validity and internal reliability were assessed. The data was also screened for missing data, ceiling, and floor effects. Data was checked for erroneous values (such as values that fell outside the maximum/minimum score values) before statistical analysis took place.

6.2.6.1 **Structural validity**

Factor analysis was used to assess the robustness of the IWQOL-Lite structure. Exploratory factor analysis in the form of principal component analysis (PCA) was used. PCA was run using eigenvalues > 1 on a varimax rotation. If the model did not match the number of domains in IWQOL-Lite, the extraction of five factors was specified as the IWQOL-Lite has five subscales. Eigenvalues represent the importance of each factor in terms of explaining the variability and correlations within the data. The criteria for item loading was a correlation coefficient of 0.5 and above. This criterion was used as the factor loadings used to retain items on the IWQOL-Lite was not defined in the research article (Kolotkin et al., 2001).

6.2.6.2 **Internal consistency**

Internal consistency of the IWQOL-Lite domains was assessed using Cronbach's alpha coefficients (Cronbach, 1951). Internal consistency measures the extent to which the items within a domain are conceptually related. The most commonly used statistic for measuring internal consistency is Cronbach's α (Cronbach, 1951). Internal consistency is high when respondents score similarly on related items. If it is not high, then the scale is likely to be measuring more than one concept or variable. Values > 0.7 represent good reliability (Nunnally, 1978). Cronbach's α values above 0.9 indicate that there may be redundant items measuring the same aspect of the concept/domain.

6.2.6.3 **Determining the floor and ceiling effects and missing responses**

Floor and ceiling effects were established by assessing the scores in the top and bottom 5% within each factor. Floor/ceiling effects were conducted for those with a BMI of 30kg/$m^{2,}$ and over as individuals not in the obesity BMI categories are likely to cause ceiling effects in the data. A floor effect exists when 15% or more of participants score in the bottom 5% of possible scores within a factor, and ceiling effects represent 15% or more participants scoring in the top 5% of possible scores (McHorney & Tarlov, 1995; Terwee, Bot, de Boer et al., 2007).

6.3 RESULTS

6.3.1 Structural validity

The initial PCA extracted six factors, so a PCA was re-run to extract five factors as the IWQOL-Lite has five domains. *Table 6.2* displays the factor loadings of the IWQOL-Lite items. Overall, the 5-factor model was similar to the structure of the IWQOL-Lite with the items, in general, loading to the correct domains. However, there were some issues with items 8, 11, 18, 21 and 31.

Table 6.2 Factor loadings of the IWQOL-Lite items

		1	2	3	4	5
Physical Functioning	Q1 Picking up objects	.125	.706	.018	-.035	.291
	Q2 Tying shoes	.001	.830	.117	.125	.217
	Q3 Getting up from chairs	.019	.785	.211	.199	.255
	Q4 Using stairs	.194	.719	.207	.079	.385
	Q5 Taking off clothes	-.061	.636	.303	.281	.386
	Q6 Mobility	.061	.765	.133	.295	.257
	Q7 Crossing legs	.108	.553	.302	.146	-.011
	Q8 Short of breath	.424	.461	.253	.098	.122
	Q9 Painful joints	.215	.648	.098	-.138	.065
	Q10 Swollen ankles	.133	.687	.000	.213	.001
	Q11 Worried about health	.642	.338	.135	-.065	.120
Self-esteem	Q12 Self-conscious	.898	.115	.134	.139	.034
	Q13 Self-esteem	.915	.055	.131	.145	.067
	Q14 Unsure of myself	.865	.095	.171	.244	.068
	Q15 Don't like myself	.837	.019	.148	.298	.085
	Q16 Afraid of rejection	.705	.027	.195	.241	.234
	Q17 Avoid mirrors	.713	.100	.199	.411	.076
	Q18 Embarrassed to be seen in public	.600	.217	.214	.549	.145
Sexual Life	Q19 Do not enjoy sexual activity	.352	.180	.064	.804	.197
	Q20 Little or no sexual desire	.296	.182	.001	.846	.095
	Q21 Difficulty with sexual performance	.135	.248	.071	.465	.609
	Q22 Avoid sexual encounters	.358	.162	.163	.808	.129
Public Distress	Q23 Ridiculed or teased	.252	.012	.622	-.118	.474
	Q24 Worry about fitting into seats	.154	.231	.898	.128	.012
	Q25 Worry about fitting through turnstiles	.257	.223	.867	.108	.050
	Q26 Worry about finding chairs strong enough	.207	.223	.783	.149	.166
	Q27 Experience discrimination	.435	.223	.554	-.029	.310
Work	Q28 Getting things accomplished	.121	.242	.212	.075	.714
	Q29 Less productive	.417	.362	-.075	.065	.556
	Q30 Don't receive raises or recognition at work	-.026	.322	.103	.144	.767
	Q31 Afraid to go on job interviews	.314	.250	.175	.165	.460

*Numbers highlighted in yellow represent the factor loadings above the cut-off point (>0.50), those highlighted in orange represent problematic items

6.3.1.1 **Problematic items**

Issues were found with five items of the IWQOL-Lite. Question eight (I am short of breath after mild exertion) cross-loaded across the physical function and the self-esteem domain, with both factors loading below the 0.50 threshold. This suggests that this question is measuring aspects of both physical functioning and self-esteem and so it not an accurate measure of physical functioning (Fabrigar & Wegener, 2012). Furthermore, question 11 (Because of my weight (BOMW) I am worried about my health) loaded onto the self-esteem domain rather than the physical functioning domain, indicating that

respondents understood the question to be related to emotion rather than physical. Question 18 (BOMW I am embarrassed to be seen in public places) loads onto both the self-esteem domain and the sexual health domain with both loadings being quite high. This indicates that this item is not a pure measure of self-esteem. Question 21 (BOMW I have difficulty with sexual performance) was also problematic as it loaded onto the work domain rather than the sexual health domain. Finally, question 31 (BOMW I am afraid to go on job interviews) loaded at 0.46. While this is close to the threshold, it is loading lower than the other three items in this domain, indicating that it is a weaker measure of this domain.

6.3.2 Internal consistency

All domains of the IWQOL-Lite had a good internal consistency. *Table 6.3* displays the Cronbach's alpha coefficients for the IWQOL-Lite domains for all BMI groups, BMI under 25 and BMI over 25. The work domain had the lowest alpha of 0.72. The self-esteem domain had a very high internal consistency of 0.95, suggesting that this domain probably contains redundant items (items measuring the same concept).

Table 6.3 Internal consistency of the IWQOL-Lite domains (Cronbach's alpha coefficients)

Domain	BMI under 25	BMI over 25	All BMI Groups
Physical functioning (11 items)	0.78	0.89	0.88
Self-esteem (7 items)	0.95	0.95	0.95
Sexual Life (4 items)	0.79	0.90	0.89
Public distress (5 items)	0.93	0.88	0.90
Work (4 items)	0.80	0.70	0.72

6.3.3 Missing data and floor/ceiling effects

Table *6.4* illustrates the percentage of scores at floor and ceiling and the percentage missing data for the participants with a BMI over 30kg/m^2. Four of the five domains of the IWQOL-Lite demonstrated large ceiling effects above the threshold recommended (>15%) (McHorney & Tarlov, 1995; Terwee, Bot, de Boer et al., 2007). Just under 7% of the data was missing for the sexual life domain, and 4.4% of data was missing for the work domain.

Table 6.4 Percentage of missing data and scores at ceiling and floor on IWQOL-Lite

IWQOL-Lite Domain	Scores at ceiling (%)	Scores at floor (%)	Missing data (%)
Physical Functioning	13.6	0	2.2
Self-esteem	27.3	2.2	2.2
Sexual life	45.2	0.6	6.7
Public distress	38.6	0	2.2
Work	40	0	4.4

*ceiling effects represent a large proportion of respondents reporting a high quality of life.
The percentages presented represent participants with a BMI over 30kg/m^2 to account for the inclusion of normal weight participants.

6.4 DISCUSSION

This study aimed to evaluate the IWQOL-Lite's structural validity, internal consistency and to examine any floor/ceiling effects and missing data in a non-representative UK community sample. In general, the structure and internal consistency of the IWQOL-Lite were good within the population used, apart from a few of the items loading onto different domains than intended. The factor structure found was similar to that intended, with the five domains of the IWQOL-Lite being represented by the intended items, for the most part. However, there were issues with five items. Two items cross-loaded on to other domains with similar factor loadings. The item BOMW I am short of breath with mild

exertion, cross-loaded onto both the physical functioning and self-esteem domain. This indicates that the item could be being interpreted psychologically and physically. In the interview analysis of Chapter 5, breathlessness with little activity was found. However, participants' spoke about the embarrassment related to this. For example, they were conscious that their friends, family, or work colleagues would notice them being out of breath when walking, and this was embarrassing for them. Therefore, it seems that this item on the IWQOL-Lite does not purely measure the physical sensation of shortness of breath. This item needs to be reconsidered and worded more precisely for it to be interpreted in the intended way.

Furthermore, two of the IWQOL-Lite items loaded onto different factors than intended. The question addressing worry about health is supposed to be scored as physical functioning item, yet it loaded strongly onto the self-esteem domain. This is understandable as worry is a cognitive process closely related to the fear emotion (Brosschot & Verkuil, 2013). Therefore, this item represents a psychological and cognitive aspect of WRQoL rather than a purely physical aspect. Also, the item "BOMW I have difficulty with sexual performance" loaded onto the work domain rather than the sexual life domain. The three other items in the work domain relate to being restricted by their weight. For example, having trouble getting things accomplished, being less productive and not receiving raises or recognition at work. Therefore, it seems that the work domain has been misinterpreted when developing the IWQOL-Lite. This relates to the lack of an iterative process when deleting and selecting the items and is likely to have been caused by a lack of input from the target population (as discussed in Chapter 3). It is recommended that before the IWQOL-Lite is used within future research, cognitive interviews are conducted to address issues with content validity, and further psychometric analyses are conducted once content validity is determined.

Additionally, this study found ceiling effects of over 15% in four of the five domains. This shows that a high proportion of respondents were scoring the highest possible scores. Ceiling effects indicate that variance in WRQoL is not being measured above a certain level (Howitt & Cramer, 2008). Having high ceiling effects suggests that the responsiveness an instrument is not adequate (Terwee et al., 2007). This would be problematic in interventions when the participants' WRQoL is improving as the instrument is unlikely to detect any further improvements in WRQoL that occur when levels are already high. Therefore, the IWQOL-Lite seems to be unable to discriminate among high levels of WRQoL within the individuals it is intended for (those with a BMI over 30). Caution should be taken when using the IWQOL-Lite in future research, and data should be checked for ceiling and floor effects. This study expands on the systematic review of existing scales (Chapter 3) and cognitive interviews with the IWQOL-Lite (Chapter 5) to further highlight the need for a WRQoL scale that is developed in an iterative way. It also provides further support for the exclusion of items in the new scale concerning sexual functioning, as this IWQOL-Lite domain was problematic for over half of participants with obesity (classified by BMI). The content validity of the IWQOL-Lite is further questioned due to the problematic items, and high ceiling effects found.

To conclude, this study has highlighted issues with the IWQOL-Lite in relation to the structure of items and domains and possible issues with its sensitivity to change, particularly at the high end of scores. This indicates that further evaluation and adaption of the IWQOL-Lite is needed before it is used to produce conclusions within research and clinical trials. The data collected within this study also included data collection for the initial factor extraction and psychometric evaluation of a draft WRQoL scale. The results of the draft WRQoL scale are presented and discussed in the next chapter.

7 INITIAL PSYCHOMETRIC EVALUATION OF A WEIGHT-SPECIFIC QUALITY OF LIFE MEASURE

The previous chapters used various methods to generate items for a WRQoL instrument. These methods incorporated patient and expert input to ensure the items are relevant to the target population, have clinical relevance and are likely to change with weight loss. The current 'gold standard', the IWQOL-Lite was found to be missing important issues relating to the impact weight had on an individual's QoL. These included issues with clothing, effects on social aspects of life, taking part in exercise and feelings/symptoms of depression. These missing aspects, along with the other themes reported by participants in the interviews, were incorporated into the new WRQoL instrument.

7.1 INITIAL EVALUATION OF THE NEW INSTRUMENT

As content validity has been established (see Chapter 5 section 5.7), the next step is to determine the structure of the scale using CTT and psychometric analyses and to conduct preliminary testing for reliability and construct validity in an adult community population. Therefore, this chapter aims to:

a) Determine the scale structure (factor extraction) of the draft instrument
b) Assess the internal consistency of the domains identified
c) Assess the construct validity of the scale through hypothesis testing (known groups validity and concurrent validity)
d) Assess the test-retest reliability of the scale domains

7.2 METHODS

Methods used in the initial evaluation of the new WRQoL instrument are detailed in Chapter 6 (from section 6.2). There were some extra data collection and statistical analyses on the new scale which are detailed below.

7.2.1 Design

Based on CTT and psychometric theory, a cross-sectional study was conducted to determine the factor structure of the new scale, reduce items and to conduct the initial evaluation of the resulting draft WRQoL instrument. Repeated measures were used to assess test-retest reliability, which involved a repeated assessment after seven days.

7.2.2 Participant characteristics

The time-one questionnaire pack was completed by 160 participants, and 94 of these participants (58.8%) completed the retest questionnaire at least seven days after. The participants have already been described in section 6.2.3, and the demographics and characteristics can be seen in *Table 6.1*. Recruitment took place as previously described in Chapter 6, section 6.2.2.

7.2.3 Materials

7.2.3.1 **Time 1 Questionnaire pack**

This questionnaire pack was described in section 6.2.4. It contained the PIS, demographics questionnaire, the draft WRQoL scale, the IWQOL-Lite items and the debrief sheet (see Appendices 4).

7.2.3.2 **Time 2 Questionnaire pack (for test-retest)**

This questionnaire pack contained the draft WRQoL instrument and a question adapted from the Global rating of change questionnaire (Juniper, Guyatt, Willan & Griffith, 1994). The Global rating of change questionnaire was used to determine whether the participants QoL had remained stable between completion when the participant's weight had remained constant (see Appendices 4 for the additional retest questions). It is a single question asking if the participant's WRQoL has changed over the past week. The response options range from a great deal worse (-7) to no change (0) to a great deal better (+7). Participants responses were used in analyses when they indicated 'no change', 'almost the same, hardly any worse' and 'almost the same, hardly any better'. The retest questionnaire was available online via qualitrics.com and in paper form. Five participants completed the paper version and posted this back to the researcher, and the remaining 89 participants completed the online version.

7.2.4 Procedure

The procedure was the same as in section 6.2.5 apart from data collection for test-retest analysis. Participants that had completed the time one questionnaire were asked if they would like to complete a shorter online questionnaire in one week. If they were happy to, a name and email address were taken, or they were given a paper copy of the retest questionnaire with a prepaid envelope. Those who provided an email address to participate in the retest were sent an email one week later with a personalised link to the Qualtrics online questionnaire.

7.2.5 Statistical Analyses

SPSS version 25 was used to conduct the statistical analysis. Data were checked for erroneous values (values that fell outside the maximum/minimum score values) before

statistical analysis took place. The psychometric testing of the new instrument consisted of determining the structure of the scale by examining factor analysis and internal consistency and assessing the concurrent validity, known-groups validity and test-retest reliability. These are described in the following sections.

7.2.6 Determining the structure

To determine the structure of the scale, factor analysis and internal consistency was used. Factor analysis was used to assess the robustness of the scales structure and to determine the domains (themes) of the scale. This stage is part of the scale development rather than an evaluation of the scale. Therefore, exploratory factor analysis was used to avoid restricting the number of scales extracted and to see the most meaningful combination of items. More specifically, principal component analysis (PCA) was used with eigenvalues > 1 on a varimax rotation. Eigenvalues represent the importance of each factor in terms of explaining the variability and correlations within the data. The criteria for item loading was a correlation coefficient of 0.5 and above.

Internal consistency measures the extent to which the items within a domain are conceptually related. The most commonly used statistic for measuring internal consistency is Cronbach's α (Cronbach, 1951). Internal consistency is high when respondents score similarly on related items. If it is not high, then the scale is likely to be measuring more than one concept or variable. Values > 0.7 represents good reliability (Nunnally, 1978).

7.2.7 Scoring method of the weight-specific QoL measure

Each domain of the scale is scored separately. Transformation of the raw score to a meaningful, comparable percentage is determined by dividing the raw total domain score

by the maximum possible score for that domain and then multiplying the result by 100, as below. Each response scale has a possible score from 0 to 9. Factor one has nine items, and so the minimum domain score is 0, and the maximum domain score is 81 (9 x 9). The response scoring was reversed for the items that were framed with a negative slant. Items 4, 14, 17, 18, 19, 22, 24, 29, 31 are framed with a positive slant and the rest with a negative slant.

$$\frac{\text{Total raw domain score}}{\text{Maximum possible domain score}} \times 100 = \text{transformed score for domain}$$

Transformed scores range from 0 (worst HRQoL) to 100 (best HRQoL) for each domain. Domain scores can still be calculated if at least 50% of the items were answered for that domain. The total raw domain score is divided by the maximum possible score out of the items answered within the domain. This can then be multiplied by 100.

7.2.8 Determining the floor and ceiling effects and missing responses

Floor and ceiling effects were established by assessing the scores in the top and bottom 5% within each factor. Floor/ceiling effects were conducted for those with a BMI of 30kg/m^2 and over, as individuals not in the obesity BMI categories are likely to cause ceiling effects in the data.

7.2.9 Hypothesis testing as an aspect of construct validity

As outlined in chapter 3, there are numerous ways to assess the construct validity of a scale. Typically, by evaluating the structural validity, hypothesis testing (or known groups

validity) and cross-cultural validity (if being used across languages or cultures). Hypothesis testing was conducted on each domain of the new instrument.

7.2.9.1 **Known-groups validity**

It is important to evaluate whether an instrument can distinguish between individuals of varying degrees of overweight/obesity. Therefore, known groups validity was evaluated for BMI and waist circumference. One-way ANOVA's were conducted with the domains of the instrument as the dependant variables and BMI/Waist circumference as the independent variable.

7.2.9.2 **BMI**

The domain scores were determined for the following subgroups of participants:

- Group 1 – those with a BMI of under 25kg/m^2
- Group 2 – those with a BMI of 25kg/m^2 to 29.99kg/m^2
- Group 3 – those with a BMI of 30kg/m^2 to 34.99kg/m^2
- Group 4 – those with a BMI of 35kg/m^2 or above

7.2.9.3 **Waist circumference**

The domain scores were determined for the following subgroups of participants:

- Group 1 – those with a low waist circumference
- Group 2 – those with a high waist circumference
- Group 3 – those with a very high waist circumference

These groups represent the waist circumferences categorised by NICE (2014) (see section 1.3.3).

