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The exploration and evaluation of the feasibility and acceptability of a religious weight management programme

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The exploration and evaluation of the feasibility and acceptability of a religious weight management programme

By Riya Patel PhD

September 2017



A thesis submitted in partial fulfilment of the University's requirements for the Degree of Doctor of Philosophy

Statement of Contribution

The author of the thesis contributed the following:

Chapter 1. The author planned the structure of thesis and then discussed this with Deborah Lycett, Anne Coufopoulos, and Andy Turner.

Chapter 2. The author conducted this literature review in its entirety.

Chapter 3. This PhD was completed in part of a larger trial that is testing the efficacy of a religious weight management programme. The Principal Investigator (Deborah Lycett) conceived the idea and developed the Taste & See intervention. The author contributed to the design of the feasibility study. The author obtained the necessary permissions (Ethics, gatekeeper permission from the participating church, permissions to use questionnaires from authors) to run the feasibility trial. The author designed the interview schedules for the qualitative studies under the guidance of Deborah Lycett. The author contributed to the design and delivery of weekly sessions of the intervention. The author collected all the participant data.

Chapter 4. The author carried out the repeated measures ANOVA, and then following tutoring by Deborah Lycett on regression analyses, the author conducted correlations to guide the choice of variables that were placed in the regression analyses.

Chapter 5. The author conducted transcribed and analysed all of the qualitative interviews. Codes and themes emerging from qualitative transcripts were discussed with Deborah Lycett, Anne Coufopoulos, and Andy Turner who are experienced in qualitative methods.

Chapter 6. This chapter contains the author's own interpretations and conclusions.

List of Publications from this PhD

Patel, R., Lycett D, Coufopoulos A, Turner A. (2017) A Feasibility Study of Taste & See: A Church-Based, Programme to Develop a Healthy Relationship with Food. Religions 8, (2), 29

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Conference Proceedings from this PhD

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Taste and See: A Feasibility Study of a Church-based Programme for a Healthy Relationship with Food. Interactive Poster Presented at the 17th International Congress of Dietetics, September 2016, Granada, Spain.

Taste and See: A Feasibility Study of a Church-based Programme for a Healthy Relationship with Food. Interactive Poster Presented at the 30th Conference of the EHPS/DHP, Behaviour Change: Making an Impact on Health and Health Services, August 2016, Aberdeen, Scotland.

'Weight Loss through the Eyes of Their Creator': A Qualitative Study of the Taste & See Intervention. Interactive Poster Presented at the 30th Conference of the EHPS/DHP, Behaviour Change: Making an Impact on Health and Health Services, August 2016, Aberdeen, Scotland.

Taste and See: A Mixed-Methods Feasibility Study of a Church-Based Programme for a Healthy Relationship with Food. Symposium Presentation at the 5th European Conference on Religion, Spirituality and Health, May 2016, Gdansk, Poland

Taste and See: A Mixed-Methods Feasibility Study of a Church-based programme for a healthy relationship with food. Symposium presentation at the Faculty of Health & Life Sciences Annual Research Conference, March 2016, Coventry University, UK.

'Weight Loss through the Eyes of Their Creator': A Qualitative Study of the Taste & See Intervention. Interactive Poster Presented at the Faculty of Health & Life Sciences Annual Research Conference, March 2016, Coventry University, UK.

Taste and See: A Mixed-Methods Feasibility Study of a Church-based Programme for a Healthy Relationship with Food. Interactive Poster Presented at the 13th International Congress on Obesity, April 2016, Vancouver, Canada.

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Taste and See: A Feasibility Study of a Church-Based, Healthy, Intuitive Eating Programme - Preliminary Results. Oral Presentation at BPS West Midlands Branch Annual Conference September 2015, Coventry, UK.

Protocol of Taste and See: A Feasibility Study of a Church-based, Healthy, Intuitive Eating Programme. Oral Presentation at 'Sewing the seeds' 1st International Spirituality in Healthcare Conference, June 2015, Dublin, Ireland.

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Thesis Abstract

Background:

Obesity treatment is a global priority. Current approaches to treating obesity have demonstrated good efficacy but the obesity epidemic continues to escalate. Holistic approaches which include a religious element are a promising intervention within obesity, as demonstrated by research conducted in the USA, but are yet to be explored in the UK.

Methods:

A mixed-methods feasibility trial with two embedded qualitative studies to investigate the feasibility and acceptability of a 3-month Christian, church-based, intuitive-eating programme.

Results:

A total of 18 participants were recruited, attendance during the programme peaked and troughed. It was feasible to recruit and train lay facilitators to deliver intervention sessions. Qualitative evidence exploring facilitators' experiences showed they were able to facilitate the sessions, but facilitating was not always easy. Facilitators experienced challenges associated with managing difficult group members, and the range of issues that can arise during group discussions.

Qualitative evidence exploring participants' experiences showed the two novel components; Christian spirituality and intuitive eating took participants on a journey. None of the participants had ever thought of bringing God into their eating, but as participants started surrendering their struggles with food to God, their faith became an invaluable resource for their weight loss journey. Similarly, the intuitive eating component was initially difficult to understand. However, as participants learned to incorporate the principles of intuitive eating into their daily lives, the negative emotions associated with food were reduced. Post-intervention all participants felt ready to move forward into the next stage of their weight loss journey.

Significant improvements were observed in mental well-being, anxiety, depression, quality-of-life, pain/discomfort uncontrolled-eating, emotional-eating, cognitive-restrained-eating, intuitive-eating and BMI post-intervention. By 6-month follow-up there was a return to baseline levels for weight, BMI, energy intake, and a partial reversal in uncontrolled eating, emotional eating, cognitive restrained eating, anxiety, depression, mental well-being and spiritual well-being. However, improvements in intuitive eating were fully sustained at this time point and total fat, saturated fat and sugar intake had reduced further.

Conclusion:

It was feasible to recruit, deliver and evaluate Taste & See in a UK church, with lay volunteers. The intervention was acceptable to both facilitators and participants and qualitative evidence showed good engagement with the content. The clinical outcomes were positive but a larger RCT is needed to demonstrate efficacy.

Key words: obesity; weight; religion; church-based; faith-based; Christian; intervention; feasibility trial; mixed-methods.

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List of Abbreviations

BCT - Behaviour Change Technique

BMI - Body Mass Index

BOCF - Baseline Observation Carried Forward

CBT - Cognitive Behaviour Therapy

CHD - Coronary Heart Disease

CI - Confidence Intervals

CR - Cognitive Restrained Eating

CRF - Cardiorespiratory Fitness

CVD - Cardiovascular Disease

EQ-5D-5L - European Quality of Life-5-Dimensions-5-Levels

EWL - Excess Weight Loss

HPA - Hypothalamic-Pituitary-Adrenal

HR - Hazard Ratio

HSE - Health Survey England

IPA - Interpretative Phenomenological Analysis

ITT - Intention-To-Treat

Kcal - Kilocalories

Kg - Kilograms

LAGB - Laparoscopic Gastric Banding

MET - Metabolic- Equivalent

MHO - Metabolically Healthy Obesity

Mins - Minutes

MRC - Medical Research Council

NICE - National Institute for Health and Clinical Excellence

OR - Odds Ratio

PA - Physical Activity

PI - Principal Investigator

QOL VAS - Quality of Life Visual Analogue Scale

RCT - Randomised Controlled Trial

RR - Relative Risk

SD - Standard Deviation

SDA - Seventh-Day Adventists

T2DM - Type 2 Diabetes Mellitus

UK - United Kingdom

USA - United States of America

VLED - Very Low Energy Diet

WC - Waist Circumference

WHO - World Health Organisation

WHR - Waist to Hip Ratio

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1 Structure of This Thesis

The purpose of this thesis is to investigate whether a weight management intervention incorporating Christian religious beliefs can be evaluated within a church in England. The evaluation explores whether participants can be recruited to such a programme, whether they find the programme acceptable and the content something they can engage with. The evaluation further explores whether it is feasible to recruit and train lay church volunteers to deliver the programme. The structure of this thesis comprises of six chapters.

Chapter one aims to provide an overview of this thesis, and how this thesis has been structured.

Chapter two provides a background to the evidence around obesity, current interventions that aim to treat obesity; the effectiveness of these approaches, non-diet approaches as an alternative treatment and introduces the concept of religion and spirituality in health and obesity. The chapter is presented in eight sections. This chapter has also been published as a protocol in Religions, the full publication can be found in Appendix A.

Chapter three provides details about the methods employed in this PhD, this includes a discussion of the mixed-methods design and reason for this approach. The chapter then introduces the development of the intervention evaluated in this PhD, detailing how the intervention was developed in line with the Medical Research Council (MRC) framework, and the methodologies employed to conduct the mixed-methods feasibility study evaluation.

Chapter four presents the feasibility results which are quantitative in nature. The findings of the feasibility study alongside the facilitator acceptability findings have been published in Religions, and the full publication can be found in Appendix B.

Chapter five presents the findings from the two embedded qualitative studies around facilitator and participant acceptability of the intervention. The qualitative

findings exploring the participant's experiences of the programme have also been published in Religions and the full publication can be found in Appendix C.

Chapter six summarises and contextualises all the findings of this PhD. It integrates the discussions of each study, providing summaries, a discussion of strengths, limitations, and consistency with existing findings. An overall conclusion is given where the implications of the PhD research are discussed and suggestions for future research are made.

2 Background

Introduction to Chapter 2

The aim of this chapter is to present an overview of the literature underpinning the research I conducted for this PhD. This provides context for the research and justification for its need. The background comprises of 8 sections which are briefly outlined below.

The first section (2.1) explores the literature around obesity, where obesity is defined and the current problem of obesity is discussed alongside the health and economic consequences of obesity. In section 2.2 I focus on the current treatment and recommendations for treating obesity in the UK. In section 2.3 I start to evaluate the current treatment and recommendations for treating obesity, and highlight the effectiveness and shortcomings of the current approaches. In section 2.4 I continue to discuss the effectiveness of current treatments by exploring long-term effectiveness of current approaches and issues associated with weight regain and weight cycling. In section 2.5 I explore the literature around the obesity paradox and present the research underpinning a paradigm shift away from conventional weight loss focused programmes. In section 2.6 I explore intuitive eating as an alternative treatment to treating obesity and weight management. In section 2.7 I discuss religion and spirituality and presents the potential role it has in eating behaviour and obesity. Finally in section 2.8 I pool all the evidence discussed in the background together to present the rationale for this PhD.

2.1 Obesity

2.1.1 Definition and Classification of Obesity

Obesity is defined as an abnormal or excessive accumulation of body fat, which can reduce health or longevity (World Health Organisation; WHO 2016). To determine weight status, and which categories are associated with increased risk of health problems, the most widely used measure is Body Mass Index (BMI). BMI is a measure that determines whether individuals are a healthy weight for their height, using the formula $BMI = weight \ measured \ in \ kilograms \ (kg)/height \ measured \ in \ meters \ (m) \ squared \ (m^2)$. Table 1 presents an adapted version of the international classification of adult weight status outlined by the WHO (2000).

Table 1: The international classification of weight status

Classification	BMI (Kg/m ²)
Underweight	<18.50
Normal Range	18.50 - 24.99
Overweight	≥ 25.00
Pre-obese (Overweight)*	25.00-29.99
Obese Class I (Moderately Obese)*	30.00-34.99
Obese Class II (Severely Obese)*	35.00-39.99
Obese Class III (Morbidly Obese)*	≥ 40.00

^{*} Categories used in the UK

Whilst BMI is recognised as a useful indicator of whether an individual is a healthy weight at population level, it is not used as a definitive measure to diagnose obesity (Romero-Corral et al. 2008). BMI is a proxy indicator of body fat, it does not account for the variation in body fat distribution, and is not able to distinguish between fat and lean body mass (Prentice & Jebb 2001). BMI does not consider the changes in body composition that occur as people age (Villareal et al. 2005). Furthermore, the BMI thresholds used to predict health consequences can vary across different populations, for example; South Asian populations have a higher risk of developing Type 2 Diabetes Mellitus (T2DM) and cardiovascular diseases (CVD) at lower BMI categories (Gray et al. 2011).

Consequently, better measures of body fat are Waist Circumference (WC) and Waist to Hip Ratio (WHR) (WHO 2008). WC measures abdominal obesity, which is

the circumference of the abdomen. To measure this, the tape measure needs to be placed around the mid-point between the lower margin of the lease palpable rib and the top of the iliac crest (WHO 2008). It is recommended men with a WC of 94 centimetres (cm), (37 inches) and women with a WC of 80 cm (31.5 inches) should try losing weight regardless of their BMI. If WC is 102cm (40 inches) or higher for men and 88cm (34 inches) or higher for women these individuals are classified as being at high risk of developing non-communicable diseases associated with central adiposity e.g., T2DM, heart disease (National Institution for Health and Care Excellence; NICE 2006).

WHR is another measure of abdominal fat, calculated by dividing the circumference of the waist, by the circumference of the hip. Hip circumference is measured by placing the tape measure around the widest portion of the buttocks and WC is measured in the same way as described above (WHO 2008). A ratio of 1.0 or more in men and 0.85 or more in women is considered as an at-risk indicator of non-communicable diseases that have been associated with central obesity e.g., T2DM, heart disease (NICE 2006).

Large prospective cohort studies support the notion that WC and WHR are a better measure independent of BMI in predicting morbidity and all-cause mortality (Balkau et al. 2007, Price et al. 2006) because the measurements can consider body variation e.g., fat and fat-free mass which cannot be determined by BMI alone. However, continual use of BMI in clinical practice is because it is easier to measure in comparison to WHR and WC particularly in those who are very obese. To measure WHR and WC correctly, the location of the tape measure, and patient phase of respiration (e.g. breathing in or out at time of measurement), stomach content and posture are important (WHO 2008). This can affect the accuracy of the measure taken and create measurement error. Therefore, NICE (2006) encourage all health care professionals to understand the limitations of BMI and appropriately choose, at an individual level, to ensure all patients who need support and access to weight management services can receive it.

2.1.2 Prevalence of Obesity

Currently the Cook Islands have the highest prevalence of obesity at 46.6%, the United States of America (USA) is ranked 12th with prevalence at 32.6% and the United Kingdom (UK) is ranked with the world's 23rd highest prevalence at 26.9% (WHO 2016). In 2014, Ng et al. conducted a systematic analysis of 1769 surveys, reports and published studies to identify the global prevalence and trends of obesity and overweight by age and country. Globally, between 1980 and 2013 the number of overweight and obese individuals increased from 921 million to 2.1 billion. Furthermore the data identified in developed countries higher rates of adult overweight and obesity were observed in men, whereas in developing countries higher rates of adult overweight and obesity were observed in women. Since 2006, the data suggested increases in adult obesity were stabilising in several high-income countries, but the incidence generally remained higher in most low and middle-income countries.

This is the largest available dataset currently predicting the trend and prevalence of obesity globally. However, an important limitation is that just under 50% of the data collected was based on national surveys that used self-report measures which are subject to bias e.g., women tend to underestimate their weight and men overestimate their height (Wen & Kowaleski-Jones 2012). To address the limitation, a bias correction was applied, where self-report data was compared to measured data by the same year, country, age groups and sex. Additionally, the authors identified issues associated with response bias, which reduces generalisability of the findings because reporting national levels presents an obscure view of remote areas and subnational variations in larger cities where response rates are typically lower.

The most recent available data from Health Survey England (HSE) reported 41% of men and 31% of women were overweight, and 24% of men and 27% of women were obese (Scantlebury & Moody 2014). This supports the trend observed by Ng et al. (2014), where the increases in obesity have stabilised over the recent years.

2.1.3 Causes of the Obesity Epidemic

Several factors have been identified as contributors to the increases in the global obesity epidemic. The Foresight report (Butland et al. 2007) has documented the complexity of these factors and how they are interrelated. Energy balance is regarded as the main explanation for the obesity epidemic, where imbalances in energy intake and energy expenditure can result in weight loss or weight gain. Weight loss occurs when energy expenditure exceeds energy intake, this is negative energy balance, whereas weight gain occurs when energy intake is greater than energy expenditure, this is positive energy balance. The authors of the Foresight report developed a system map incorporating over a 100 variables recognised to influence energy balance. The factors range from biological, psychological, social, environmental, and individual influences. The report is briefly summarised below with supporting evidence to demonstrate the range of factors contributing to the obesity epidemic.

Engaging in physical activity (PA) is one way a negative energy balance can be achieved, and the lack of PA has been suggested to be a factor contributing to the increase in obesity globally. Using the WHO global health observatory data repository, Hallal et al. (2012), described the global estimates of PA through using self-reported data collected from 122 countries (representing 89.9% of the world's population). 31% (95% Confidence Interval [CI] 30.9-31.2) of the world's adult population is physically inactive, (not engaging in either, 30 minutes (mins) of moderate-intensity PA on at least five days every week, or 20mins of vigorous-intensity PA at least three days every week, or an equivalent combination of 600 metabolic- equivalent (MET) – min per week).

In the UK, PA recommendations state adults should aim to participate in at least 150mins of moderate-intensity PA per week to experience health benefits. For obese populations, approximately one hour per day for weight loss and weight loss maintenance is suggested (Hill & Wyatt 2005). Self-report data from HSE examining PA among a representative UK population of 15,102 adults identified only 39% of men and 29% of women met the recommendations for PA (NHS Information Centre for Health and Social Care 2011). Additionally, a portion of the

population group (n = 4507) were asked to wear accelerometers for seven days to provide a more objective measure of PA. Using accelerometers to measure PA produces accurate data about PA through measuring accelerating forces through micro-electro-mechanical sensors. Objective measures also reduce overestimation (Adams et al. 2005); recall bias (Matthews 2002), and misreporting (Sallis & Saelens 2000). The issue of over-estimation is demonstrated, by accelerometer data showing PA levels decreased significantly to 6% of men and 4% of women. Collectively this evidence demonstrates only a small proportion of individuals globally and in the UK are meeting the recommended levels of PA. This highlights how the lack of energy expenditure through decreased PA is contributing to obesity.

The Foresight report (Butland et al. 2007) highlights several reasons contributing to reduced levels of PA. One suggested explanation is occupation related PA has decreased. Exploring trends of occupation related PA in the USA, Church and colleagues (2011) identified over the past five decades, PA has decreased significantly. In 1960, 48% of the workforce in the industry required engagement in moderate intensity PA, compared to only 20% in 2008. Since 1960, the estimated mean energy expenditure due to occupation related PA has decreased by 100 calories per day in both men and women (Church et al. 2011). This is in part due to technological advancements, which require individuals to engage in less strenuous work, and most jobs are further characterised by low physical loads. Reduced PA promotes greater sedentary behaviour typically in the form of sitting at a desk for long periods of time which is another factor contributing to reduced PA.

Additionally, the built environment further contributes to decreases in PA. The built environment is defined as a human-made space in which people live, work, and recreate on a day-to-day basis. Through applying socio-ecological models that describe how individuals interact with their environments, the built environment can both support and hinder engagement in PA. Systematic review evidence of 47 studies (44 cross-sectional studies and 3 longitudinal studies), identified several key environmental determinants of PA in adults (Wendel-Vos et al. 2007). The review concluded social support and having a companion to complete PA with was

strongly associated with different types of PA. Within the physical environment, the availability, accessibility, and convenience of recreational facilities and trail paths were strong environmental predictors of engagement in PA. Systematic review evidence exploring the relationship between the physical environment and different domains of PA in European adults confirms the findings of the review described above. From 70 studies (69 cross sectional, and 1 longitudinal) engagement in PA was identified to have a positive association with five environmental factors walkability (friendliness of the area, walkable roads), access to shops/services work, safety from traffic (particularly for cycling), urbanisation degree, and quality of the environment (low levels of crime, considered safe, clean environment) (Van Holle et al. 2012).

The research evidence demonstrating the impact of the built environment and its relationship to obesity primarily derives from cross-sectional studies. Whilst these studies can demonstrate plausibility, consistency, coherence and specificity of the relationship between the built environment and PA, the nature of the studies do not permit understanding of causality or temporal precedence (e.g., has the built environment contributed to increases in obesity, or do increases in obesity lead to a more built-up environment) (McCormack & Shiell 2011). Therefore, whilst the built environment has been identified as an important factor, it cannot solely account for increases in obesity associated with energy expenditure.

Energy intake is the other side of the energy balance equation. Several studies have observed trends which indicate overconsumption of food is resulting in individuals exceeding their daily energy intakes. In the UK, annual data is collected about food intake and purchases through self-reported food diaries over two weeks (NHS Information Centre for Health and Social Care 2011). In a large representative sample (n = 13,196), the data demonstrated energy intake is 5% higher than estimated average requirement for adults. Globally, the population consumes a diet which is characterised by high levels of saturated fat, sugars, refined and processed foods and low fibre. Whilst there is evidence suggesting over-consumption at a population level, the evidence is not entirely robust. Data collected about food consumption relies on self-reporting of diet, which is under-estimated. Therefore, overconsumption of food is likely to be higher than the current figures suggest.

The food environment may contribute to increased food consumption. The Lancet published a series of articles on obesity; of which the first paper in the series highlighted simultaneous increases in obesity across the globe were shaped by changes in global food systems and local environments (Swinburn et al. 2011). Such changes include increased availability and affordability of energy-dense fast foods, which has led to a change in diet composition and increases in energy intake. The commercialisation of food e.g., increasing media coverage of high fat and sugary foods, increasing portion sizes, the increasing size of plates and dinnerware are all factors identified to be contributing to the increased consumption of food. Levitsky and Pacanowski, (2011) have suggested such factors provide individuals with unconscious nudges to eat and over-consume.

Energy intake can also be influenced by the social environment for example, food intake can be affected by friendships. Quasi-experimental studies have shown an association between friends or partner's weight status and energy intake of an individual. Salvy et al. (2009) found when overweight youths ate with familiar overweight peers; more food was consumed than when eating with normal weight familiar peers and overweight unfamiliar peers. Similarly, when males eat with friends, energy intake is significantly higher than when males eat alone (Shide & Rolls 1991).

Energy intake is further influenced by choice of food consumed, when food is consumed, and the amount of food that is consumed. These choices and decisions all operate at an individual level. When investigating why certain individuals can maintain their weight and others cannot, and the high variability of body size among individuals across similar environments highlights the importance of individual factors that are also involved with over-consumption of food. For example, French et al. (2012) reviewed seven eating behaviours in relation to energy intake and body weight. The findings identified from eating behaviours; food responsiveness, enjoyment of eating, satiety responsiveness, eating in the absence of hunger, reinforcing value of food, eating disinhibition (a tendency to over-eat, eating in response to negative affect) and impulsivity/self-control, disinhibition of eating was most consistently associated with prospective weight gain.

Other individual eating behaviours often explored are dietary restraint and self-regulation. Dietary restraint is intentionally applying strategies (e.g., limiting fat intake, not eating dessert) to lose or maintain weight. Self-regulation is the ability to appraise, evaluate and consciously monitor oneself. In a review of cross-sectional studies investigating dietary restraint and self-regulation in relation to weight management, a lower body weight was associated with individuals with higher dietary restraint and higher levels of self-regulation (Johnson et al. 2012). The findings identified a potential mechanism between self-regulation and dietary restraint wherein, individuals who engage in self-regulation can adhere to dietary restraints which promotes better management of weight. Whilst plausibility of this mechanism is suggested, causality cannot be implied due to the cross-sectional nature of these studies.

Also at an individual level there are biological factors that can contribute to overconsumption of food. When considering the physiology of body weight control, this is governed by homeostasis, which is involved with maintaining stability (Outland 2010). The homeostatic response in weight and appetite regulation involves several hormones (ghrelin, leptin, peptide YY) (Outland 2013). Heritable factors which disrupts the secretion of these hormones have been suggested to be responsible for the individual variation in BMI (Farooqi & O' Rahilly 2007). Whilst genetics do have a role in obesity to some extent, the rapid rise in obesity cannot be explained by genetics alone (Cheung & Mao 2012, Xia & Grant 2013).

To summarise, the causes of obesity identified here demonstrate that there is a complex interplay between the food environment, behaviours of the individual (food consumption and engagement in PA) and individual factors (genetics and biology) that collectively contribute to increasing levels of obesity (See figure 1). Whilst the Foresight report highlights the complex interaction between the different variables, the evidence is still unable to explain the increases in obesity that have occurred over a short period of time, nor is it able to explain the variation in rates of increase amongst some developed countries, where slower rates of increase have been observed (Ng et al. 2014). Furthermore, whilst individual factors are acknowledged in the main report, the breadth of coverage

around psychological factors associated with obesity is still limited. There is no mention of religious factors that have been associated with obesity. In section 2.7.4 the role of religion in obesity and eating behaviour is explored and highlights why this is also an important individual factor to acknowledge.