7.2.9.4 **Concurrent validity**

To assess the concurrent validity of the new scale, it was compared with the Impact of Weight of Quality of Life – Lite (IWQOL-Lite) items (Kolotkin et al., 2001). This scale was chosen as it is well established and is often considered as the "gold standard" WRQoL scale. Spearman's correlations were computed between comparable domains of the IWQOL-Lite and the new instrument. *Table 7.1* shows the scales which were hypothesised to be correlated.

Table 7.1 Hypothesised correlations between new scale domains and IWQOL-Lite domains for concurrent validity

	IWQOL-lite Domains		
New instrument domains	**Physical Functioning**	**Self-esteem**	**Public distress**
1. Confidence with self		x	
2. Getting around	x		
4. Weight stigma			X

x; indicates hypothesised correlations

7.2.9.5 **Test-retest reliability**

Test-retest reliability measures the stability of a questionnaire. It is important to determine whether changes measured on a PROM are genuine or due to chance fluctuations. If the questionnaire is completed on a second occasion and the participant's health status (or weight) is stable, similar scores should be obtained for each domain on both occasions. Participants were invited to complete the questionnaire for a second-time one-week after completing the first. Using a scale of integers from -7 (negative scores representing worsening QoL) to +7 (positive scores represented an improved QoL) patients were asked to rate any change in their overall QoL since they last completed the questionnaire. Possible responses were; 7 = a very great deal, 6 = a great deal. 5 = a good deal, 4 =

moderately, 3 = somewhat, 2 = a little, 1 = almost the same, 0 = none (Juniper et al., 1994). Intra-class correlations were used to evaluate the test-retest reliability of each domain in those participants whose QoL had remained stable (answered -1, 0 or 1).

7.3 RESULTS

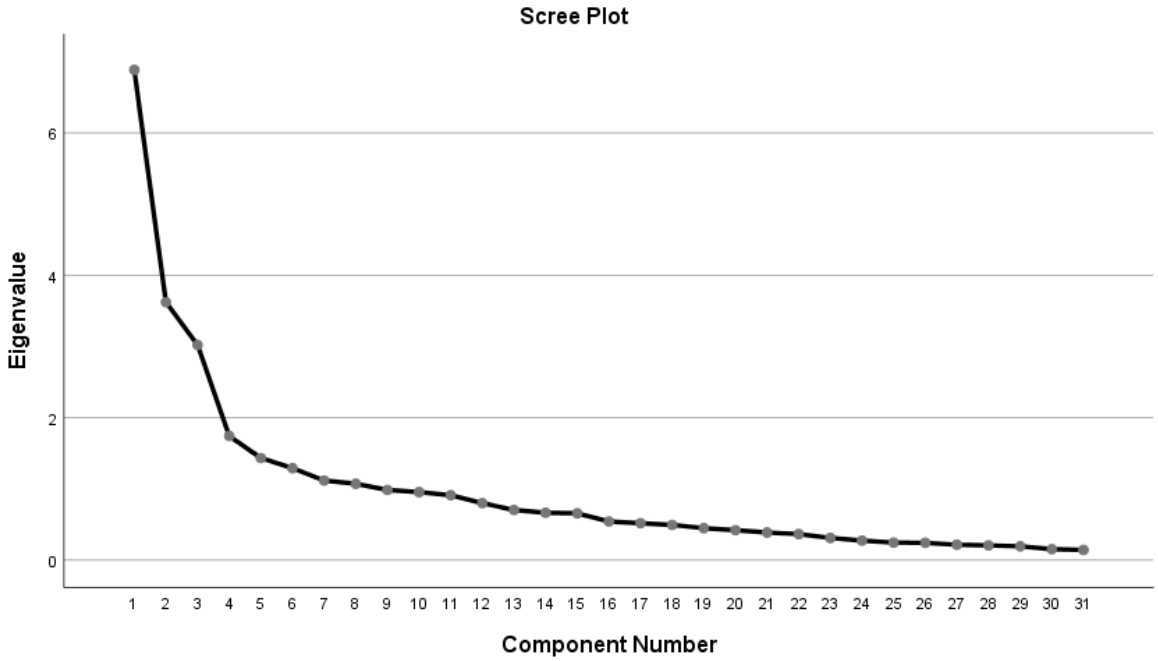
7.3.1 Face validity

Establishing face validity is an ongoing process throughout the development and validation of PROM's. The face validity and acceptability of the scale were confirmed by the participants' willingness to complete it and their comments, which were mainly confirming aspects of their lives affected by excess weight. Twelve per cent of participants wrote comments on the questionnaire. Most of these were constructive comments. Given this, the questionnaire meets the criteria for both acceptability and face validity.

7.3.2 Factor extraction

The initial PCA indicated a potential for 8 factors with eigenvalues > 1. *Figure 7.1* contains the scree plot with factors with eigenvalues > 1. The scree plot begins to level out around factors 4 to 6. Therefore, several other factor solutions were also considered by requesting a solution varying from 2 factors up to 7. This process was taken to determine the most clinically meaningful solution. Within the two-factor model, 15 items did not load to either factor, and the model only explained 34% of the variance in answers, so it was dismissed. Models for 6- and 7-factor were also dismissed due to having only two items on a number of the factors. Having only two items on a sub-scale makes it problematic when evaluating the reliability of the scale. The remaining factor solutions were discussed as potential models.

Figure 7.1 Scree plot of factors with eigenvalues > 1



Items 3 (I am healthy), 5 (I have disturbed sleep) and 6 (I am breathless going upstairs) consistently did not load across these models, so these items were removed. Once removed, PCA was re-run with fixed factors of 3, 4 and 5. Following this, item 24 (I enjoy shopping for clothes) was removed as it did not load consistently across these models. Across all models, factors 1 and 2 were consistent and contained conceptually related items. The four-factor model was decided to best represent the interview analysis in both the pilot interviews and the main item generation interviews. *Table 7.2* presents the factor loading of all items (before any were removed) for the four-factor model.

Table 7.2 Factor loadings for the four domains on the draft questionnaire before item reduction

	Component			
	1	2	3	4
Q1 Aches & Pains	.121	.556	-.143	-.026
Q2 Worry Future Health	.497	.301	.028	.268
Q3 Healthy	.377	.305	-.066	.098
Q4 No Energy	.157	.084	.661	-.055
Q5 Disturbed Sleep	.344	.216	-.249	.143
Q6 Breathless	.397	.356	.109	.218
Q7 Standing Long Periods	.084	.675	.036	.030
Q8 Walking Difficult	.066	.852	.087	-.013
Q9 Bending Down	.063	.772	.062	.091
Q10 Getting Up from Seated	.071	.822	.078	.096
Q11 Washing Difficult	-.107	.692	.148	.144
Q12 Avoid PA	.052	.204	.705	.053
Q13 Worry Fitting in Seats	-.246	.116	.750	.296
Q14 Eating Under Control	.569	.193	.067	-.238
Q15 Judged Eat in Public	.021	.018	.682	.413
Q16 Avoid Eating in Front Others	.235	.195	.147	.451[a]
Q17 Feel Good About Self	.781	-.080	-.013	.043
Q18 Happy with Weight	.848	.021	-.041	.106
Q19 Feel Confident	.781	-.089	.032	.161
Q20 Depressed	.467	-.045	.061	.537
Q21 Embarrassed Appearance	.686	.052	.101	.377
Q22 Look Good in Clothes	.570	.013	.459	.048
Q23 Choose Clothes to Hide	.680	.118	.029	.298
Q24 Enjoy Shopping Clothes	.369	.094	-.103	.391
Q25 Finding Right Clothes Difficult	.518	.113	-.032	.450
Q26 Avoid Social Situations	.380	.048	.052	.427[a]
Q27 Teased by Others	.059	-.013	-.069	.536
Q28 Discriminated Against	-.052	.237	.122	.670
Q29 Taken Seriously	.016	-.091	.618	.015
Q30 Strain on Relationships	.206	-.013	.076	.562
Q31 Valued by Others	.004	.000	.743	-.151

*Items being retained are highlighted;
[a] these items are being retained despite being under the cut-off value. This is because these aspects of WRQoL were seen to be important to participants.

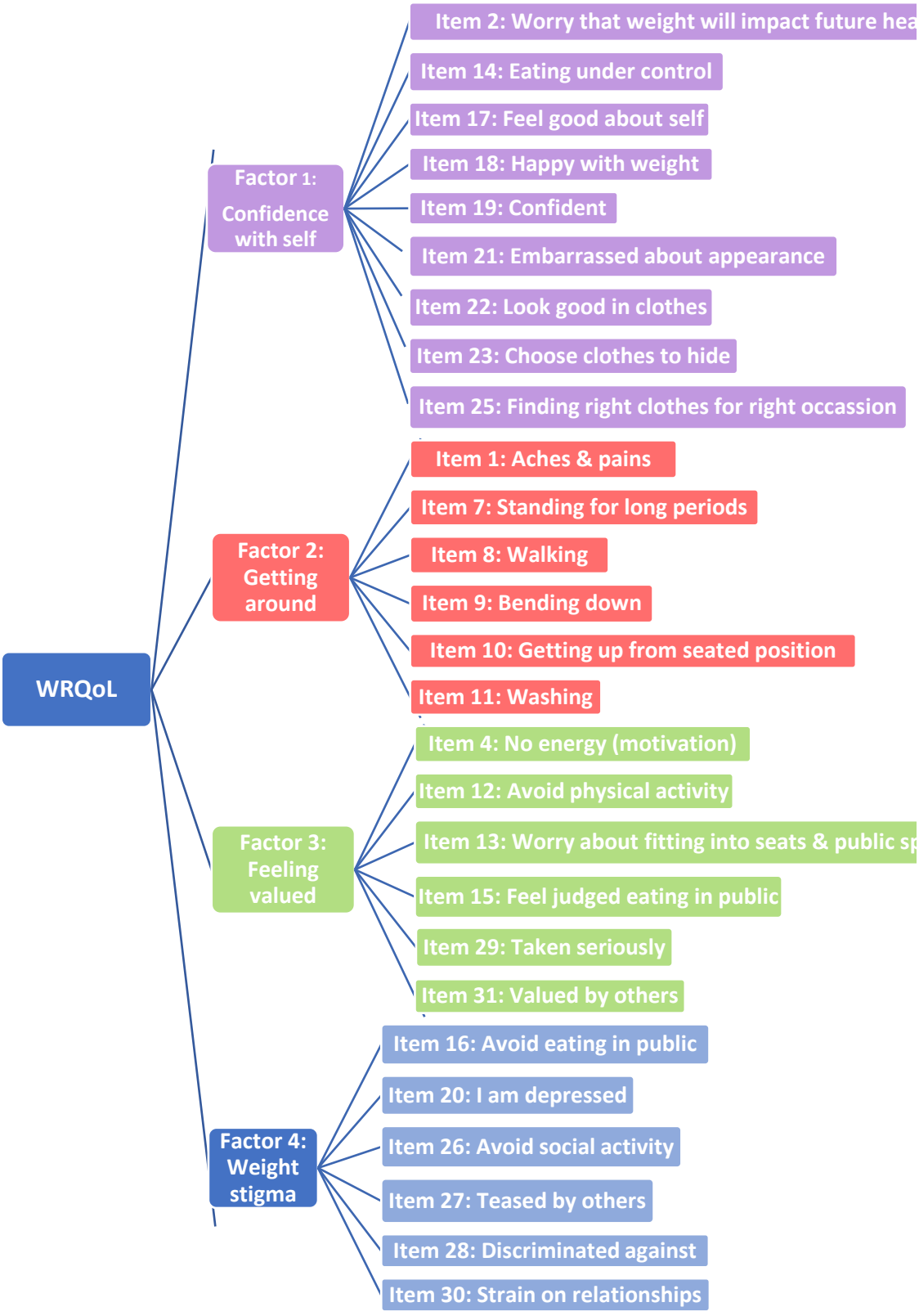
Separate PCA's were run for men and women to explore any differences in the factor structure between genders. The rotated component matrix for men and for women are displayed in Appendices 5). Overall, it was encouraging to see that the items loaded similarly across the matrices. Factors two and three on the four-factor model contained the same items for men and women. There were some discrepancies between the factor loadings of items on factor one and factor four. For example, for males, question 21 (embarrassed about my appearance) cross-loaded across factors one and four above 0.5. Whereas, for females, this item loaded strongly onto factor one, as it did in the overall

matrix (*Table 7.2*). Also, question 26 (I avoid social situations) did not load above the threshold for males on any of the factors. However, it should be noted that it is implausible to achieve perfect matches in factor structures for two different samples. This is especially the case for the male sample as it was underpowered (*n = 63*). A sample size of at least 100 is needed to make reliable conclusions from PCA. However, there is initial evidence that the factor structure is similar for both males and females, and therefore no changes were made at this stage based on these PCA's.

7.3.3 Domains identified through exploratory factor analysis

The research team (two researchers who conducted the interview analysis and a psychometrician) discussed the four factors to determine what concept they related to. This was done in relation to the item generation interviews to ensure the instrument represented the interview findings as closely as possible. *Figure 7.2* illustrates the domains identified and the items included within each domain. Factor one represented psychological aspects of WRQoL such as body image and confidence and was named 'Confidence with self'. Factor two represented physical and mobility issues related to weight and was named 'Getting around'. Factor three represented feeling judged and devalued in social interactions and was named 'Feeling valued'. Finally, factor four represented being discriminated or experiencing stigma and was named 'Weight stigma'.

Figure 7.2 Item to factor loading map of the final draft



7.3.4 Internal consistency

Internal consistency was assessed for the four domains identified. *Table 7.3* displays the Cronbach Alpha's for the draft instrument for all BMI groups, BMI under 25 and BMI over 25. All were above 0.7 for the whole group, showing that items within each domain are conceptually related. Alphas are also reported for those with a BMI of under 25 and over 25. The Cronbach Alpha's were higher for individuals with BMI over 25 apart from Factor 3 (Feeling valued); however, this was only marginally different.

Table 7.3 Internal consistency for domains of new scale (Cronbach's alpha)

Domain	BMI under 25	BMI over 25	All BMI groups
Factor 1 (9 items) Confidence with self	0.82	0.87	0.87
Factor 2 (6 items) Getting around	0.62	0.86	0.81
Factor 3 (6 items) Feeling valued	0.80	0.79	0.80
Factor 4 (6 items) Weight stigma	0.68	0.74	0.71

7.3.5 Assessment of ceiling/floor effects and missing data

Domains 1-3 displayed no ceiling or floor effects and had a very small percentage of missing data in respondents with a BMI of 30kg/m^2 and over. The weight stigma domain displayed a ceiling effect of 28.9%, indicating that a large number of respondents were scoring within the top 5% of possible scores. *Table 7.4* displays the percentage of missing data, and scores at ceiling and floor.

Table 7.4 Percentage of scores missing and at floor/ceiling in the new instrument for those with a BMI over 30

Domain	Scores at ceiling (%)	Scores at floor (%)	Missing data (%)
1. Confidence with self	0	0	1.9
2. Getting around	4.4	0	0.6
3. Feeling valued	4.4	4.4	1.3
4. Weight stigma	28.9	0	1.3

The lower reliability and high ceiling effect indicate that factor 4 may be somewhat problematic. When looking back at the factor loadings for the final items within this domain, items 16, 20 and 30 had factor loadings lower than the cut off previously stated (0.50). These were included due to the perceived importance of these concepts within the interviews. Due to the issues with reliability and ceiling effects, internal consistency was conducted for factor 4 with items 16, 20 and 30 removed. This increased the internal consistency to 0.79, but removing these items also increased the ceiling effects further. Therefore, it was decided that these items would remain at this stage in the instrument's development. However, these items should be further explored with the target population to reconsider their meaning and importance.

7.3.6 Hypothesis testing for construct validity: Known-groups validity

BMI and waist circumference measurements were available for all 160 participants who had completed the questionnaire.

7.3.6.1 **BMI**

Table 7.5 presents the mean score and standard deviations for each domain of the questionnaire for the four BMI groups. Significant main effects were found for all four domains: factor one (confidence with self) ($F=13.11$, $p<0.001$); factor 2 (getting around)

(F=6.10, p=0.001); Factor 3 (F=3.15, p<0.027); Factor 4 (Weight stigma) (F=5.52, p=0.001).

Table 7.5 Known groups validity: Mean percentage scores for BMI groups

BMI	**Under 25kg/m^2**	**25-29.9kg/m^2**	**30-34.9kg/m^2**	**35kg/m^2 or above**	**P value**
Domains	**n = 59**	**n = 56**	**n = 26**	**n = 19**	
Confidence with self	70.66 (17.38)	62.79 (17.88)	58.74 (20.61)	40.81 (19.46)	<0.001
Getting around	88.23 (11.37)	85.81 (15.28)	85.19 (15.11)	71.93 (19.99)	0.001
Feeling valued	80.35 (17.90)	79.20 (16.63)	72.29 (24.03)	67.45 (17.04)	0.027
Weight stigma	94.29 (9.38)	90.43 (11.55)	92.31 (10.78)	82.75 (13.61)	0.001

*Numbers represent mean percentage score (standard deviation).

Post hoc analysis indicated that the scale could differentiate between BMI groups, but this varied within each domain of the scale.

7.3.6.1.1 Factor 1: Confidence with self

Post hoc comparisons using Tukey HSD demonstrated a stepping down effect from BMIs of under 25kg/m^2 to BMIs of 35kg/m^2 or over [(BMI < 25kg/m^2 vs. 30-34.9kg/m^2 (p = 0.032); BMI 30-34.9kg/m^2 vs. 35kg/m^2 + (p < 0.001)]. Confidence with self was highest within individuals with a BMI of under 25kg/m^2. This decreased across the BMI groups, with the 35 kg/m^2 and over group scoring lowest on confidence with self. This indicates that the instrument can distinguish between each obesity BMI group.

7.3.6.1.2 Factor 2: Getting around

Post hoc comparisons using Tukey HSD indicated that the mean score for the 'getting around' domain was significantly lower in the 35kg/m^2 and over group than the under 25kg/m2 (p<.001), 25-29.9kg/m2 (p=.003) and 30-34.9kg/m2 (p=.016) BMI groups.

7.3.6.1.3 Factor 3: Feeling valued

Post hoc comparisons indicated significantly lower mean scores in the 35kg/m^2 and over group than the under 25kg/m2 (p=.04) BMI group and near significantly lower mean scores in the 35kg/m2 and over group than the 25-29.9kg/m2 (p=.08) BMI group.

7.3.6.1.4 Factor 4: Weight Stigma

Post hoc comparisons indicated significantly lower mean scores in the 35kg/m^2 or over BMI group than in the under 25kg/m^2 (p=.001), 25-29.9kg/m^2 (p=.04) and 30-34.9kg/m^2 (p=.02) BMI groups.

7.3.6.2 Waist circumference

Table 7.6 presents the mean score and standard deviations for each domain of the questionnaire for the waist circumference groups. Significant main effects were found for all domains apart from the weight stigma domain: factor one (confidence with self) (F=13.11, p<0.001); factor 2 (getting around) (F=6.10, p=0.001); Factor 3 (F=3.15, p<0.027).

Table 7.6 Known-groups validity: mean percentage scores for waist circumference categories

Waist circumference (cm) Domains	**Low**	**High**	**Very high**	**P-values**
	n = 78	**n = 35**	**n = 46**	
Confidence with self	68.52 (17.33)	61.59 (19.92)	52.55 (20.75)	< 0.001
Getting around	88.94 (11.75)	84.07 (14.44)	79.83 (18.25)	0.004
Feeling valued	80.52 (16.59)	80.48 (12.64)	70.09 (23.30)	0.005
Weight stigma	91.37 (10.64)	90.95 (11.14)	88.20 (11.24)	.283

Numbers represent mean percentage score (standard deviation).

7.3.6.3 **Concurrent validity**

Three domains on the new scale were comparable to the domains of the IWQOL-Lite. One hundred sixty participants completed both questionnaires at the same time. *Table 7.7* displays the correlation coefficients for the comparable domains of the draft instrument and the IWQOL-Lite. The three domains correlated well; confidence with self and self-esteem (r = 0.81); getting around and physical functioning (r = 0.74); weight stigma and public distress (r = 0.59), indicating good concurrent validity in these factors.

Table 7.7 Concurrent validity: correlations between comparable domains of the new instrument and the IWQOL-Lite

	IWQOL-lite Domains		
New instrument domains	**Physical Functioning**	**Self-esteem**	**Public distress**
Confidence with self		r = 0.81	
Getting around	r = 0.74		
Weight stigma			r = 0.59

**All correlations were significant at the 0.01 level*

7.3.7 Test-retest reliability

Ninety-four of the 160 participants completed the questionnaire on a second occasion, at least seven days after the first completion (range 7-11 days). Eighty-five of these reported that their QoL and weight had remained stable over the seven days (scores of -1, 0 and +1 were considered to represent stable QoL). So only these participant scores were included in the analysis. *Table 7.8* presents the intraclass coefficients (ICC) for each domain and the 95% confidence intervals split by BMI. All ICC's for the BMI over 25 and the overall sample were above the recommended threshold of 0.70, indicating that the scores on the draft scale are stable over time when no change in the concept occurs.

Table 7.8 Intraclass coefficients for each domain with 95% confidence intervals (Cronbach's alpha)

Domain	BMI under 25	BMI over 25	All BMIs
Confidence with self	0.79	0.85	0.85 (0.78-0.90)
Getting around	0.78	0.74	0.75 (0.71-0.87)
Feeling valued	0.62	0.74	0.70 (0.58-0.80)
Weight Stigma	0.69	0.80	0.78 (0.68-0.85)

7.4 SUMMARY OF THE INITIAL EVALUATION OF THE NEW INSTRUMENT

This chapter describes the initial validation process of the WRQoL measure resulting in a 27-item questionnaire reflecting four domains (confidence with self, mobility, feeling valued and weight stigma). The results suggest that the questionnaire is structurally robust with good concurrent validity, internal and test-retest reliability and can distinguish between levels of obesity severity (BMI and waist circumference). *Table 7.9* contains the

final version of the new instrument, including the instructions for completion and response scale.

Domains one to three have good evidence for the validity and reliability and have been consistent in the factor analyses. However, the weight stigma domain is problematic as it has a ceiling effect of 28.9%, which is above the 15% threshold. This suggests that it is not able to discriminate among the high levels of QoL in this domain. However, this domain was retained in the final draft instrument as the concepts included in these items were identified as important to individuals interviewed in both the pilot interviews and the item generation interviews. It could be that experiences of weight stigma are not very frequent, and so may not be experienced daily as the recall period requires. This is similar to the IWQOL-Lite's Public Distress domain which had a ceiling effect of 38.6% (see section 6.3.3). This indicates that more feedback from the target population is needed for the final draft version of the new instrument. This will help to refine this subscale further to improve its content validity and psychometric properties. Once further content validation has been gained, and the scale has been refined, psychometric analyses should be performed on the new version of the scale using a separate and large sample. The next chapter will discuss the findings of the thesis, along with the strengths, limitations, and future recommendations.

Table 7.9 The introductory information, items, and response options for the final version of the new WRQoL scale

New Weight-Related Quality of Life Instrument

Introductory information

The following questionnaire is designed to find out how your weight/body shape affects your life.

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel today.

Questions start on the next page.

Items*	**Response scale**
I worry that my weight will impact my future health	0 (Not at all) to 9 (All the time)
My eating is under-control	0 (Not at all) to 9 (All the time)
I feel good about myself	0 (Not at all) to 9 (All the time)
I am happy about my weight	0 (Very unhappy) to 9 (Very happy)
I feel confident	0 (Not at all) to 9 (All the time)
I am embarrassed about my appearance	0 (Not at all) to 9 (All the time)
I look good in my clothes	0 (never) to 9 (always)
I choose clothes that hide my body shape	0 (never) to 9 (always)
Finding the right clothes for the right occasion is difficult (for example, wedding, evening, work etc.)	0 (Not at all) to 9 (All the time)
I have aches and pains (for example, in knees, hips, ankles, back, feet and/or joints)	0 (Not at all) to 9 (All the time)
Standing for long periods is difficult	0 (Not at all) to 9 (All the time)
Walking is difficult	0 (Not at all) to 9 (All the time)
Bending down is difficult (for example, tying shoes, cutting toenails, picking things up from the floor etc.)	0 (Not at all) to 9 (All the time)
Getting up from a seated position is difficult (for example, chairs, cars etc.)	0 (Not at all) to 9 (All the time)
Washing myself is difficult	0 (Not at all) to 9 (All the time)
I have no energy	0 (No energy) to 9 (Lots of energy)
I avoid physical activity	0 (never) to 9 (always)
I worry about fitting in seats and public spaces (for example, aeroplane seats/seatbelts, turnstiles, bus seats, train/bus aisles etc.)	0 (Not at all) to 9 (All the time)
I feel judged when I eat in public	0 (Not at all) to 9 (All the time)
I am taken seriously (for example, by health care professionals, work colleagues, etc.)	0 (Not at all) to 9 (All the time)
I feel valued by others	0 (Not at all) to 9 (All the time)
I avoid eating in public	0 (Not at all) to 9 (All the time)
I am depressed	0 (Not at all) to 9 (All the time)
I avoid social situations (for example, physical activities, meeting with friends/work colleagues)	0 (never) to 9 (always)
I am teased	0 (Not at all) to 9 (All the time)
I feel discriminated against	0 (Not at all) to 9 (All the time)
There is a strain on my personal relationships	0 (Not at all) to 9 (All the time)

* 'Confidence with self' items are coloured in pink; 'Getting around' items are coloured in orange; 'Feeling valued' items are coloured in green; 'Weight stigma' items are coloured in blue.

8 DISCUSSION AND FUTURE DIRECTIONS

This PhD programme of work has met the three following aims:

a) Determined the need for a new weight-related quality of life (WRQoL) scale to evaluate community and clinical obesity interventions in the UK
b) The development of a new WRQoL scale using input from those it is intended for
c) The initial testing of the first version of a new WRQoL scale

The merits and limitations of this work will be discussed separately for each aim, and then the original contribution to knowledge will be outlined.

8.1 DETERMINING THE NEED FOR A NEW WRQoL SCALE

Before a scale is developed, it should be ascertained that no existing scales are available (FDA & HSS, 2009). If there are existing scales, they should be assessed for appropriateness and their validity, reliability, and responsiveness. The increasing prevalence of obesity, along with the UK's treatment pathway, indicates that community and primary care lifestyle and behaviour change interventions will become increasingly prevalent. These types of obesity treatments show inconsistent improvements in HRQoL with weight loss. It was hypothesised that there might be issues with existing scales and so the first aim of this thesis was to *assess the need for a new WRQoL scale*. Various aspects of this PhD programme contributed to assessing the need for a new WRQoL. These included a systematic review of existing scales, and evaluation of the IWQOL-Lite in a UK population.

8.1.1 Systematic review of existing WRQoL scales

First, a systematic review was conducted to identify and evaluate existing WRQoL scales (Chapter 3). The systematic review adds to the literature as it provides an in-depth evaluation of existing WRQoL scales concerning their psychometric properties, and strengths and weaknesses. The review of existing scales followed specific standards and recommendations for PROM development and evaluation. These evaluations will allow researchers to decide on an appropriate WRQoL instrument to use in descriptive and evaluative studies of weight-loss interventions. It also adds to knowledge as it indicates that many existing WRQoL scales are lacking evidence of their content validity and responsiveness. Content validity and responsiveness are essential for the interpretation of changes in scores on a WRQoL instrument (Terwee, Prinsen, Chiarotto et al., 2018). Hopefully, this finding will prompt authors to improve their instruments and validate them further.

The IWQOL-Lite had the most published validation papers. It was considered the 'gold standard' WRQoL scale as it was often used to evaluate the criterion validity of other scales. However, issues were highlighted with the development of the IWQOL-Lite items leading to the questioning of its content validity. First, the items were based on the original IWQOL items. The generation of these items is unclear as there is no detailed information regarding the interviews or focus groups that took place. The participants used in the item generation of the IWQOL were inpatients of a weight-loss facility, and so had morbid obesity. The IWQOL-Lite item selection was based on statistical methods where 43 of the 74-items were deleted. The remaining items have not been subject to face or content validity evaluation by the target population. Therefore, it is unclear whether the items are relevant to less severe cases of obesity such that are seen in Tier 2 weight management services. A WRQoL scale used to evaluate weight interventions should be

able to detect changes across BMI's, so the items must be relevant across weight loss stages and BMI groups. The systematic review concluded that a new WRQoL instrument was needed and the IWQOL-Lite should be evaluated in a UK sample.

In contrast to this systematic review, Duval and colleagues (2006) conducted a review of obesity-specific HRQoL questionnaires and rated the IWQOL-Lite to have good measurement properties. However, Duval and colleagues (2006) did not assess the content validity of the IWQOL-Lite or any of the other scales identified. Nor was the methodological quality of the studies assessed. Only the outcome of the studies was evaluated. Content validity is arguably the most crucial measurement property as problems with content validity cannot be rectified by demonstrating evidence of other measurement properties (Terwee et al., 2018). Likely, content validity was not assessed by Duval et al. (2006) because there were no agreed standards of demonstrating content validity at that time.

There are now recommendations regarding the development of PROMs, including HRQoL scales (Terwee et al., 2018; FDA & HHS, 2009). The standards include generating items based on patient input, gaining patient input on the initial items and when items are deleted, or wording is changed (FDA & HHS, 2009; Leidy & Vernon, 2008). These standards were used in the systematic review conducted for this PhD programme (detailed in chapter 3). They were also used by De Vries and colleagues (2018) when assessing the appropriateness of HRQoL measures for use in body contouring. De Vries and colleagues (2018) support the current systematic review as they also questioned the content validity of the IWQOL-Lite and also indicated a lack of consistent reporting in the studies evaluating psychometric properties.

It should be noted that the systematic review in this thesis evaluated the scales for use in community and primary care tier 2 and 3 interventions. Therefore, the scales evaluated could be relevant, with good psychometric properties in other populations or treatment types, such as bariatric surgery. However, there is a need for existing WRQoL scales to be evaluated using COSMIN methodology for use in bariatric surgery populations as this has not been done. This would provide comparable information and evaluation of existing scales to allow HCP's and researchers to decide on the most appropriate scale for use in bariatric populations. Despite being specific to community interventions, the review highlighted many scales to be missing the evaluation of important psychometric properties. These include content validity, measurement error and responsiveness. Therefore, it is recommended that existing bariatric and non-bariatric WRQoL scales are fully evaluated to ensure they have good psychometric properties.

Furthermore, it could be possible that WRQoL scales were missed in the systematic review, or further evaluation studies could have been published since the review. However, at the time the review was undertaken, the three independent researchers (including the author) were confident that all scales were found. This is because the search strategy was comprehensive in terms of the terms used for the construct, population, type of instrument and development and validation measurement properties. Also, the inclusion of three independent researchers meant that the title, abstract and full-text screening was undertaken rigorously, limiting the likelihood of relevant papers being missed.

8.1.2 Evaluation of the IWQOL-Lite

A qualitative exploration of the impact of carrying extra weight on everyday life was conducted (Chapter 4), in addition to the evaluation of the IWQOL-Lite's content validity

(Chapter 5), structural validity and internal consistency (Chapter 6). The cognitive interviews used to evaluate the IWQOL-Lite highlighted some problems with items and domains. The elements deemed missing from the IWQOL-Lite include issues with clothing, social aspects, eating, exercise, depression, mobility issues, and issues with sleep. The work, sexual life domain and the item regarding fitting through turnstiles were deemed irrelevant, with the sexual life domain causing participants to be uncomfortable when completing it. The sexual health domain on the IWQOL-Lite was brought up frequently in the cognitive interviews. Participants indicated that this domain made them feel embarrassed or uncomfortable. In some cases, this section was thought to be irrelevant as they were not in an intimate relationship.

Talking about sex is often embarrassing and can cause offence (Dyer & das Nair, 2013), and people tend to avoid talking about their sexual experiences (Anderson, Kunkelg & Dennis, 2010). Surveys investigating sexual health and behaviours generally have a 40% non-return rate (Fenton, Johnson, McManus & Erens, 2001). If sexual health is included in an instrument, people are likely to miss these items out, creating an item response bias. Those that miss out items on purpose are either more or less likely to have experience of the behaviour (Fenton et al., 2001). Therefore, this leaves a gap in knowledge regarding sexual health and could cause issues when interpreting the results of research, such as ceiling effects. Due to this and the reluctance to talk about sex life in the preliminary and item generation interviews, no specific items on sex were included in the new instrument. This is further justified and discussed as a limitation of the new scale in section 8.3.1.2.

The psychometric evaluation of the IWQOL-Lite showed good internal consistency and adequate structural validity. However, a few problematic items were found in the factor analysis. Firstly, a few items loaded across two domains, indicating that these items are

not a pure measure of the domain it is intended for. For example, the item 'I am embarrassed to be seen in public' cross-loaded onto the self-esteem domain and the public distress domain. Two items loaded onto the wrong domains with one of them being quite peculiar. For example, the item 'I have difficulty with sexual performance' loaded onto the work domain rather than the sexual life domain. These issues could indicate that the work domain on the IWQOL-Lite is measuring aspects relating to productivity or functioning rather than work specific concerns.

Issues were also highlighted by the high levels of scores in the 5% maximum levels of WRQoL in four of the five domains on the IWQOL-Lite (range 27.3-45.2%). This indicates substantial ceiling effects in the domains of self-esteem, sexual life, public distress and work. Ceiling effects were only calculated for those with a BMI of over 30kg/m^2 as the sample also included individuals of normal weight. A ceiling effect suggests that there is a lack of comprehensive items covering these domains and that there are issues with responsiveness (Higginson & Carr, 2001). The physical functioning domain was the only domain without a ceiling effect. This domain contains 11 items, whereas the remaining domains contain 4-7 items, supporting the idea that there is a lack of comprehensive items in the domains with ceiling effects. These high ceiling effects in individuals with obesity is concerning as the IWQOL-Lite has been used to assess clinical trials and to draw conclusions about QoL in obesity. If the scale is gaining such high ceiling effects, it shows that the scale is not able to detect further improvements in WRQoL in those with a high WRQoL.

Therefore, taken together, the results of the systematic review and the further evaluation of the IWQOL-Lite's psychometric properties highlights important issues. Issues with content validity and likely the responsiveness of the IWQOL-Lite indicates that it should

be used with caution within UK samples. Adaptation and further evaluation of the IWQOL-Lite are needed before it is used in further research and clinical trials. This is especially true if the results of research using the IWQOL-Lite are to be used to make medicine and food labelling claims (FDA & HHS, 2009).

8.2 THE DEVELOPMENT OF A NEW WRQoL SCALE

The results of the systematic review, qualitative and quantitative evaluation of the IWQOL-Lite informed the need for a WRQoL scale relevant for overweight and obesity interventions. Therefore, a WRQoL instrument was developed following best practices as discussed in Chapter 2 (see section 2.5). There were four qualitative aspects involved in the development of the WRQoL scale. These were a) preliminary interviews to generate an informed interview schedule, b) item generation interviews, c) expert input for item selection and d) cognitive interviews to test for face validity of the draft questionnaire. As WRQoL is a subjective concept, input from the target population was seen to be a crucial part of item generation and for the evaluation of content validity.

8.2.1 Preliminary and Item Generation Interviews

The first two qualitative aspects (preliminary and item generation interviews) created an understanding of how being overweight, losing weight and regaining weight affects different areas of HRQoL. The majority of themes found matched the content of existing WRQoL scales. However, there were a few new aspects which are not covered in other scales. These were: worry for future health, limited participation in social activities, using clothes to hide, being unable to find clothes for the right occasion, issues relating to eating in public and not being taken seriously by HCPs. These findings relate to psychosocial aspects of life and can have implications on health and QoL.

In Chapter 1, the clinical impact of weight on psychosocial health were discussed. A person who is dissatisfied with their body (or parts of their body) uses clothes to hide their body. Measuring body dissatisfaction and weight concerns can help to identify individuals who are at risk of impaired psychosocial functioning and reduced emotional wellbeing (Mond et al., 2011; Mond et al., 2007). Having a poorer body image has been found to motivate people to exercise in an attempt to lose weight. However, those who are motivated purely by appearance reasons are more likely to drop out of interventions (Palmeira et al., 2010; Roberts & Ashley, 1999). Therefore, including items on clothing and body image can provide HCP's with an understanding of their patient's psychosocial health and will allow them to identify better those who need extra support. These aspects were important to participants and affected their QoL; therefore, they were discussed in the expert panel to be included in the new instrument.

The interview findings (preliminary and item generation interviews) describe QoL in a UK community population and illustrate the impact that overweight and obesity can have on an individuals life. There are relatively few studies that have looked at QoL specific to obesity in a qualitative manner. Other authors have employed obesity patients to develop obesity specific scales, but their qualitative findings are rarely discussed and published. The qualitative studies that have explored the lived experiences of obesity or WRQoL often focus on patients undergoing bariatric surgery (Keleidari, Jamalouee, Mahmoudieh, Zolfaghari & Gharzi, 2017), or obesity in countries other than the UK (Keleidari et al., 2017; Thomas, Hyde, Karunaratne, Herbert & Komesaroff, 2008). Qualitative interviews enable rich data, and while some might not be relevant for item generation, it can still generate ideas and areas for further exploration (Willig, 2013). For example, the qualitative aspects of this work highlighted issues with body image,

avoiding health care, possible disordered eating, which are important aspects of obesity that should be addressed in future research.