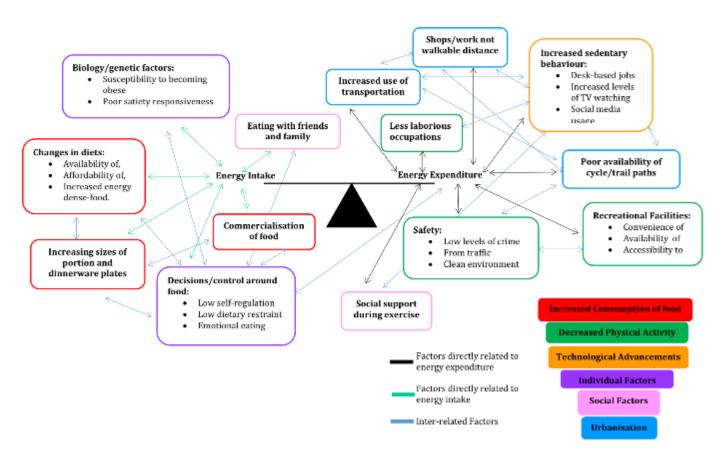


Figure 1: Adapted obesity Foresight map illustrating factors contributing to obesity.

2.1.4 Consequences of Obesity

Obesity is associated with several consequences, it is regarded as the largest factor contributing to the burden of disease worldwide (Ezzati et al., 2002). As the degree of obesity increases, the likelihood of developing negative health consequences increases. In this section, the literature around the physical health, psychological and economic consequences of obesity will be discussed.

2.1.4.1 Physical Health Consequences of Obesity

There is a clear link between obesity and the development of comorbidities, resulting in premature death, and living with a double burden of disease. In this section I will focus on the following health consequences associated with obesity; CVD, T2DM, and cancer. The WHO (2016) highlights 44% of the diabetes burden, 23% of the ischaemic heart disease burden, and approximately 7-41% of certain cancer burdens are attributable to overweight and obesity (Frühbeck et al. 2013). Treating these conditions increases healthcare utilisation, and the direct costs to the National Health Service (NHS) to an already over-burdened healthcare system (Wang et al. 2011).

CVD is an umbrella term describing conditions that affect the heart and blood vessels, it includes coronary heart disease (CHD) and stroke. Obesity significantly increases an individual's risk of developing atherosclerosis, which is the process of fatty deposits building up around the inner artery wall over time. This narrows the blood vessels increasing the likelihood of a clot. This further causes arteries to become blocked; when blocked arteries limit blood supply to the heart it can cause an acute coronary syndrome and when blocked arteries limit blood supply to the brain it can cause an ischaemic stroke. The extra pressure of blood volume on narrow vasculature increases blood pressure, damaging blood vessels further and leads to atherogenesis.

A meta-analysis pooling data from 21 prospective studies, after adjusting for age, sex, PA and smoking, showed the adjusted Relative Risks (RR's) for moderate overweight (BMI 25.0-29.9) and obese (BMI \geq 30.0) compared to normal weight individuals in developing CHD were RR = 1.32 [95% CI 1.24-1.40] and RR = 1.81 [95% CI 1.56- 2.10] respectively (Bogers et al. 2007). RR's were further adjusted for blood pressure and cholesterol levels, and further reduced for both moderate overweight and obesity, RR = 1.17 [95% CI 1.11 – 1.23], and RR = 1.49 [95% CI 1.32 – 1.67] respectively. The findings demonstrated being overweight or obese, placed an increased risk of developing CHD from the other main risk factors (high blood pressure, high cholesterol, smoking, PA) (Bogers et al. 2007). The findings of this study did not account for confounders like diet, and the majority of the

samples in the studies were white so the findings are not entirely generalizable as metabolic risk factors have been identified to develop in lower BMI categories for ethnic groups.

Meta-regression analysis of 15 prospective cohort studies investigating the association of WC and WHR with the increased risk of incident CVD, identified WHR was more strongly associated with CVD than WC (De Koning et al. 2007). A 1cm increase in WC increased the event of CVD by 1% [95% CI 1-3], and 0.01 increase in WHR increased the event of CVD by 5% [95% CI 4-7].

Longitudinal evidence has further demonstrated obesity is associated with an increase risk in heart failure, at 14 years follow-up, obese subjects risk of heart failure had doubled (Kenchaiah et al. 2002). For women, the Hazard Ratio (HR) = 2.12 [95% CI 1.51-2.97], and for men HR = 1.90 [95% CI 1.30 - 2.79]. The findings also identified a graded increase in risk of heart failure across the BMI categories. Per increase in BMI category HR increases in women were HR = 1.46 [95% CI 1.23-1.72] and in men HR = 1.37 [95% CI 1.13 - 1.67].

CVD is a common complication of T2DM. Individuals who have T2DM, have a 2-3x higher risk of developing CVD in comparison to those who do not have T2DM (Abraham 2004). T2DM is the combination of poor insulin production from pancreatic β -cells and insulin resistance. Body fat is suggested to be a critical factor which can determine the development of insulin resistance. When there is excess fat in the body, fat cells secrete free fatty acids. This secretion affects insulin signalling, and can make cells in the body become insulin resistant. When cells become less sensitive to insulin, there is an increase in blood glucose because the insulin has not transported the glucose out of the blood. As a result, the excess glucose remaining in the blood stream, is not transported to cells to be used for energy; as a result the pancreas secretes more insulin, in an attempt to reduce the level of glucose in the blood. This over-secretion of insulin is hyperinsulinemia, which accompanies insulin resistance. Excess insulin in the body is further problematic as it contributes to an accumulation of fat and a vicious cycle continues (Al-Goblan, Al-Alfi & Khan 2014). A meta-analysis of 18 prospective

cohort studies investigating the association between overweight obesity and the risk of developing T2DM found obese persons had a 7 x higher risk of developing T2DM (RR = 7.19 [95% CI 5.74 - 9.00]. Overweight was associated with a 3 x higher risk of developing T2DM (RR = 2.92 [95% CI 2.57 - 3.32]) in comparison to normal weight counterparts (Abdullah et al. 2010).

Obesity has also been associated with an increased risk of developing cancer; a systematic review and meta-analysis of 141 prospective cohort studies identified BMI is associated with increased risks of developing several cancers (Renehan et al. 2008) In men a 5kg/m² increase in BMI was strongly associated with an increased RR of oesophageal adenocarcinoma (RR = 1.55 [95% CI 1.33- 1.74]), thyroid (RR = 1.24 [95% CI 1.04 - 1.70]), colon (RR = 1.24 [95% CI 1.20-1.28]), and renal (RR= 1.24 [95% CI 1.15 - 1.34]) cancers. In women, a 5kg/m² BMI increase with endometrial (RR= 1.59 [95% CI 1.50 – 1.68]), gallbladder (RR = 1.59 [95% CI 1.02 – 2.45]), oesophageal adenocarcinoma (RR = 1.51 [95% CI 1.31 – 1.74]), and renal (RR = 1.34 [95% CI 1.25 - 1.43]) cancers. Increased risks were observed among both common and uncommon malignancies, and stronger associations between BMI and pre-and post-menopausal breast cancers were found in Asia-Pacific populations (Renehan et al. 2008). The mechanisms that explain the link between excess weight and cancer risk are not entirely clear. However WC is suggested to be associated with a greater risk of developing post-menopausal cancers (Cleary & Grossman 2009). Large population based studies investigating gynaecological cancers, have suggested adipose tissues can produce excess amounts of oestrogen, which can facilitate the development of hormonedependent tumours e.g., oestrogen dependent breast cancer (Kendall et al. 2007, Munsell et al. 2014).

Furthermore, obesity is also associated with all-cause mortality. A meta-analysis of 239 prospective cohort studies carried out across four continents (Asia, Australia and New Zealand, Europe and North America) found individuals who had a BMI between 20-25 had the lowest chance of death. Individuals with a BMI lower or higher than this range had an increased chance of death. The HR's indicated that for every additional five unit increases in BMI overweight and obese individuals

living in Europe and East Asia had a 39% increased risk of dying (HR = 1.39 [95% CI 1.34 - 1.43]). The findings further identified an increased risk of death associated with BMI was greater at younger ages. The increased RR of death for additional five units increases in individuals with a BMI over 25 was 52% in individuals who were aged between 35 – 49 (HR = 1.52 [95% CI 1.47 - 1.56]). Among individuals who were aged between 70-89 years, the increased RR of death was 21% (HR = 1.21 [95% CI 1.17 - 1.25]) (The Global BMI Mortality Collaboration 2016).

2.1.4.2 Psychological Consequences of Obesity

Obese individuals are also at greater risk of developing psychological distress and mental health problems. Research investigating the psychological consequences of overweight and obesity has focused almost exclusively on developed countries, with the findings remaining inconsistent. Systematic review evidence of prospective studies has identified a bi-directional association between depression and obesity. Obese individuals have a 55% increased risk of developing depression, and depressed individuals have a 58% increased risk of becoming obese (Luppino et al. 2010). Anxiety is also associated with obesity, Gariepy et al. (2010) conducted a systematic review and meta-analysis of 16 observational studies (2 prospective cohort and 14 cross-sectional studies) where a metaanalysis was performed on 13 cross-sectional studies. The pooled odds ratio (OR) was 1.40 (95 % CI 1.23-1.57), demonstrating a positive association between obesity and anxiety disorders. However, the confidence that can be placed in this association is weak, there was high heterogeneity amongst the studies, for example the populations across the studies varied, and the study designs mean causal inferences cannot be made nor can the direction of the relationship be determined.

Attempts have been made to understand the bi-directional link between depression and obesity. Explanations for the increases in weight gain centre around the role of the hypothalamic-pituitary-adrenal (HPA) axis (Nieuwenhuizen & Rutters 2008). The HPA axis is a neuro-endocrine system that is responsible for the regulation of stress through secreting the hormone cortisol. The HPA axis has

been suggested to have a role in energy balance, which has been demonstrated through Addison's disease and Cushings syndrome (Björntorp & Rosmond 2000). The two conditions represent two extremes of plasma cortisolism. Addison's disease is when the body experiences hypocortisolism, where there is insufficient levels of cortisol in the blood stream, which results in weight loss. Whereas, cushing's syndrome is characterised by hypercortisolism, which is the increased secretion of cortisol in the blood stream. This can cause symptoms like hyper tension, insulin resistance hyperglycaemia, which are symptoms of metabolic syndrome that often coexists with obesity, as well as rapid weight gain.

One explanation suggests when individuals experience chronic stress, the HPA axis releases high levels of cortisol into the bloodstream (Torres & Nowson 2007). Increased cortisol levels are suggested to create hedonic desires among individuals to crave energy dense foods, leading to weight gain when consumed.

In addition to the secretion of cortisol, activation of the HPA axis also causes the release of endogenous opioids. These opioids can cause an increased intake of palatable food, and vice versa the palatable food increases the release of endogenous opioids creating a cycle where consumption of calorie-dense food is reinforced as a mechanism to cope with stress (Drolet et al. 2001). Hyperactivity of the HPA axis can also occur among individuals who are chronically stressed, which is a major risk factor for weight gain and visceral obesity. Increased levels of cortisol that are released during stress are associated with an accumulation of abdominal fat mass, suggesting increased central adiposity is an outcome of hormonal dysregulation (Nieuwenhuizen & Rutters 2008).

2.1.4.3 Consequences of Weight Discrimination

Weight discrimination is the experience of being treated unfairly because of one's body weight. Systematic review evidence has shown weight discrimination occurs across several domains. In employment settings, obese individuals are less likely to be hired, at an interpersonal level, obese individuals are more likely to be lonely, and within medical settings, obese individuals experience stigma from health

professionals (Puhl & Heuer 2009). National surveys in the UK and USA have shown up to 7% of individuals with an overweight BMI, 14% of individuals with a moderately obese BMI and 43% of individuals with a severely obese BMI, experience weight discrimination, experiences of weight discrimination are suggested to increase as BMI increases (Andreyeva, Puhl, & Brownell 2008, Jackson, et al. 2015). Weight discrimination has a mediating effect on depression and well-being among obese persons. It has also been associated with mortality, and weight gain. The following section will explore the research evidence in this area.

2.1.4.3.1 Mediating Effects on Depression and Well-Being

Large prospective cohort study evidence of UK and US participants concluded there was a prospective association between obesity and increases in depressive symptoms in adulthood, where weight discrimination was a mediator (Robinson, Sutin & Daly 2017). Perceived weight discrimination was linked to an increase in depressive symptoms, and explained 31% of the total effect on obesity related depressive symptoms (Robinson et al. 2017).

This effect has been further demonstrated on other markers of psychological well-being namely, quality of life, life satisfaction and depressive symptoms (Jackson, Beeken & Wardle 2015). When associations between everyday experiences of weight discrimination, obesity and these three markers were explored, obese individuals showed significantly lower scores across all three measures. When perceived weight discrimination was investigated as a mediator, it could explain 40% of the total effect of obesity on psychological well-being. The variance explained in this study is higher than that of Robinson et al. (2017), it demonstrates greater plausibility of the association and greater coherence as the weight discrimination was explored as a mediator in relation to other markers of psychological well-being.

A cross-sectional study explored the relationship between internalised weightbased stereotypes, emotional well-being, the likelihood of dieting, and binge eating behaviours (Puhl, Moss-Racusin, & Schwartz 2007). The findings identified individuals who internalised weight-based stereotypes reported higher levels of binge-eating and refused to engage in dieting behaviours in comparison to individuals who did not internalise weight-based stereotypes. Whilst the sample size of this study was large (n= 1013), all women in the sample were white, this limits the generalisability as it is cannot reflect individuals who belong to other ethnic groups. Cross-sectional studies cannot determine the direction of the causality, and the assessment of internalised stigma was not completed using a standardised measure.

2.1.4.3.2 Weight Discrimination and Mortality

Weight discrimination has also been directly associated with an increased risk of mortality in both an older nationally representative population (50 year +) and in a middle-aged nationally representative population (20-74 years). A longitudinal study showed, weight discrimination measured through everyday experiences of weight discrimination was associated with a 60% increased mortality risk in both older participants (HR = 1.57 [95% CI 1.34-1.84]) and middle aged participants (HR = 1.59 [95% CI 1.09 – 2.31]). The association between weight discrimination and mortality remained even when behavioural factors like (PA) and clinical risk factors like (smoking status, disease burden, depressive symptoms, and BMI) were accounted for. Whilst the magnitude of the association is arguably too large to ignore the association was no longer significant after adjusting for confounders (Sutin, Stephan & Terracciano 2015).

2.1.4.3.3 Weight Discrimination and Weight Gain

A longitudinal study found participants who experienced weight discrimination were approximately 2.5 times more likely to become obese at follow up (OR = 2.54 [95% CI 1.58 – 4.08]) (Sutin & Terracciano 2013). The study results further demonstrated participants who were already obese at baseline were three times more likely to remain obese at four-year follow-up (OR = 3.20 [95% CI 2.06-4.97]) in comparison to those who had not experienced weight discrimination. However,

none of the associations identified in this study were adjusted for demographic factors or experiences of other forms of discrimination (e.g., race and age).

The association between weight discrimination and weight gain, has also been observed among obese treatment seeking participants as well as those who are not trying to lose weight, for example; findings from a pre and post-test design study, showed overweight and obese adults participating in an 18-week behavioural weight loss programme who experienced greater weight bias were less consistent with their self-monitoring of exercise and daily calorie intake (Carels et al. 2009). In addition to this, greater energy intake was reported as well as lower energy expenditure and higher levels of attrition from the weight management programme.

The findings of these studies are further supported by experimental studies. In one experimental study participants were randomly assigned to read either a stigmatising article around weight or a non-stigmatising news message (Major et al. 2014). Individuals who perceived themselves as overweight, and were exposed to the stigmatising newspaper article consumed a significantly higher number of calories and scored themselves as significantly less capable of controlling their food intake. This particular finding highlights the importance of internalised weight stigma, because among the women who were overweight but did not identify themselves as overweight, exposure to the stigmatising media article did not have a significant impact.

Similarly, Schvey et al. (2011) randomly assigned overweight and normal weight women to watch either a neutral, or weight stigmatising video. After viewing the video women were provided with three bowls of calorie dense snacks (300g of plain M&M's, 300g of Jelly Belly Jellybeans, and 86g of SunChips). Women, who were overweight and assigned to the stigmatising video group ate 3x more kilocalories (Kcal) than overweight women who watched the neutral video (302 vs. 89 Kcal). The calories consumed were also significantly more in the overweight group who watched the stigmatising video than the normal weight group who watched the stigmatising video (302 vs 170 Kcal).

These findings begin to demonstrate how weight discrimination can lead to weight gain however, experimental research has its limitations. Both studies did not account for hunger, and so it cannot be determined whether hunger prompted snacking, and Schvey et al. (2011) did not measure the time between watching the video and consumption of the snacks therefore, the results cannot imply whether snacking on high calorie food was instantaneous or after some time. Collectively the evidence presented here begins to demonstrate the issue of weight discrimination, and how it is something that needs to be addressed during treatment of obesity as it is associated with behaviours not conducive for weight loss.

2.1.5 Economic Consequences of Obesity

Global estimates indicate that approximately between 0.7% and 2.8% of a country's total healthcare expenditures are spent on treating obesity and obesity related conditions (Withrow & Alter 2011). This figure is estimated to be 7% in more developed countries (Withrow & Alter 2011). In the UK, the direct cost of obesity to the NHS is estimated at more than £5 billion per year (Wang et al. 2011). This is largely due to the increased risk of T2DM, CVD and cancer, which increases healthcare utilisation and services needed to treat these conditions (Wang et al. 2011). Obesity also presents the economy with indirect costs through loss of earnings and absences in the workplaces. In the UK, the indirect cost of obesity is estimated to be £16 billion per year (Wang et al. 2011). By 2050, the Foresight (Butland et al. 2007) projects if the trends in obesity continue to escalate the indirect costs will rise to £50 billion per year. Predicting the future costs of obesity has been challenging, and the Foresight report has been criticised to over-estimate the costs associated with obesity. Jack (2007), in a commentary published in the Lancet suggested that the Foresight report presented 'guestimates' and that the figures were not representative of the actual extent of the problem.

So far, I have highlighted obesity is an intricate condition, the cause of obesity is multi-dimensional involving several interacting factors and is not caused by one single factor. The impact of obesity is widespread, affecting physical health, psychological health and the wider economy. The following section will introduce the current approaches to treating obesity and will evaluate the efficacy of these approaches.

2.2 Current Approaches to Treating Obesity within the UK

In the UK, the treatment of obesity can be categorised as surgical and non-surgical interventions. Non-surgical interventions typically target individual lifestyles through exercise and diet, but they can also include medical (pharmacological) intervention. In the UK, pharmacological treatment is included in the clinical care pathway as an additional tool for treating obesity. NICE (2006) have published clear clinical guidelines outlining the clinical care pathway on the prevention, identification, assessment and management of overweight and obesity in adults and children.

The pathway provides healthcare professionals treating overweight and obese individuals with an overview of what services should be offered to patients depending on their level of obesity and risk of comorbidities. Healthcare providers are expected to work in a person-centred manner where the choice of treatment should be negotiated with the patient. The pathway of healthcare follows a hierarchical structure with provision of care increasing as patients move through the hierarchy. The aim of this hierarchy is patients receive the level of care most appropriate to their needs and it comprises of four tiers which are discussed below.

Tier 1: At this level, health promotion is carried out at a population level. It involves directing patients to a local weight management programme, discussing ways to modify their lifestyles (e.g., improving diet and increasing PA) through small changes easily incorporated into patients' daily lives.

Tier 2: At this level, the target population includes patients who have failed to lose 5kg or 5% of their body weight. Therefore, patients in this tier are referred to a

specialist as well as being directed to community weight management programmes.

Tier 3: At this level, patients received a specialised weight management service which is usually conducted under the supervision of a dietitian or GP.

Tier 4: At this level, patient's medical needs are recognised as complex requiring specialist input from a multi-disciplinary team. During this stage weight loss surgery will be considered and offered as a treatment option.

2.2.1 Behavioural Interventions

Behavioural interventions aim to influence change over an individual's dietary and/or PA. Systematic review evidence of 36 randomised controlled trials (RCT's) identified behavioural treatments (e.g., reinforcement, goal-setting, selfmonitoring, problem solving behaviour change techniques [BCT's]) reduced body weight (weight mean difference -2.5kg [95% CI -1.7 - -3.3]) in comparison to control groups (Shaw et al. 2005). This mean difference increased to 10kg, when behavioural treatments combined diet and exercise in comparison to diet/exercise alone. Cognitive behaviour therapy (CBT) when combined with diet and exercise also showed greater weight loss compared to diet/ exercise alone (weight mean difference – 4.9kg [95% CI -7.3 - -2.4]). The overall findings of the systematic review demonstrated the magnitude of weight loss achieved increased in behavioural interventions when the intervention incorporated many behavioural strategies, were longer in duration and had frequent clinical contact (Shaw et al. 2005). Whilst this is efficacious, this is not always feasible to achieve within an intervention in particular the frequent clinical contact time. In the studies this time was typically fortnightly sessions lasting 60mins, this is not practical or feasible in the current NHS system. This is due to time and staff constraints within the current NHS system. Furthermore, among behavioural interventions where frequency of clinical time and intensity was high only a marginal improvement in long-term weight loss was achieved.

More recent evidence has shown interventions which combine dietary changes and PA yield greater weight loss in the long-term than diet or PA alone. An updated systematic review (Johns et al. 2014) showed in the short-term, weight loss magnitude is similar in diet-only interventions and behavioural weight management programmes that include both diet and PA. However, in the long-term, weight management programmes that combine both diet and PA resulted in greater weight loss. Comparisons of PA only interventions with weight management programmes that combined diet and PA, demonstrated PA only programmes are less effective in both the short and long term (Johns et al. 2014). This finding is consistent with an older systematic review which also directly compared diet, PA, and behavioural programs to diet and behavioural only (Avenell et al. 2004). The findings identified that at 12-months multicomponent programmes resulted in a greater weight loss of 3.02kg (95% CI 4.94 to 1.11kg) in comparison to diet and PA only programmes (Avenell et al. 2004).

Many behavioural interventions that are diet focused, typically orient around manipulating an individual's macronutrient intake. A bayesian network analysis of 48 RCT's, concluded low-carbohydrate diets (e.g., Atkins diet) (8.73kg [95% CI 7.27 to 10.20kg] and low-fat diets (e.g., Ornish) (7.99kg [95% CI 6.01 to 9.92kg] were associated with greatest weight loss compared to moderate macronutrient diets (e.g., Biggest Loser, Weight Watchers) at 6-month follow-up and 7.25kg [95% CI 5.33 to 9.25kg] and 7.27kg [95% CI 5.26 to 9.34kg] at 12-month follow-up respectively (Johnston et al. 2014). However, many of the studies included in the review did not explicitly measure participant's adherence to the dietary program which may have been different from the instructions given for example, in terms of macronutrient composition.

Another systematic review and meta-analysis of 19 RCT's identified that irrespective of the macronutrient composition in low carbohydrate diets, and isoenergetic balanced diets achieved similar reductions in weight loss and cardiovascular risk for two years in overweight and obese adults who did or did not have T2DM (Naude et al. 2014). Although the review did not explicitly address macronutrient quality of the diets (e.g., how much carbohydrates, protein and fats

were recommended for consumption) to explain the effects of the diets on cardiovascular risk, the findings suggest that less emphasis should be placed on manipulating an individual's macronutrient composition and more emphasis on reduction in total energy intake and behaviour change adherence which is important for future weight-loss interventions to consider. Collectively the findings suggest that less emphasis should be placed on manipulating an individual's macronutrient composition; greater emphasis on reduction in total energy intake and behaviour change adherence may be a better approach for successful weight management.

Behavioural interventions also include commercial weight loss programmes (e.g., Slimming World, Weight Watchers, Jenny Craig) which although not delivered by primary care, are available through NHS referral. In comparison to standard care received in primary care, RCT evidence has shown that commercial weight loss programmes are more cost-effective, efficacious, and demonstrate greater weight loss (Jebb et al. 2011; Jolly et al. 2011). The findings around the success of primary care interventions are mixed. A prospective study showed that following a low intensity counselling session during a primary care consultation can result in weight loss and maintenance. At three-year follow-up, 18% of the cohort had lost \geq 5% of their baseline body weight, 70% of participants had stabilised their weight and 12% had gained weight \geq 5% (Korhonen et al. 2014). The participants in this study were at an elevated risk of developing CVD therefore whether the study findings cannot determine whether participant's weight loss was a result of the counselling received during their consultations or whether patients being told they are at risk of developing CVD motivated patients to lose weight.