8.2.1.1 **Priming effect**

A possible limitation in the item generation interviews was the potential priming effect of the IWQOL-Lite (as the interviews were split into two sections; IWQOL-Lite and item generation). Issues with work were not found in the preliminary interviews and were only brought up in the main interviews after completing the IWQOL-Lite, which has a 'work' domain. This suggests that the IWQOL-Lite was priming individuals to talk about this and so the work domain could be of lesser importance than other issues brought up in the interviews. However, problems with work are relevant to other themes found in the interviews. For example, the work issues represented by the IWQOL-Lite represented discrimination, feeling unvalued, being self-conscious and productivity relating to physical functioning or mobility. The cognitive interviews on the IWQOL-Lite highlighted that the work domain was not relevant to everyone within a community population. For example, the unemployed, students and retired individuals. Therefore, having a work domain would be problematic as it is too specific.

Priming was also believed to have occurred in the item generation interviews for the finding of body temperature. This was highlighted by the second interview analyser, who thought the questions asked relating to body temperature were leading the participants to talk about body temperature when it might not have been important to them. Body temperature was not included in the new instrument due to this and due to it being unlikely to change with weight loss. First, it was seen as both negative (such as being too hot, causing sweating) and positive (such as being warmer in cold climates). Not knowing whether it represents a positive or negative aspect would make it difficult to interpret the

results of an item on body temperature. It is also unknown whether losing weight would affect body temperature as some individuals experienced a completely different impact of weight on their body temperature (for example, always cold despite extra weight). This priming effect highlighted the importance of having an independent second researcher analysing the interview transcripts. No other issues with the interviews were highlighted by the second researcher, indicating agreement in the themes found.

8.2.1.2 **Data collection and participant sampling**

The development of the conceptual framework of WRQoL over the two stages of qualitative exploration (preliminary interviews and item generation interviews), indicates the importance of both aspects. If item generation had occurred from the preliminary interviews, the new instrument could have missed important aspects relating to obesity-specific HRQoL. It could even have included aspects that are not relevant to the majority of the target population. The FDA guidelines (2009) recommend input from patients/target population, but they do not specify how many participants would be considered sufficient. This is likely due to the varying demographics different disease can affect. Approximately 80 participants were included in the qualitative aspects of scale development. While there are no 'rules' indicating how many participants should be included, it is generally agreed that interviews should be conducted until saturation occurs (Leidy & Vernon, 2008). Saturation is the point where no new themes or descriptions are introduced by the participants. The number of interviews needed to reach saturation depends on a) the complexity of the concept and b) the diversity of the population of participants with relevant experiences (Leidy & Vernon, 2008).

To represent the key variables in the preliminary interviews and the item generation interviews, it was calculated that around 60 interviews were needed. Saturation occurred

at around 55 interviews, and a couple more interviews were conducted to increase the confidence in the reliability of the themes and the content validity of the new scale. Obesity is a multifaceted disease in terms of its aetiology and consequences on the individual. This means it can affect numerous people with differing demographics, characteristics and social/environmental situations. Therefore, item generation should involve patients/participants with varying demographics to ensure a good representation of the target population is gained (FDA & HHS, 2009). These interviews defined several key variables and employed 58 participants to help achieve a representative sample and a range of experiences along different weight loss stages. This meant that expected changes in HRQoL with weight loss could be inferred from patient experiences. Ultimately, these interviews have ensured the content validity of the new instrument.

The recruitment of participants utilised a self-selection process within community locations, where individuals got in touch if they wanted to take part rather than being approached. This meant that there was limited potential to have control over the range of participant demographics covered in the interviews. In the preliminary interviews, there were only three male participants (out of 10). This could have introduced bias in the analysis of the initial interviews by not fully representing male views/experiences. However, the item generation interviews included 17 males which allowed further exploration and inclusion of their views and experiences. Males included in each qualitative stage of development equated to approximately 38%, which is similar to some existing scales (e.g. Niero, Martin, Finger et al., 2002). However, the item generation of previous WRQoL scales either employed experts or a narrow sample and in some cases the gender split is often not detailed (e.g. Mannucci, Ricca, Barciulli et al., 1999; Kolotkin et al., 1995). Where patients were involved, these were mainly females and clinical obesity patients. The new WRQoL instrument developed throughout this PhD programme

utilised 17 males in addition to 31 females at differing weight loss stages. Having included males within the item generation phase and the cognitive interview phase means that both male and female aspects of WRQoL are covered and represented on the new scale. Therefore, the items of this scale are more relevant and appropriate for both males and females and across weight loss stages than existing scales.

Furthermore, as recruitment took place in community locations, there was no access to clinical records to discover participants weight loss status. This meant that weight loss status had to be self-reported by the participants in all aspects of the scale development and initial psychometric testing. Research has indicated that self-reported weight and height is subject to bias, with the self-report bias being higher in those in the overweight and obesity BMI categories (Maukonen, Mannisto & Tolonen, 2018). However, the participants' weight, height and waist circumference were all measured by the author of this PhD; therefore, these were not subject to self-report bias. But there could have been some measurement errors in weight, height and waist circumference. For example, some participants could have been breathing in when having their waist circumference measured, which could have affected the measurement value. However, a protocol was followed as closely as possible to minimise any measurement errors.

In addition, recruitment at some locations was unsuccessful compared to others. For example, at some locations (such as SW) the poster was handed to a member of staff who displayed the poster. However, it was not checked whether the poster was put up or whether the research was mentioned to their users. Only two participants were recruited from SW, and similar was true for other places where the poster was displayed (for example, at TESCO locations no participants were recruited). On the other hand, recruitment was more successful via Facebook and at locations where potential

participants were directly approached. It would seem that not having a presence when recruiting or having a direct and easy way for the participants to ask questions is not conducive to successful recruitment. The use of social media in recruiting participants has been found to be cheaper, faster and has the potential to reach a broader range of people (Whitaker, Stevelink & Fear, 2017). Therefore, future research should utilise social media to improve recruitment. However, it can lead to an overrepresentation of white females and an underrepresentation of ethnic minorities and populations without access to the internet (Whitaker et al., 2017). So, it is best to use social media alongside other methods to access potentially underrepresented groups.

While the sample of participants within the qualitative interviews included more variety than previous scales (such as BMI and weight loss status), there was a lack of ethnic diversity. Therefore, it is possible that the items are not relevant to Black and Ethnic Minority populations. This is similar to previous WRQoL scales where mainly individuals from White/Caucasian ethnic groups are included (e.g. Kolotkin et al., 2001). However, the majority of existing scales did not specify the ethnic diversity of the sample used in item generation phases (Camolas et al., 2016; Duval et al., 2006; Ziegler et al., 2005; Mannucci et al., 1999; Le Pen et al., 1998). The percentage of individuals recruited who self-identified themselves as part of an Asian, Black, and Mixed Ethnic group was representative of the area statistics. While the numbers are representative of the national/area statistics of ethnic minority groups, such a small number of interviews with individuals from BEM populations does not allow a full understanding of how weight affects QoL in these individuals. There could be cultural factors that differentially influence the view of overweight/obesity. Therefore, in future research, this scale should be tested for content validity in Asian, Black, and Mixed Ethnic groups to ensure the items and instructions are relevant, comprehensive and comprehendible.

Underrepresentation of minority ethnic groups has also been found in medical research (Gill, Plumridge, Khunti & Greenfield, 2013; Rooney, Bhopal, Halani et al., 2011; Smart & Harrison, 2017). Attempts to explain this underrepresentation has been made through qualitative methods. Gill et al. (2013) interviewed individuals from minority ethnic groups who had and had not participated in heart failure screening research. The main barriers to participation included a lack of understanding of the nature and purpose of research in general; previous negative experiences of market research (for example, they believed their participation would not change anything), and language barriers. Potential recruiting techniques were also identified. These included being directly approached (face-to-face), clearly explaining the reasons and potential benefits of the research and involving religious/community leaders.

Whilst Gill et al. (2013) were investigating the lack of participation in health screening research; their findings provide useful information that can be applied to other research. Other research has recommended similar techniques such as developing culturally sensitive recruitment materials, offering payment and developing trust with participants and their communities (Renert, Russell-Mayhew & Arthur, 2013; Rooney et al., 2011). As the current research relied mainly on self-recruitment, this could explain the lack of participants recruited from ethnic minority groups. Future research aiming to gain a variety of ethnic populations should actively seek to include ethnic minority groups using the recruitment strategies recommended by Gill et al. (2013). This way, research will be more representative of all ethnic groups.

Furthermore, recruiting for and conducting 58 interviews lasting approximately an hour each is very time-consuming. It could have been beneficial to conduct focus groups with the target population rather than one to one interviews. This would have saved time to

allow for the next round of psychometric testing. Focus groups require homogenous groups to enable participants to express their thoughts spontaneously. It is important that focus groups *do not* include participants with too distant cultural levels, social status and hierarchical positions to avoid individuals feeling ashamed to talk about their life experiences in front of people they feel distant from (Acocella, 2012). Therefore, using focus groups would have required careful planning to avoid this. This could have led to a less representative sample if focus groups include individuals with similar backgrounds and characteristics. In this research, one-to-one interviews were time-consuming, but it allowed participants to be open and honest in a non-judgemental environment.

8.2.2 Expert Panel and Cognitive Interviews

After the item generation interviews, an expert panel agreed on 30-items to make up the draft instrument. These items covered the majority of the themes or subthemes found in the item generation and preliminary interviews. Some of the themes identified in the interviews were not included in the draft WRQoL scale. The decision to generate items based on the themes identified from the interviews was guided by the FDA's recommendations for item inclusion (see section 5.6 for criteria of item generation; FDA & HSS, 2009). The reasons included: unlikely to be sensitive to change, not enough was known about the theme, it was not relevant to the majority of people, or it represented an uncomfortable topic. Examples of these will be given in the following paragraphs.

The theme of work was not included as it was deemed too specific and would not be relevant to the majority of people (for example, students, unemployed, those who are retired). However, the aspects found in the work theme of the item generation interviews were considered to represent other aspects of HRQoL rather than work. For example, maintaining a professional appearance was relating to clothing and was incorporated in

the item “finding the right clothes for the right occasion is difficult”. There were also some aspects relating to eating that were not included in the draft WRQoL scale. They were not included because it was unlikely that they would change after weight loss. Comfort with food was one of the aspects not included. Comfort eating has been found to be predicted by binge eating rather than weight loss, and so behaviours relating to comfort with food are unlikely to improve with weight loss if binge eating is not under control (Brunault, Frammery, Couet et al., 2015). To measure issues relating to comfort eating and binge eating, investigators should include an instrument specific to eating behaviour that has good psychometric properties, such as the Addiction-like Eating Behaviour Scale (Ruddock, Christiansen, Halford & Hardman, 2017).

After the generation of the items, further participant input was gained to test for face validity and comprehensiveness of the draft questionnaire. Sexual confidence was not included in the scale due to the embarrassment and awkwardness it may cause and the potential for response bias (as detailed in section 8.1.2 and is further discussed in section 8.3.1.3). However, an item regarding strain on personal relationships was added after the cognitive debriefing interviews as this was thought to be missing from the draft instrument. This item could provoke conversation with a HCP, potentially highlighting issues with sexual health. A few changes were made to the wording of some items to aid in the understanding. Overall, only minor issues were mentioned, and the draft scale was well accepted. Once the changes had been made, the draft instrument was ready for factor extraction and initial evaluation.

8.3 PRELIMINARY PSYCHOMETRIC EVALUATION OF A WRQoL INSTRUMENT

The psychometric evaluation of the new WRQoL instrument was used to determine its structure, internal consistency of the domains, its known-groups validity and its test-retest reliability. These analyses are described in chapter 7. The resulting questionnaire comprises of 27-items, making it short and practical to use within research and clinical practice. The items are distributed over four domains; confidence with self, getting around (mobility); feeling valued, and weight stigma. The testing process indicated that based on the present data, the new instrument represents a structurally robust measure. It possesses good face, content, construct and concurrent validity and is internally reliable, reliable over time and can discriminate between BMI and waist circumference categories. It is thought to have good participant acceptability as there were low levels of missing responses. When comparing the psychometric evaluation of the IWQOL-Lite and the new scale, the new scale shows good potential for responsiveness due to only having ceiling effects in one domain (which will be further explored). The IWQOL-Lite produced ceiling effects on all domains, indicating a lack of sensitivity for the highest ranges of QoL. The new scale is still being developed, and with more patient input and psychometric testing, it is likely to become a more appropriate, valid and reliable scale in a UK community population than the IWQOL-Lite.

Four items were deleted as they did not load across the four factors. The items removed were; ‘I am healthy’, ‘I have disturbed sleep’, ‘breathlessness going upstairs’ and ‘I enjoy shopping for clothes’. The item regarding health was thought to be too broad, and in fact, the IWQOL-Lite had a similar item which was highlighted as problematic by factor analysis. However, the item ‘I am worried that my weight will impact my future health’ was not problematic. This represented the worry aspect of the subtheme of ‘Health

Conditions/scares' from the item generation interviews and was included in the 'confidence with self' domain. The other three questionable items that were removed from the new scale were possibly too extreme. This is because the psychometrics study recruited a community population that included a range of BMI's from 18 to 46.3 (*mean = 27.6*), so not all of these participants will have experienced problems with sleeping and breathlessness because of their weight.

Breathlessness with activity is a very common symptom of obesity (Gibson, 2000). It is due to a substantial increase in respiratory work required, especially in those with morbid obesity (Kress et al., 1999). The majority of the sample did not have morbid obesity, and so breathlessness was probably not an issue for them. However, if further cognitive interviews reveal breathlessness to be missing and important, it can be reintroduced. If this happens, care will be needed when wording the item and using the target population to help with wording is recommended. Within the interview's, embarrassment was also brought up with breathlessness. For example, individuals expressed being embarrassed to walk with friends or work colleagues in case they noticed their breathlessness. Therefore, introducing embarrassment rather than purely breathlessness could represent a more important aspect of WRQoL.

Furthermore, it is possible that there were gender differences in WRQoL. As outlined in Chapter 7, separate PCA's were conducted for males and females on the draft scale. The four-factor model was similar across genders, with only a few discrepancies. Perfect matches were not expected, especially since the men's sample was underpowered. A larger sample of both males and females would be needed to assess any differences reliably. As there are only a few differences, it gives a good indication that the overall structure of the items is relevant to both men and women. It is not typical to see scales

evaluated separately for men and women in published work, although that does not mean it should not be done. It could potentially identify items that are specific to either males or females that are affecting the scoring for one gender but not the other. Therefore, evaluating a scale in this way could help interpret the scores of a scale. However, creating separate WRQoL scales for men and women for use in clinical trials and research may not be appropriate or practical.

The development of separate scales for men and women would not be ideal as comparisons between genders could not be made. Also, larger sample sizes would be needed when using the scale within research or clinical trials if males and females were analysed separately. This may make the scale impractical for use within the research. The items of the new scale were developed using input from men and women (as previously stated), providing confidence and evidence that the items are relevant for both. Typically, previous WRQoL scales have generated items using a small sample of females. Therefore, the new WRQoL scale is more relevant and valid for males and females.

8.3.1 Merits and limitations

8.3.1.1 **Problematic items and domains**

Within factor 3 the item 'I have no energy' initially surprised the research team (the two qualitative researchers and the psychometrician) as it was initially intended to measure energy in a physical sense or tiredness. However, it seems it could also relate to energy as in motivation or drive to do things. A lack of drive or motivation was found in the pilot interviews, but ultimately more information needs to be gained from the target population about this item and what it means to them. This will probably lead to rewording the question. The psychometric evaluation highlighted factor 4 (weight stigma) to be somewhat problematic. This is regarding having lower reliability (Cronbach alpha was

still acceptable) and having a high ceiling effect. The ceiling effect indicated that a lot of participants with BMI's of 30kg/m^2 and above scored highly in this domain. From the interview findings, this result is unexpected. Therefore, further exploration of this domain is needed within the target population. It could be that weight stigma is not experienced daily, and so the recall period may need changing. However, the FDA (2009) indicate that PROMs should measure the current status of the participant, so further consideration of this is required. With additional exploration and participant input, the structure and items of this instrument may change to improve its face validity and reliability.

8.3.1.2 **The omission of sexual life items**

A limitation of the new scale is the lack of items assessing the effect of weight on sex life. Not assessing the impact of weight on sex life could miss important information regarding WRQoL. The IWQOL-Lite and other existing WRQoL scales include a domain covering Sex Life or Sexual Functioning (Ziegler et al., 2005; Kolotkin et al., 2001). Improvements in sexual functioning, measured by the IWQOL-Lite, have been found with weight loss, indicating that weight affects an individual's sex life (Kolotkin, Zunker & Østbye, 2012; Kolotkin, Binks & Crosby, 2006). The decision to omit items about sex was not made lightly. The reasons for excluding sexual life items were due to issues with sexual health domains in previous scales and a lack of detailed information gained on sex in the interviews.

The psychometric evaluation of the IWQOL-Lite indicated a ceiling effect for participants with a BMI over 30kg/m^2 in the Sexual Functioning domain, with 45.2% of the sample at ceiling. Additionally, there was 6.2% of missing data for that domain. This shows that around half of the participants either had an issue completing this domain, or they were not impacted by their weight in terms of sexual functioning. Similar findings

have been shown in previous evaluations of sexual life domains. For example, the evaluation of the QOLOD (derived from IWQOL items) also found ceiling effects in the sex domain (Ziegler et al., 2005); however, these were lower than the current study. The development of the IWQOL-Lite took place in the USA, and the QOLOD took place in France. The UK population may be less inclined and less comfortable with the topic of sex life (Moreira, Glasser, Nicolosi, Duarte & Gingell, 2008). For example, the LupusQOL was developed in the UK and had issues with items relating to intimate relationships with 38% of responses reported to be inappropriate, missing or showed ceiling or floor effects (McElhone, Abbott, Shelmerdine et al., 2007).

Further, many participants were interviewed in their own homes, and other individuals were present in the house at the time. When sexual relationships were mentioned, they spoke quietly and briefly even when asked follow up questions. It was sensed by the interviewer that participants were not comfortable talking about sex, as they may be overheard by their partners or family members. Because of the sensed discomfort, the interviewer also felt uncomfortable and refrained from delving deeper into the questions around sex life. Due to this, not enough in-depth information was gained from enough participants to generate items on this. Therefore, further exploration is needed regarding the effects of obesity on sexual health. The careful wording of items derived from this exploration will also be needed to ensure participants are comfortable answering them.

On reflection, it would have been beneficial to receive specific training on interviewing about sensitive or embarrassing topics to enable more detailed discussions. Individuals with sexual problems in the UK are unlikely to seek help (Moreira, Glasser, Nicolosi, Duarte & Gingell, 2008) and HCP's have been found to avoid talking about sex with their patients (Dyer & das Nair, 2013). Therefore, including items regarding sex life could help

them broach the issue. However, if patients do not want to talk about their sex life, they may not answer the questions truthfully, hence creating ceiling effects. This is an issue that needs further exploration. A more acceptable way to ask about sexual health problems is required to measure it accurately. Future research could use online platforms to conduct interviews to overcome the issue of discomfort and embarrassment of talking about sex. For example, using IM interviews or forum discussions could enable individuals to share their intimate experiences while maintaining anonymity from both the researcher and their family/peers (James & Busher, 2016). It would be useful to find out why people avoid or incorrectly answer sexual health questions, and asking people through IM could be helpful. The only issue with using this technique is that it can lead to restricting who can participate, as it requires some level of technical proficiency and access to the internet (James & Busher, 2016).

8.3.1.3 **Data collection and participant sampling**

The difficulty of data collection should be noted. As participants were recruited from community locations, gaining access to individuals with overweight/obesity required planning and required the utilisation of different methods and locations (for example, Facebook, gyms and workplaces). If a clinical sample was used, data collection would have probably taken less time and may have been easier. This is because individuals with obesity could have been accessed in one place (or fewer places). The mean BMI in the psychometric testing phase (27.6kg/m^2) was slightly lower than the qualitative stages (32kg/m^2). This suggests that the higher BMI groups were less represented than, the lower groups.

Having access to clinical populations would have allowed the inclusion of more individuals in the higher BMI obesity groups. However, not everyone with

obesity/overweight gain access to NHS services to seek help for their weight and so a clinical sample may not have been as representative of a community sample in terms of other characteristics. For example, the interviews highlighted that many individuals with obesity avoided seeking medical care in fear that their weight would be mentioned. If this is the case then utilising only clinical populations would have missed these individuals. Including clinical populations alongside community samples in further evaluation of the new scale should be considered to enable better representation of all BMI groups. Again, there was also a lack of ethnic diversity in this sample. Therefore, the techniques recommended earlier should be employed in future recruitment when testing the psychometric properties of the scale.

8.3.2 Sensitivity and responsiveness

The new scale has not yet been evaluated in terms of its sensitivity to change over time, so it is not possible to estimate clinically relevant changes in HRQoL. This is because the new scale still needs to be finalised (see section 8.5 for a discussion of future work). However, the results of test-retest reliability provide evidence of the scales stability. This will enable its use in longitudinal research as there can be confidence that any observed changes reflect a true effect, even though the meaning of the magnitude of change has not yet been determined. However, the test-retest reliability of the scale provides a basis for the evaluation of sensitivity to change and responsiveness. Once further evaluation of validity and reliability has been conducted, the new scale will be tested for sensitivity and responsiveness.

The interpretation of data from HRQoL scales should not be based solely on *P* values, especially when HRQoL is a secondary outcome. This is because interventions are typically powered for a physical outcome (such as BMI) rather than a secondary outcome

(typically HRQoL) and statistically significant changes may not reflect meaningful changes to the patient (Kushner & Foster, 2000). Therefore, the new scale needs to be assessed for its ability to detect improvement or deterioration when patients feel that their HRQoL has improved or deteriorated; otherwise known as sensitivity to change (Beaton, Bombardier, Katz & Wright, 2001). Establishing sensitivity to change is advocated by the FDA (2009) in addition to estimating the minimal important difference (MID). The MID is the smallest change that patients perceive to be beneficial or harmful (Rai, Yazdany, Fortin & Aviña-Zubieta, 2015). The evaluation and calculation of sensitivity to change and the MID will allow for better interpretation of the scores achieved on the new scale in terms of whether a meaningful change had occurred. Once calculated, the scale will be able to detect meaningful change and can be used to evaluate clinical trials, interventions and obesity treatments.

8.4 APPLICATION OF THE SCALE

The primary purposes of the WRQoL scale are to provide a profile of WRQoL and to evaluate the effect of overweight and obesity treatments. This evaluation can take place on a large collective basis by implementing the scale as a primary or secondary outcome in clinical trials or intervention research. But it would also be appropriate for use to evaluate change in WRQoL on an individual basis, for example, within community interventions and within primary care settings. It could provide additional information during consultations to aid clinical decision making. As the four domains of the new scale are scored separately, it provides a profile of an individual's HRQoL. This will allow individuals to be assessed on a domain or item basis if there are specific issues that need addressing. The scale could be used within clinical practice at the annual review of patients with chronic conditions. For example, patients with diabetes are likely to be advised to lose weight to help control their condition and so the scale would be useful to

assess the diabetes impact of weight loss on WRQoL. A similar use by physiotherapists' would be appropriate for patients awaiting knee surgery who have been advised to lose weight before their surgery. Using the scale in these ways would allow a more holistic evaluation of the individuals' health rather than just focusing on the number generated by the scales.

Discussing the results of a patients WRQoL assessment in the settings discussed can stimulate conversation. Focusing explicitly on the impact the excess weight is having on the way the individual is living their life can help them to realise when change is needed. For example, within one of the interviews, a woman expressed that she only realised the impact her weight was having when she noticed she only owned slip-on shoes. She had avoided buying shoes with laces as it was difficult for her to tie them. As body weight is gained slowly, the impact weight is having on a person's life is often not noticed until specific attention is given to it. Therefore, the items could highlight to HCPs and community intervention leaders the individualistic approach required to help encourage and cement behaviour change in individuals with overweight and obesity. If weight is mainly affecting body image or self-confidence aspects of QoL than referral to services such as psychological wellbeing and counselling could help to relieve these symptoms and increase the individuals QoL. A community intervention leader would be unable to give medical advice, and so would need resources to signpost individuals when needed.

If these aspects can be addressed, then there will be fewer barriers for the individual when managing their weight through improvements in their lifestyle and positive behaviour change. Therefore, this scale will benefit patients with overweight and obesity as they will be treated in a more meaningful and individualistic way to them rather than purely on their physiological health or symptoms. It will also benefit HCPs and community

leaders as they will be able to provide more specific and targeted advice or treatment to their patients with overweight and obesity. In order for the scale to be used by a wide variety of settings (community and primary care settings), a manual will need to be created. This will provide instructions on how to administer the scale, score the scale and to interpret the scores. The interpretation of the scores will depend on the further evaluation of validity and reliability in addition to the assessment of sensitivity to change and MID (as discussed earlier in section 8.3.2).

8.5 FUTURE RECOMMENDATIONS

Careful consideration needs to be taken when choosing a PROM to be used in clinical trials or community interventions. Scales used need to match the aims and scope of the research. Despite the increase in measurement of HRQoL within obesity, it still seems to be an afterthought; not as important as measuring weight loss. However, changes in HRQoL, if measured and reported accurately, could provide crucial information regarding the success and evaluation of weight loss treatments and interventions.

Before the WRQoL measure developed during this thesis can be used to evaluate weight loss treatments and interventions, it needs to be given back to the target population to gain more information about its content validity. This will be happening in future research outside of this thesis. It is an accepted and recommended process to go back and forth to the target population when items are deleted or changed. The development of a PROM is supposed to be an iterative process, so stages need to be repeated to improve the measure and ensure its validity and reliability (FDA & HHS, 2009). This process was not followed in the development of the scales identified and evaluated in the systematic review (Chapter 3), and so this highlights a unique aspect of this new instrument. It will have strong evidence for face and content validity which is the first requirement of any PROM

(Terwee et al., 2018). The content of the new scale will be followed up with the participants who indicated their interest to receive a summary of results. This will allow clarification of the interview findings and may lead to the amendment of the scale content. The full psychometric evaluation will then take place to ensure the reliability and validity of the measure. As previously mentioned, it would be useful to evaluate the item and domain structure of the scale separately for males and females to assess whether any items are being interpreted differently across genders. Therefore, a larger sample size of at least 150 participants of each gender would be needed.

Additionally, the author intends to gain input from health economists to develop a 'utility' version of the new WRQoL scale. An accurate estimate of the benefit of treatments alongside their cost is vital to inform NICE funding recommendations, and therefore patient access to new treatments. Discrete choice and time trade-off tasks will be undertaken to derive utility weights for health states associated with weight. This will enable the valuation of these important participant-reported outcomes on the conventional utility-scale that is used to obtain quality-adjusted life years as the preferred outcome in economic evaluation. Subsequently, the instruments will be evaluated for sensitivity to change and responsiveness.

There are currently no WRQoL utility measures for use in adult obesity populations, and so clinical trials and intervention studies are being evaluated using generic utility measures. These do not include condition-specific concerns and thus are likely to be less sensitive and responsive to overweight/obesity populations. Having a weight-specific HRQoL utility measure would enable better interpretation and evaluation of obesity/overweight treatments and interventions.

8.6 CONTRIBUTION TO KNOWLEDGE

This PhD programme has contributed to knowledge through:

a) The provision of clear information as to the country of origin, intended population (e.g. morbid obesity), and the evaluation of the existing WRQoL instruments development and psychometric properties.
b) Providing a clear description from people who have experienced weight issues, how overweight/obesity (and weight loss) impacts on important aspects of daily life.
c) The development and preliminary evaluation of a WRQoL instrument with the 'collaboration' of those for whom the measure is intended for. The instrument will be able to describe and evaluate changes in WRQoL in UK community and clinical samples.

8.7 CONCLUSION

To conclude, this PhD programme of work has enabled the development of a WRQoL scale with strong evidence for content validity, internal consistency and good potential in terms of external reliability. The development has used a rigorous process of item generation through participant input, expert input and preliminary psychometric testing. This instrument is ready for further evaluation via participant input and psychometric testing to continue the iterative process of PROM development. Once this has been conducted, the instrument will be suitable for use in community weight loss treatments and interventions in the UK and should be sensitive across weight loss stages.

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Appendix 1. Systematic Review (Chapter 3)

Search Strategy

1. health related quality of life.mp. [mp=ti, ab, tx, ct, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, ui, sy]
2. Health Status/
3. well being.mp.
4. well*being.mp.
5. Adaptation, Psychological/
6. "Severity of Illness Index"/
7. Patient Satisfaction/
8. Attitude to Health/
9. attitude to health.mp.
10. "Activities of Daily Living"/
11. "Activities of Daily Living"/px [Psychology]
12. quality-adjusted life years/
13. "Quality of Life"/
14. "Quality of Life"/px [Psychology]
15. weight*related quality of life.mp.
16. weight related quality of life.mp.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. HRQoL.ti,ab.
19. HRQoL.mp.
20. HRQL.mp.
21. HRQL.ti,ab.
22. 17 or 18 or 19 or 20 or 21
23. WRQoL.mp.
24. WRQoL.ab,ti.
25. WRQL.mp.
26. WRQL.ti,ab.
27. 23 or 24 or 25 or 26
28. 22 or 27
29. Obesity/
30. exp Obesity/
31. *Obesity/
32. exp *Obesity/
33. overweight/
34. obesity.mp.
35. overweight.mp.
36. 29 or 30 or 31 or 32 or 33 or 34 or 35
37. body weight/
38. Body Weight/
39. weight loss.mp.
40. weight loss/
41. 36 or 37 or 38 or 39 or 40
42. exp Bariatrics/
43. Bariatrics.mp.
44. exp *Bariatrics/
45. *Bariatrics/
46. 42 or 43 or 44 or 45
47. 41 or 46
48. obesity, morbid/
49. 47 or 48
50. humans/
51. 49 and 50
52. adults.mp.
53. 51 and 52
54. 50 and 52
55. 28 and 54
56. 49 and 54
57. 55 and 56
58. Patient Reported Outcome Measure/
59. "Patient Reported Outcome Measure"/
60. prom.ti,ab.
61. proms.ti,ab.
62. 58 or 59 or 60 or 61
63. patient.ti,ab.
64. self.ti,ab.
65. carer.ti,ab.
66. 63 or 64 or 65
67. report.ti,ab.
68. reported.ti,ab.
69. reporting.ti,ab.
70. rated.ti,ab.
71. rating.ti,ab.
72. ratings.ti,ab.
73. 67 or 68 or 69
74. 70 or 71 or 72
75. 73 or 74
76. 66 and 75
77. questionnaire.ti,ab.
78. measure.ti,ab.
79. questionnaires.ti,ab.
80. measures.ti,ab.
81. instrument*.ti,ab.
82. profile*.ti,ab.
83. scale*.ti,ab.
84. status.ti,ab.
85. 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84
86. survey*.ti,ab.
87. 85 or 86
88. 62 or 87
89. instrumentation/
90. methods/
91. "Validation Studies".pt.
92. "Comparative Study".pt.
93. "psychometrics"/
94. psychometr*.ti,ab.
95. clinimetr*.tw.
96. clinometr*.tw.
97. "outcome assessment (health care)"/
98. "outcome assessment".ti,ab.
99. "outcome measure".ti,ab.
100. "observer variation"/
101. "observer variation".ti,ab.
102. "health status indicators"/
103. "reproducibility of results"/

104. reproducib*.ti,ab.
105. "discriminant analysis"/
106. reliab*.ti,ab.
107. unreliab*.ti,ab.
108. valid*.ti,ab.
109. "coefficient of variation".ti,ab.
110. homogeneity.ti,ab.
111. homogeneous.ti,ab.
112. "internal consistency".ti,ab.
113. 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112
114. development.ti,ab.
115. 113 or 114
116. cronbach*.ti,ab.
117. alpha.ti,ab.
118. alphas.ti,ab.
119. 117 or 118
120. 116 and 119
121. item.ti,ab.
122. correlation,ti.ab.
123. selection*.ti,ab.
124. reduction*.ti,ab.
125. 122 or 123 or 124
126. 121 and 125
127. 115 or 120 or 126
128. agreement.tw.
129. precision.tw.
130. imprecision.tw.
131. "precise values".tw.
132. test-retest.ti,ab.
133. 128 or 129 or 130 or 131 or 132
134. test.ti,ab.
135. retest.ti,ab.
136. 134 and 135
137. 127 or 133 or 136
138. 134 or 135
139. 106 and 138
140. 137 or 139
141. stability.ti,ab.
142. interrater.ti,ab.
143. inter-rater.ti,ab.
144. intrarater.ti,ab.
145. intra-rater.ti,ab.
146. intertester.ti,ab.
147. inter-tester.ti,ab.
148. intratester.ti,ab.
149. intra-tester.ti,ab.
150. interobserver.ti,ab.
151. inter-observer.ti,ab.
152. intraobserver.ti,ab.
153. intra-observer.ti,ab.
154. intertechnician.ti,ab.
155. inter-technician.ti,ab.
156. intratechnician.ti,ab.
157. intra-technician.ti,ab.
158. interexaminer.ti,ab.
159. inter-examiner.ti,ab.
160. intraexaminer.ti,ab.
161. intra-examiner.ti,ab.
162. interassay.ti,ab.
163. inter-assay.ti,ab.
164. intraassay.ti,ab.
165. intra-assay.ti,ab.
166. interindividual.ti,ab.
167. inter-individual.ti,ab.
168. intraindividual.ti,ab.
169. intra-individual.ti,ab.
170. interparticipant.ti,ab.
171. inter-participant.ti,ab.
172. intraparticipant.ti,ab.
173. intra-participant.ti,ab.
174. kappa.ti,ab.
175. kappa's.ti,ab.
176. kappas.ti,ab.
177. repeatab*.tw.
178. 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148 or 149 or 150 or 151 or 152 or 153 or 154 or 155 or 156 or 157 or 158 or 159 or 160 or 161 or 162 or 163 or 164 or 165 or 166 or 167 or 168 or 169 or 170 or 171 or 172 or 173 or 174 or 175 or 176 or 177
179. 140 or 178
180. replicab*.tw.
181. repeated.tw.
182. 180 or 181
183. measure.tw.
184. measures.tw.
185. findings.tw.
186. result.tw.
187. results.tw.
188. test.tw.
189. tests.tw.
190. 183 or 184 or 185 or 186 or 187 or 188 or 189
191. 182 and 190
192. 179 or 191
193. generaliza*.ti,ab.
194. generalisa*.ti,ab.
195. concordance.ti,ab.
196. 193 or 194 or 195
197. 192 or 196
198. intraclass.ti,ab.
199. correlation*.ti,ab.
200. 198 and 199
201. 197 or 200
202. discriminative.ti,ab.
203. "known groups".ti,ab.
204. "known group".ti,ab.
205. "factor analysis".ti,ab.
206. "factor analyses".ti,ab.
207. "factor structure".ti,ab.