A systematic review and meta-analysis of 15 RCT's showed behavioural programmes delivered in primary care achieved a mean weight loss of -1.36kg at 12 months and at 24 months this decreased to -1.23kg (Booth et al. 2014). The findings of this review need to be considered in light of the following limitations, the weight loss did not meet the recommended threshold of >5% of a patient's body weight, there was high heterogeneity amongst the studies (63.8%), and 7 out of 15 studies were not included in the final meta-analysis. The lack of success

demonstrated by primary care initiatives and the success demonstrated by commercial weight loss programmes, there are increasing movements towards developing programmes that can treat obesity within the community settings.

Very Low Energy Diets (VLED) are another treatment option for obesity carried out in primary care under the guidance of a dietitian. A VLED provides less than 800 Kcal a day, of high protein and minimal carbohydrate, to encourage weight loss with minimal loss of lean tissue. It is supplemented with vitamins, minerals, electrolytes and fatty acids to ensure adequate levels of nutrition are still obtained (Delbridge & Proietto 2006). It is an option that is mostly used with patients who have a clinical need for rapid weight loss e.g., fertility treatment or joint replacement (NICE 2006). Several systematic reviews have shown mixed findings around VLED's and their effectiveness. A systematic review of eight RCT's, two cohort studies and six pre-post studies showed at 16 weeks VLED's resulted in a weight loss of 22kg (Asher et al. 2013). A more recent meta-analysis of 12 RCT's showed when VLED's are combined with behavioural programmes an additional 3.9kg can be lost at 12 months in comparison to a similar behavioural programme only (Parretti et al. 2016). The review recommended that VLED's should be incorporated into behavioural weight management programmes as they can lead to greater weight loss. However, despite the increased weight loss, adherence to VLED's is an issue, in the review there was evidence of premature discontinuation of treatment in 19% of the VLED group and weight regain still persisted in these individuals.

Of all the treatments that are available, evidence identifies that intentional weight loss attempts through adapting dietary behaviours (e.g., reducing calorie intake, restricting certain food groups, dietary choices, using weight management aids) and increasing PA are the most utilised approaches to achieve weight loss and weight maintenance (Santos et al. 2017). A systematic review and meta-analysis concluded from general populations worldwide, 42% of adults reported trying to lose weight and for ethnic minority populations this figure increased to 44% of adult's worldwide (Santos et al. 2017). Specifically in the UK the age-standardised prevalence of weight loss attempts in the English population has increased from

39% in 1997 to 47% in 2013. In 2013, 10% of those with BMI <22; 30% with BMI \geqslant 22 to <25; 53% with BMI \geqslant 25 to <30; and 76% with BMI \geqslant 30 were trying to lose weight (Piernas, Aveyard & Jebb 2016). Whilst evidence has identified weight loss through behavioural interventions (e.g., amending dietary behaviours, adhering to energy-restricted diets) can produce successful results, these results may only be experienced in the short-term. The effectiveness of these are discussed in greater detail in section 2.3.

2.2.2 Pharmacological Interventions

In the UK, there is currently only one medical treatment that is available and licenced to be prescribed solely to treat obesity, this is Orlistat. Orlistat works by preventing lipases (enzymes in the intestine) from breaking down fat. By preventing the breakdown of fat, it prevents the body from absorbing fat, it has been shown to be effective in preventing fat absorption by 30% (Drew et al. 2007). A Cochrane meta-analysis of 11 RCT's that used 120mg Orlistat three times a day showed a greater weight loss of 2.7kg [95% CI 2.3- 3.1] than the placebo group (Padwal et al. 2003). Another review highlighted that Orlistat can result in 3% more weight loss in overweight and obese adults than dieting alone (Drew et al. 2007). However, attrition rates are problematic for Orlistat. Attrition rates have been reported to range from 14% to 52%, these are significantly higher in clinical practice ranging from 64% to 77% as demonstrated by pharmocoepidemiological studies (Vray et al. 2005). High attrition rates are due to the side effects (diarrhoea as a result of non-compliance to a low-fat diet). Weight loss maintenance is also a problem, as continual use of Orlistat is recommended for maintenance of weight loss which is not being achieved.

Previously, Sibutramine was an anti-obesity drug that was prescribed to patients with a BMI over 30. However, in 2010 it was withdrawn in the UK due to evidence suggesting it increased risks of strokes and myocardial infarctions (MI's). The SCOUT RCT trial (James 2005, James et al. 2010) conducted a multi-trial doubleblind, placebo-controlled trial evaluating the potential benefits of weight management and cardiovascular events in overweight and obese adults at high

risk for cardiovascular events. The findings of the SCOUT trial found people taking sibutramine showed a 16% rise in the risk of non-fatal MI or stroke (James et al. 2010, Sayburn 2010). As a result, it was decided the drug will no longer be prescribed and was withdrawn throughout Europe and the USA.

2.2.3 Surgical Interventions for Obesity

In the UK, the three most commonly performed bariatric surgery procedures are laparoscopic gastric banding (LAGB), gastric bypass (GB) and sleeve gastrectomy (Booth et al. 2016). LAGB involves a small adjustable band being placed around the upper part of the stomach. This creates a small pouch limiting the amount of food an individual can eat, and so inducing weight loss (Mason et al. 1997).

GB involves dividing the stomach and small intestine. The stomach is divided into a small pouch and large remnant pouch, to which the small intestine is rearranged and connected to both. The operation works by reducing the amount of food that can be eaten, and the amount of food that can be absorbed by the small intestine (Mason et al 1997).

Sleeve gastrectomy involves removing approximately 80% of the stomach. The remaining 20% of your stomach is stapled together to form a small thin sleeve which can hold up to half a cup of water. It works by making the individual feel fuller quicker, and reducing the intake of food due to the small size of the stomach (Mason et al. 1997).

Bariatric surgery has been shown to be an effective treatment for obesity resulting in initial rapid weight loss. A systematic review of 54 prospective studies investigating the different treatments and associated initial rapid excess weight loss (EWL) and has demonstrated the efficacy of bariatric surgery as a treatment for obesity (Buchwald 2002). Gastric banding resulted in an initial EWL of 48.6%, but Roux-en-Y gastric bypass resulted in a greater initial EWL of 68.6%. A meta-analysis of 134 studies (5 RCT's, 28 non-RCT's, and 100 uncontrolled case series) showed in the first two years of surgery EWL for gastric banding was 47.5% [95% CI 40.7-54.2], for gastric bypass 61.6% [95% CI 56.7 – 66.5], for gastroplasty

68.2% [95% CI 61.5 – 74.8], and for duodenal switch 70.1% [95% CI 66.3 – 73.9] (Buchwald et al. 2004). The reviews highlight that bariatric surgery is effective in the short-term resulting in rapid weight loss that can be seen within the first two years post-surgery.

Prospective studies and systematic reviews also indicate successful long-term weight loss maintenance post-surgery. A large 15-year follow-up prospective longitudinal study of 3227 patients who were treated by LAGB (O'Brien et al. 2013) showed at 15-years there was an EWL of 47.1% (95% CI = 8.3). This was similar to the mean EWL observed at 10 years 47% (95% CI = 1.3). The weight loss observed in this study remained regardless of whether the patients had additional procedures post-surgery. A systematic review was also conducted alongside this prospective study, and the findings further consolidated the findings of the prospective study. A total of 19 studies (1 prospective non-randomised matched intervention study, and the remaining prospective and retrospective longitudinal studies) demonstrated at 10-year follow-up there was a weighted mean of more than 50% EWL (O'Brien et al. 2013).

Collectively the results demonstrate the long-term effectiveness of LAGB, which supersedes the success of non-surgical interventions (as discussed later). It is important to highlight whilst the findings the study are positive, there is a need for better quality studies e.g., RCT's examining the effectiveness, because a major limitation that has been found with observational studies is the loss of participants to follow up. Two of the studies in this systematic review identified their longest follow-up period to be at 14 and 15 years (Pories et al. 1995, Sjöström et al. 2007). However only 10 of their participants were followed up to this point, and so the results are not representative of their whole sample or an adequate threshold of percentage reached at follow-up, limiting the generalisability of these findings and reducing the strength of the association.

Another systematic review of 29 studies (10 RCT's, 1 matched cohort study, 6 prospective studies, 1 retrospective study and eleven case-series studies) showed gastric bypass surgery was considered most effective in achieving long term

weight loss and remission of T2DM, hypertension and hyperlipidaemia (Puzziferri et al. 2014). An updated systematic review and meta-analysis indicated that in comparison to a previously reported meta-analysis, the rate of mortality observed in their review was significantly lower, bariatric surgery particularly sleeve gastrectomy was identified as most effective in weight loss than gastric bypass and adjustable gastric banding (Chang et al. 2014).

Despite the effectiveness of bariatric surgery, the cost of surgery and post-surgery care means that not all individuals who are eligible for bariatric surgery will receive surgery. In the UK, access to bariatric surgery is restricted (Gulliford et al. 2017). There are 1142000 (336,000 men and 806,000 women) people living with morbid obesity in England, of which 979000 (303,000 men and 676,000 women) are eligible for bariatric surgery (NHS Information Centre 2009) yet approximately only 8000 obesity surgeries are carried out in England each year (NHS Information Centre 2009). The large discrepancy between those who are eligible and those who access bariatric surgery highlights why despite being an effective solution bariatric surgery is not feasible to carry out as a main treatment option.

Gulliford et al. (2017) evaluated the costs and outcomes associated with increasing access to bariatric surgery for severe and morbidly obese patients. The findings identified, for each individual treated by bariatric surgery, an additional 2.142 QALYS (95% CI 2.031-2.256) were gained. Patients who were aged between 20 and 74 years and morbidly obese the cost per QALY gained was £7,129 (95% CI £6775 - £7506). Among morbidly obese patients who had T2DM, surgery was even more cost-effective at £6176 (95% CI £5894 - £6457). The modelling conducted in this study pooled together existing systematic review evidence conducted around the cost-effectiveness of bariatric surgery alongside data collected on 3045 people who were morbidly or severely obese with 176495 matched obese individuals who had not had surgery. The findings indicate weight loss surgery is effective at reducing obesity and the health problems that arise due to obesity in a cost-effective manner. The modelling conducted in this review was conducted prospectively and based on actual use of NHS resources rather than using indirect measures (e.g., insurance claims) enabling it to align with existing figures.

Collectively the evidence collected by this study when pooled with evidence from existing systematic reviews and meta-analyses suggests that bariatric surgery is a successful treatment for morbidly obese patients, and should be more accessible to patients.

Whilst largely successful, bariatric surgery can be unsuccessful for some patients. In order to achieve successful weight loss, patients are required to develop and maintain a new lifestyle, which includes only eating three small meals a day, eating very slowly, and avoiding high fat foods and liquids with meals (Bocchieri et al. 2002). Success further depends on psychological factors such as emotional regulation, breaking habitual behaviours, and addressing disordered overeating (Raman, Smith & Hay 2013). For some patients, these changes are easy to make post-surgery, but for others it presents significant challenges negatively impacting their psychological, physical health and well-being (Coulman et al. 2017). Freire et al. (2012) conducted a cross-sectional study to assess lifestyle habits (e.g., PA levels, food patterns, adherence to nutritional follow-up visits) of patients who underwent Roux-En-Y gastric bypass surgery. 56% of the patients experienced weight regain, with 29% regaining over 10% of the minimum weight reached following surgery. Weight regain was highest at over 5 years with 84.8% of the sample experiencing weight regain, suggesting that weight regain rates increase significantly with time after surgery. Poor attendance at nutritional counselling follow-up visits, increased sedentary behaviour, and poor diet quality were significant predictors of weight regain.

A systematic review of 16 studies (7 case series, 5 cross-sectional surveys, four non-RCT's) showed several reasons can predict weight regain post-surgery (Karmali et al. 2013). The authors dichotomised the causes into either patient characteristics or surgery specific causes. Patient characteristics included individual specific causes for example, appetite hormonal imbalances (high levels of ghrelin and low peptide YY), and metabolic fluctuations in glucose have been suggested to create increase hunger in some patients. Dietary non-compliance and decreased levels of PA have further been identified as patient characteristics contributing to weight regain post bariatric surgery. Mental health causes were the

final patient characteristic identified, if patients undergoing surgery have binge eating disorder, or engage in binge eating behaviours, weight regain is significantly higher which is supported by previous systematic review findings (Kalarchian et al. 2002, Odom et al. 2012). Surgery specific characteristics relate to issues that can arise due to the different types of bariatric surgery. There is evidence that in up to 50% of patients the adjustable gastric band can expand over time, as a result this increases the size of the pouch that was originally created leading to increased consumption in food (Kuzmak & Burak 1993). Furthermore, premature explantation of the adjustable gastric band makes maintenance of weight more difficult. Among patients who receive Roux-En-Y gastric banding, stomal dilation has been shown to contribute to weight regain. Stomal dilation means a greater quantity of food needs to be consumed in order for the patient to experience satiety. Dilation of the stoma decreases the restrictive effect of the gastric band, which is why more food is required for patients to experience fullness, proving counterintuitive for weight loss. The review concluded multiple factors contribute to weight regain post-surgery, these can exist alone or overlap, leading to complications that include the need for a second operation. Whilst the findings of weight regain are seen to only occur in a small subset of patients higher quality studies are required to investigate the extent of weight regain post-surgery.

Additionally, qualitative evidence has been conducted to explore further patient characteristics that contribute to surgery failure and weight regain. A metasynthesis of 3 studies pooled together (Coulman et al. 2017), identified patients report experiencing challenges related to emotional eating, control around eating, coping with feelings of hunger post-surgery which hinder the effectiveness of the surgery. Beyond this meta-synthesis, qualitative research has consistently reported around psychological issues remaining unaddressed post-surgery (Natvik et al. 2013, Wood & Ogden 2016). Geraci et al (2014) identified two overarching themes; 'food after the first-year post-surgery' and 'bariatric surgery is not a magic pill'. The discourses across these themes identified psychological issues like using food to cope with stress, and tendencies to reach for unhealthy foods did not just disappear. Similar findings have been described among patients who are undergoing plastic surgery to remove their excess skin produced by the successful

weight loss (Ogden Birch & Wood 2015). Ogden et al. (2015) found amongst their participants the decision to undergo plastic surgery symbolised the last stage of their weight loss journey, and during this stage participants discussed their underlying issues that contributed to their initial weight problem remained unaddressed. The transferability of these findings is demonstrated when considered in relation to systematic review evidence identifying patients with binge-eating disorder and patterns are less likely to maintain weight loss due to the inability to address the underlying issues causing their initial weight issues (Odom et al. 2010). The evidence presented here further highlights the need to address emotional and psychological issues associated with food, because successful bariatric surgery requires the participant to have a healthier relationship with food and be more autonomous.

2.3 Effectiveness of Bariatric Surgery Compared with Behavioural Weight Management Programmes

A systematic review and meta-analysis of 11 RCT studies investigating the differences in weight, rate of T2DM, metabolic syndrome remission between bariatric surgery and non-surgical treatment showed post bariatric surgery patients lost more body weight (mean difference -26kg [95% CI -31 to -21]) than individuals after non-surgical treatment (Gloy et al. 2013). In relation to remission rates of T2DM the rates decreased (RR = 22.1 [95% CI 3.1 - 154.3]) in the completer case only, and in a conservative case scenario where it was assumed all individuals in the non-surgical interventions experienced T2DM remission the RR decreased to (5.3 [95% CI 1.8-15.8]. This finding suggests the rate of T2DM remission was still lower in the surgery group in comparison to the control groups. In relation to metabolic syndrome, the RR in completer case only analysis was (2.4) [95% CI 1.6-3.6]) and conservative analysis the RR was (1.5 [95% CI 0.9 - 2.3]). Reduction in metabolic syndrome was only better in bariatric surgery patients when the completer only case analysis not the conservative analysis. The findings of this review need to be considered in light of several limitations, the wide confidence intervals suggest the results should be interpreted with caution; a number of studies were not rated of good quality, compromising the overall effect sizes observed. There was high attrition bias in four of the studies which further

impacted the findings and meta-analysis. There was also reporting bias reported in the individual studies, with patients who had comorbidities not being included in the final analyses, further limiting the generalisability of the findings.

A systematic review conducted by Medicare (Mann et al. 2007), investigated the long-term outcomes of energy restricted diets. The 31 studies reviewed included 7 long-term RCT's, and 24 prospective studies. The evidence of long-term randomised controlled studies of follow-up periods ranging from 2 years to 10.5 years identified the average weight loss maintained across the studies was 1.1kg (range: -4.6kg to +1.6kg) for participants in the energy restricted diet conditions. Whilst this evidence suggests these diets are efficacious in the long term for small weight reduction, there are important considerations in terms of the heterogeneity of these studies which make it hard to draw firm conclusions. Only one study (n=202) investigated energy restriction in isolation and in this study the individuals in the diet conditions maintained an average weight loss of 1.7kg at the 30-month follow-up, which was similar to the control group (Jeffery & Wing 1995). One study specifically related to obesity prevention involved participating in a low intensity intervention that encouraged participants to make small changes to their diet and PA levels, resulted in weight gain across all groups (a mean 1.6kg at 3 year follow-up) (Jeffery & French 1999). The remaining RCT's for weight loss included other potentially confounding lifestyle interventions, i.e. increasing PA which can over-estimate the results of the intervention. Some also included smoking cessation which would have resulted in weight gain (Lycett et al. 2011) and masked potential weight loss. In 14 studies that followed participants for at least four years, an average weight loss of 14kg was achieved initially, but by follow-up this was only 3kg. One study reported a weight gain of more than 5kg above participants starting weight at five-year follow-up. A further seven studies supported weight regain overshot initial weight loss, concluding 41% of participants weighed more at follow-up than their starting weight. It is important to note that these were not RCT's, however, in the absence of such long term RCT's this observational data cannot be ignored. Collectively the systematic review evidence by Mann et al., (2007) concluded energy restricted diets led to short-term weight loss and a sustained lower weight in some people. However, for many these

benefits remained short-term as weight was regained. Longitudinally, between one to two thirds of dieters regain more weight at a 4-year follow-up and beyond than they initially lose. This is a particularly important finding as most behavioural interventions targeting diet aim to reduce calorie intake through dietary restriction.

Additional systematic reviews since suggest that people usually regain a third of their weight loss within a year and the rest within 3-5years. For example, systematic review and meta-analysis evidence of 44 RCT's identified interventions that combined diet and PA yielded greater changes in weight in comparison to controls (-2.6kg [95% CI - 3.6 - -1.6 at 36 months) and in at-risk population (patients with a mean/median BMI \geq 30kg/m²) (Dombrowski et al. 2010).

Another systematic review of 12 studies (22 intervention arms) identified over half the weight patients lost post intervention, was regained at one year follow up (Barte et al. 2010). Whilst the findings of this review fit with the existing evidence, the studies were only obtained from one database, there was limited description around study selection, data extraction, and study designs included in the review, therefore these results are not conclusive.

Pooling together the evidence presented so far, among the current approaches to treating obesity, bariatric surgery is most effective but it is not widely accessible, and can leave underlying eating behaviours unaddressed in some patients. Behavioural interventions targeting diet are effective in the short-term, but demonstrate limited long-term efficacy. Poor long-term maintenance has been associated with psychosocial issues that arise from weight regain and weight loss, and subsequently weight cycling. These issues shall be discussed in the following section.

2.4 Problems of Weight Regain and Weight Cycling

As discussed in the previous section, long-term weight loss maintenance is poor, when weight loss maintenance is not achieved individuals are recognised to enter

weight cycles. Weight cycling defined by a pattern of repetitive weight loss and weight regain, has been associated with health consequences, this section will explore the research evidence in this area.

One of the earliest studies cited to support the evidence around negative health consequences associated with weight cycling is the Framingham Heart study. The Framingham Heart study (Lissner et al. 1991) examined a large nationally representative sample (n=5209) prospectively over a 32-year period to investigate the association between weight cycling and total mortality and cardiovascular morbidity and mortality. Weight cycling was defined by generating a coefficient of variation for each participant's BMI that was collected during the nine time points of the study. This provided an indication of the variability of weight which enabled the researchers to better measure weight cycling in the prospective study. After controlling for confounders like obesity, trends in weight over time and indicators of cardiovascular risk, a significant association between high variability in body weight and an increased total mortality and CHD remained, suggesting patients are at a higher risk of CHD and death if their body weight fluctuates greatly than patients who have a stable body weight. More recently, a large prospective study in Germany found large fluctuations in weight in men was associated with mortality over the 15-year follow up period in comparison to individuals with stable body weight (Rzehak et al. 2007). Together, these results suggest weight cycling places individuals at risk of mortality and cardiovascular health problems, it also shows weight cycling is consequential for men as well as women.

The research around weight cycling and health consequences has been met with controversy. The evidence presented earlier highlights the negative health consequences that have been associated with repeated intentional weight loss attempts, however there is the potential these results are confounded by weight loss associated with relapsing ultimately terminal diseases like cancer. For example, in the Framingham study (Lissner et al. 1991), whether weight loss was intentional or unintentional was not accounted for. In a large population based cross-sectional study, overweight women were asked about their intentions to lose weight (Meltzer & Everhart 1996). Among the women who lost weight, 41% intended to lose weight but 19% did not intend to lose weight but still lost weight.

The findings of this study highlight a confounder that is overlooked and difficult to account for which is subclinical disease (Meltzer & Everhart 1996). Subclinical diseases are underlying diseases not yet identified by the individual, but can be factors causing weight loss and leading to an increased mortality, and other health consequences.

This is further supported by a prospective study that found among 1401 diabetic adults, intentional attempts to lose weight irrespective of whether weight was lost was associated with a reduced risk of all-cause mortality (Gregg et al. 2004). Individuals trying to lose weight had a 23% lower mortality rate (HRR = 0.77 [95%] CI 0.55-0.99]) than those not trying to lose weight. This association remained significant following weight loss (HRR 0.83 [95% CI 0.63 – 1.08]). Participants who reported weight loss was unintentional, a 58% (HRR = 1.58 [95% CI 1.08 – 2.31]) increase in all-cause mortality rate was identified. This finding reiterates the need to consider intention behind weight loss, because patients who are unintentionally losing weight are suggested to be suffering from a subclinical disease not yet identified. When intentions underpinning weight loss are not accounted for, the findings can be misinterpreted and suggest weight loss is bad for your health when in fact this weight loss is a result of pre-existing ill health. Furthermore, much of the research evidence derives from observational studies (prospective longitudinal and cross-sectional studies). Whilst these studies can describe the strength of associations over time, their methodological limitations mean they cannot determine whether intentional weight loss is beneficial or harmful to individuals.

2.4.1 Weight Cycling, Weight Gain and Increased Food Consumption

Another health consequence often associated with weight cycling is weight gain and increased food consumption. As previously discussed the most common strategy employed to lose weight, involves increasing dietary restraint (Santos et al. 2017). Prospective cohort studies have shown that dietary restraint as defined by restriction of food intake to control body weight, is related to weight gain and increased likelihood of becoming obese at six-year follow-up (Chaput et al. 2009), and at three-year follow-up dietary restraint was associated with increases in BMI

in females, and weight fluctuations were associated with increases in BMI in both males and females (van Strien, Herman, & Verheijden 2014).

One explanation for the increased weight gain, and increased over consumption of food, is that food restriction from increased dietary restraint can lead to hunger and feelings of deprivation or preoccupation with food, which, in turn, may trigger overconsumption. Once individuals have over consumed food, weight gain is expected, which results in individuals restarting their diets to lose weight demonstrating the repetitive pattern weight regain, weight loss, and so weight cycling.

A quasi-prospective study where participants were followed for 7 days by keeping craving frequency food diaries, found females who were dieting to lose weight experienced greater cravings, with less ability to resist the cravings in compared to non-dieters (Massey & Hill 2012). When exploring the food diaries the data showed the foods dieters craved were foods they had restricted as part of their diets. Among females watching their weight there were similarities in their food cravings and dietary restraint to both dieters and non-dieters. Whilst the findings of the study remained consistent with previous studies, it did not have a measure of food restriction and so it cannot be concluded whether food cravings were a result of food deprivation.