208. "factor structures".ti,ab.
209. dimension*.ti,ab.
210. subscale*.ti,ab.
211. 202 or 203 or 204 or 205 or 206 or 207 or 208 or 209 or 210
212. 201 or 211
213. multitrait.ti,ab.
214. scaling.ti,ab.
215. analysis.ti,ab.
216. analyses.ti,ab.
217. 215 or 216
218. 213 and 214 and 217
219. 212 or 218
220. "item discriminant".ti,ab.
221. "interscale correlation*".ti,ab.
222. error.ti,ab.
223. errors.ti,ab.
224. "individual variability".ti,ab.
225. "interval variability".ti,ab.
226. "rate variability".ti,ab.
227. 220 or 221 or 222 or 223 or 224 or 225 or 226
228. 219 or 227
229. values.ti,ab.
230. 215 or 229
231. variability.ti,ab.
232. 230 and 231
233. 228 or 232
234. uncertainty.ti,ab.
235. measurement.ti,ab.
236. measuring.ti,ab.
237. 235 or 236
238. 234 and 237
239. 233 or 238
240. "standard error of measurement".ti,ab.
241. sensitiv*.ti,ab.
242. responsive*.ti,ab.
243. 239 or 240 or 241 or 242
244. limit.ti,ab.
245. detection.ti,ab.
246. 244 and 245
247. 243 or 246
248. "minimal detectable concentration".ti,ab.
249. interpretab*.ti,ab.
250. 247 or 248 or 249
251. minimal.ti,ab.
252. minimally.ti,ab.
253. clinical.ti,ab.
254. clinically.ti,ab.
255. 251 or 252 or 253 or 254
256. important.ti,ab.
257. significant.ti,ab.
258. detectable.ti,ab.
259. 256 or 257 or 258
260. change.ti,ab.
261. difference.ti,ab.
262. 260 or 261
263. 255 and 259 and 262
264. 250 or 263
265. small*.ti,ab.
266. real.ti,ab.
267. 266 or 258
268. 265 and 267 and 262
269. 264 or 268
270. "meaningful change".ti,ab.
271. "ceiling effect".ti,ab.
272. "floor effect".ti,ab.
273. "item response model".ti,ab.
274. irt.ti,ab.
275. rasch.ti,ab.
276. "differential item functioning".ti,ab.
277. dif.ti,ab.
278. "computer adaptive testing".ti,ab.
279. "item bank".ti,ab.
280. "cross-cultural equivalence".ti,ab.
281. 269 or 270 or 271 or 272 or 273 or 274 or 275 or 276 or 277 or 278 or 279 or 28
282. 57 and 281
283. "addresses".pt.
284. "biography".pt.
285. "case reports".pt.
286. "comment".pt.
287. "directory".pt.
288. "editorial".pt.
289. "festschrift".pt.
290. "interview".pt.
291. "lectures".pt.
292. "legal cases".pt.
293. "legislation".pt.
294. "letter".pt.
295. "news".pt.
296. "newspaper article".pt.
297. "patient education handout".pt.
298. "popular works".pt.
299. "congresses".pt.
300. "consensus development conference".pt.
301. "consensus development conference, nih".pt.
302. "practice guideline".pt.
303. 283 or 284 or 285 or 286 or 287 or 288 or 289 or 290 or 291 or 292 or 293 or 294 or 295 or 296 or 297 or 298 or 299 or 300 or 301 or 302
304. 282 not 303

Non-Bariatric scales COSMIN ratings per study

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
IWQOL (2)						
Kolotkin, Head, Hamilton & Tse (1995)	No definition or conceptual framework of QoL provided. Limited information on the development of items, especially in terms of participant demographics involved in item development (no BMI range, number of participants involved in each stage of development). ? Inadequate	NR	No evidence of structural validity provided Statistic conducted for each subscale ? Inadequate	Inappropriate statistical analysis used Time frame not long enough ? Inadequate	No hypothesis stated Low sample size to split by gender ? Doubtful	NR
Kolotkin, Head & Brookhart (1997)	NR	NR	No evidence of structural validity Statistic conducted for each subscale	NR	Constructs measured by comparator instruments is clear and comparable. No hypotheses with expected relationship	NR

			Scales with missing data were excluded (selection bias) but % missing data not given ? Inadequate		direction and magnitude stated. ? Doubtful	
IWQOL-Lite (6)						
Kolotkin, Crosby, Kosloski & Williams (2001)	IWQOL items deleted via purely statistical methods. No patient involvement to assess relevance, comprehensiveness or understanding of items	Scores of IWQOL-Lite computed from IWQOL. Confirmatory factory analysis N=991 Hypothesised second order model where items were assigned to scales and scales were considered to be part of a higher order construct (HRQoL)	Cronbach alphas for each scale. Missing data not reported nor what was done with any missing data. Scores of shorter IWQOL-Lite computed from longer IWQOL version	NR	Hypotheses not stated in methods section. Scores of shorter IWQOL-Lite computed from longer IWQOL version	No reliable comparison to no change as only 6 patients did not change in the construct over the year. Hypotheses were not explicitly stated in methods section. Not clear what the effectiveness of the open label study (effect size not stated) or whether the responsiveness of

	? Inadequate	(χ^2 [429] = 2316, NFI = 0.91, TLI = 0.92, CFI = 0.93, SRMR = 0.05) ? Inadequate	? Inadequate		? Inadequate	the IWQOL-Lite and effectiveness of the intervention were tested separately or within the same study. Scores of shorter IWQOL-Lite computed from longer IWQOL version ? Inadequate
Kolotkin & Crosby (2002)	NR	NR	N=494 Missing data not reported Only very low quality evidence for structural validity Cronbach's alpha for each subscale: Physical function, 0.935	N=112 14 days (averaged) No stability evidence ICC's for each subscale and total score: PF, 0.877 SE, 0.870 SL, 0.849 PD, 0.814 WK, 0.840	Hypotheses stated in methods section, but direction and magnitude not specified. Missing data not reported	NR

			Self-esteem, 0.944 Sexual Life, 0.921 Public distress, 0.916 Work, 0.816 Total, 0.958 ? Adequate	+ Doubtful	+ Doubtful	
Kolotkin, Crosby, Corey-Lisle, Li et al. (2006)	NR	NR	Schizophrenia (n=111) Bipolar (n=100) Structural validity unknown ? 	Schizophrenia (N=34) Bipolar(N=31) 7-14 days No evidence provided for stability of construct over this time period + Inadequate	Hypotheses stated in methods + Adequate	NR

			Doubtful			
LEWIN-TAG (1)						
Mathias, Williamson, Colwell, Cisternas et al. (1997)	? Inadequate	Not relevant	Not relevant	N=21 7 days ICC 0.65 - Doubtful	Scales of different constructs and no hypotheses stated + Doubtful	Used Guyatts statistic ? Inadequate
OSQOL (1)						
Le Pen, Levy, Loos, Benzet et al. (1998)	No definition of QoL General population but, limited information regarding demographics included 12 interviews Recall period unknown No information on Comprehensiveness, relevance & understanding ? Doubtful	Shorter version of scale computed from longer version PCA - % variance explained not reported 11 items across 4 domains ? Inadequate	Shorter version of scale computed from longer version Not enough evidence for structural validity Total score only Cronbach alpha = 0.77 ? Inadequate	NR	NR	NR

ORWELL-97 (1)						
Mannucci, Ricca, Barciulli, Bernardo et al. (1999)	Limited detail No demographics ? Inadequate	Factor analysis conducted after subscales decided Poorly loading items retained - Doubtful	Cronbach's alpha conducted for total score = 0.83 No evidence of unidimensionality ? Inadequate	Use correlation instead of ICC No test of stability Within 7 days ? Inadequate	No hypotheses stated which is especially important due to the complexity of the scale Conducted on the structure of the scale and not the structure factor analysis produced. ? Inadequate	NR
ORWELL-R (1)						
Camolas, Ferreira, Mannucci, Mascarenhas et al. (2016)	Limited detail No demographics ?	Community sample 3 factors (χ^2 [182] = 919.02, TLI = 0.90, CFI = 0.91, SRMR = 0.05, RMSEA = 0.07) -	Total score only Not scored as subscales No evidence for unidimensionality ?	ICC total score 0.78 3-10 weeks Clinical sample only No evidence for stability ?	No Hypotheses ?	NR

	Inadequate	Adequate	Inadequate	Inadequate	Inadequate	
OWLQOL (2)						
Niero, Martin, Finger, Lucas et al. (2002)	No definition of concept or explanation where domains came from in development study. Needs-based theoretical model for perceived QoL. Cognitive debriefing interviews but not on final 17-item version Cross culturally adapted but some items may not be relevant to UK population. Demographics of cognitive interview participants not given ? Doubtful	NR	NR	NR	NR	NR

Patrick, Bushnell & Rothman (2004)	NR	Items deleted but not explained. Mention 5 factors in development but change to unidimensional scale in psychometric paper with no explanation. Not completed on final scale (scores computed) + Inadequate	Cronbachs alpha = 0.93-0.96 ? Doubtful	N=56 No evidence provided for stability ICC = 0.95 + Doubtful	No hypotheses Final scale computed from longer version + Doubtful	No hypotheses ? Doubtful
QOLOD (1)						
Ziegler, Filipecki & Guillemin (2005)	Based on IWQOL with 17 extra items No definition of HRQOL Limited detail of patient involvement	PCA conducted but no statistics are reported	N = 69-72 Cronbach's alpha reported for each subscale	N = 46-51 Scores for shorter version computed from longer	Longer version compared to SF-12 Data not provided	NR

	? Inadequate	? Inadequate	? Doubtful	version ICC for each subscale Evidence of stability provided + Inadequate	+ Inadequate	
Laval						
Duval, Marceau, Lescelleur, Hould et al. (2006)	Evaluative instrument No conceptual framework/definition of QoL N=25 Candidates for bariatric surgery, mean BMI 51, no range Conducted in French No cognitive debriefing interviews Limited details on interview process	NR	NR	NR	NR	NR

	? Doubtful					
Therrien, Marceau, Turgeon et al (2011)		NR	No evidence of structural validity Cronbach's alphas for each domain (6) all okay apart from sexual life domain which was below the threshold ? Doubtful	2 weeks No evidence of stability N=90 ICC for each domain + Doubtful	19/26 met + Adequate	Effectiveness of treatment not reported 15/26 hypotheses met - not 75% - Inadequate

Bariatric scales COSMIN ratings per study

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
MA-QoLQ-II (2)						
Moorehead, Ardelt-Gattinger, Lechner & Oria (2003)	Development based on experts and patient input but not described and demographics not included ? Inadequate	NR	No evidence of unidimensionality Cronbach alpha = 0.84 ? doubtful	NR	Missing data not reported, no hypotheses stated N=110 ? inadequate	NR
Charalampakis, Daskalakis, Bertsias, Papadakis & Melissas, (2012)	NR	NR	N=175 No evidence for unidimensionality Cronbach alpha = 0.85 ? Doubtful	N=40 2 weeks *assumed stability* ICC = 0.981 + Doubtful	N=175 Missing data not reported No hypotheses Sf-36 (?) VAS (?) BMI (+) ? Inadequate	NR

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
The Bariatric Quality of Life (BQL) (1)						
Weiner, Sauerland, Fein, Blanco et al., 2005	Development based on feedback from patients completing BAROS and SF-36. Demographics of p's not included ? Inadequate	Scored as unidimensional scale EFA found 3 factors explaining 39.4-44.3% variance - Doubtful	Cronbach alphas reported for non qol and qol aspect of scale and not for 3 factors found for structural validity ? Inadequate	Bland Altman plot Not conducted on target population – hospitalised patients with normal BMI 48hours ? Inadequate	Unclear which participant group was used to assess this No hypotheses presented ? Inadequate	No hypotheses N=133 ? Inadequate
BODY-Q (3)						
Klassen, Cano, Scott, Johnson & Pusic, 2012	Good detail of item generation	NR	NR	NR	NR	NR

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
	Population different to population if interest in SR Very good ?					
Klassen, Cano, Scott, Tsangris & Pusic, 2014	Good detail of cognitive interviews Population different to SR population Very good ?	NR	NR	NR	NR	NR
Klassen, Cane, Alderman, Soldin et al., 2016	NR	Rasch analysis Model fit not reported	Structural validity rated as indeterminate making internal consistency	N=44 1 week Assumed stability Good ICCs in 4/5 HRQoL scales -	NR	N=134 Clinical meaning of increases in score unknown. Hard to interpret whether

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
		? Adequate	difficult to interpret. ? V.good	Physical scale < 0.70 + Adequate		improvements are meaningful. Most p's lost weight & sig improvement on 4/5 scales (not sexual scale) +/- Doubtful
Bariatric and obesity-specific survey (BOSS) (1)						
Tayyem, Atkinson & Martin, 2014	Doubtful in target population of SR Relevance and comprehensiveness not assessed ? Doubtful	RoB: Exploratory FA - adequate N = 236 - adequate Variance not reported - Doubtful Not conducted on completion of final scale - inadequate CGMP's:	Conducted for each subscale - V.good Cronbach alpha used - v.good Unclear as to which group of participants this was conducted on - doubtful	RoB: Unclear if patients were stable in interim - doubtful 2 weeks = appropriate - v.good Assumed similar test	No hypotheses Data not presented & domains compared not outlined 42 item computed from 81 item N=236 + Doubtful	NR

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
		Information to compare to criteria not reported - ? ? Inadequate	CGMP'S: Evidence for structural validity unclear - ? ? Doubtful	conditions - adequate ICC model described - adequate Did not complete final version - doubtful CGMP's + sufficient + doubtful		
Post Bariatric Outcome Tool (PBOT) (1)						
Al-Hadithy, Welbourn, Aditya, Stewart & Soldin, 2014	Hand/arm scale referenced for development ? Inadequate	NR	Structural validity not assessed N = 10 ? Inadequate	N = 10 Bland altman plot ? Inadequate	n = 10 + Inadequate	NR
Body-QoL (2)						

Measure Study (n)	Content Validity	Structural Validity	Internal Consistency	Reliability	Hypothesis Testing	Responsiveness
Danilla, Dominguez, Cuevas, Calderon et al., 2014	? V. good	NR	N = 29 Total score not domains ? Inadequate	NR	NR	NR
Danilla, Cuevas, Aedo, Dominguez et al., 2016		Stats not reported ? Adequate	? V.good	N = 34 + Doubtful	+ Adequate	N=17 + Inadequate
QOLOS (1)						
Muller, Crosby, Selle, Osterhus et al., 2017	Items were developed from interviews and focus group interviews with 19 post-operative bariatric surgery patients Exact methodology not reported. NR	Scores computed from longer draft version of scale Analysis should be repeated on p's completing the final version to confirm + Doubtful	Scores computed from longer draft version of scale + Doubtful	NR	+ Adequate	NR

Appendix 2. Ethics and Measures for Preliminary Interviews (Chapter 4)

Ethical Approval Letter

24th October 2016

Emma Bray/Rebecca Louise Jefferson
School of Psychology
University of Central Lancashire

Dear Emma,

Re: PSYSOC Ethics Committee Application Unique Reference Number: PSYSOC 307

The PSYSOC ethics committee has granted approval of your proposal application 'Development of an adult weight-specific quality of life measure'. 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 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).

Yours sincerely,

Cath Larkins
Deputy Vice-Chair
PSYSOC 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.

Participant Information Sheet

Interview study exploring the impact of weight on cognitions, emotions and behaviour

You are being invited to take part in an interview as part of a research study. Before you decide if you want to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. If there is anything that is not clear or if you would like more information, just ask.

Please note: If you have never been overweight, if you are pregnant, have been diagnosed as terminally ill or are seeing a doctor for an eating disorder or a chronic illness that has resulted in a weight problem or you are unable to stand unassisted we are unable to include you in the current research. Please let the researcher know if you fall into one of these categories.

What is the purpose of the interview?

The purpose is to find out how your weight/ body shape affects different aspects of your life. The information provided during the interview will be used alongside interview data from other participants to develop a way of measuring weight-related quality of life. This study forms a part of a research students PhD.

Why have I been chosen?

You have been chosen to participate in this interview as you have shown your interest in the research by responding to the advert.

Do I have to take part?

It is up to you as to whether you take part or not. If you do take part, after reading this information sheet and asking any questions you may have, you will be asked to sign a consent form to say that you understand what the study involves. If you decide to take part, you are still free to withdraw at any time during the interview and up to 7 days after the interview without giving a reason. After these 7 days your interview data will no longer be identifiable, as it will have been anonymised, therefore it will not be possible to withdraw after this time.

What will I have to do?

If you decide to participate you will be asked to attend a one to one interview at a convenient time and location near to where you live (e.g. community centre, library etc.). The interview will be led by a research student from the University of Central Lancashire. The interview will involve a discussion about the way your weight or body shape affects how you think and feel and how this effects the different aspects of your life (e.g. work, social activities, and relationships). The interview is expected to last an hour. The interview will be tape recorded and notes may be taken throughout. If you do not want to answer a particular question you can refuse to. After the interview, the researcher will measure your weight, height and waist circumference and you will be

asked to fill in a demographic questionnaire. This will ensure we interview a range of people with differing backgrounds, weights and body shapes. Before having your measurements taken you will be asked to remove your shoes and any coats or jumpers, so please ensure you wear thin clothing underneath any removable layers. **Please note that the researcher taking the measurements will be female.**

What are the possible benefits of taking part?

The information gained from this study will help develop a way to assess how a person's weight is affecting their quality of life, and whether this improves through weight and lifestyle interventions.

Will my taking part in this study be kept confidential?

Yes. Ethical and legal practices will be followed and all information about you will be handled in confidence. Your name will be removed from the interview transcripts and documents recording your weight, height and waist circumference to keep your identity confidential. Direct quotes may be used in publications but these will be labelled with an ID number and anything which could identify you will be removed. Interview tapes will be destroyed once typed up and transcriptions will be kept on a password protected computer only accessible to the research student and her two supervisors. Any paper copies of the transcribed interview and any other documents will be kept in a locked filing cabinet.

What will happen to the results of the research?

The results of the interview will be used to develop a measure of quality of life for future research and for health care providers. The results will also be written up as part of the students PhD thesis and may be published in health professional journals and presented at conferences in the UK and abroad.

Who is organising and funding the research?

The research is funded by the College of Science and Technology and organised by the School of Psychology at the University of Central Lancashire as part of a PhD study.

Who has reviewed the study?

The UCLan PSYSOC ethics committee has reviewed and approved the current research.

What happens now?

If you are happy to participate or have any questions, please contact Rebecca Jefferson (PhD research student) via email rljefferson@uclan.ac.uk or via telephone 07754483357.

Thank you for taking time to consider participating in this study.

If you have any concerns or complaints about any aspect of the way you have been approached or are treated during this study, you can contact the lead supervisor, Dr Emma Bray on 01776 893883 (ebray@uclan.ac.uk) or the university officer for ethics on OfficerforEthics@uclan.ac.uk.

If you are worried about your weight, please visit your local GP for advice. Alternatively, you can visit the NHS website for advice and to find out about local weight loss groups (http://www.nhs.uk/Livewell/loseweight/Pages/WhataGPcando.aspx).

Consent Form

Interview study exploring the impact of weight on cognitions, emotions and behaviour

Participant ID: _____

Please initial box

1. I confirm that I have read and understood the information sheet dated October 2016 (version 1) 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 during the interview and up to 7 days after the interview, without giving any reason. ☐

3. I understand that it will not be possible to withdraw my data from the study after the 7-day window ☐

4. I understand that the interview will be recorded, typed up and notes will be taken during the interview ☐

5. I understand that the conversations in that interview may be used when the research team write about the study. However, any quotes will be anonymised, and no information will be used in any presentations or reports that could lead to my identification. ☐

6. I understand that only the researcher and the two research supervisors will have access to information I provide ☐

7. I agree for my weight, height and waist circumference to be measured and recorded after the interview. ☐

8. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Debrief Sheet

The current research aimed to explore how weight affects the different aspects of individuals' lives. This exploration will be used to develop a questionnaire which will reliably measure weight-related quality of life.

To explore weight-related quality of life, you were asked to talk about your weight and how it affects the different aspects of your life. Your interview will now be transcribed and analysed alongside other participants interview data in order to create the items of the questionnaire.

Why is this research important?

Quality of life is important for motivation. If weight loss programmes and interventions do not improve an individual's quality of life, there will be a high risk of regaining weight and returning to their original lifestyle. Having a measure of quality of life will allow researchers, health care providers/organisations to develop more successful weight loss programmes and interventions. It will also allow health care providers to identify individuals that may need extra support.

What if I want to withdraw my data?

If you do not your interview to be transcribed and analysed, you have 7 days from the date of your interview to inform the researcher. After this, your interview will have been transcribed and anonymised, so it will not be possible to remove it from the analysis.