The dual process model: the reflective-impulsive model (Strack & Deutsch 2004) has also been applied to understand overconsumption of high calorie food (Houben Roefs & Jansen 2010). According to this model, eating behaviour is guided via two cognitive processes; reflective or explicit processes and impulsive or implicit processes. Reflective processes are ones that require deliberate thought processing, and so are slow, well-thought out utilising cognitive resources (Strack & Deutsch 2004). Whereas, impulsive thought processes are automatic and fast acting. When this is applied to dietary restraint behaviour, when individuals choose to engage in dietary restraint behaviour, they have engaged in explicit processes and set a goal to lose weight. However, high calorie food is perceived both negatively by reflective processes because it is counterintuitive to weight loss, but also positively by the impulsive thought processes because it can produce

feelings of positive affect. This leads to an internal battle between the two motivational processes, where the impulsive system overpowers the reflective, causing the individual to indulge in high calorie food.

To demonstrate this model, Houben, Roefs and Jansen (2010) conducted three experimental studies. In the first two experimental studies Houben, Roefs and Jansen (2010), demonstrated dietary restraint is associated with stronger positive implicit attitudes towards high calorie food. In their second study (Houben, Roefs, & Jansen 2012), this relationship was explored further through understanding positive and negative implicit associations with the palatability of food in low (< 1.0 kcal/g, e.g., fruits and salads), moderate (1.0-3.0 kcal/g, e.g., steak and cooked potatoes) and high calorie foods (e.g., > 3.0 kcal/g, pizza and french fries). Using single category implicit association tests, the experimental findings showed individuals who engage in dietary restraint, hold positive implicit attitudes towards palatable food irrespective of its calorie density. This positive implicit association with palatable food demonstrates how the implicit system creates a higher motivational drive to overeat. According to these findings the inhibitory process system is impaired through depleted cognitive resources that have been used in sticking to the goal of weight loss, and so resulting in the implicit rendering the individual unable to resist their desire to consume the palatable food.

Cross-sectional study evidence has shown that in comparison to non-weight-cyclers, severe weight cycling among overweight and obese individuals was associated with depressive symptoms, binge eating, higher weight suppression and higher current and maximum-ever BMI (de Zwaan, Engeli & Müller 2015). Severe weight cycling was furthermore common in females than males and is associated with higher reward sensitivity, as measured by the behavioural inhibition system (BIS) and behavioural activation system (BAS) questionnaire. BAS can measure an individual's sensitivity to rewards that have been associated with impulsive behaviours like overeating. There are many strengths to this study, the findings of this study are the first to provide evidence of the association between reward sensitivity and severe weight cycling as an important factor that can explain weight regain following weight loss, in a large non-probability population.

However, cross-sectional studies lack temporality, and the nature of these studies mean it is difficult to identify a dose-response relationship between variables measured (Hoppe et al. 2009). Therefore, the findings need to be interpreted with caution being mindful of these limitations.

So far, I have presented the evidence around weight cycling and negative health consequences, as well as highlighting the limitations of the research conducted in this area. The evidence around weight cycling and mortality is unclear, but the evidence around weight cycling and weight gain and increased food consumption is more plausible and cannot be ignored. The evidence presented here is part of an accumulating volume of evidence in support of a paradigm shift away from dietfocused obesity treatments. More evidence in support of this shift will be explored in the following section.

2.5 The Obesity Paradox

2.5.1 The Obesity Paradox in those with CVD

As discussed in section 2.1., obesity and overweight measured by using BMI has been associated with an increased risk of developing physical health consequences. However, evidence has begun suggesting that this may not be the case for all individuals living with obesity. Obesity paradox refers to a phenomenon that has derived from research findings suggesting that being obese serves a protective function both in the short and long-term in patients with CVD (Lavie et al. 2014).

A meta-analysis of 40 cohort studies comprising of 250,152 patients with CHD with a mean follow-up of 3.8 year (range 1-17 years) showed a low BMI < 20kg/m^2 had an increased RR for total mortality (RR = 1.37 [95% CI 1.32-1.43]), and cardiovascular mortality (RR = 1.45 [95% CI 1.16-1.81]) (Romero-Corral et al. 2006). Severe obesity BMI <35kg/m², did not have an increased risk of total mortality (RR=1.10 [95% CI 0.87-1.41]), but had the highest increased risk for cardiovascular mortality (RR = 1.88 [95% CI 1.05-3.34]) in comparison to normal BMI. In comparison to normal BMI, overweight category (BMI 25-29.9) had the lowest risk for total mortality (RR = 0.87 [95% CI 0.81-0.95]), and cardiovascular

mortality (RR = 0.88 [95% CI 0.75-1.02]). Obese patients (BMI 30-35kg/m²) on the other hand had no increased risk for total mortality (RR = 0.93 [95% CI 0.85-1.03]), or cardiovascular mortality (RR = 0.9 [95% CI 0.82-1.15). This suggests that better outcomes for cardiovascular and total mortality are seen in the overweight and mildly obese groups. However, there was high heterogeneity between studies which showed there was significantly high variability across the studies. This relates to the sub-populations of patients, unequal participants in BMI cohorts which could be associated with selection bias.

Flegal, Kit, Orpana and Graubard (2013), conducted a systematic review and metaanalysis investigating the association of all-cause mortality with overweight and
obesity. The study pooled together findings from 97 observational studies, using a
random effects model to calculate summary HR's for overweight (BMI 25<30kg/m²), obesity (BMI <30kg/m², all grades combined), grade 1 obesity (BMI
30-<35kg/m²) and grades 2 and 3 obesity (BMI of >35kg/m²) relative to normal
weight BMI 18.5 - < 35kg/m²). The summary HR's were 0.94 (95% CI 0.91-0.96),
1.18 (95% CI 1.12-1.25), 0.95 (95% CI 0.88- 1.01), and 1.29 (95% CI 1.18-1.41
respectively. Individuals who were in the overweight category, had a 6%
significantly lower mortality rate than the normal BMI group, the class 1 obese
group had a 5% lower mortality than normal BMI group but this did not reach
statistical significance. The findings of this study are consistent with previous
findings that have shown lower mortality among overweight and moderately
obese patients

Whilst there is evidence suggesting weight loss amongst CVD patients can result in negative outcomes, purposeful weight loss remains a clinical recommendation as it has benefits related to improved rehabilitation following MI. Furthermore, evidence of the paradox does not extend to morbidly obese patients (BMI > 40kg/m^2). A prospective study comprising of 50,149 participants with ST-segment elevation myocardial infarction (STEMI) showed in hospital mortality was highest among normal BMI and class 3 obesity patients (Das et al. 2011). When baseline factors were corrected for in hospital mortality was only increased in class 3 obese patients. The impact of severe obesity is not accounted for in many studies, they

typically represent a small percentage of the sample in studies to date (de Schutter, Lavie & Milani 2014), however, this study whilst only assessing in hospital mortality rates, is one of the largest studies available to suggest severe obesity does not have the protective functions obesity is paradoxically suggested to have. A meta-analysis of 6 studies involving 15923 patients with CHD, showed at 2.3 years follow up WC and WHR were positively associated with total mortality (HR 1.70 [95% CI 1.58-18.3) (Coutinho et al. 2011). BMI was inversely associated with mortality (HR = 0.64 [95% CI 0.59-0.59]). The findings suggest that in patients with CHD, central obesity measured by WHR and WC is associated with total mortality, not BMI. The findings of this study begin to demonstrate the criticisms associated with using BMI when investigating obesity paradox amongst CVD patients. BMI aggregates the different variations of fat free mass and body fat under several categories and does not reflect the metabolic profile that varying amounts of fat free mass and body fat have (Chrysant and Chrysant 2013).

The evidence in support of obesity paradox remains controversial, several explanations have been suggested to potentially explain these findings. Fat cells may serve protective mechanisms unknown to scientists possibly through improved metabolic reserve. Additionally, obese individuals are identified earlier as high risk for CVD, and treated earlier and more vigorously with antihypertensive agents and statins (Haslam 2014). Metabolically healthy obesity is another aspect of the obesity paradox and will be discussed in the following section.

2.5.2 The Obesity Paradox in 'Metabolically Healthy Obesity'.

Metabolically Healthy Obesity (MHO) or 'fit and fat' refers to a phenomenon where physical fitness has been perceived as a predictor of morbidity and mortality risk independent of BMI. The explanation behind this mechanism is that individuals who are fit, have high levels of cardiorespiratory fitness (CRF) which is the ability of circulatory, respiratory and muscular systems to supply oxygen during sustained PA (McAuley & Beavers 2014). High levels of CRF are suggested to reduce the adverse effects of obesity on morbidity and mortality (Fogelholm

2010). Kodama et al. (2009) conducted a meta-analysis of 33 studies, to investigate the association of CRF with all-cause mortality and CVD events. Dose-response analyses concluded each 1MET increment in CRF was associated with a risk reduction of 13% [0.87 (95% CI 0.84-.90)] and 15% [0.85 (95% CI 0.82-0.88)] from all-cause mortality and CVD events respectively. In addition, after adjusting for heterogeneity of the study characteristics, individuals with low CRF had a significantly higher risk of all-cause mortality and CVD events in comparison to individuals who had moderate to high level of CRF. The analysis adjusted for several confounders including; age, sex, smoking, coronary risk factors, abnormal exercise cardiogram, follow up period, instrument for assessing CRF and exercise testing method, wherein the risk-reduction for all-cause mortality and CVD events per 1 MET increment remained significant. Findings from a meta-analysis of 10 studies further highlighted regardless of BMI, unfit individuals have a two-fold higher risk of all-cause mortality than fit individuals (Barry et al. 2014). Overweight or obese individuals who were fit had a risk of all-cause mortality similar to fit normal weight individuals, supporting the benefit of PA as a mediator against all-cause mortality in obese persons.

Collectively the evidence begins to identify that CRF is an important mediator against the negative consequences of obesity. However, the evidence in this area remains controversial and is argued to only reflect a small proportion of the obese population. Furthermore, there remains debate around exactly what the optimal duration, frequency, and type of exercise is to experience the health benefits discussed. There is also evidence that health benefits can be experienced irrespective of weight loss, which begins to illustrate the paradigm shift that has developed in how weight management should be approached. Focusing on health and not weight loss has been argued to be a worthy avenue of exploration in higher quality controlled studies, the next part of this chapter will further explore the research evidence that has contributed to this paradigm shift. There is evidence that has shown improved health can be achieved in the absence of weight loss. I will now discuss this, which provides the rationale for using intuitive eating within the intervention evaluated within this thesis.

2.5.3 Improved Health in the Absence of Weight Loss

An accumulating volume of evidence is beginning to document improved health benefits associated with weight loss, can be achieved without losing weight. A review of 21 RCT's showed weight loss was an inadequate proxy for health outcomes (Tomiyama et al. 2013). Of the 21 studies, only ten were able to report a statistically significant weight loss between the intervention and control group. At follow-up, which ranged from two to ten years, a mean 1.49kg was lost in the intervention, compared with the controls (diet vs no diet). There were small improvements in diastolic and systolic blood pressure, fasting blood glucose, cholesterol, and triglyceride levels however, during correlational analyses were shown unrelated to weight loss. When examining confounding factors, the findings suggested that the health behaviours e.g., increased exercise, healthy eating, contributed to health benefits rather than weight loss itself.

Such findings are further supported by evidence from long term RCT's investigating the outcome of cardiovascular mortality. Adopting a Mediterranean diet irrespective of weight loss can reduce cardiovascular mortality. Mediterranean dietary patterns vary but they typically consist of high monounsaturated/saturated fat ratio, low to moderate red wine consumption, high consumption of legumes, high consumption of grains and cereals, high consumption of fruit and vegetables, low consumption of meat and meat products and increased consumption of fish, and moderate consumption of milk and dairy products (Rees et al. 2013).

Systematic review evidence of 11 RCT's showed Mediterranean diets had statistically significant decreases in total cholesterol (-0.23 [95% CI -0.27 – 0.2]), in comparison to control groups (-0.06 [95% CI -0.13 – 0.01]). The findings of this review are more representative because studies that incorporated other intervention components (e.g., physical exercise or behavioural interventions) were excluded to minimise confounding effects and ensure the effectiveness of the Mediterranean diet is being reported (Rees et al. 2013). The findings from this review are further supported by RCT evidence not included in the review (Estruch

et al. 2013). Participants who were at high risk of developing CVD but had not yet developed CVD were randomly assigned to either an energy-unrestricted Mediterranean diet with extra virgin oil, an energy un-restricted Mediterranean diet with nuts (hazelnuts, walnuts, almonds) or a control diet (advice to reduce dietary fat). The results identified a relative risk reduction of 30% in likelihood of developing CVD in comparison to the control group. The relative risks for both are presented respectively; RR = 0.70 [95% CI 0.54 – 0.92] and RR = 0.72 [95% CI 0.54 – 0.96]. The adoption of a Mediterranean diet among those who were at high cardiovascular risk was demonstrated to reduce the incidence in CVD events, further supporting the evidence that Mediterranean diets can reduce cardiovascular mortality irrespective of weight loss.

2.6 Intuitive Eating and Weight Loss

To summarise so far, obesity is a rising health problem, dietary solutions which are typically addressed in behavioural interventions, resulting in energy restriction – regardless of macronutrient composition – are effective in the short term but for many, may not be successful in the long-term. Whilst surgery is effective and able to sustain long term weight loss, it is not available to all individuals, and for some individuals the psychological issues associated with eating remain unaddressed post-surgery. Weight loss is not a simple linear process and poor adherence to energy-restricting diets can lead to weight cycling which has its own negative psychological and possibly physiological health consequences which reduce quality of life. Improved psychological and physiological health can also be achieved irrespective of weight loss and may lead to improved quality of life beyond that achieved through the on-going pursuit weight loss. In this section, the evidence around intuitive eating shall be presented and how it can serve as an approach to support weight management.

Intuitive eating programmes focus on achieving mental well-being and generating self-efficacy so that people eat healthily in response to physical hunger, rather than unhealthily in response to emotional hunger (Tylka et al. 2014). Intuitive eating comprises four central facets; unconditional permission to eat, eating for physical

rather than emotional reasons, reliance on internal hunger and satiety cues and body-food choice congruence (Tylka 2006, Tylka & Kroon van Diest 2013). A systematic review of 20 interventions (including randomised controlled studies) based on intuitive eating principals found that intuitive eating led to a decrease in several disordered eating habits (Schaefer & Magnuson 2014). Only one study reported weight gain in subjects during the 1-year follow-up period (Higgins & Gray 1998). The remaining studies demonstrated significant weight loss or weight maintenance. Irrespective of weight loss, studies led to improvements in improving systolic blood pressure (Bacon et al. 2005, Bacon et al. 2002), diastolic blood pressure (Carroll, Borkoles & Polman 2007), total cholesterol level (Bacon et al. 2005, Bacon et al. 2002), HDL cholesterol level (Bacon et al. 2005, Carroll et al. 2007), LDL cholesterol level (Bacon et al. 2005, Bacon et al. 2002), triglyceride level (Bacon et al., 2002) and cardiorespiratory fitness (e.g., oxygen consumption during exercise) (Bacon et al. 2005, Bacon et al. 2002, Carroll et al. 2007, Ciliska, 1998). In the longer term, Carrier et al. (1994) showed that at 3 year follow up; participants maintained increased PA levels, improved self-esteem and decreased restrained eating. As well as this, four studies followed participants for 2 years, and reported the maintenance of decreased cholesterol levels, blood pressure, restrained eating, disordered eating and increased diet quality, body satisfaction, PA, stress management and self-esteem (Katzer et al. 2008, Hawley et al. 2008, Mellin et al. 1997, Roughan et al. 1990). It is important to note that these studies were quasi-experimental in design and RCT's with long term follow-up are needed to substantiate these findings.

The effect of intuitive eating on dietary intake was only reported in five out of twenty studies. The findings identified that individuals who learned to eat in response to internal cues significantly decreased their energy and fat intake and increased fruit and vegetable consumption in comparison to controls. Intuitive eating based studies were also able to achieve lower attrition rates than dieting interventions with rates of completion reaching up to 92% (Mann et al. 2007).

Mindfulness based weight loss interventions can provide further support for the evidence behind intuitive eating in relation to weight loss. Mindfulness eating

shares principles similar to intuitive eating, for example; increasing awareness of senses and experiences is similar to increasing awareness of hunger and satiety. Mindfulness principles of accepting experiences and emotions in the current moment rather than trying to change them is similar to intuitive eating components of body-food-choice congruence and experiencing liberation in all areas is similar to unconditional permission to eat element (O'Reilly et al. 2014, Olson & Emery 2015).

Systematic review evidence (13 RCT and 6 observational studies) has shown among studies where weight loss was the primary outcome measured 13 of the studies reported significant weight loss among participants within the mindfulness condition (Olson & Emery 2015). The effect sizes of significant weight loss ranged from 0.01 to 0.68 among RCTs and 0.04 to 0.42 among the observational studies. The quality of the studies in this review was not high, whilst positive results associated with mindfulness were demonstrated many studies did not measure mindfulness properly or explicitly. The review highlighted positive results, but reiterates the need for higher quality studies to be conducted in the area.

Pooling together the evidence discussed here, intuitive eating based interventions provide promising results for weight loss and related health outcomes, but high quality studies are lacking. Furthermore, whilst these go some way to address the psychological and emotional aspects of obesity, a truly holistic approach also needs to consider spiritual and religious aspects of obesity. The potential role of religion and spirituality in health shall now be discussed.

2.7 Religion and Spirituality

Over the last 20 years there has been a rapid increase in the number of observational studies that have investigated religion, spirituality and health (Koenig 2014). Before I move into discussing this further, I will explain the definitions of religion and spirituality used in this thesis.

2.7.1 Defining Religion and Spirituality

There is great variation in defining and conceptualising religion and spirituality (King & Koenig 2009). The two terms represent multi-dimensional concepts, however there is an agreed consensus amongst researchers that religion and spirituality do overlap but are also conceptually distinct entities (Büssing et al. 2005).

Religion or religiosity can be defined as a system of organised beliefs and practices, related to the Transcendent, divine or sacred, which can be expressed through three key dimensions; organisational (e.g., church attendance, involvement with church activities) non-organisational (e.g., private prayer, meditation) and religion importance or salience (e.g., subjective religiousness, intrinsic religiosity, religious attachment) (Büssing & Koenig 2010, Koenig, King, & Carson 2012).

Spirituality has been defined as an individual journey (King & Koenig 2009). When spirituality is thought of through this definition, it can be described as a process wherein individuals are searching for meaning and purpose in life. This may be a secular spirituality, where there are no religious beliefs underlying spirituality rather a belief in the universe and interconnectedness with the world (Koenig et al. 2012).

Traditionally, spirituality is considered to be grounded within religion, this definition views spirituality as a component of religion and not separate from religion. According to this definition, religious spirituality refers to a spirituality whereby the meaning and purpose in life is sourced from an individual's belief in a deity and the teachings of religious scriptures (Koenig et al. 2012). It is this religious spirituality that defined the Christian spirituality in the intervention tested in this PhD.

There is much debate around the definition of spirituality and the literature cautions against narrowing the definition too far, as this may diminish and reduce its meaning and create presumptions. However, boundaries within the definition of spirituality are very important for research purposes. To evaluate changes in spirituality we need to be able to measure it and to measure it we need to be able

to first define it. Much research in the field of spirituality and health is confounded by contaminated measures whereby aspects of spirituality e.g. hope, purpose, are not distinct from the outcomes that spiritual interventions aims to effect e.g.mental well-being (Koenig 2008, Tsuang & Simpson 2008). Therefore, for medical research King and Koenig (2009) recommend using definitions that are specific to the population group under study and this is what we have done with our term 'Christian spirituality.'

2.7.2 Religion, Spirituality and Psychological Well-Being

While I have defined religion and spirituality in the earlier section for the purpose of the research undertaken for this PhD, the following evidence that is presented will consider religion and spirituality together as the overlap and mixed definitions in the literature mean it impossible to separate. For example, studies have discussed spirituality, but then presented results on religiosity e.g., increased praying behaviours, talking to God more.

Systematic review evidence has shown prior to 2010, there were 326 observational studies investigating the association between religion/spirituality and well-being (Koenig et al. 2012). 79% (256/326) demonstrated positive associations between religion/spirituality and well-being. Less than 1% of the studies demonstrated a significant inverse association between the constructs (Koenig et al. 2012). A 10-year prospective study identified religiosity served as a protective mechanism against depression among high risk individuals (Miller et al. 2012). In a sample of 114 adult off-springs of depressed (n=72) and non-depressed parents (n=42) after controlling for the covariates gender, age, history of depression, and risk status (based on parental depression), those who indicated that religion or spirituality was highly important to them were 73% less likely to be depressed (OR = 0.27 [95% CI 0.07-1.08]). In the low-risk group without a history of depressed parents, religious variables did not predict depression at follow-up. However, among high risk patients, those indicating at baseline that religion or spirituality was highly important to them were 90% less likely to have major depression (OR = 0.10 [95% CI 0.01-0.92]) (Miller et al. 2012). A synoptic

review of studies applying the Multidimensional Inventory for Religious/Spiritual Well-being showed religiosity and spirituality is positively related to a variety of mental health indicators, and can serve as a protective function amongst patients recovering from mental illnesses like addictions or suicidal behaviours (Unterrainer et al. 2014).

The association of religion and spirituality with mental health also depends on the dimension under measure. Considering organisational religiosity, individuals who frequently attend religious services demonstrate greater psychological well-being (Francis & Kaldor 2002), and decreased risk of developing depression (Maselko et al. 2009). Considering non-organisational religiosity, or intrinsic religiosity (e.g., regular engagement in prayer, studying scriptures) this has been found to positively influence well-being (Byrd et al. 2007). Findings from comparisons of inpatients with and without clinical depression have demonstrated that patients who pray more than once a day were 48% less likely to experience major depression and 54% less likely to experience major depression in comparison to their less frequently praying counterparts (Koenig 2007). Considering the third dimension of religious saliency, observational evidence found individuals that hold a salient religious identity, display more effective coping skills (Banthia et al. 2007), and greater life satisfaction (Gautherier et al. 2006), which arguably contributes to greater psychological well-being. Religious identity saliency has also been positively correlated with quality of life and subjective well-being (Abdel-Khalek 2012).

Religion and spirituality can also have a negative impact on well-being. Leurent et al. (2013) conducted an international longitudinal cohort study comprising of two follow up periods 6 and twelve months across seven countries. The findings identified; 10.5% of participants who were spiritual in their beliefs (not following a religion), 10.3% of participants who were religious (defined by the practice of faith e.g., attending a religious place of worship) and 7% of the participants who held secular beliefs (not religious or spiritual) experienced an episode of depression at the 12 month follow up. The findings further identified that in the UK individuals who were spiritual were 3x more likely to experience an episode of depression in comparison to the secular group, as demonstrated by the OR (OR = 2.73, [95% CI

1.59 – 4.68]). The findings suggest religious/spiritual beliefs do not always promote positive psychological well-being.

Several reasons have been identified for why religious and/or spiritual beliefs can negatively impact psychological well-being. When individuals are faced with life events that are stressful or incomprehensible, a natural response is for individuals to conduct an attributional search to better understand the situation and assign blame (Exline & Rose 2013). Among individuals who have a strong religious identity, this search could result in God being held accountable and blamed. Cross-sectional evidence has shown when this happens it creates feelings of anger within the individual towards God (Exline & Grubbs 2011). A review identified that feelings of anger towards God are associated with greater levels of depression, other forms of negative spiritual coping and struggle, emotional distress and higher mortality rates (Exline & Rose 2013). One explanation for this is anger towards God creates an internal conflict, where individuals cannot communicate their feelings of anger, because such emotions can be perceived with judgement and considered morally wrong. Inability to admit these feelings leads to worsening of psychological health (Exline & Rose 2013, Exline & Grubbs 2011).

There is also exploratory evidence that has investigated predictors of spiritual struggle, Ano and Pargament (2013) identified 3 key factors strongly associated with spiritual struggles. The strongest association was the appraisal of the situation, where the more negatively a situation is appraised there were greater feelings of spiritual struggle. An insecure ambivalent attachment to God (lack confidence in God, or believe in His ability to provide) was the second highest predictor of spiritual struggle, and neuroticism personality trait (more likely to experience negative emotions like anxiety fear worry) was also associated with spiritual struggle.

Bonelli et al. (2012) conducted a systematic review of quantitative research that had examined religious/spiritual involvement and depressive symptoms during a time span of 50 years (1962 – 2011). The findings of this review suggested depression was associated with religious individuals who are struggling with

issues in their personal lives e.g., loss of child, marital problems, domestic abuse. Collectively these findings begin to suggest there are several mechanisms underpinning the negative impact of religion and spirituality on psychological well-being.