Want to know the findings?

If you are interested in what is found from the interviews, please tick the box on the following page and provide your preferred method of communication (email or post) and you will be sent a summary of the findings once they become available.

If you have any further questions, please do not hesitate to contact me using the details below. If you have any concerns regarding the current research or the way you have been treated, please contact the Lead Supervisor or the University Officer for Ethics (details below).

If you are worried about your weight, please visit your local GP for advice. Alternatively, you can visit the NHS website for advice and to find out about local weight loss groups (http://www.nhs.uk/Livewell/loseweight/Pages/WhataGPcando.aspx).

Thank you for taking time to participate in this research.

Sincerely,

Rebecca Jefferson
PhD research student
School of Psychology,
University of Central Lancashire
Email - rljefferson@uclan.ac.uk

Lead Supervisor: Dr Emma Bray
Email - ebray@uclan.ac.uk
Telephone - 01776 893883
University Officer for Ethics
Email - OfficerforEthics@uclan.ac.uk

☐ Yes I would like to receive a summary of the results

Name: _____

Email address: _____

OR

Postal address:

House Name/No. _____
Address line 1 _____
Address line 2 _____
Town _____
County _____
Postcode _____

Please return this page to the researcher

Research Poster for Preliminary Interviews

VOLUNTEERS NEEDED

We are looking for adults (both male and female) aged 18 and over to participate in a research study exploring how your weight/body shape affects your quality of life.

What will it involve?

You will be asked to take part in an interview which will involve a chat about your weight and how it affects different aspects of your life.

Want to know more?

Contact Rebecca Jefferson (PhD research student from the School of Psychology, UCLan) for more information:

Email: rljefferson@uclan.ac.uk

Telephone: 07754483357

Please note you will be unable to participate if you fall into any of the following categories:

- ***Have never been overweight***
- ***You are pregnant,***
- ***Have been diagnosed as terminally ill***
- ***Seeing a doctor for an eating disorder***
- ***Seeing a doctor for a chronic illness resulting in a weight problem***
- ***Cannot stand unassisted***

Email Template

Dear ,

Thank you for your interest in my research.

I have attached a participant information sheet, providing further details of the research and what it will involve. Please read through this carefully.

If you are still interested in taking part, please could you provide the following details;

- Gender
- Age
- Ethnic group
- A brief history on your weight (for example, have lost weight and kept it off, regained weight after losing it, never tried to lose weight etc.)

These details will be only be seen by me. Your email response will be deleted after the interview or if you decide you don't want to participate.

If you decide you do not want to participate based on the information given, please let me know. You do not need to give a reason, but please feel free to give one if you would like to.

If you have any questions, please ask.

I will look forward to hearing from you.

Best Wishes,

Rebecca Jefferson
PhD Research Student
UCLan, Preston

Demographics Questionnaire

1. Are you male or female?

☐ Male ☐ Female

2. How old are you in years? _____

3. Please tick one category that best represents your highest level of education?

☐ High School or equivalent
☐ A-levels or equivalent
☐ Vocational/technical school (2years)
☐ Bachelor's degree
☐ Master's degree
☐ Doctoral Degree
☐ Professional degree (MD, JD)
☐ Other _____

4. Which of the following categories best describes your current employment status? **(Tick all that apply)**

☐ Employed
☐ Not employed
☐ Student
☐ Retired
☐ Disabled, not able to work

5. Do you currently receive income support?

☐ No
☐ Yes

6. Which of these apply to the property you currently live in?

☐ Owned outright
☐ Buying on a mortgage
☐ Renting from council
☐ Renting from housing association/trust
☐ Renting from private landlord
☐ Other

7. Race

☐ White
☐ Asian
☐ Black/ African/ Caribbean/ Black British
☐ Mixed Race
☐ Other

8. What is your current marital status?

☐ Divorced
☐ Living with another
☐ Married
☐ Separated
☐ Single
☐ Widowed

9. Which statement best describes your previous weight loss attempts?

☐ I have previously lost weight but have since put some or all of it back on
☐ I have previously lost weight and have kept it off
☐ I have attempted to lose weight, but have not lost any weight
☐ I have never tried to lose weight

10. Do you have any health conditions? **(please tick all that apply)**

☐ Type I Diabetes
☐ Type II Diabetes
☐ Asthma
☐ High Blood Pressure
☐ Heart Disease
☐ Other, (please specify) _____

Lone Working Procedure

6.1 **Does the activity involve field work, lone working or travel to unfamiliar places**?
☒Yes ☐No
If yes, answer the following questions *If no, go to Section 7*
6.2 **Where will the activity be undertaken**?
N.B. If your work involves field work or travel to unfamiliar places (e.g. outside the UK) please attach a risk assessment specific to that place *Give location(s) details (e.g. UCLan campus only)*
The activity will take place in public places such as community centres and libraries and at UCLan Preston and Burnley campus. If necessary, the interviews will take place at the participants homes.
6.3 **Does the activity involve lone working**?
☒Yes ☐No
If yes please provide further details below and attach a completed risk assessment form *Describe the lone working element, clearly explaining the risks associated and specify how you will minimise these*
Rebecca Jefferson will be conducting interviews away from the university and on her own. To ensure her safety, interviews will be mainly conducted in public places and the date, time and place will be made known to her supervisors before hand. Rebecca will also have a lone working mobile and a procedure will be in place to let her supervisor know if she is safe. When conducting interviews in participants homes or in unknown areas Rebecca will check in with her supervisor after each interview and if she hasn't got in contact 30mins after the end of the interview her supervisor will make necessary arrangements to get in contact. There will also be a code word if Rebecca feels threatened or in any danger.

Appendix 3. Ethics and Measures for Item Generation Interviews (Chapter 5)

Ethical Approval Letter for Main Interviews and Psychometrics

12 October 2017

Janice Abbott/ Rebecca Jefferson

School of Psychology

University of Central Lancashire

Dear Janice and Rebecca

Re: PSYSOC Ethics Committee Application

Unique Reference Number: PSYSOC 307, Phase 2

The PSYSOC ethics committee has granted approval of your proposal application 'Development of an adult weight-specific quality of life measure' Phase 2. Approval is granted up to the end of project date.

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 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).

Yours sincerely

Christine Barter

Vice-Chair

PSYSOC 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.*

Participant Information Sheet

Interview study exploring the impact of weight on cognitions, emotions and behaviour

You are being invited to take part in an interview as part of a research study. Before you decide if you want to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If there is anything that is not clear or if you would like more information, just ask.

Please note: If you have never been overweight, if you are pregnant, have been diagnosed as terminally ill or are seeing a doctor for an eating disorder or a chronic illness that has resulted in a weight problem or you are unable to stand unassisted we are unable to include you in the current research. Please let the researcher know if you fall into one of these categories.

What is the purpose of the interview?

The purpose is to find out how your weight/ body shape affects different aspects of your life. The information provided during the interview will be used alongside interview data from other participants to develop a way of measuring weight-related quality of life. This study forms a part of a research students PhD.

Why have I been chosen?

You have been chosen to participate in this interview as you have shown your interest in the research.

Do I have to take part?

It is up to you as to whether you take part or not. If you do take part, after reading this information sheet and asking any questions you may have, you will be asked to sign a consent form to say that you understand what the study involves. If you decide to take part, you are still free to withdraw at any time during the interview and up to 7 days after the interview without giving a reason. After these 7 days your interview data will no longer be identifiable, as it will have been anonymised, therefore it will not be possible to withdraw after this time.

What will I have to do?

If you decide to participate you will be asked to attend a one to one interview at a convenient time and location (e.g. community centre, library etc.). The interview will involve filling out a short questionnaire followed by a discussion about the way your weight or body shape affects how you think and feel and how this effects the different aspects of your life (e.g. work, social activities, and relationships). The interview is expected to last an hour. The interview will be tape recorded and notes may be taken throughout. You can stop the interview at any time. After the interview, the researcher will measure your weight, height and waist circumference and you will be asked to fill in

a demographic questionnaire. This will ensure we interview a range of people with differing backgrounds, weights and body shapes. Before having your measurements taken you will be asked to remove your shoes and any coats or jumpers, so please ensure you wear thin clothing underneath any removable layers. **Please note that the researcher taking the measurements will be female.**

What are the possible benefits of taking part?

The information gained from this study will help develop a way to assess how a person's weight is affecting their quality of life, and whether this improves through weight and lifestyle interventions.

Will my taking part in this study be kept confidential?

Yes. Ethical and legal practices will be followed and all information about you will be handled in confidence. Your name will be removed from the interview transcripts and documents recording your weight, height and waist circumference to keep your identity confidential. Direct quotes may be used in publications but these will be labelled with an ID number and anything which could identify you will be removed. Interview tapes will be destroyed once typed up and transcriptions will be kept on a password protected computer only accessible to the research student and her two supervisors. Any paper copies of the transcribed interview and any other documents will be kept in a locked filing cabinet.

What will happen to the results of the research?

The results of the interview will be used to develop a measure of quality of life for future research and for health care providers. The results will also be written up as part of the students PhD thesis and may be published in health professional journals and presented at conferences in the UK and abroad.

Who is organising and funding the research?

The research is funded by the College of Science and Technology and organised by the School of Psychology at the University of Central Lancashire as part of a PhD study.

Who has reviewed the study?

The UCLan PSYSOC ethics committee has reviewed and approved the current research.

What happens now?

If you are happy to participate or have any questions, please contact Rebecca Jefferson (PhD research student) via email rljefferson@uclan.ac.uk or via telephone 07754483357.

Thank you for taking time to consider participating in this study.

If you have any concerns or complaints about any aspect of the way you have been approached or are treated during this study, you can contact the lead supervisor, Dr Janice Abbott on 01776 893790 (JAbbott@uclan.ac.uk) or the university officer for ethics on OfficerforEthics@uclan.ac.uk.

If you are worried about your weight, please visit your local GP for advice. Alternatively, you can visit the NHS website for advice and to find out about local weight loss groups (http://www.nhs.uk/Livewell/loseweight/Pages/WhataGPcando.aspx).

Consent Form

Consent form

Interview study exploring the impact of weight on cognitions, emotions and behaviour

Participant ID: _____

Please initial box

1. I confirm that I have read and understood the information sheet dated October 2017 (version 2) 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 during the interview and up to 7 days after the interview, without giving any reason. ☐
3. I understand that it will not be possible to withdraw my data from the study after the 7-day window ☐
4. I understand that the interview will be recorded, typed up and notes will be taken during the interview ☐
5. I understand that the conversations in that interview may be used when the research team write about the study. However, any quotes will be anonymised, and no information will be used in any presentations or reports that could lead to my identification. ☐
6. I understand that only the researcher and the two research supervisors will have access to information I provide. ☐
7. I agree for my weight, height and waist circumference to be measured and recorded after the interview. ☐
8. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Debrief Sheet

The current research aimed to explore how weight affects the different aspects of individuals' lives. This exploration will be used to develop a questionnaire which will reliably measure weight-related quality of life.

To explore weight-related quality of life, you were asked to talk about your weight and how it affects the different aspects of your life. Your interview will now be transcribed and analysed alongside other participants interview data in order to create the items of the questionnaire.

Why is this research important?

Quality of life is important for motivation. If weight loss programmes and interventions do not improve an individual's quality of life, there will be a high risk of regaining weight and returning to their original lifestyle. Having a measure of quality of life will allow researchers, health care providers/organisations to develop more successful weight loss programmes and interventions. It will also allow health care providers to identify individuals that may need extra support.

What if I want to withdraw my data?

If you do not want your interview to be transcribed and analysed, you have 7 days from the date of your interview to inform the researcher. After this, your interview will have been transcribed and anonymised, so it will not be possible to remove it from the analysis.

Want to know the findings?

If you are interested in what is found from the interviews, please tick the box on the following page and provide your preferred method of communication (email or post) and you will be sent a summary of the findings once they become available.

If you have any further questions, please do not hesitate to contact me using the details below. If you have any concerns regarding the current research or the way you have been treated, please contact the Lead Supervisor or the University Officer for Ethics (details below).

If you are worried about your weight, please visit your local GP for advice. Alternatively, you can visit the NHS website for advice and to find out about local weight loss groups (http://www.nhs.uk/Livewell/loseweight/Pages/WhataGPcando.aspx).

Thank you for taking time to participate in this research.

Sincerely,

Rebecca Jefferson
PhD research student
School of Psychology,
University of Central Lancashire
Email - rljefferson@uclan.ac.uk

Lead Supervisor: Dr Janice Abbott
Email – jabbott@uclan.ac.uk
Telephone - 01776 893790

University Officer for Ethics
Email - OfficerforEthics@uclan.ac.uk

☐ Yes I would like to receive a summary of the results

Name: _____

Email address: _____

OR

Postal address:

House Name/No. _____
Address line 1 _____
Address line 2 _____
Town _____
County _____
Postcode _____

Please return this page to the researcher

Research Poster for Item Generation Interviews

VOLUNTEERS NEEDED

We are looking for adults (both male and female) aged 18 and over to participate in a research study exploring how your weight/body shape affects your quality of life.

What will it involve?

You will be asked to take part in an interview which will involve a chat about your weight and how it affects different aspects of your life.

Want to know more?

Contact Rebecca Jefferson (PhD research student from the School of Psychology, UCLan) for more information:

Email: rljefferson@uclan.ac.uk

Telephone: 07754483357

Please note you will be unable to participate if you fall into any of the following categories:

- ***Have never been overweight***
- ***You are pregnant,***
- ***Have been diagnosed as terminally ill***
- ***Seeing a doctor for an eating disorder***
- ***Seeing a doctor for a chronic illness resulting in a weight problem***
- ***Cannot stand unassisted***

Weight and quality of life RLJefferson@uclan.ac.uk 07754483357

Weight and quality of life RLJefferson@uclan.ac.uk 07754483357
Weight and quality of life RLJefferson@uclan.ac.uk 07754483357
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Weight and quality of life RLJefferson@uclan.ac.uk 07754483357

Impact Of Weight On Quality Of Life – Lite Questions & Response Options

PHYSICAL FUNCTION

1 Because of my weight I have trouble picking up objects:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

2 Because of my weight I have trouble tying my shoes

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

3 Because of my weight I have difficulty getting up from chairs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

4 Because of my weight I have trouble using stairs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

5 Because of my weight I have difficulty putting on or taking off my clothes:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

6 Because of my weight I have trouble with mobility:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

7 Because of my weight I have trouble crossing my legs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

8 I feel short of breath with only mild exertion:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

9 I am troubled by painful or stiff joints:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

10 My ankles and lower legs are swollen at the end of the day:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

11 I am worried about my health:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

SELF-ESTEEM

1 Because of my weight I am self-conscious:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

2 Because of my weight my self-esteem is not what it could be:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

3 Because of my weight I feel unsure of myself:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

4 Because of my weight I don't like myself:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

5 Because of my weight I am afraid of being rejected:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

6 Because of my weight I avoid looking in mirrors or seeing myself in photographs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

7 Because of my weight I am embarrassed to be seen in public places:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

SEXUAL LIFE

1 Because of my weight I do not enjoy sexual activity:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

2 Because of my weight I have little or no sexual desire:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

3 Because of my weight I have difficulty with sexual performance:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

4 Because of my weight I avoid sexual encounters whenever possible:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

PUBLIC DISTRESS

1 Because of my weight I experience ridicule, teasing, or unwanted attention:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

2 Because of my weight I worry about fitting into seats in public places (e.g. theatres, restaurants, cars, or airplanes):

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

3 Because of my weight I worry about fitting through turnstiles:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

4 Because of my weight I worry about finding chairs that are strong enough to hold my weight:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

5 Because of my weight I experience discrimination by others:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

WORK

1 Because of my weight I have trouble getting things accomplished or meeting my responsibilities:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

2 Because of my weight I am less productive than I could be:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

3 Because of my weight I don’t receive appropriate raises, promotions or recognition at work:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

4 Because of my weight I am afraid to go on job interviews:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
5	4	3	2	1

END OF QUESTIONS

Interview Schedule for Main Interviews

Section A – Usability and feasibility of the IWQOL-Lite across all BMI groups

1. What was it like to complete the questionnaire?
2. How easy was it to complete?
    a. Any issues with the language used?
    b. Any issues with the scoring system?
3. Did you experience any problems answering the questions?
    a. Which ones?
    b. What do you think it is asking?
4. Were there any questions which you felt were harder to answer than others?
    a. Which ones?
    b. Why?
5. Were there any questions which you felt uncomfortable answering?
    a. Which ones?
    b. Why?
6. Are there any questions that you have left out or wanted to leave out?
    a. Which ones?
    b. Why?
7. How does the change in the introducing statement on questions 8-11 affect how you answered these?
    a. Did you answer these as if they were about your weight?
8. There may be some issues that weight affects which are important to some people but may not be included in this questionnaire. Are there any issues that apply to you that aren't covered?
9. There also may be issues that are covered by the scale which you do not feel are relevant to some people. Did you find any issues that were not relevant to you?

Section B – Exploration of HCF for Item Generation

General Q's

1. What do you think are the most significant aspects of being overweight?

Physical Functioning – pain, fitness/energy

1. How does your weight affect your mobility?
    a. Do you experience any pain?
        i. Where?
    b. Does it affect your physical fitness?
        i. How?
    c. Does it affect your energy levels?
        i. How?
2. How does your weight affect how hot or cold you feel? In what way?
3. What do you think your health will be like in the future?
    a. How does this make you feel?

Psychosocial Functioning – self-esteem, fixation on weight, feeling judged

1. How do you feel about yourself?
2. How often do you think about your weight?
3. When you think about your weight, how does it make you feel?

Body Image – body dissatisfaction, using clothes to hide, feeling comfortable in clothes, intimacy

1. How do you feel about your appearance?
2. Do you think your weight affects your appearance?
3. Does your weight affect your intimate relationships?
    a. How?
4. Has your weight ever effected your sexual performance?
5. Does your weight affect your clothing choices?
    a. How?
    b. Do you avoid wearing certain things because of your weight?
6. How do you feel in your clothes?

Shopping for clothes – Limited by fashion, Norms, Representation of size

1. When shopping for clothes have you ever felt restricted in what you can buy and wear?
2. How do you feel about the representation of models in the fashion industry?
    a. Has this ever affected how you feel about your weight?

Future health, Health care restrictions, public transport

1. How does your weight affect your day to day activities?
2. How does your weight affect your job/attempt at getting a job?
    a. How are you treated by your employers?
    b. How are you treated by your employees?
3. Have you ever felt you have been judged by others because of your weight?
    a. How did this make you feel?
4. Do you use public transport?
    a. Does your weight affect this experience?
        i. How?

Food – emotions, self-control

1. What is your relationship with food like?
    a. Do you ever feel guilty after eating?
        i. Could you give an example of this?
        ii. Why do you think you feel guilty?
    b. Do you ever comfort eat?
        i. Could you give an example?
    c. What is your self-control with food like?
        i. How does this make you feel?

Appendix 4. Measures for Psychometric Data Collection (Chapter 6 & 7)

Research Poster

Questionnaire Pack

Weight/body Shape and Quality of Life: Testing a New Questionnaire

You are being invited to fill out a questionnaire as part of a research study. Before you decide if you want to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If there is anything that is not clear or if you would like more information, just ask.

Please let the researcher know if: you have never been overweight, you are pregnant, have been diagnosed as terminally ill or are seeing a doctor for an eating disorder or a chronic illness that has resulted in a weight problem or you are unable to stand unassisted.

What is the purpose of the research?

The purpose is to evaluate a new questionnaire which aims to measure the effects of carrying excess weight on the different aspects of people's lives. This study forms a part of a research students PhD.

Why have I been chosen?

You have been chosen to participate in this study because the research aims to obtain a variety of people from the general population. There is no specific reason that you have been approached.

Do I have to take part?

It is up to you as to whether you take part or not. If you decide to take part, you are still free to withdraw at any time up until you hand in the questionnaire and you or the researcher leaves the appointment location. You will be unable to withdraw your questionnaire after this as it will have been anonymised and therefore your data will be unidentifiable.

What will I have to do?

If you decide to participate you will be asked to attend an appointment with the researcher, at a convenient time and location (e.g. community centre, library etc.). You will be asked to fill out a questionnaire. After this, the researcher will ask to measure your weight, height and waist circumference. This will ensure we gain data from a range of people with differing backgrounds, weights and body shapes. Before having your measurements taken you will be asked to remove your shoes and any coats or jumpers, so please ensure you wear thin clothing underneath any removable layers. **Please note that the researcher taking the measurements will be female.** This is likely to take around 15-20 minutes to complete.

What are the possible benefits of taking part?

The information gained from this study will help develop a way to assess how a person's weight is affecting their quality of life, and whether this improves through weight and lifestyle interventions.

Will my taking part in this study be kept confidential?

Yes. Ethical and legal practices will be followed and all information about you will be handled in confidence. Your name will not be recorded on the questionnaire to keep your identity confidential.

What will happen to the results of the research?

The results of the research will be used to evaluate a new measure of quality of life for future research and for health care providers. The results will also be written up as part of the students PhD thesis and may be published in health professional journals and presented at conferences in the UK and abroad.

Who is organising and funding the research?

The research is funded by the College of Science and Technology and organised by the School of Psychology at the University of Central Lancashire as part of a PhD study.

Who has reviewed the study?

The UCLan PSYSOC ethics committee has reviewed and approved the current research.

If you have any questions before you begin please contact;

Rebecca Jefferson: Phone: 07754483357; **Email: rljefferson@uclan.ac.uk**

Thank you for taking time to consider participating in this study.

Please turn over if you are happy to continue.

1. Are you male or female?

☐ Male ☐ Female ☐ Other, _____

2. How old are you in years? _____

3. Please tick one category that best represents your highest level of education?

☐ High School or equivalent
☐ A-levels or equivalent
☐ Vocational/technical school (2years)
☐ Bachelor's degree
☐ Master's degree
☐ Doctoral Degree
☐ Professional degree (MD, JD)
☐ Other _____

4. Which of the following categories best describes your current employment status? **(Tick all that apply)**

☐ Employed
☐ Not employed
☐ Student
☐ Retired
☐ Disabled, not able to work

5. Do you currently receive income support?

☐ No
☐ Yes

6. Which of these apply to the property you currently live in?

☐ Owned outright
☐ Buying on a mortgage
☐ Renting from council
☐ Renting from housing association/trust
☐ Renting from private landlord
☐ Other

7. Race

☐ White
☐ Asian
☐ Black/ African/ Caribbean/ Black British
☐ Mixed Race
☐ Other

8. What is your current marital status?

☐ Divorced
☐ Living with another
☐ Married
☐ Separated
☐ Single
☐ Widowed

9. Which statement best describes your previous weight loss attempts?

☐ I have previously lost weight but have since put some or all of it back on
☐ I have previously lost weight and have kept it off
☐ I have attempted to lose weight, but have not lost any weight
☐ I have never tried to lose weight

10. Do you have any health conditions? **(please tick all that apply)**

☐ Type I Diabetes
☐ Type II Diabetes
☐ Asthma
☐ High Blood Pressure
☐ Heart Disease
☐ Other, (please specify) _____

Section 2: New Weight-Related Quality of Life Instrument

Date: ____/____/____

The following questionnaire is designed to find out how your weight/body shape affects your life.

Please read the instructions on the top of each page before answering the items.

There are no right or wrong answers. It is your views that are important to us.

Questions start on the next page.

Please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

1. I have aches and pains (for example, in knees, hips, ankles, back, feet and/or joints).

Not at all — All the time

0	1	2	3	4	5	6	7	8	9

2. I worry that my weight will impact my future health.

Not at all — All the time

0	1	2	3	4	5	6	7	8	9

3. I am healthy.

Very Healthy — Very Unhealthy

0	1	2	3	4	5	6	7	8	9

4. I have no energy.

No energy — Lots of energy

0	1	2	3	4	5	6	7	8	9

Please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

5. I have disturbed sleep.

Not at all									All the time
0	1	2	3	4	5	6	7	8	9

6. I am breathless going upstairs.

Not at all									All the time
0	1	2	3	4	5	6	7	8	9

7. Standing for long periods is difficult.

Not at all									All the time
0	1	2	3	4	5	6	7	8	9

8. Walking is difficult.

Not at all									All the time
0	1	2	3	4	5	6	7	8	9

Please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

9. Bending down is difficult (for example, tying shoes, cutting toenails, picking things up from the floor etc.).

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

10. Getting up from a seated position is difficult (for example, chairs, cars etc.).

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

11. Washing myself is difficult.

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

12. I avoid physical activity.

Never Always

0	1	2	3	4	5	6	7	8	9

13. I worry about fitting in seats and public spaces (for example, aeroplane seats/seatbelts, turnstiles, bus seats, train/bus aisles etc.).

Not at all All the time

0	1	2	3	4	5	6	7	8	9

14. My eating is under-control.

Not at all All the time

0	1	2	3	4	5	6	7	8	9

15. I feel judged when I eat in public.

Not at all All the time

0	1	2	3	4	5	6	7	8	9

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

16. I avoid eating in front of others.

Not at all | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | All the time

17. I feel good about myself.

Not at all | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | All the time

18. I am happy with my weight.

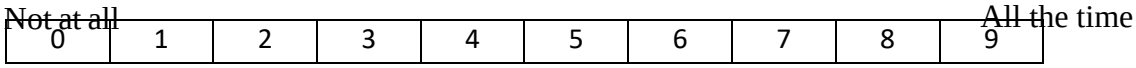
Very Unhappy | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Very Happy

19. I feel confident.

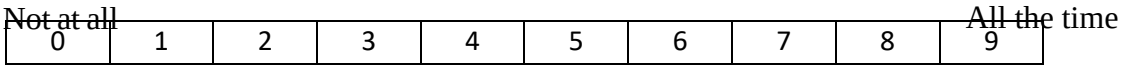
Not at all | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | All the time

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

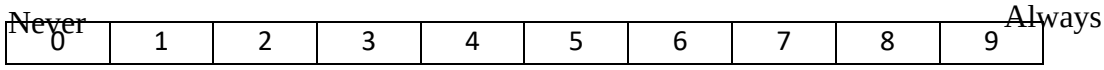
20. I am depressed.



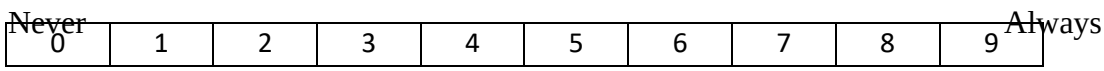
21. I am embarrassed about my appearance.



22. I look good in my clothes.



23. I choose clothes that hide my body shape.



Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

24. I enjoy shopping for clothes.

Never Always

0	1	2	3	4	5	6	7	8	9

25. Finding the right clothes for the right occasion is difficult (for example, wedding, evening, work, leisure/exercise etc.).

Not at all All the time

0	1	2	3	4	5	6	7	8	9

26. I avoid social situations (for example, physical activities, meeting with friends/work colleagues).

Never Always

0	1	2	3	4	5	6	7	8	9

27. I am teased by others.

Not at all All the time

0	1	2	3	4	5	6	7	8	9

Based on your weight, please read each question and circle the number which most applies to you. Your answers should reflect how you feel **today.**

28. I feel discriminated against.

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

29. I am taken seriously (for example, by doctors, nurses, work colleagues, etc.).

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

30. There is a strain on my personal relationships (e.g. family, friends, intimate partner).

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

31. I feel valued by others.

Not at all

0	1	2	3	4	5	6	7	8	9

All the time

If you have any comments about this questionnaire, please write them here:

END OF SECTION 2
Please turn over to continue

Section 3: Impact of weight on quality of life – Lite version

PHYSICAL FUNCTION

1 Because of my weight I have trouble picking up objects:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

2 Because of my weight I have trouble tying my shoes:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

3 Because of my weight I have difficulty getting up from chairs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

4 Because of my weight I have trouble using stairs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

5 Because of my weight I have difficulty putting on or taking off my clothes:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

6 Because of my weight I have trouble with mobility:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

7 Because of my weight I have trouble crossing my legs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

8 I feel short of breath with only mild exertion:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

9 I am troubled by painful or stiff joints:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

10 My ankles and lower legs are swollen at the end of the day:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

11 I am worried about my health:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

SELF-ESTEEM

1 Because of my weight I am self-conscious:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

2 Because of my weight my self-esteem is not what it could be:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

3 Because of my weight I feel unsure of myself:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

4 Because of my weight I don’t like myself:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

5 Because of my weight I am afraid of being rejected:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

6 Because of my weight I avoid looking in mirrors or seeing myself in photographs:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

7 Because of my weight I am embarrassed to be seen in public places:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

SEXUAL LIFE

1 Because of my weight I do not enjoy sexual activity:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

2 Because of my weight I have little or no sexual desire:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

3 Because of my weight I have difficulty with sexual performance:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

4 Because of my weight I avoid sexual encounters whenever possible:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

PUBLIC DISTRESS

1 Because of my weight I experience ridicule, teasing, or unwanted attention:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

2 Because of my weight I worry about fitting into seats in public places (e.g. theatres, restaurants, cars, or airplanes):

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

3 Because of my weight I worry about fitting through turnstiles:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

4 Because of my weight I worry about finding chairs that are strong enough to hold my weight:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

5 Because of my weight I experience discrimination by others:

ALWAYS TRUE ☐ | USUALLY TRUE ☐ | SOMETIMES TRUE ☐ | RARELY TRUE ☐ | NEVER TRUE ☐

WORK

1 Because of my weight I have trouble getting things accomplished or meeting my responsibilities:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

2 Because of my weight I am less productive than I could be:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

3 Because of my weight I don't receive appropriate raises, promotions or recognition at work:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

4 Because of my weight I am afraid to go on job interviews:

ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
☐	☐	☐	☐	☐

END OF QUESTIONS.
Thank you for your time.
Please hand back to the researcher ready for your measurements to be taken.

To be completed by the researcher:

Height (cm): _____

Weight (kg): _____

Debrief Sheet

The current research aimed to test a new measure of weight-related quality of life. The new measure has been developed from interviews with individuals who have experienced being overweight. Your responses will help to improve the new measure and make sure it is an accurate and valid measure.

Why is this research important?

Quality of life is important for motivation. If weight loss programmes and interventions do not improve an individual's quality of life, there will be a high risk of regaining weight and returning to their original lifestyle. Having a measure of quality of life will allow researchers, health care providers/organisations to develop more successful weight loss programmes and interventions. It will also allow health care providers to identify individuals that may need extra support.

What if I want to withdraw my data?

Once you have handed in your questionnaire, your data will be unidentifiable. This means that you will not be able to withdraw your data after you or the researcher has left the appointment location. Please think carefully about whether you want to withdraw our data before you or the researcher leaves.

Want to know the findings?

If you are interested in what is found from the current research project, please tick the box on the following page and provide your preferred method of communication (email or post) and you will be sent a summary of the findings once they become available. You can also participate in this research again in one week. You will be asked to complete a short questionnaire, which can be emailed or sent via post. Your measurements will not be taken again. If you would like to do this, please tick the box on the next page.

If you have any further questions, please do not hesitate to contact me using the details below. If you have any concerns regarding the current research or the way you have been treated, please contact the Lead Supervisor or the University Officer for Ethics (details below).

If you are worried about your weight, please visit your local GP for advice. Alternatively, you can visit the NHS website for advice and to find out about local weight loss groups (http://www.nhs.uk/Livewell/loseweight/Pages/WhataGPcando.aspx).

Thank you for taking time to participate in this research.

Sincerely,

Rebecca Jefferson
PhD research student
School of Psychology,
University of Central Lancashire
Email - rljefferson@uclan.ac.uk
Telephone - 07754483357

Lead Supervisor: Dr Janice Abbott
Email – jabbott@uclan.ac.uk
Telephone - 01776 893790

University Officer for Ethics
Email - OfficerforEthics@uclan.ac.uk

☐ I would like to receive a summary of the results

☐ I would like to participate again in 1 week

Name: _____

Email address: _____

OR

Postal address:

House Name/No. _____
Address line 1 _____
Address line 2 _____
Town _____
County _____
Postcode _____

Please return this page to the researcher

Retest Questionnaire Extra Questions – Section 2

SECTION 2

1. How has your weight changed in the last week? (If yes please state how much)

   ☐ Increased by _____

   ☐ Decreased by _____

   ☐ No change

   ☐ Other, (please specify) _____

2. Over the past week has there been any change in your overall quality of life related to your weight? (Please tick the statement that most represents the change you have experienced)

   ☐ A very great deal worse
   ☐ A great deal worse
   ☐ A good deal worse
   ☐ Moderately worse
   ☐ Somewhat worse
   ☐ A little worse
   ☐ Almost the same, hardly any worse at all

   ☐ No change

   ☐ Almost the same, hardly any better at all
   ☐ A little better
   ☐ Somewhat better
   ☐ Moderately better
   ☐ A good deal better
   ☐ A great deal better
   ☐ A very great deal better

END OF QUESTIONS. THANK YOU FOR YOUR TIME.

Appendix 5: Gender PCA's for Draft WRQoL Scale (Chapter 7)

Female: Rotated Component Matrix[a,B]

	Component			
	1	2	3	4
Q1 Aches & Pains	.151	.440	-.208	.012
Q2 Worry Future Health	.504	.393	.071	.130
Q3 Healthy	.472	.358	.083	-.037
Q4 No Energy	.221	.135	.732	-.041
Q5 Disturbed Sleep	.242	.165	-.374	.121
Q6 Breathless	.440	.440	.130	-.095
Q7 Standing Long Periods	.144	.650	.087	.018
Q8 Walking Difficult	.157	.821	.111	.076
Q9 Bending Down	.044	.764	.037	.323
Q10 Getting Up from Seated	-.011	.842	.049	.174
Q11 Washing Difficult	-.046	.691	.184	.130
Q12 Avoid PA	.204	.216	.725	-.046
Q13 Worry Fitting in Seats	-.043	.219	.694	.340
Q14 Eating Under Control	.552	.280	.128	-.253
Q15 Judged Eat in Public	.124	.150	.476	.588
Q16 Avoid Eating in Front Others	.203	.327	.037	.497
Q17 Feel Good About Self	.748	-.038	-.059	.056
Q18 Happy with Weight	.829	.072	-.110	.114
Q19 Feel Confident	.851	-.085	.071	.106
Q20 Depressed	.564	-.012	.117	.436
Q21 Embarrassed Appearance	.783	.180	.128	.179
Q22 Look Good in Clothes	.654	-.056	.441	.099
Q23 Choose Clothes to Hide	.775	.159	-.016	.161
Q24 Enjoy Shopping Clothes	.559	.133	-.095	.300
Q25 Finding Right Clothes Difficult	.743	.177	.009	.189
Q26 Avoid Social Situations	.465	.050	-.016	.387
Q27 Teased by Others	.096	.052	.001	.653
Q28 Discriminated Against	.074	.344	.175	.618
Q29 Taken Seriously	.006	-.003	.553	.196
Q30 Strain on Relationships	.314	-.013	.113	.461
Q31 Valued by Others	-.026	.006	.689	.080

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 6 iterations. b. Only cases for which Gender = Female are used in the analysis phase

Male: Rotated Component Matrix[a,b]

	Component			
	1	2	3	4
Q1 Aches & Pains	-.029	.666	-.160	.024
Q2 Worry Future Health	.419	.228	-.069	.414
Q3 Healthy	.287	.247	-.255	.180
Q4 No Energy	.033	.065	.502	-.132
Q5 Disturbed Sleep	.478	.267	-.088	.425
Q6 Breathless	.232	.348	.177	.457
Q7 Standing Long Periods	-.005	.696	-.047	-.036
Q8 Walking Difficult	.000	.851	.034	-.018
Q9 Bending Down	.155	.763	-.007	-.040
Q10 Getting Up from Seated	.201	.814	.073	.094
Q11 Washing Difficult	-.133	.683	.188	.314
Q12 Avoid PA	-.171	.246	.725	.042
Q13 Worry Fitting in Seats	-.493	-.006	.755	.098
Q14 Eating Under Control	.530	.157	-.091	-.244
Q15 Judged Eat in Public	-.085	-.097	.870	-.022
Q16 Avoid Eating in Front Others	.443	.126	.242	.142
Q17 Feel Good About Self	.815	-.067	-.010	-.023
Q18 Happy with Weight	.875	-.040	-.068	.104
Q19 Feel Confident	.686	-.086	-.050	.124
Q20 Depressed	.292	-.138	-.057	.610
Q21 Embarrassed Appearance	.510	-.147	.026	.529
Q22 Look Good in Clothes	.415	.104	.430	.087
Q23 Choose Clothes to Hide	.484	.189	.107	.306
Q24 Enjoy Shopping Clothes	.150	-.026	-.155	.469
Q25 Finding Right Clothes Difficult	-.106	.191	-.174	.504
Q26 Avoid Social Situations	.105	.175	.027	.249
Q27 Teased by Others	.236	-.198	-.154	.408
Q28 Discriminated Against	-.148	.023	.051	.702
Q29 Taken Seriously	.134	-.208	.677	-.057
Q30 Strain on Relationships	-.033	.048	-.017	.573
Q31 Valued by Others	.135	-.043	.745	-.194

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 5 iterations. b. Only cases for which Gender = Male are used in the analysis phase.