The evidence presented here begins to demonstrate religion and spirituality can have both a positive and negative impact upon psychological well-being. Whilst the evidence in this area continues to accumulate the following things need to be highlighted. The findings of an association between religion and spirituality and psychological well-being do demonstrate plausibility and coherence, as the reports of the association between religion spirituality and psychological well-being outcomes have been consistently observed and identified across different population groups. However, the evidence discussed in this section derives largely from cross-sectional and prospective cohort studies. These types of studies are observational, therefore lack ability to demonstrate cause and effect between variables and outcomes measured. Furthermore, the cross-sectional studies lack temporality. Therefore, when measuring outcomes like depression, anxiety or relationship with God or an individual's religion and spirituality, scores on these variables only reflect the time point during which the data was collected. This is not an accurate reflection of the outcome; and the results from this can be misrepresented if confounders are not considered. For example, if an individual is experiencing little or no stress, their reports of low levels of anxiety and depression may show stronger associations with a positive relationship with God, and more frequent attendance at church. However, if there are times of hardship, or stress then this can lead to negative effects on mental health, which again might not reflect the individual's overall religion and spirituality and mental health. Observational studies also limit understanding of the actual mechanisms whereby religion and spirituality can impact health outcomes (Stewart et al. 2013). This reiterates the need for higher quality studies that can investigate the causal link between religion, spirituality and mental health (King 2014).

2.7.3 Religion Spirituality and Chronic Conditions

Similar to psychological well-being; religion and spirituality have also been associated with better health outcomes for individuals living with chronic conditions (Büssing & Koenig 2010).

Systematic review of 49 studies has shown patients spirituality and practice of their religious faith is associated with increased knowledge about their disease, and greater treatment adherence (Stewart et al. 2013). Across the articles there were reports of patients frequently interacting with God about their disease states through prayer which provided comfort and was also associated with greater quality of life (Park & Nachman 2010; Keefe et al 2001). In relation to cancer, three meta-analyses have shown religion and spirituality is significantly associated with better physical mental, and social health. In relation to physical health metaanalysis data from observational studies showed religion and spirituality was positively associated with overall physical health (z=0.153, p<0.001), this association was not moderated by sociodemographic or clinical variables (Jim et al. 2015). In relation to mental health, the meta-analysis showed there was a significant positive association between religion, spirituality and mental health, this was the strongest association found across the three meta-analyses (Salsman et al. 2015). Religion and spirituality was also significantly positively associated with social health outcomes (z = 0.2, P<0.001) (Sherman et al. 2015). Although the findings derive from observational studies, they collectively suggest that greater levels of religion and spirituality is associated with better patient-reported physical, mental and social health outcomes in cancer patients.

Several qualitative studies have supported these findings, and can provide insight into the personal changes underpinning the beneficial effects observed in the literature. Amongst older Christian women, themes around God's involvement, prayer as a mediator, spirituality as a coping mechanism, emerged. The four themes represented how spirituality supported the women to self-manage their illnesses (Harvey & Cook 2010). The women identified spirituality was a source of empowerment, which reflected in better illness outcomes and positively influenced their well-being (Harvey & Cook 2010). Similarly, Newlin et al. (2008)

found in patients with diabetes, spirituality was associated with significant improvements in glycaemic control and self-management behaviours.

A systematic review exploring the role of spirituality in experiences of chronic pain, highlighted several ways religion and spirituality can help patients manage chronic pain (Wachholtz et al. 2007). The findings of this review are further applicable to understanding how religion and spirituality can help patient's selfmanage chronic conditions. Individuals make attributions in order to create understanding, this can be both positive and negative. To better cope and manage chronic conditions, patients can engage in sense-making where they seek purpose in their experiences. Individuals also make attributions related to control, when patients are confident in their own ability to manage symptoms the increased selfefficacy can create greater tolerance of pain or chronic condition. Religion and spirituality provides patients with different coping techniques for example reading and meditating on scriptures can provide encouragement. This can also provide distraction from pain, it can also cause the patient to relax, because it gives the patient allocated time to not ruminate over their condition. Involvement with religious communities provides access to social support which can significantly influence health outcomes.

The research presented here does not aim to suggest that religion and spirituality can cure chronic conditions rather it is highlighting that religion and spirituality can exert influence on other health domains (e.g., emotional, psychological, social) which can subsequently impact health outcomes alongside medical interventions. Through these sections I have shown religion and spirituality can have both positive and negative impact on patient outcomes, whilst highlighting this is an important aspect of an individual that needs to be acknowledged in order to develop a truly holistic healthcare intervention. In the following section I will present the existing research around religion, spirituality and obesity and present the rationale for adding these elements into an intervention for obesity.

2.7.4 Religion Spirituality and Obesity

The evidence investigating religion, spirituality and obesity is still within its infancy. A systematic review of cross-sectional and prospective cohort studies up to 2010 found 36 studies investigating the association between religion or spirituality and body weight. Of these, seven (19%) reported a lower body weight among those who associated themselves with a religion, 14 (39%) reported a higher body weight, 2 (6%) had mixed results, and 13 (36%) found no association between body weight and religion. However, the highest quality cross-sectional studies found religious involvement was associated with a higher BMI, but, in longitudinal studies, no association was found (Koenig et al. 2012).

Systematic review evidence which included large clustered RCT's of faith-based (adding a spiritual dimension by including bible study, prayer, journaling and spiritual themes) and faith placed (occurring at a place of worship) church interventions found body weight loss occurred in 70% of these interventions. Of the 18 studies included in the review a total of 60% of the interventions reported increased fruit and vegetable intake and 38% reported increased PA, however, more rigorously designed studies are still needed (Lancaster et al. 2014). (Individual studies from this review are discussed in more detail in section 3.3.3.). A more recent systematic review of 85 observational studies (76 cross-sectional studies & 9 longitudinal studies), exploring the association between religion and body weight showed greater religiosity (e.g., religious attendance, commitment, prayer) was significantly associated with higher body weight (Yeary, Sobal, & Wethington 2017). However this association was not found amongst studies exploring the association between religion and body weight in Seventh-Day Adventists (SDA). SDA's had a lower body weight than other denominations in cross-sectional analyses. SDA's doctrine espouses lacto-vegetarian diets, and so among SDA religion has been positively associated with a better diet, which includes higher consumption of fruit and vegetables (Tan, Chan & Reidpath 2016, Tan, Chan & Reidpath 2013), higher fish intake, (Obisesan, Livingston, Trulear and Gillum, 2006) and lowered fat intake (Tan et al. 2013) all of which are suggested to be protective against obesity in this population. Collectively these findings suggest there are strong associations between religion and body weight, where the majority of research evidence suggests religion is associated with a higher body

weight. However, the cross-sectional studies cannot determine whether religion influences body weight or whether body weight is influenced by religion, reiterating the need for higher quality studies. The findings also demonstrate, interventions that incorporate a religious element are promising and worth further investigation.

Nearly all the studies examining spirituality, religion and obesity so far have been carried out in the USA. In the USA, there is a clear rationale for the development of faith-based obesity interventions. African-Americans (typical recipients of faithbased interventions) have a higher prevalence of obesity in comparison to wider population, and perceive the church as a trusted entity for their health and wellbeing. In the UK, a similar rationale exists, a cross-sectional study using HSE 2012 data showed religious affiliation was associated with being more overweight (0.9kg/m² higher BMI in those associated to a religion than those not associated to a religion) (Lycett 2015). The evidence of this association was strongest among those affiliated to a Christian religion. This study measured religion/spirituality, but this was measured through religious affiliation so while it does not explore the association between intrinsic religiosity or spiritual health and BMI, it does suggest those affiliated to the Christian faith might be an important population to target for obesity interventions. Further evidence beyond this study suggests Christians are more likely to be overweight (Kim, Sobal & Wethington 2003; Kortt & Dollery 2014). However, the mechanisms explaining this association are not entirely understood, there is some evidence where it is suggested food is not perceived the same way as alcohol and smoking, and so the perceived health risks associated with over-eating are not considered. There is a need for more exploratory work to better understand perceptions and understanding of attitudes towards food within the context of health amongst the Christian sub-population.

To further support this thesis rationale, the WHO (2009), in its global strategy on diet, PA and health has recommended further exploration into the role of religious communities to tackle obesity through faith-based weight management programmes. This is further supported by the NICE (2016) public health guidelines where researchers are encouraged to collaborate with local communities in

particular faith organisations with intentions to improve health and wellbeing and reduce health inequalities. Faith organisations are recognised as a promising setting for obesity prevention, a recent narrative review identified several studies are currently using religious venues to deliver healthcare based interventions and or discuss health related topics (Maynard 2017). Furthermore, tackling obesity within religious settings taps into existing social structures, whilst mobilising a voluntary workforce and promoting self-management, this is also cost-effective (WHO 2009). Pooling together the evidence presented, the rationale for this PhD shall now be presented.

2.8 Rationale for this PhD

The energy-balance model is an oversimplified solution to a complex problem such as obesity. The evidence presented in the background highlights the need for a fresh perspective needed to treat obesity. Obesity is a complex condition and current treatment options neglect important aspects contributing to the development and continuation of obesity. There is a need for obesity interventions to address emotional and psychological aspects of eating and obesity. Interventions also need to address the issues associated with poor weight loss maintenance. Intuitive eating based programmes go some way to address both physical and psychological aspects of obesity, but they do not specifically address spiritual or religious aspects. For example, feelings of guilt, self-loathing, and rejection that are experienced by frequent weight cyclers, for some can have religious meanings and religious answers.

A truly holistic approach should address religion and spirituality as well as physical, social and psychological dimensions of a person. To date, the US church-based interventions although add a religious element; still adopt a conventional approach to obesity which focuses on achieving weight loss through dietary restriction. Therefore, combining the evidence presented around the success of faith-based interventions and intuitive eating based interventions for weight loss, a more holistic approach to treat obesity is presented. This PhD will explore the feasibility of delivering and evaluating an intervention that adds religious elements to the broad principles of intuitive eating within a church setting.

3 Methods

Introduction to Chapter 3

The aim of this chapter is to present the methods used to conduct the studies in this PhD. The chapter comprises of a further 6 sections which shall be detailed below.

Section 3.1 situates the PhD in its chosen epistemological and ontological perspective. It then introduces the aims of the PhD and highlights how these aims drove the mixed-methods research design used. Section 3.2 outlines the MRC framework for design and evaluation of complex interventions. Section 3.3 describes the process of intervention selection, development and evaluation in accordance with the MRC framework. Section 3.4 discusses the quantitative methods and ethics of the feasibility trial that was conducted as part of the research for this PhD. Section 3.5 introduces the embedded qualitative studies. It discusses the data collection methods, presents the ethics upheld, and the data analysis techniques used to analyse the qualitative studies. Section 3.6 is a reflexivity where I have reflected on how my role and experience could have affected the results of the study. I discuss how I approached the data analysis and the steps I took to minimise my influence as a researcher over the data collected.

3.1 Paradigm and Theoretical (Methodological) Approaches Taken in this Thesis

The primary aim of this PhD was to evaluate a religious weight management programme. This involved determining whether a religious weight management programme would be feasible to run and evaluate within a church setting, and whether lay facilitators could be trained to deliver the programme. In addition to this, it was to also determine the acceptance of participating in the programme and engagement with the programme, and whether facilitators found delivering the programme acceptable.

Traditionally there exists a divide between quantitative and qualitative research methods as they represent two incompatible paradigms underpinned by different assumptions of the nature of (ontology) and ways of knowing and understanding reality (epistemology) (Dures et al. 2010). A quantitative paradigm typically assumes a positivist epistemology, where it assumes reality is objective, quantifiable and universal adopting a realist belief in an independent reality that is knowable (Dures et al. 2010). Quantitative paradigms can demonstrate cause and effect through their methodologies, they are considered the gold standard of research method designs and so utilised most in health research (Hoppe et al. 2009). On the other hand, a qualitative research paradigm assumes a constructivist epistemology where is it believed reality is socially constructed, and meaning is a product of construction. As individuals engage with the world and objects in their surroundings they develop meaning and create their own realities that are either shared by others or specific to the individual. Under a qualitative paradigm, rather than a single reality, multiple notions of reality exist all subjective to the individual (Bishop 2014). Such notions of reality differ from individual to individual and as meaning is created by the individual there are different meanings and perceptions held about the same phenomenon (Chamberlain et al. 2011)

In recent years, mixed-methods has emerged as a third major research paradigm to the traditional quantitative and qualitative research paradigms (Dures et al. 2010; Teddlie and Tashakkori 2009). Whilst still a controversial paradigm, mixed methods research can be defined as a single study wherein both quantitative and qualitative data is collected and analysed (Cresswell and Pano-Clark 2011). Mixed-

methods research draws on the notion neither quantitative or qualitative research paradigms can solely explain reality in its entirety (Yardley & Bishop 2008), instead the two can be used to complement each other and enhance our understanding of the knowledge obtained (Greene 2008). To address the issues associated with epistemology, mixed methods research can be situated within a pragmatist epistemology (Johnson & Onwuegbuzie 2004). Pragmatism is argued to be able to address the philosophical challenges that are related to mixed-methods research (Bishop 2014). Pragmatism is not associated with any one system of reality, this therefore enables the researchers to embrace the differences between quantitative and qualitative research methods and draw on both of their assumptions in their research as appropriate to their research question (Cresswell 2003). To address the technical challenges associated with how and when to combine the quantitative and qualitative methods, typologies of mixed methods design have been developed. There are a significant number of mixed-methods design typologies (Cresswell & Plano-Clark 2011, Morse & Niehaus 2009; Johnson & Onwuegbuzie 2004). However, when summarised typologies orient themselves around the timing of when quantitative and qualitative research is conducted in the mixed-methods design and the relative emphasis placed on the two paradigms (Bishop 2014).

3.1.1 Mixed-Method Study Objectives of this PhD

To adequately and appropriately conduct mixed-methods Denscombe (2008) identifies there is a need to explicitly state the research questions, and present a clear justification for why mixed-methods research methodology is being used.

The mixed-methods design of this PhD was driven by five main research questions;

- To determine how feasible it is to deliver and evaluate a religious weight management programme in a UK church.
- To investigate change in quantifiable measures of physical, psychological and spiritual well-being in participants pre and post programme, and at sixmonth follow-up.

- To assess change in quantifiable measures of eating behaviour, nutritional intake and PA pre and post programme, and at six-month follow-up and to explore resulting associations between these variables.
- To qualitatively explore the experience of facilitators in delivering and facilitating a religious weight management programme, and their acceptability thereof.
- To qualitatively explore the participants acceptability of and engagement with a religious weight management programme.

Therefore, to address these questions, an embedded-experiment mixed-methods design typology was used (Cresswell & Plano-Clark 2011), where two qualitative studies were embedded within a larger quantitative feasibility study. Qualitative and quantitative data was collected concurrently, where semi-structured interviews with participants about their acceptability was collected at the end of the intervention (12 weeks) alongside end of intervention quantitative measures. Qualitative data around facilitator acceptability was also conducted post intervention, to explore facilitators' experiences of facilitating the intervention, and identify any changes they felt should occur in the programme structure or delivery.

3.2 Medical Research Council Framework

The rationale behind using both quantitative and qualitative methods further derives from the MRC guidelines for the evaluation of complex intervention (Campbell et al. 2000, Craig et al. 2008). Quantitative research methods allows testing of cause and effect through RCT designs, it enables researchers to demonstrate change in variables measures, and allows researchers to study complex relations between outcomes, and produce generalizable findings that can be implemented wide scale following successful outcomes. Quantitative research methods further allow evaluation of recruitment, retention, compliance to intervention, response rates, which are particularly important to establish at feasibility and piloting stage. This further helps researchers to establish whether a full-scale RCT is warranted, and refinement of study design and intervention

protocol is needed. Whilst quantitative measures are necessary and provide vital data about a complex intervention, the MRC framework also emphasises the need to use qualitative research methods. According to these guidelines another important part of an evaluation process is the qualitative exploration of an intervention. This can provide valuable insights into successful and unsuccessful mechanisms of an intervention, as well as providing evidence of any unexpected outcomes not always easily disclosed through quantitative measures. Furthermore, this can also generate better understanding of compliance and acceptability of the intervention, and is suited for interventions intended to be widely implemented in different contexts.

3.2.1 Complex Interventions and the Development of the MRC Framework

Complex interventions are defined as interventions that incorporate multiple components that work independently or interact to influence specified outcome or outcomes (Campbell et al. 2000, Craig et al. 2008). Developing and evaluating complex interventions can be challenging. Datta and Petticrew (2013) conducted a content analysis of 207 published articles to identify the challenges of designing, implementing and evaluating complex interventions as described by investigators. The findings of this analysis found the investigators involved in the development and evaluation of complex health interventions incurred challenges related to; intervention design, standardisation of definitions and treatment fidelity, intervention implementation, contextual characteristics, outcomes and evaluation. Many of the challenges were interrelated for example, treatment fidelity and intervention implementation. The analysis found many complex interventions cannot be delivered in a standardised way; depending on context there is variation in delivery of the intervention, and how it is implemented across various settings impacting fidelity of the intervention.

Considering outcomes and evaluations, one primary outcome which typically involves determining effectiveness is not suffice for complex interventions (Campbell et al. 2007). Datta and Petticrew (2013) identified further how researchers face challenges in not only effectively measuring outcomes in a valid and reliable manner, but many complex interventions have more than one outcome, and measuring bio-psycho social outcomes as well as clinical outcomes

creates further challenges. Similar issues were reported in a commentary by Richards and Borglin (2011), investigators report issues in specifying both interventions and comparisons and selecting appropriate comparators, leading to the selection of methodology ill-suited to the research design. Furthermore, many healthcare interventions do not get implemented until a considerable time has elapsed from when they were first shown to be effective reiterating issues with implementation (Richards & Borglin 2011).

In response to these challenges the MRC developed a framework which guides researchers through the development and evaluation process of complex interventions. The first version of the MRC framework (Campbell et al. 2000) was a stepwise approach comprising of 5 phases, which can be sequential or iterative.

In the preclinical phase, the evidence base and theory that will underpin the complex intervention needs to be identified.

In phase I, investigators need to delineate all intervention components to understand what the active components are and how these will interact with each other to bring about effectiveness of the intervention.

In phase II investigators are recommended to conduct an exploratory trial, this includes testing feasibility, acceptability, and identifying key parameters to inform the development of a full-scale RCT. Key parameters include, identifying estimations of recruitment, sample size, appropriate comparators, and expected changes in intervention outcomes.

In phase III, the results of from phase II will be used to run a fully powered RCT to investigate effectiveness of the intervention.

In phase IV is to determine real-life effectiveness of the intervention; long-term surveillance through an observational study might be considered. In this phase the broader impact of the intervention is evaluated, outside the context of a RCT.

3.2.2 Revised MRC Framework (2008)

The first version of the MRC framework drew on protocols typically used to develop and evaluate drugs within biomedical trials. Health behaviour change

interventions do not always work or fit within such frameworks and as a result the 2008 revised framework was developed (Campbell et al. 2007). There were several other limitations identified by other researchers who had used the initial framework. A key limitation of the original framework was it assumed evaluating complex interventions was linear. The first framework characterised the process of intervention development and evaluation in terms of the phases of drug development. In practice complex intervention, development evaluation and implementation is not linear, so the revised framework expands on the process further.

Other limitations of the initial framework included not enough focus and emphasis on the developmental phase of the intervention. This phase has been reported to be undermined, because often issues like sample size, recruitment, retention rates, should be considered at this preliminary stage are overlooked, creating problems for investigators at full RCT phase. Additionally, healthcare interventions are rarely conducted in one context, involving one sample, the revised framework highlights the need to understand context, and situate the evaluation, and the impact of the intervention within several contexts. These include; participants background, prevalence of the health problem under investigation, the setting wherein the intervention is delivered, healthcare professionals knowledge and expertise (Campbell et al. 2007). The revised framework details five phases outlined in turn below.

Development Phase: The key aim is to develop an intervention that can maximise the likelihood of generating positive effects on the outcome being addressed. In order to do this there a three sub-phases:

- *Identifying the evidence base:* Identify the relevant and most current evidence base, best achieved through a systematic review.
- *Identify or develop the theory:* this stage emphasises the need to adopt or develop a theory from the existing evidence base to demonstrate the process of change likely to occur during the intervention. Theory can be further supplemented through conducting primary research e.g., semi-

- structured interviews with stakeholders, or intervention deliverers to better understand the needs the intervention should fulfil.
- *Modelling process and outcomes:* This refers to describing the expected processes underpinning the intervention. This phase is guided by answering questions around; how the intervention is proposed to work, what outcomes will the intervention change, are there any barriers to participating or facilitating the intervention, are there any obstacles preventing the implementation of the intervention? At this stage, a clear understanding of the mechanisms involved within the complex intervention is required, if these interact, then how they are related to the intervention outcome (Faes et al. 2010). This phase is crucial because it can identify whether a full trial is warranted.

Feasibility and piloting: This phase includes vital preliminary work which includes determining acceptability, estimating rates of recruitment and retention, and calculating appropriate sample size. Evidence from previous studies has identified trials often report difficulties with recruiting to target, non-compliance and issues with delivering intervention, unanticipated levels of attrition, under reporting of acceptability (Califf et al. 2012, Richards et al. 2014). This stage is therefore paramount before a fully powered RCT is conducted.

Evaluation: This phase involves determining effectiveness of the intervention, which is typically achieved through conducting an RCT. It is also recommended that an economic evaluation be carried out during this stage, if it has not already been conducted during the modelling stage. Assessment of cost-effectiveness is to ensure the cost of the study is justified by the benefit that can be gained from the intervention. The revised framework also mentions conducting a process evaluation, alongside the evaluation of the intervention. Process evaluations identify which mechanisms and contextual factors are associated with intervention outcomes and assess fidelity, this provides important data around how the intervention can be implemented in the future.

Implementation: This phase refers to translating research evidence into practice. Dissemination of results is not just through publishing in peer reviewed scientific

journals, it also involves using results of the study to impact policy, and identify long-term impact of the intervention through follow up and observational studies occurring beyond the evaluation of a RCT. A detailed description of the intervention should be disseminated allowing for replication, and investigators are encouraged to disseminate results even if they are not positive.

3.3 Development Phase of a Religious Weight Management Programme

The aim of this chapter is to introduce the development and feasibility phase of a religious weight management programme tested in this PhD. The MRC framework was used a guidance, and is used to outline this chapter.

3.3.1 Identification of the Existing Evidence Base

The MRC framework states identification of the existing evidence-base should be completed by carrying out a systematic review. A systematic review was not conducted because there were already three comprehensive systematic reviews recently published (Koenig et al. 2012, Lancaster et al. 2014, Kim et al. 2017). These were used to assist identifying the existing evidence-base phase, and determine whether faith-based interventions are worth evaluating.

3.3.2 Findings of the Systematic Reviews

The first systematic review was conducted by Koenig, et al. (2012), examined 36 cross-sectional and prospective cohort studies up to 2010 that investigated the association between religion or spirituality and body weight. Of these, seven (19%) reported a lower body weight among those who associated themselves with a religion, 14 (39%) reported a higher body weight, 2 (6%) had mixed results, and 13 (36%) found no association between body weight and religion. However, the highest quality cross-sectional studies found that religious involvement was associated with a higher BMI, but, in longitudinal studies, no association was found (Koenig, et al. 2012). Another systematic review was conducted in 2014, by Lancaster et al. which investigated faith-based and faith-placed interventions that targeted obesity among African-American communities. Collectively the results of these two systematic reviews highlight that adding a spiritual/religious dimension to weight management programmes could result in achieving weight loss, and

changes in dietary behaviours. Kim et al. (2017) showed greater religiosity is associated with higher body weight.

The evidence suggests such interventions are worthwhile because they can reach a large community regularly, attrition is lower amongst these groups, and an adequate level of participants are reached at follow up. Furthermore, qualitative evidence from focus groups and interviews with church leaders and pastors demonstrates church leaders care about the health and well-being of their congregation (Holt et al. 2006, Markens et al. 2002). They are supportive of healthcare initiatives that aim to promote health and well-being to their congregation. This suggests church-based interventions are a potential source worth evaluating in the UK.

Evidence has identified religion has a role in diet and eating behaviour. As outlined in chapter 1, there is increasing evidence supporting this however, the majority of the work derives from the USA. Therefore, the next part of the evaluation phase was to identify a suitable intervention for a UK population that either exists and has not been formally evaluated, or develop a new intervention.

3.3.3 Searching For a Suitable Intervention

Several faith-based weight management programmes have been trialled in the USA. 'Sisters in motion' is an example of a faith-based intervention trialled at RCT level (Duru et al. 2010). The intervention was designed to increase PA amongst African American women. It adopted behavioural strategies of goal-setting, increasing self-efficacy, positive reinforcement, and social support within an 8-week programme. The results of the study showed at 8 weeks, the intervention group increased their weekly average of steps by 9883, compared to an increase of 2526 steps by the control group. Systolic blood pressure decreased by 12.5mmHg, in comparison to 1.5mmHg decrease by the control.

Further evidence from RCT's has come from Resnicow et al. (2001, 2005) they have trialled several different faith-based and faith-placed interventions with successful outcomes. 'Eat for life' (Resnicow et al., 2001) was a culturally sensitive self-help programme where the intervention group were given 5-a-day self-help materials that included a spiritual theme, and received 3 motivational interviewing

counselling calls. The post-intervention results found in comparison to the control the intervention group had increased their consumption of fruit and vegetable. Another example includes the 'Healthy Body Healthy Spirit' intervention (Resnicow et al., 2005), where participants were given culturally sensitive diet and PA materials, the results showed in comparison to the control, the intervention group significantly increased their fruit and vegetable consumption, and PA levels.

Furthermore, Kim et al. (2008) designed a faith-based weight management intervention called WORD-8 (Wholeness, Oneness, Righteousness, and Deliverance -8 weeks). This intervention adopted social cognitive theory, social support models and the stages of change transtheoretical model. Comprising of 8 weekly learning modules (e.g., portion sizes, calorie-counting, PA, eating out, healthy cooking) each session was accompanied by a recap of the previous week's session, PA with an exercise tape, a Bible study about health, and prayer. Trialled through a quasi-experimental design, participants lost an average of 1.6kg at the post-intervention, with reports of increased PA.

Collectively, interventions trialled in the USA have demonstrated successful outcomes, through weight loss, increased fruit and vegetable consumption, and PA and decreasing blood pressure. However, the replication of such interventions is difficult. Implementing faith-based interventions that have been discussed above in the UK, represents many challenges, these interventions have been designed specifically for the African-American community, incorporating culturally specific information about food and diet, as well as targeting health conditions that are most prevalent in this community (e.g., T2DM, CVD). Therefore, the translation of such intervention to a UK church community setting is not entirely appropriate. As a result, an existing religious weight management programme that was UK based was sought.

An established programme was sought because it is more economical to test this first rather than 'reinvent the wheel'. There is good precedence of doing this within primary care where commercial weight loss management programmes e.g. weight watchers, slimming world have been robustly trialled so they can be used within the NHS (Jebb et al. 2012, Jolly et al. 2012)

Anecdotal evidence has demonstrated the use of certain US faith-based interventions. These include 'weigh down and thin within' and the 'Daniel plan'. Weigh down and thin within, is an example of an American faith-based religious weight management programme ran in several churches in the US, but not evaluated. It was written by a registered dietitian, and incorporates principles of intuitive eating with Christian spirituality. However, 'word of mouth' reports suggest the intervention is not acceptable due to the food discussed and the language used was disliked by the English for being 'too American'. Additionally, the Christian theology used was not well-received suggesting it was straying away from mainstream Christianity.

The Daniel Plan is another example of a US programme, which focuses on encouraging self-discipline and increasing ones discipline around food in line with the Christian principle of looking after the body God gave you. The plan itself was deemed not acceptable to use because it was not based on good nutritional science. For example, it recommends exclusion of many foods e.g., gluten containing foods and dairy products which could lead to vitamin D and calcium deficiency.

Finally, a 12-week spiritual weight management programme that incorporated principles of 'awareness eating' and Christian spirituality was purchased. This was a UK based programme that had been written by an English author who had herself struggled with yo-yo dieting all her life. This programme has been running successfully across churches in the UK already, and anecdotal evidence from the affiliated website showed good acceptability of the programme. The programme had a number of materials associated with it, this included programme content as PowerPoint slides, daily bible readings, and a personal testimony written in book format. On first inspection, the content appeared to be line with the evidence-base, however as the materials were being more thoroughly reviewed in preparation for delivery it became clear there were significant gaps in what was covered. There was a lack of cohesive structure to the course, evidence sources used in the programme were unreliable and there was no guarantee materials used were free from copyright infringement. Additionally, the tone of the materials did not meet with the expected standard of professionalism for healthcare professionals. For example, a session around dieting would have left the impression, diets in their entirety are unsuccessful. This does not accurately represent the literature, and it became clear whilst there was some evidence underpinning the materials, this was also accompanied by the author's personal thoughts and beliefs.

The Principal Investigator (PI) met with the author, and discussed the concerns and proposed changes the team wanted to make to the programme content, and materials. However, the outcome of this meeting meant the purchased programme would no longer be used, and so new materials were designed by the research team.

3.3.4 The Development of Taste & See

The new programme that was delivered was called Taste & See, this was delivered to the participants instead of the existing programme. The content and delivery of Taste & See still matched what participants were expecting e.g., weekly sessions with the aim of freeing participants from dietary restriction, by engaging with intuitive eating and drawing on spiritual resources to deal with emotional eating. However, Taste & See contained all new material developed from a scientific evidence-base, the theoretical underpinning is described below.

3.3.5 The Theoretical Underpinning of Taste & See

The theoretical underpinning of the Taste & See intervention is displayed in Figure 2 (page 90). The PI built this conceptual framework that consisted of evidence-base currently known about weight management. Taste & See addresses cyclical behaviour associated with intentional weight loss attempts. In the red cycle (figure 2), the diet and weight regain cycle is displayed. This demonstrates a typical intentional weight loss cycle; where an individual decides they want to intentionally lose weight, and so go on a diet which involves a form of dietary restriction. When dietary restriction is difficult to sustain, it can lead to cravings at this point, some individual's succumb to the cravings, which can cause them to experience feelings of guilt and shame. For some individuals this can then lead to an all or nothing effect where they give up their dietary restriction and regain weight to then find themselves at the start of the cycle again. This cyclic pattern of behaviour is not the case for every individual, but it is a cycle that develops following repeated bouts of weight loss followed by weight regain.

In order to break this cycle; the intervention incorporated psychological principles of intuitive eating (amber in figure 2) as described by Tylka et al. (2006, 2010). Intuitive eating comprises of four elements as described in the background; an unconditional permission to eat, learning to be guided by physiological signals of hunger and fullness, self-acceptance and body appreciation and finally eating only for physiological purposes and not emotional reasons. Mapped onto these principles are Christian spiritual principles; freedom, responsibility, love and forgiveness that are taken from the Bible.

It is expected that as outlined in figure 2, at each stage of the diet weight –regain cycle, the intuitive eating and Christian spirituality principles will map onto these to address the issue outlined in the diet weight-regain cycle. For example, in the dietary restriction stage, individuals might choose to restrict a particular food or food group. To counter this, and prevent progression to the second phase of the diet weight-regain cycle, the intuitive component of an unconditional permission to eat is mapped onto this, alongside the Christian principle of freedom. The freedom and unconditional permission to eat begins to address the issue; weight loss can only be achieved by restriction of a specific food, therefore breaking the cycle at this stage.

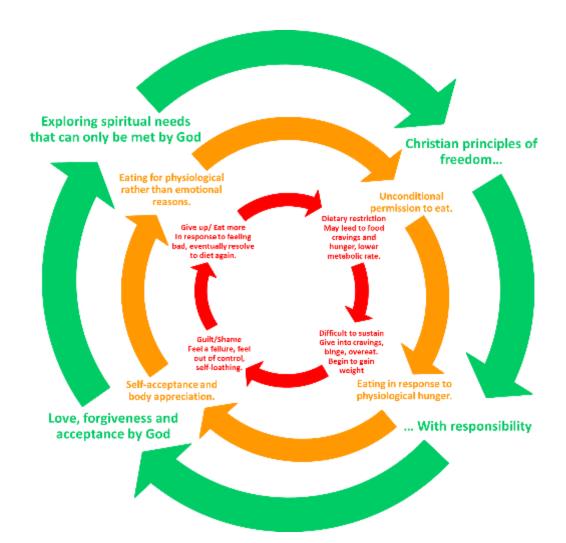


Figure 2: Theoretical underpinning of Taste & See

3.3.6 Intervention

The Taste & See intervention consists of approximately ten, 90 min, weekly sessions which take participants on a journey from identifying problematic eating behaviours to begin making changes. The programme incorporates 25 Behaviour Change Techniques (BCT's) (Table 2, page 92) from the taxonomy of behaviour change version 1 (Abraham & Michie 2008). BCT's are an active component of an intervention that are used to change and/or target a behaviour. These are outlined in the table with the accompanying sessions. The intervention drew on the PI's experiences throughout clinical practice and understanding of behaviour change in obesity, the intervention was not developed out of BCT's, but the BCT's contained within it are highlighted in the intervention in line with good practice to help readers understand the content. Each week, there is a theme (Table 2, page 92) and the following elements are included:

- Scientific content of evidence-based dietetic practice,
- Group activities to consider application of these dietetic principles in participants' own lives,
- Biblical view on the issues raised,
- Opportunity, without obligation, to respond individually to spiritual content if participants wish to do so,
- Activity for the week to practice making health behaviour changes,
- Daily Bible reading and prayer material for those who want to engage with this.

In this section I have discussed the MRC framework, and how the intervention tested in this thesis was designed in relation to this framework. In the following section I will outline the methods used to conduct the feasibility trial of the Taste & See intervention.

Table 2: Content of the Taste & See programme.

Session	Key Points, Activities and (Key Behaviour Change Techniques)	Scientific Principle	Biblical Principle
Session 1: Your Relationship with Food To develop an awareness of self, of eating habits and of a God who cares about this	Everyone in the group has a similar problem (social support—general and emotional); this is something that you can involve God in, if you would like to (conserving mental resources). Complete food and mood diary (self-monitoring of behaviour)	The holistic aspects of eating The evidence for addressing the spiritual in weight management.	We are physical and spiritual beings. God loves us and wants to be involved in our lives
Session 2: What dietary rules do you follow? To introduce intuitive eating versus dietary restriction	Dietary rules can be unhelpful, find out what yours are and consider whether they help or hinder you. What are the alternatives? (self-talk, reframing, cognitive dissonance, regulate negative emotions, behaviour substitution, habit reversal and formation, health consequences, emotional consequences, self-assessment of affective consequences, action planning).	The diet and weight regain cycle. The evidence for finding what approach suits you The evidence for intuitive eating	Freedom with responsibility "Everything permissible but no everything is beneficial"
Session 3: Are you really hungry? To identify hunger and fullness	Do you eat when you are full? Activities to practice listening to your body signals of hunger and fullness (anticipated regret, behavioural rehearsal anticipation of future reward, avoidance—changing exposure to cues for the behaviour, self-monitoring of behaviour, action planning and implementation intentions).	Hormonal regulation of appetite What is a healthy diet?	Created by God A time for everything
Session 4: Enjoying food again To feel free to enjoy food	Practice eating attentively, enjoy what you are eating, stop when you have finished. Is it appropriate to feel guilty? (behaviour rehearsal, anticipating reward, restructuring of the physical environment, goal setting, habit formation, regulate negative emotions)	Evidence for eating attentively, reducing distractions mindful eating exercise	The blessings of God, he loves to give us good gifts
Session 5: Why else do we eat? To understand impulsive responses to feel happier, to feel less bored, to reduce stress	To identify times when we eat in response to emotion (self-monitoring of behaviour, action planning and implementation intentions, emotional consequence, self-assessment of affective consequences, self-talk, reframing, cognitive dissonance)	Dopamine pathway	The reality of life in an imperfect world/why things went wrong

Table 2 continued.

	Tubic 2 continued.		
Session 6: What can we do instead? To identify ways to tackle boredom, stress and low mood	Plan alternative approaches, set clear goals of what to do differently this week in response to a specific trigger (distraction, avoidance—changing exposure to cues for the behaviour, goal setting, behaviour substitution habit reversal and formation action planning and implementation intentions, problem solving and coping planning, regulate negative emotions, self-talk, reframing)	Evidence based physical activity and relaxation suggestions	Spiritual coping Hope in difficult times
Session 7: Leaving the past behind To identify past hurts or habits that still influence our relationship with food today, to find healing in forgiveness	Practice forgiveness (self-monitoring, self-assessment of affective consequences, self-talk, reframing, cognitive dissonance, regulate negative emotions, problem solving and coping planning, behaviour rehearsal, self-affirmation)	Evidence of the impact of adverse child events Evidence for forgiveness	"Forgive us as we forgive others"
Session 8: You are loved and you are lovely To understand the truth of who you are	You are valued and loved for who you are (self-affirmation verbal persuasion to boost self-efficacy, identity associated with changed behaviour, social support-emotional, self-talk, reframing, cognitive dissonance, regulate negative emotions)	Body congruence Tips to build self-esteem	God's love and acceptance
Session 9: Moving forward To consolidate new attitudes and behaviours, to identify specific aspects of healthy living to work on	It takes time and practice, but we have supernatural help (conserving mental resources, self-affirmation, verbal persuasion to boost self-efficacy, identity associated with changed behaviour, social support-emotional, self-talk, reframing, cognitive dissonance, regulate negative emotions, goal setting, behaviour substitution, habit formation, action planning, and implementation intentions, problem solving and coping planning, distraction)	Goal setting Habit formation Tips and ideas for a healthy lifestyle	New creation, with God's spirit at work within us
Session 10: Pressing on/The future To equip participants to be able to continue the Taste & See principles without weekly support	It won't always be easy, but we can live in forgiveness and freedom (self-affirmation, identity associated with changed behaviour, self-talk, reframing, cognitive dissonance, regulate negative emotions, goal setting, behaviour substitution, habit formation, action planning and implementation intentions, problem solving and coping planning, distraction, anticipation of future reward, avoidance—changing exposure to cues for the behaviour)	Identifying and planning for lapses Evidence for behaviour change maintenance	Pressing on and managing failure

3.4 Methods of the Feasibility Study

In the following section I will describe the methods used to conduct the mixed-methods feasibility study for this PhD. I start by discussing the study design of the feasibility trial, and then discuss the embedded qualitative studies. The CONSORT reporting guidelines (Moher et al. 2010) were followed to report the methods and results of this thesis (Appendix D).

3.4.1 Study Design

This was a mixed-methods feasibility study. The feasibility study was a one-group pre-test-post-test design. Participants attended a total of 12 weekly 90-min sessions over a three-month period, of which ten sessions contained the main programme content and one session either side of this was solely for data collection. Participants were followed up at the end of the programme and again at six months post-intervention (nine months from baseline) to investigate change in physical, psychological, and spiritual well-being.

3.4.2 Study setting

The intervention was run within a UK Baptist Church.

3.4.3 Participants

All of the members from the church congregations were invited to participate in the intervention. Although this intervention incorporated Christian beliefs, it was not exclusively for Christians. For a better indication of acceptability, it was deemed appropriate to understand the relevance of this programme to those who do not attend church as well, as many who affiliate themselves to the Christian religion in England do not attend church regularly (Ashworth & Farthing 2007). Furthermore, evidence has suggested that those who are not religious may still be interested in participating in a programme based on Christian principles (Ronel & Libman 2003) and so assessing acceptability of the programme amongst this population is beneficial for future trials and enhancing the programme. In addition, people from other faiths and none, attend churches for community events (Churchcare 2012), so they also were not excluded if they wanted to participate.

There was a clear inclusion and exclusion criteria for participants which is detailed below. Participants were invited to attend an information and screening session.

3.4.3.1 Inclusion Criteria

- Aged 18 years or over
- BMI greater than 25kg/m²
- Participants with a BMI between 18.5kg/m² and 25kg/m² if this is accompanied by a poor relationship with food as measured by the three factors eating scale (TFEQ-R21; Karlsson et al. 2000). Only participants who had scores above the minimum threshold were eligible to participate.
- Able to read, understand and consent to study procedures.

3.4.3.2 Exclusion Criteria

- Aged less than 18 years
- Individuals that are pregnant.
- BMI less than 25 without evidence of problematic eating behaviour.
- BMI less than 18.5kg/m².
- Any medical condition in which weight loss is contradicted, for example an individual receiving chemotherapy.
- Currently losing weight, intentionally or unintentionally at a rate of 2kg or more in the last four weeks.
- Participating in any other intervention.

3.4.4 Participant Recruitment

Feasibility studies also test the feasibility of recruitment, and so for this study participants were recruited through three avenues:

- 1. The intervention was advertised to the congregation through a research poster, the church newsletter, website and announcements at Sunday services.
- 2. Outside of the congregation, word of mouth invitations to participate were made to interested friends and acquaintances.

3. An article about the study and an invitation to participate was placed in the local parish council magazine which is distributed to all households in the area where the intervention took place.

Recruitment responses and rates need to be determined during feasibility studies because several studies have suggested this is often overlooked in RCT's (Richards et al. 2014). Considering recruitment response and retention helps determine parameters for the future RCT, leading to the development of a better informed RCT (Richards et al. 2014).

3.4.5 Ethics of Feasibility Study

Ethical approval for the feasibility trial was obtained from Coventry University Research Ethics Committee (see front page of the thesis). The trial was conducted in accordance with Ethical guidelines of the British Psychological Society and the recommendations for clinicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki, 1964, and later revisions.

Potential participants were invited to attend an information session about the intervention one week before the intervention began. During this session potential participants were provided with a brief synopsis of the intervention content, what was involved in evaluating the intervention and an opportunity to ask questions. The aim of this session was to allow potential participants to acquire a detailed understanding of what participating in the intervention involved before deciding to participate. At the end of the session participants were given Participant Information Sheet (PIS) to take away and read, and a seven-day food diary to complete if they decided to take part. Participants were also screened for eligibility during this session.

The PIS (Appendix E) detailed information about the trial, and emphasised participation was entirely voluntary. Participants were reassured their data would be stored securely and their identity will be anonymised using participant ID's. If participants decided to participate, they were asked to sign informed consent forms (Appendix F).

3.4.6 Sample Size

There are currently no formal guidelines available for what an appropriate sample size is for a feasibility study (Arain et al. 2010). Given the aims of a feasibility study, Whitehead et al. (2016) suggests that the sample size of a feasibility trial should be related to the size of the future definitive RCT. In order to run an adequately powered RCT for feasibility purposes we aimed to recruit at least eight participants.

Eight participants would give enough power to detect large differences in weight. It is possible that, over ten weeks, a weight loss outcome of 5kg (SD [Standard Deviation] = 5) would occur (a rate of 0.5kg per week). In order to detect this with 80% power and an alpha level of 0.05, a sample size of eight was required, which was calculated using an online sample size calculator designed by the University of California San Francisco (UCFS) Clinical and Translational Science Institute (Appendix G).

3.4.7 Outcome measures

3.4.7.1 Primary Outcome Measures

Clinical Measures

Clinical outcomes of blood pressure (BP), height, weight, BMI, and percentage body fat were measured using a standard protocol and medically validated equipment (Appendices H, I & J) at baseline, 12 weeks and at 6-month follow-up. All measurements were recorded on an individual data collection sheet, separate from the questionnaire pack.

Intuitive Eating and Eating Behaviour Problems

Intuitive eating and eating behaviour were measured at baseline, three-month and six-month follow up.

Intuitive eating was measured using the revised intuitive eating scale (2nd edition) (IES-2, Tylka & Kroon Van Diest, 2013). The IES-2 scale measures all four dimensions of intuitive eating; unconditional permission to eat, eating for physical rather than emotional reasons, reliance on hunger and satiety cues, and body-food

choice congruence, and produces a total intuitive eating score. It comprises of 23 items, and scores can range from one to five, where high scores are indicative of high levels of intuitive eating.

Problematic eating behaviours were measured using the TFEQ-R21 (Karlsson et al. 2000). The TFEQ-R21 scale covers three eating domains: uncontrolled eating (UE), cognitive restraint (CR) and emotional eating (EE). The questionnaire is a 21-item validated measure whereby a percentage score (transformed from raw scores above 9 (UE), 6 (CR) and 6 (EE) indicates some elements of problematic eating are likely). The TFEQ-R21 is a reliable and established tool to measure these three domains of eating, it is sensitive to change and has been used in many interventions to measure changes in these outcomes (Cappelleri et al. 2009, Laurenius et al. 2012, Danielsen et al. 2013)

3.4.7.2 Secondary outcome measures

All of the following measures except organisational, and non-organisational religiosity were measured at baseline, three and six-month follow-up. Organisational and non-organisational religiosity were only measured at three and six-month follow-up.

Depression

Depression was measured using the Patient Health Questionnaire (PHQ-9) (Kroenke & Spitzer 2002), it scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cut points for mild, moderate, moderately severe and severe depression, respectively (Kroenke & Spitzer 2002).

Anxiety

Anxiety was measured using the Generalised Anxiety Disorder (GAD-7) questionnaire (Spitzer et al. 2006). The GAD-7 scores 7 common anxiety symptoms, on a scale ranging from 0" (not at all) to "3" (nearly every day). Scores can range from 0 - 21, scores of 5, 10, and 15 represent cut points for mild, moderate, and severe anxiety, respectively (Spitzer et al. 2006).

Mental Well-Being

Mental well-being was measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) (Tennant et al. 2007). It is 14 item scale covering both feeling and functioning aspects of mental well-being on a scale ranging from 1 (not at all) to 5(all of the time). Scores can range from 14-70, where a higher scores suggests greater mental well-being (Tennant et al. 2007).

Health Related Quality of Life

Health related quality of life was measured using the European Quality of Life-5-Dimensions-5-Levels (EQ-5D-5L; Herdman et al. 2011). It comprises of 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) which are measured using 5 levels (1-5) and the quality of life visual analogue scale (QOL VAS) to assess overall health (0-100). The four measures are highly validated, and the GAD-7 and PHQ-9 is recommended for use by NICE and currently used in NHS primary care for assessing depression and anxiety (Löwe et al. 2008).

Spiritual Well-Being

Spiritual well-being was measured using the Spiritual Well-Being Scale (SWBS) (Paloutzian & Ellison 1982). It is a 20-item instrument, where an overall score ranging, from 20-40 reflects low overall spiritual well-being, a score in the range of 41-99 reflects moderate spiritual well-being and a score in the range of 100-120 reflects of high spiritual well-being. The scale comprises of two sub-scales of ten items. The first subscale; religious well-being assesses individuals experiences of having a satisfying relationship with God or a higher being. Scores on this subscale ranging from 10-20 reflects an unsatisfactory relationship with God. A score in the range of 21-49 reflect a moderate sense of religious well-being. A score in the range of 50-60 reflects a positive relationship with God. The second subscale; existential well-being assesses an individual's sense of life satisfaction and purpose. Scores ranging from 10-20 suggest a low life satisfaction uncertainty of life purpose. A score in the range of 21-49 suggests a moderate levels of life

satisfaction and purpose. A score in the range of 50 – 60 suggests a high level of life satisfaction and purpose (Paloutzian & Ellison 1982). The measure is widely used in the psychological study of religion and is considered to be an appropriate measure for spiritual well-being. Whilst, the SWBS has been shown to have ceiling effects within evangelical Christian samples, it was one of several measures that were used to assess spiritual and religious well-being. It has good face validity and is a good measure of spiritual well-being across a mixed sample (Bufford et al. 1991).

Religiousness has three major dimensions; organisational, non-organisational and subjective or intrinsic religiosity; therefore, it is important to select measures that are able to capture all elements of this conceptualisation.

Intrinsic Religiosity

Intrinsic religiosity, can be defined as the quality of a relationship with God or a higher power, in terms of feeling loved by and close to God.

This was measured by the four item religious love sub-scale of the Sorokin multidimensional inventory of love experience (SMILE; Levin et al. 2010). Scores range from 4-16, with higher scores indicating greater experience of love.

The nine-item attachment to God scale developed by Rowatt and Kirkpatrick (2002) was also used. The scale adopts a two-dimensional conceptualisation of attachment comprising of avoidance (vs. security) and anxiety dimensions. This scale includes negative, as well as positive items, it ranges from 7-21, where higher scores indicates an insecure relationship with God.

Organisational Religiosity

The first two items of the Duke University Religion Index (DUREL; Koenig & Büssing, 2010) were used to measure religious involvement, such as, church attendance. This measures the organisational dimension of religiousness. Scores range from 2-10, with high scores indicating greater religious involvement.

Non-Organisational Religiosity

To measure non-organisational dimension, an adapted version of the religious support scale by Krause (1999) was used, it comprises of 4 subscales; emotional support received from others, emotional support provided to others, negative interaction, and anticipate support. The scores of sub-scales range from 4-20, with high scores indicating greater emotional support received and provided, greater negative interaction and anticipated support.

Physical Activity

PA was measured using the Stanford 7-day physical activity recall (Sallis et al. 1985). The Stanford 7-day recall is a robust measure, measuring both work-related and non-work-related PA. It is a well-validated measure assessing the level of habitual PA through identifying the time individuals spend engaging in light, moderate, hard and very hard activity as well as sleep. The measure has demonstrated high correlations with PA diaries and interview administered recall (Dishman & Steinhardt 1988) and is suitable for assessing changes in individual PA levels.

Nutrient Intake

Nutrient intake was determined by a detailed seven-day food intake diary. Participants were encouraged to weigh their food when completing the seven day food diary. Despite under-reporting in obese individuals, a seven day weighed intake diary continues to be the most accurate measure of dietary intake and is sensitive to individual changes in nutrient composition (Bingham et al 1994; Wrieden et al. 2003).

3.4.8 Data Analysis

Change in clinical measures, psychological and spiritual well-being scales have been presented using descriptive statistics. The significance of these changes over time were analysed using inferential statistics. Data was collected and analysed using the statistical software IBM SPSS Statistics programme Version 22.

Multivariate regression modelling was also carried out to explore whether there were associations between changes in variables. There was a small sample size, so

stepwise regression modelling was selected to ensure the models produced were stable.

3.5 Embedded Qualitative Studies

Two qualitative studies embedded within the main quantitative feasibility study. The methods for each of these studies shall be discussed below. The Consolidated criteria for reporting qualitative research (Tong et al. 2008) was used to write up the qualitative studies (Appendix K).

3.5.1 Qualitative Evaluation of Facilitator Acceptability

The programme was written so it could be delivered and facilitated by church members without a health professional background. Church members volunteered to facilitate the delivery of the programme. A qualitative study was carried out with programme facilitators to assess the feasibility of training church members to deliver the Taste & See programme, and the acceptability of the facilitators to deliver the programme.

3.5.1.1 Facilitator Training

All facilitators received basic training provided by a registered dietitian, church minister and qualified counsellor in the following areas:

- Ethical code of conduct and agreement regarding good clinical practice and spiritual diversity
- Group facilitation, communication skills
- Principles of behaviour change and intuitive eating
- NICE evidence based guidelines on healthy eating and PA
- When to refer on to a professional counsellor or GP
- Collecting data and evaluation/trial procedures

3.5.2 Qualitative Evaluation of Participant Acceptability and Engagement

A second qualitative study, explored the participants experience of the Taste & See programme.

3.5.3 Participants

All of the participants who participated in the Taste & See intervention were invited to participate in post-intervention interviews.

3.5.4 Data Collection

Data for both qualitative studies was collected using individual semi-structured interviews. All of this data was collected through face-to-face semi-structured interviews post-intervention. The interview schedules for both the facilitators (table 3) and participants (table 4) were designed and used as an aide-memoire during the interviews. All of the interviews were audio-recorded and transcribed verbatim. I conducted the interviews under the supervision of my supervisor; the interviews were carried out at the church where the intervention was delivered. Only the interviewers and participants were present during the interviews.

Table 3: Facilitator interview schedule

- 1. Can we begin by discussing your thoughts about the programme?
- 2. Why did you want to volunteer to help with this programme?
- 3. How well would you say the expectations you had as a volunteer matched your experiences of volunteering for this programme?
- 4. How did you find the training?
- 5. How adequate would you describe the level of training you received was in enabling you to facilitate this programme?
- 6. How useful and relevant was the training you received?
- 7. Could you please tell me your thoughts about the delivery of the programme?
- 8. How useful would you have found a debrief session of all facilitators at the end of each session?
- 9. How has facilitating this programme changed you, if it has?
- 10. Can we discuss whether you experienced any difficulties facilitating this programme?
- 11. When considering the role of health professionals and their input in programme delivery, how well do you think this worked?
- 12. What did you think about the location for the programme?
- 13. What do you think was the most successful aspect of this programme?
- 14. What aspect of the programme did you think was least successful?
- 15. How do you think the programme could be improved?
- 16. Would you like to discuss anything else that we have not been able to discuss?

Table 4: Participant interview schedule

- 1. What did you think of this programme?
- 2. What were you initial expectations?
- 3. What did you find most helpful about this programme?
- 4. What did you find least helpful about this programme?
- 5. Could you please tell me how you found the religious and spiritual aspect of the programme?
- 6. Could you please tell me how you found the intuitive eating/ non dieting aspect of the programme?
- 7. Could you please tell me your thoughts about the programme being delivered at a church?
- 8. How helpful were all of the resources provided with the programme?
- 9. How does this programme compare with your previous attempts to diet?
- 10. What would you describe as the most successful part of this intervention?
- 11. Could you tell me about anything that you did not like about the programme?
- 12. How did you find the data collection for research purposes?
- 13. Overall, how would you describe your experience of the programme?
- 14. Before we finish, is there anything you would like to discuss about the programme that we haven't had a chance to discuss?

All of the interviews were carried out in accordance with realist research practice (Sobh & Perry 2006, Maxwell 2012), during the interviews I summarised the key points covered to establish whether I had correctly interpreted the participants and facilitators. This allowed for revision and clarification of their views. Both participants and facilitators were also offered a chance to add to their answers at any point, and were provided an opportunity again at the end of their interviews. Transcripts were not returned for checking and facilitators and participants were not asked to provide feedback on the results. This was because I wanted to explore how participants and facilitators felt about the programme as soon they completed the programme. With further time to reflect, these feelings may have changed; in particular, strong feelings important to the acceptance of the programme may have been diluted.

3.5.5 Ethics for the Embedded Qualitative Studies

Ethical approval for the embedded qualitative studies was obtained from Coventry University Research Ethics Committee (see front page of the thesis). The studies were conducted in accordance with the Ethical guideline of the British Psychological Society and the recommendations for clinicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki, 1964, and later revisions.

3.5.5.1 Informed Consent

Information about the post-intervention semi-structured interviews was included in the PIS. There was a section on the informed consent form where participants could agree to participate in the interviews.

Information sheets were also provided to facilitators about semi-structured interviews. Signed informed consent forms had to be completed following agreement to take part.

3.5.5.2 Confidentiality and anonymity

Participants and facilitators were given separate ID numbers, which were used to identify them. Only the researcher had access to the recording of the interviews. The transcripts contained no identifying information, and any personal

information was changed to maintain anonymity. All of the data was securely stored in a locked filing cabinet, only the researcher had access to this.

3.5.5.3 Right to Withdraw

Participants and facilitators were informed they could withdraw from the interviews at any point, without providing reasons for their withdrawal.

3.5.5.4 Data Storage and Destruction

In accordance with the requirements of the new Data Protection Act (2018), all hard copies of the participant data that were collected as part of this feasibility trial have been placed in the archiving storage unit at Coventry University. The data will be preserved securely for ten years and will be destroyed safely and securely in September 2027.

3.5.6 Data Analysis of the Qualitative Studies

Qualitative data was analysed using thematic analysis. As outlined in section (3.1) this PhD used a pragmatic epistemology, pragmatism is not associated with any one system of reality (e.g., positivism, socio-cultural), it favours using the differences between quantitative and qualitative research methods, to best answer the research question. Thematic analysis was deemed as most appropriate to utilise because unlike other qualitative data analysis techniques that are utilised in health research e.g., IPA, grounded theory, (which shall be discussed in turn below), thematic analysis is flexible because it does not belong to one specific epistemology. This provides a level of flexibility, complementing the pragmatic epistemology underpinning this PhD.

Grounded theory is an approach that aims to understand social and psychological processes suggested to underpin human behaviour. It is best suited when used to explore an area of research where little to no theory or research. The fundamental purpose of grounded theory is to produce theoretical understanding of a phenomenon, it aims to take the essence of the data to create a theory to show how each of the themes produced are inter-related to explain a phenomenon (Dey 1999). Grounded theory was not appropriate, because the aims of the qualitative studies in this thesis, were to simply observe and explore acceptability in the context of the trial, not develop a new theory to understand acceptability.

IPA adopts a hermeneutic epistemology, concerned with interpreting meaning of a phenomenon, at an idiographic level. It focuses on a specific phenomenon within a specific context, and intends to give participants a voice through the analysis. The depth of the analysis moves beyond simple description, but has two interpretive layers to it (double hermeneutics), the researcher making sense of the participant making sense of their world. IPA aims to understand how people ascribe meaning to their experiences in their interactions with the environment (Smith 2004) this depth and deeper level of meaning was not sought, and so IPA was deemed inappropriate to use in this PhD.

In accordance with Braun and Clarke (2006) (Figure 3), each transcript was analysed separately, and coded deductively at a semantic level. Semantic level coding was most appropriate because it codes data explicitly based on what participants say, this aligns with the adopted realist approach. A realist approach was adopted, where the participant's and facilitator's experiences were taken at face value, because it could be assumed participants were reporting the truth about their experiences of the programme. A latent approach is more interpretive, where the researcher begins to add their own interpretation based on their own understanding of the phenomenon and so not appropriate to use here. I conducted the interviews under the supervision of my supervisor and transcribed all of the data as a method to further familiarize myself with the data. The transcripts were read and re-read, and line-by-line coding was completed. Following line by line coding, a list of all the codes generated from this process were collated. When the codes were collated, the codes were searched for potential groupings. This coding process progressed by moving back and forth across the data set in an iterative process where codes and groupings of codes were checked against the existing quote and the whole dataset. This was to ensure that the interpretation and findings were true to the dataset. Following on from this process, themes and subthemes were identified, these were defined with a short description and supporting narratives. In addition to this, to support the final report a thematic table was populated to demonstrate the analysis process with codes, sub-themes and super-ordinate themes. This table is presented alongside the qualitative results. Throughout the analysis process, peer review was performed by

supervisors DL and AT. I had frequent discussions with DL, to ensure the data interpretation was credible, valid and shared.

• Familiarising yourself with the data. • Transcribing data (if necessary), reading and re-reading the data, jotting down initial ideas. Phase 1 Generating initial codes Coding interesting features of the data in a systematic fashion across the entire data set, collating data Phase 2 relevant to each code Searching for themes • Coding codes into potential themes, gathering the data relevant to each potential theme Phase 3 Reviewing themes • Checking the themes application in relation to the coded extracts (level 1) and the entire data set (level 2), generating a thematic map of the analysis. Phase 4 Defining and naming themes ongoing analysis to refine the specifics of each theme, and the overall narrative by the analysis; generating clear definitions and names for each theme. Phase 5 Producing the report • The final oppurtunity for analysis. Selecting vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing the scholaraly Phase 6 report on the analysis.

Figure 3: Adapted version of Braun and Clarke's (2006) thematic analysis stages

In Appendix L I have included an example of how I followed each of Braun & Clarke's (2006) stages of thematic analysis and an example of an analysed transcript (Appendix M).

3.6 Reflexivity

I am a Ph.D. student with a background in health psychology and obesity. I had established professional relationships with the participants and facilitators through my research role in the trial. I am an insider to the phenomena under

focus, because I am a British Indian woman who belongs to the Christian faith. I actively practice my faith by attending church weekly. I also have personal, as well as academic, understanding of the weight-related issues (e.g., weight stigma) participants discussed.

There are benefits to being an insider in qualitative research; as an insider I can share and identify with the experiences of participants. I am equipped with insights into the phenomena and possesses the ability to understand implied content (Kacen & Chaitin 2006). With this in mind, being an insider can also be problematic, there is risk of blurring boundaries due to the familiarised understanding, my own beliefs can be imposed through directing the interview discussion, and over-disclosure of my experiences can occur shifting the focus of the interview away from the participant (Drake 2010).

To counter this, I considered these issues in the early phases of my research. I kept a journal where I engaged in deep reflexivity, during the interviews I continuously asked for clarification of participants' accounts, to ensure their voices were not lost or misinterpreted. In particular, I reflected on my role during the interviews and made changes in my approach throughout (see appendix N), I thought about the questions I asked and the manner they were phrased to ensure a clear participant voice was coming through from the interviews. Particular care was taken during the coding and analysis of data to ensure deductive coding was completed in accordance with the aims of the study, rather than directed by my influence. I refrained from insinuating meaning based on what the participants had said. A clear audit trail was created with annotations, highlighting my thought processes when collating the codes into sub-themes and then themes.

In this chapter I have outlined the methods of this PhD and discussed the pragmatic epistemology underpinning this PhD. In the next chapter I will present the quantitative feasibility results of the trial.

4 Quantitative Feasibility Study Results

Introduction to Chapter 4

This chapter presents the results of the quantitative feasibility study and has been presented through 6 sections.

Section 4.1 presents the results of participant recruitment, retention throughout the trial. Section 4.2 presents the demographic details of the participants involved in the trial. Section 4.3 presents the results of changes in outcomes between baseline and 3-months. Section 4.4 presents the results of changes in outcomes between baseline and 6-month follow up (9 months from baseline). Section 4.5 presents results of changes in religious variables organisational religiosity and religious social support between 3-month and 6-month follow up. Section 4.6 presents the results of the regression analyses exploring the associations between the changes in outcomes variables. The results further adhere to the CONSORT reporting guidelines of feasibility and pilot studies (Appendix D).

4.1 Participant Recruitment and Retention through the Trial

A total of 18 participants were recruited between March 2015 and April 2015. The majority of the sample was recruited from one church (15), one participant responded to the community advert and two participants were recruited through word of mouth. All 18 participants participated, and only one participant was lost to follow-up at three months, and so data was collected on 17 participants in July 2015. At the six-month follow-up (February 2016), (nine months from baseline), three participants were lost to follow-up and so data was collected on 15 participants. Intention-To-Treat (ITT) analysis was carried out at both time points; missing data was inputted using Baseline Observation Carried Forward (BOCF).

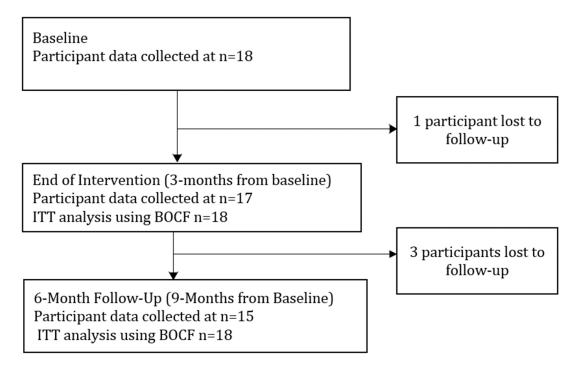


Figure 4: This figure shows the flow of participant's through the feasibility trial

Attendance at individual sessions declined as the intervention progressed; attendance throughout the programme peaked and troughed (Figure 5). At follow-up, participants identified reasons for non-attendance on specific weeks were prior work commitments, caring for a family member and pre-booked holidays.

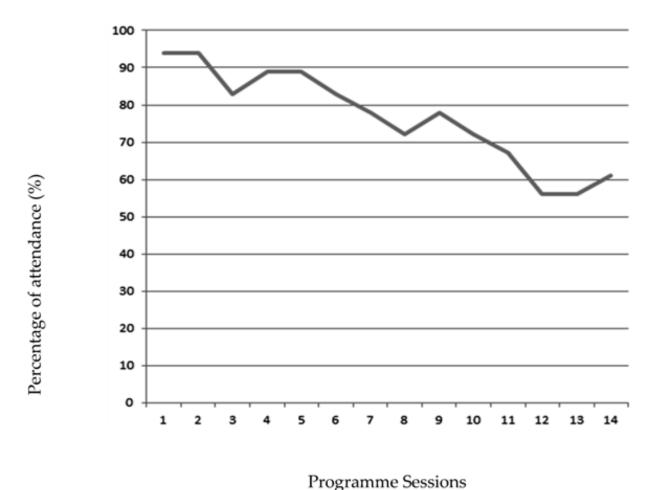


Figure 5: Line graph displaying participant attendance during the programme.

4.2 Participant Demographic Details

The participants were predominantly white females, who were Christian and in the obese BMI category with a mean age of 47.3 (SD 14.8) (Table 5). Of the 18 participants, 15 participants had a BMI greater than 25kg/m² with mean (SD) UE, CR, EE scores of 57 (19), 29 (20), and 67 (23) respectively. Three participants had a BMI between 18.5 and 25kg/m² with mean (SD) UE, CR, EE scores of 50 (20), 50 (28) and 43 (19) respectively.

Table 5: Descriptive statistics of participants

• •	Mear	ı SD	Min	Max
Age (Years)	47	14	19	72
BMI	33.1	7.95	22.2	52.8

		N (% Frequency)
BMI category:	Healthy (BMI 18.5 – 24.9kg/m²) & high TFEQ	3 (17)
	Overweight (BMI 25-29.9 kg/m²)	4 (22)
	Obese (BMI 30-39.9kg/m²)	8 (44)
	Morbidly Obese (BMI >40kg/m²)	3 (17)
Sex:	Male	3 (17)
	Female	15 (83)
Ethnicity:	White	16 (88)
	Black	1 (6)
	Asian	1(6)
Religion:	Christian	16 (88)
	Sikh	1 (6)
	Spiritual, but not religious	1 (6)

4.3 Changes in Outcomes from Baseline to End of Intervention

At the end of the intervention there was a significant increase in QOL VAS, cognitive restrained eating, mental well-being and the intuitive eating dimensions of eating for physical rather than emotional reasons and reliance on hunger cues. There were also significant decreases in EQ-5D-5L pain/discomfort, BMI, uncontrolled eating, emotional eating and anxiety. There was a mean reduction in weight, energy intake, total fat and saturated fat intake. There was a mean increase in spiritual well-being, although these were not statistically significant. There was a negligible mean change in all other variables (Table 6).

4.4 Changes in Outcomes at Follow-Up

Changes at six-month follow-up (nine months from baseline) showed a partial reversal in the improvement in mean scores of uncontrolled eating, emotional eating, cognitive restrained eating, anxiety, depression, mental well-being and

spiritual well-being. Nonetheless, the figures for uncontrolled eating, emotional eating, mental well-being and anxiety were still significantly improved, at this time point, in comparison to their baseline and three-month values. The significant improvements in intuitive eating behaviour seen at the end of the intervention were virtually unchanged during the following six months, such that the same significant improvements as at the end of the intervention were sustained nine months after baseline. There was an important amount of weight regain and BMI increase, with a corresponding increase in energy intake between baseline and sixmonth follow-up (nine months from baseline). However, dietary macronutrient composition showed although total energy intake had returned to baseline levels, this increase in energy came from polysaccharides and protein, while total fat, saturated fat and sugar intake was further reduced during this time period, indicating positive ongoing dietary change after the end of the intervention even though these values did not reach statistical significance.

Table 6: Repeated measures ANOVA displaying the main interaction between changes from baseline to 3 months and 6 months Baseline 3 Months (end 95% CI for mean 6 Months (9 Mean 95% CI for mean Mean of months from change difference change difference Baseline -Baseline baseline) intervention) 3 months SE 9 months Upper M SD M SD M SD SE Lower Upper Lower Weight (Kg) 1.5 89.2 87.6 18.9 -3.2 -0.10 0.6 -1.7 18.9 89.1 19.1 -1.60.6 0.1 Body Fat (%) 44.3 9.5 41.4 13.8 43.9 9.5 -2.9 2.2 -8.8 3.1 -0.3 0.8 -2.5 1.9 Body Mass Index (BMI) 7.90 32.6 8.1 -0.6* 0.2 -1.1 -0.002 0.02 0.2 -0.6 0.6 33.11 8.0 33.1 Systolic Blood Pressure 123 17 2 3.02 -5.1 -5.6 3.9 124 16 127 18 10.9 -0.8 1.8 4.5 Diastolic Blood Pressure 81 10 82 10 81 10 1 2.5 -5.5 7.5 0.41.5 -3.7 72 16.2 13.5 11.7* 3.7 7.4 3.8 -2.5 17.4 61 68 1.9 QOL VAS 19 21.6 Uncontrolled Eating 56.0 18.8 39.5 19.8 42.6 21.5 -16.5* 3.7 -26.2 -6.7 -13.4* 4.5 -25.3 -1.4 Cognitive Restrained 22.7 32.4 43.5 22.5 42.6 18.5 11.1* 3.8 0.9 21.3 10.2 4.9 -2.7 23.1 Eating Emotional Eating 62.7 23.5 43.2 23.5 45.9 22.6 -19.4* 3.8 -29.4 -9.5 -16.7* 3.6 -26.3 -7.1 Intuitive Eating (IE) Total 2.5 0.8 0.5 2.9 0.6 0.6* 0.3 0.9 0.5* 0.2 3.1 0.6 0.1 0.1 IE: Unconditional 0.7 3.0 0.9 3.2 0.7 3.1 0.6 0.2 0.2 -0.3 0.7 0.1 0.2 -0.5 Permission to eat IE: Eating for Physical 0.7* 2.3 0.7 2.9 0.9 2.9 0.9 0.1 0.3 1.04 0.62*0.1 0.3 0.9 Hunger IE: Reliance on Hunger 0.2 2.0 8.0 3 0.9 2.8 1.09 1.1* 0.2 0.6 1.5 0.8* 0.2 1.4 IE: Body Food Choice 0.4 3.0 0.9 0.9 0.9 0.4*0.7 3.4 0.9 3.4 0.2 -0.1 0.1 0.8 Congruence Mental Well-being 6.7* 3.9* 7.8 45.6 6.1 52.3 5.5 49.4 7.1 1.3 3.4 10.04 1.5 0.01 Anxiety 5.5 7.5 4.4 3.3 2.8 5.8 -4.1*0.9 -6.5 -1.6 -1.6* 0.6 -3.2 -0.02 Depression 6.6 5.2 3.6 2.9 5.9 5.1 -3* 0.9 -5.3 -0.7 -0.6 0.9 -2.9 1.8 Spiritual Well-being (SWB) 93.3 15.1 98.1 13.2 96.2 13.7 4.8 2.8 -2.6 12.1 2.9 2.2 -2.9 8.7 Total SWB: Religious Well-being 12.1 49.7 8.2 49.2 10.6 8.0 5.6 48.9 1.8 -4.030.3 1.2 -2.8 3.4 SWB: Existential Well-5.7 5.8 47 6.2 2.6 6.5 44.4 48.4 4 1.7 -0.48.4 1.5 -1.3 Being

Table 6 continued	Base	eline	3 M	onths	6 M	onths	Mean Change at	SE	95% CI f		Mean change at	SE		for mean rence
	M	SD	M	SD	M	SD	3 months		Lower	Upper	6 months		Lower	Upper
Religious Love	17.7	3.6	18.1	2.3	17.9	3.9	0.4	0.5	-0.9	1.7	0.2	0.2	-0.3	0.6
ATG Avoidance	2.4	1.39	2.0	1.10	2.3	1.38	-0.4	0.2	-0.9	0.1	-0.1	0.2	-0.6	0.3
ATG Anxiety	2.9	1.19	2.6	1.25	3.2	1.44	-0.4	0.3	-1.01	0.3	0.3	0.3	-0.6	1.1
Energy Expenditure (Kcal)	3173	711	3079	744	3158	642	-93	43	-208	22	-14	59	-172	143
Nutritional Intake: Energy Without Alcohol (Kcal)	2131	1278	1713	551	2018	1311	-418	370	-1415	580	-112	71	-304	79
Nutritional Intake: Energy (Kcal)	2150	1271	1711	546	2056	1301	-439	366	-1426	549	-93	69	-281	94
Protein (g)	67.0	12.7	66	16.2	69.1	13.5	-1.0	2.4	-7.6	5.5	2.1	1.3	-1.4	5.6
Carbohydrate (g)	211.1	50.9	202.2	56.4	203.5	46.8	-8.9	6.1	-25.2	7.4	-7.6	10.2	-34.9	19.7
Complex Carbohydrate (g)	101.2	32.9	105.4	30.9	120.7	37.4	4.2	6.5	-13.4	21.8	19.5	8.8	-4.1	43.1
Sugar (g)	88.4	35.8	81.3	35.3	77.1	26.1	-7.1	3.8	-17.3	3.2	-11.3	6.1	-27.6	5.1
Fibre (g)	18.0	6.2	15.7	8.1	16.8	7.5	-2.3	1.4	-6.1	1.5	-1.2	1.04	-3.4	1.6
Fat (g)	71.5	26.2	64.2	32.5	61.3	24.3	-7.3	5.9	-23.1	8.5	-10.2	4.8	-23.1	2.7
Saturated Fatty acids (g)	26.8	10.9	24.4	12.6	21.7	7.9	-2.4	2.2	-8.4	3.6	-5.1	2.1	-10.6	0.4
Mono-unsaturated fatty acids (g)	23.4	9.3	21.1	11.6	20.2	8.6	-2.3	2	-7.8	3.1	-3.2	2.04	-8.7	2.3
Poly-unsaturated fatty acids (g)	10.5	3.9	9.6	4.9	10.6	4.2	-0.9	0.8	-3.1	1.3	0.2	0.7	-1.7	2.1
Sodium (mg)	1894	483.7	1658	760.7	1851	617.6	-236	138.9	-610.5	137.9	-43	113.4	-348.6	262.6
Salt Equivalence (g)	4.7	1.2	4.2	1.9	4.6	1.5	-0.6	0.4	-1.5	0.4	-0.1	0.3	-0.9	0.7
Calcium (mg)	709	194.8	631	264.1	675	209.8	-77.1	60.4	-239.7	85.6	-33.9	32.8	-122.3	54.5
Potassium (mg)	2519	602.4	2272	827.4	2577	581.2	-247.1	222.0	-845.2	350.9	58.2	82.5	-164.2	280.5
Magnesium (mg)	202	73.4	180	81.6	228	84.2	-21	20.1	-75.3	33	26.5	2.3	-6.6	59.6
Phosphorus (mg)	963	193.6	881	309.1	1079	236.04	-81	83.1	-305.2	142.6	117.1	51.9	-22.9	257.1
					4.0.4									

8.5

Iron (mg)

0.8

7.9

0.9

10.1

0.6

1.6

0.9

-0.9

4.2

-0.6

0.7

1.3

-2.5

Bas	eline		of	mon	ths from	Mean change Baseline -	SE			Mean change Baseline -	SE		for mean erence
M	SD	M	SD	M	SD	3 months		Lower	Upper	9 months		Lower	Upper
6.6	1.4	6.3	2.3	8.4	2.9	-0.4	0.5	-1.7	0.99	1.8	0.8	-0.3	3.9
0.9	0.2	0.8	0.3	1.1	0.5	-0.1	0.1	-0.4	0.1	0.2	0.2	-0.2	0.7
100	45	90	46.6	99	43.2	-9.6	11.1	-39.4	20.2	-1.3	6.5	-18.9	16.2
1.2	0.4	1.1	0.5	1.4	0.5	-0.1	0.1	-0.3	0.2	0.2	0.1	-0.1	0.5
12.6	45.2	12.9	45.1	12.7	45.1	0.4	0.5	-0.9	1.8	0.1	0.1	-0.2	0.4
15.8	6.8	15.5	7.6	17.7	6.3	-0.3	1.3	-3.9	3.3	1.9	1.4	-1.9	5.8
1.3	0.5	1.2	0.6	1.4	0.5	-0.1	0.1	-0.3	0.2	0.1	0.1	-0.2	0.5
3.8	1.4	3.4	1.4	4.3	2.5	-0.40	0.48	-1.69	0.89	0.53	0.66	-1.25	2.3
205	47	194	63.3	211	59.9	-9.9	19.1	-61.3	41.4	7.1	16.6	-37.5	51.7
1.5	1.3	1.4	1.28	2.1	1.5	-0.08	0.26	-0.78	0.6	0.6	0.4	-0.4	1.6
	M 6.6 0.9 100 1.2 12.6 15.8 1.3 3.8 205	6.6 1.4 0.9 0.2 100 45 1.2 0.4 12.6 45.2 15.8 6.8 1.3 0.5 3.8 1.4 205 47	M SD M 6.6 1.4 6.3 0.9 0.2 0.8 100 45 90 1.2 0.4 1.1 12.6 45.2 12.9 15.8 6.8 15.5 1.3 0.5 1.2 3.8 1.4 3.4 205 47 194	of intervention) M SD M SD 6.6 1.4 6.3 2.3 0.9 0.2 0.8 0.3 100 45 90 46.6 1.2 0.4 1.1 0.5 12.6 45.2 12.9 45.1 15.8 6.8 15.5 7.6 1.3 0.5 1.2 0.6 3.8 1.4 3.4 1.4 205 47 194 63.3	M SD M SD M 6.6 1.4 6.3 2.3 8.4 0.9 0.2 0.8 0.3 1.1 100 45 90 46.6 99 1.2 0.4 1.1 0.5 1.4 12.6 45.2 12.9 45.1 12.7 15.8 6.8 15.5 7.6 17.7 1.3 0.5 1.2 0.6 1.4 3.8 1.4 3.4 1.4 4.3 205 47 194 63.3 211	of intervention) months from baseline) M SD M SD M SD 6.6 1.4 6.3 2.3 8.4 2.9 0.9 0.2 0.8 0.3 1.1 0.5 100 45 90 46.6 99 43.2 1.2 0.4 1.1 0.5 1.4 0.5 12.6 45.2 12.9 45.1 12.7 45.1 15.8 6.8 15.5 7.6 17.7 6.3 1.3 0.5 1.2 0.6 1.4 0.5 3.8 1.4 3.4 1.4 4.3 2.5 205 47 194 63.3 211 59.9	of intervention) months from baseline) change Baseline - 3 months M SD M SD M SD 3 months 6.6 1.4 6.3 2.3 8.4 2.9 -0.4 0.9 0.2 0.8 0.3 1.1 0.5 -0.1 100 45 90 46.6 99 43.2 -9.6 1.2 0.4 1.1 0.5 1.4 0.5 -0.1 12.6 45.2 12.9 45.1 12.7 45.1 0.4 15.8 6.8 15.5 7.6 17.7 6.3 -0.3 1.3 0.5 1.2 0.6 1.4 0.5 -0.1 3.8 1.4 3.4 1.4 4.3 2.5 -0.40 205 47 194 63.3 211 59.9 -9.9	M SD 3 months 6.6 1.4 6.3 2.3 8.4 2.9 -0.4 0.5 0.9 0.2 0.8 0.3 1.1 0.5 -0.1 0.1 100 45 90 46.6 99 43.2 -9.6 11.1 1.2 0.4 1.1 0.5 1.4 0.5 -0.1 0.1 12.6 45.2 12.9 45.1 12.7 45.1 0.4 0.5 15.8 6.8 15.5 7.6 17.7 6.3 -0.3 1.3 1.3 0.5 1.2 0.6 1.4 0.5 -0.1 0.1 3.8 1.4 3.4 1.4 4.3 2.5 -0.40 0.48 205 47 194 63.3 211 59.9 -9.9 19.1	M SD M SD M SD M SD M SD M Lower 6.6 1.4 6.3 2.3 8.4 2.9 -0.4 0.5 -1.7 0.9 0.2 0.8 0.3 1.1 0.5 -0.1 0.1 -0.4 100 45 90 46.6 99 43.2 -9.6 11.1 -39.4 1.2 0.4 1.1 0.5 1.4 0.5 -0.1 0.1 -0.3 12.6 45.2 12.9 45.1 12.7 45.1 0.4 0.5 -0.9 15.8 6.8 15.5 7.6 17.7 6.3 -0.3 1.3 -3.9 1.3 0.5 1.2 0.6 1.4 0.5 -0.1 0.1 -0.3 3.8 1.4 3.4 1.4 4.3 2.5 -0.40 0.48 -1.69 205 47 194 63.3	M SD M SD M SD M SD M SD M SD Jamenths Lower Upper 6.6 1.4 6.3 2.3 8.4 2.9 -0.4 0.5 -1.7 0.99 0.9 0.2 0.8 0.3 1.1 0.5 -0.1 0.1 -0.4 0.1 100 45 90 46.6 99 43.2 -9.6 11.1 -39.4 20.2 1.2 0.4 1.1 0.5 1.4 0.5 -0.1 0.1 -0.3 0.2 12.6 45.2 12.9 45.1 12.7 45.1 0.4 0.5 -0.9 1.8 15.8 6.8 15.5 7.6 17.7 6.3 -0.3 1.3 -3.9 3.3 1.3 0.5 1.2 0.6 1.4 0.5	M SD Lower Upper 9 months 6.6 1.4 6.3 2.3 8.4 2.9 -0.4 0.5 -1.7 0.99 1.8 0.9 0.2 0.8 0.3 1.1 0.5 -0.1 0.1 -0.4 0.1 0.2 100 45 90 46.6 99 43.2 -9.6 11.1 -39.4 20.2 -1.3 1.2 0.4 1.1 0.5 1.4 0.5 -0.1 0.1 -0.3 0.2 0.2 12.6 45.2 12.9 45.1 12.7 45.1 0.4 0.5 -0.9 1.8 0.1 15.8 6.8 15.5 7.6 17.7 6.3 -0.3 1.3 -3.9 3.3 1.9 1.3 0.5 1.2	$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	M SD A C.04 0.5 -0.1 0.1 -0.4 0.1 0.2 0.2 0.2 0.2 0.2 0.1 -0.1 0.1

-4.4

-9.5

-0.9

-3.8

-289

20.9

6.6

0.7

4.9

407

-60.6

-27.2

-2.7

-17.2

-1387

53.4

6.7

0.2

4.7

-53

51.8

8.3

0.9

9.6

809

155.6

3.4

0.6

1.7

161

-365.7

-2.5

-1.5

-0.01

-489

472.5

15.8

1.9

9.3

382

Table 6 Continued

Vitamin A (µg)

Vitamin C (mg)

Vitamin E (mg)

Beta-carotene (µg)

Selenium (µg)

327

63.0

7.2

31

2125

331

33.9

2.9

14

1435

322

53.6

6.3

27.3

1836

338.9

36.1

3.9

13.3

1142.6

380

69.7

7.5

35.8

2072

593.6

32.9

2.9

12.2

1386

4.5 Changes in Religious Social Support and Organisational Religiosity

Religious involvement at an organisational level, and religious social support variables were only measured at three months and nine months from baseline. These variables were not measured at baseline because participants did not have any group interaction at baseline.

A paired samples t-test was conducted on these variables, to investigate mean differences in these variables between three months and nine months from baseline. There was a statistically significant mean increase in organisational religiosity as measured by the first two items of the DUREL scale, religious social support sub-scale; emotional support received. These were of a magnitude of 0.1 on a scale ranging from 2-10, and 0.1 on a scale ranging from 4 to 20 respectively. There was also a statistically significant mean decrease in the remaining three sub-scales of the religious social support scale (-0.1); emotional support provided (-0.1), negative interactions in the groups (-0.1) and anticipated support (-0.3). (Table 7).

Table 7: Paired samples t-test displaying the changes in organisational religiosity and religious social support between 3 and 6 months

		hs (End of vention)	6 months (9 months from baseline)		Mean difference	SD	95% CI for mean difference	
Outcomes	Mean	SD	Mean	SD			Lower	Upper
DUREL	9.9	2	10.1	2.4	0.1*	0.9	-0.3	0.6
RSS: Emotional support received	9.2	2.7	9.4	3.2	0.1*	1.4	-0.6	0.8
RSS: Emotional support provided	8.8	2.9	8.7	2.8	-0.1*	1.9	-1.1	0.9
RSS: negative interactions	4.6	1.4	4.4	1.2	-0.1*	1	-0.6	0.4
RSS: Anticipated support	9.8	3.3	9.5	3.2	-0.3*	1.9	-1.3	0.7

NOTE: * P < 0.01.

4.6 Regression Analysis

Linear regression analysis using the stepwise method were conducted to further explore the significant changes in outcomes. Due to the small sample size stepwise method was chosen to ensure stable models were produced. It was expected that changes in outcomes were associated with other outcomes measured in the study,

correlation analyses adjusted using Bonferroni were conducted (Appendix O). Bonferroni correction is an adjustment made to P values when several dependent or independent statistical tests are being performed simultaneously on a single data set (Field 2013). The Bonferroni correction is used to reduce the chances of obtaining false-positive results (type I errors) when multiple pair wise tests are performed (Field 2013). As we conducted multiple tests we applied the Bonferonni correction. Where there were significant associations, these were entered into the regression models to explore the associations between variables.

4.6.1 Associations with Changes at Three-Month Follow-Up

Quality of Life Visual - Analogue Scale (QOL VAS)

QOL VAS increased by a mean of 11.7, measured on scale ranging from 0 to 100. When uncontrolled eating behaviour, cognitive restrained eating behaviour, and avoidant attachment style with God were entered into the regression model a two-step model was produced.

In the first step, change in cognitive restrained eating behaviour was associated with QOL VAS such that as cognitive restrained eating behaviour scores increased by one unit on a scale of 0-100, QOL VAS scores increased by 0.6 units. In the second step, avoidant attachment style with God was added, and as participants scores increased by one unit on a scale of 7-2, QOL VAS decreased by 10.2 units (Table 8).

Table 8: Linear regression analysis for the association between change in QOL VAS with; uncontrolled eating behaviour, cognitive restrained eating behaviour, and avoidant attachment style with God

Model		Regression coefficients	95 % Confider	nce interval	P value
		coefficients	Lower Bound	Upper Bound	-
1	(Constant)	5.1	-2.7	12.9	0.2
	Change in cognitive restrained eating behaviour	0.6	0.2	1	0.006
2	(Constant)	2.2	-4.5	8.9	0.5
	Change in cognitive restrained eating behaviour	0.5	0.1	0.8	0.01
	Change in avoidant attachment style with God	-10.2	-17.38	-2.9	0.01

Uncontrolled Eating Behaviour

Uncontrolled eating behaviour reduced by a mean of 16.5, measured on scale ranging from 0 to 100. When changes in; QOL VAS, eating for physical rather than emotional reasons and mental well-being were entered into the regression model, eating for physical reasons rather than emotional reasons was significantly associated with uncontrolled eating behaviour. Such that as participants eating for physical reasons score increased by one unit on scale ranging from 1 -5, uncontrolled eating behaviour decreased by 16.7 units (Table 9).

Table 9: Linear regression analysis for the association between changes in uncontrolled eating behaviour with OOL-VAS eating for physical reasons rather than emotional reasons and mental well-being

Mode	el	Regression	95% confider	95% confidence interval		
			Lower Bound Bound	Upper		
1	(constant)	-5.3	-14.7	4.0	0.3	
	Change in Eating for Physical Reasons rather than Emotional Reasons	-16.7	-27.3	-6.1	0.004	

<u>Cognitive Restrained Eating Behaviour</u>

Cognitive restrained eating behaviour increased by a mean of 11.1, measured on a scale ranging from 0 to 100. When changes in energy intake, QOL VAS, body food-choice congruence, mental well-being, depression, spiritual well-being and existential well-being were entered into the regression model, a two-step model was produced.

In the first step, change in existential well-being was the only variable entered. As participant existential well-being scores increased by one unit on a scale of 10-60, cognitive restrained eating behaviour scores increased by 1.4 units on a scale of 0-100. In the second step, QOL VAS was added, and as participants QOL VAS scores increased by one unit on a scale of 0-100, cognitive restrained eating behaviour increased by half a unit (Table 10).

Table 10: Linear regression analysis for the association between changes in cognitive restrained eating behaviour with; change in energy intake, QOL-VAS, body food-choice congruence, mental well-being, depression, spiritual well-being and existential well-being

Model		Regression	95% confid	95% confidence interval		
		coefficients	Lower bound	Upper bound		
1	(constant)	7.2	-0.3	14.6	0.06	
	Change in Existential Well-Being	1.4	0.5	2.3	0.005	
2	(Constant)	2.5	-4.2	9.1	0.4	
,	Change in Existential Well-Being	1.1	0.4	1.9	0.005	
	Change in QOL-VAS	0.5	0.2	0.8	0.007	

Emotional Eating Behaviour

Emotional eating behaviour reduced by a mean of 19.4, as measured on a scale ranging from 0-100. Changes in intuitive eating scores, eating for physical reasons rather than emotional, reliance on hunger cues, and body food choice congruence, were entered in the regression model.

Intuitive eating was significantly associated with emotional eating behaviour, such that as participants intuitive eating score increased by one unit on a scale ranging from 1-5 emotional eating decreased by 18.7 units (Table 11).

Table 11: Linear regression analysis for the association between changes in emotional eating behaviour with intuitive eating scores, eating for physical reasons rather than emotional, reliance on hunger cues, and body food choice congruence.

Mode	el	Regression	95% confide	P value	
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	-8.1	-17.9	1.9	0.1
	Change in intuitive eating	-18.7	-31.1	-6.3	0.006

Eating for Physical Reasons Rather than Emotional Reasons

Eating for physical reasons rather than emotional reasons increased by a mean 0.7, as measured on a scale ranging from 1 to 5. When changes in uncontrolled eating, and emotional eating were entered into the regression model, a two-step model was produced.

In the first step the change in eating for physical reasons rather than emotional reasons was significantly associated with uncontrolled eating, such that as uncontrolled eating increased by one unit on a scale ranging from 0-100, eating for physical reasons rather than emotional reasons decreased by 0.03 units. In the second step, eating for physical reasons rather than emotional reasons was added,

as emotional eating increased by one unit on a scale ranging from 0-100, eating for physical reasons rather than emotional reasons decreased by 0.02 units (Table 12).

Table 12: Linear regression analysis for the association between changes in eating for physical reasons rather than emotional reasons with: uncontrolled eating and emotional eating.

Model		Regression	95% confid	ence interval	P value
		coefficients	Lower bound	Upper bound	
1	(constant)	0.3	-0.1	0.6	0.1
	Change in Uncontrolled Eating	-0.03	-0.04	-0.01	0.004
2	(Constant)	0.04	-0.3	0.4	8.0
	Change in Uncontrolled Eating	-0.02	-0.03	-0.01	0.01
	Change in Emotional Eating	-0.02	-0.03	-0.002	0.03

Reliance on Hunger cues

Reliance on hunger increased by a mean of 1.1, measured on a scale ranging from 1 to 5. The regression model exploring the association between changes in reliance on hunger with; emotional eating, showed change in reliance on hunger was significantly associated with emotional eating. Such that as emotional eating increased by one unit on a scale ranging from 0-100, reliance on hunger decreased by 0.03 units (Table 13).

Table 13: Linear regression analysis for the association between changes in changes in reliance on hunger with: emotional eating

Model		Regression	95% confide	P value	
		coefficients	Lower bound	Upper bound	
1	(constant)	0.5	-0.02	1.01	0.06
	Change in Emotional Eating	-0.03	-0.05	-0.01	0.01

Mental Well-Being

Mental well-being increased by a mean of 6.7, as measured on a scale ranging from 14 to 70. Changes in systolic blood pressure, BMI, uncontrolled eating behaviour, cognitive restrained eating behaviour and spiritual well-being were entered into the regression model, a three-step model was produced.

In the first step, change in uncontrolled eating behaviour was the only variable entered. As participant's uncontrolled eating behaviour scores increased by one unit on a scale of 0-100, change in mental well-being decreased by 0.2 units on a

scale of 14 to 70. In the second step, change in spiritual well-being was added, as participant's spiritual well-being score increased by one unit on a scale of 20 to 120, change in mental well-being increased by 0.2 units. In the third step, change in BMI was added, as participant's BMI increased by one unit, mental well-being decreased by -2.2 units (Table 14).

Table 14: Linear regression analysis for the association between changes in mental well-being with; systolic blood pressure, BMI, uncontrolled eating behaviour cognitive restrained eating behaviour and spiritual well-being

Model		Regression	95% confider	ice interval	P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	3.36	0.1	6.6	0.04
	Change in uncontrolled eating	-0.2	-0.3	-0.06	0.01
	behaviour				
2	(Constant)	2.6	-0.3	5.6	0.07
	Change in Uncontrolled eating	-0.2	-0.3	-0.1	0.01
	behaviour				
	Change in spiritual well-being	0.2	0.02	0.4	0.03
3	(Constant)	1.9	-0.8	4.5	0.2
	Change in Uncontrolled Eating	-0.2	-0.3	-0.05	0.01
	behaviour				
	Change in Spiritual Well-being	0.2	0.05	0.3	0.01
	Change in BMI	-2.2	-4.2	-0.2	0.03

Anxiety

Anxiety reduced by a mean of 4.1, measured on a scale ranging from 0 to 21.

Changes in depression and avoidant attachment style with God were entered into the regression model, a two-step model was produced.

In the first step, avoidant attachment style with God was entered, where as participants score increased by one unit on a scale of 7 to 21, anxiety increased by 3.4 units. In the second step, depression was added, and as depression increased by one unit on a scale of 0-27, anxiety increased by half a unit (Table 15).

Table 15: Linear regression analysis for the association between changes in anxiety with; depression and avoidant attachment style with God

Model		Regression	95% confidence interval		P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	-2.7	-4.4	-0.9	0.01
	Change in avoidant attachment with	3.4	1.4	5.5	0.002
	God				
2	(Constant)	-1.5	-3.2	0.2	0.09
	Change in avoidant attachment with	2.9	1.1	4.7	0.003
	God				
	Change in Depression	0.5	0.1	0.8	0.02

4.6.2 Associations with Changes at Six-Month Follow-Up (Nine Months from Baseline)

Uncontrolled Eating Behaviour

At six-months, uncontrolled eating behaviour had reduced by a mean of 13.4, as measured on a scale ranging from 0-100. Changes in dietary intake of sugar, body fat, intuitive eating, eating for physical reasons rather than emotional reasons, body food-choice congruence, mental well-being, and anxiety were entered into the regression model.

The regression model found only change in body food-choice congruence was significantly associated with uncontrolled eating behaviour. As participant's body food-choice congruence score increased by one unit on a scale of 1 to 5, uncontrolled eating behaviour decreased by 25.1 units (Table 16).

Table 16: Linear regression analysis for the association between changes in uncontrolled eating behaviour with; dietary intake of sugar, body fat, intuitive eating, eating for physical reasons rather than emotional reasons, body food-choice congruence, mental well-being, and anxiety.

Model	•	Regression	95% confide	nce interval	P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	-0.7	-8.1	6.8	0.8
	Change in body food-choice congruence	-25.1	-34.7	-15.5	0.001

Emotional Eating Behaviour

At six-months emotional eating behaviour had reduced by a mean of 16.7, as measured on a scale from 0 - 100.

When changes in nutritional intake of fat, saturated fat, systolic blood pressure, intuitive eating and eating for physical rather than emotional reasons were entered into a regression model, a two-step model was produced.

In the first step, intuitive eating was added, as participant's intuitive eating scores increased by one unit on a scale of 1 to 5 participants emotional eating decreased by 27 units. In the second step, eating for physical reasons rather than emotional reasons was added, as participants eating for physical rather than emotional reasons score increased by one unit of a scale of 1 to 5, emotional eating behaviour decreased by 10.5 units (Table 17).

Table 17: Linear regression analysis for the association between changes in emotional eating behaviour with nutritional intake of fat, saturated fat, systolic blood pressure, intuitive eating and eating for physical rather than emotional reasons.

Model		Regression	95% confidence interval		P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	-3.5	-11.8	4.8	0.4
	Change in intuitive eating	-26.9	-39.8	-13.9	0.001
2	(Constant)	-0.6	-8.4	7.2	0.9
	Change in intuitive eating	-18.9	-32.5	-5.3	0.01
	Change in eating for physical rather	-10.5	-20.4	-0.6	0.04
	than emotional reasons.				

Intuitive Eating

Intuitive eating increased by a mean of 0.5 units, as measured on a scale ranging from 1 to 5. When changes in uncontrolled eating, and emotional eating were entered in to the regression model. Only emotional eating was significantly associated with change in intuitive eating behaviour, such that as emotional eating increased by one unit on a scale of 0-100, intuitive eating decreased by 0.03 units (Table 18).

Table 18: Linear regression analysis to explore the association between changes in intuitive eating with; uncontrolled eating, emotional eating.

unco	ntroned eating, emotional eating.				
Model		Regression	Regression 95% confidence interval		
		coefficients	Lower Bound	Upper	
		Bound			
1	(constant)	0.1	-0.1	0.3	0.4
	Change in Emotional Eating	-0.03	-0.04	-0.02	0.001

Eating for physical reasons rather than emotional reasons

Eating for physical reasons rather than emotional reasons increased by a mean of 0.6 units, as measured on a scale ranging from 1 to 5. When change in energy intake, nutritional intake of carbohydrates, sugar, fat, mono-unsaturated fat, uncontrolled eating, emotional eating, intuitive eating and body food choice congruence were entered into the regression model, a two-step model was produced.

In the first step, uncontrolled eating behaviour was added, as uncontrolled eating behaviour increased by one unit on a scale of 0 to 100, eating for physical reasons rather than emotional reasons decreased by 0.02 units. In the second step,

emotional eating was added, as emotional eating increased by one unit on a scale of 0 to 100, eating for physical reasons rather than emotional reasons decreased by 0.02 units (Table 19).

Table 19: Linear regression analysis to explore the association between changes in eating for physical reasons rather than emotional reasons with; change in energy intake, nutritional intake of carbohydrates, sugar, fat, mono-unsaturated fat, uncontrolled eating, emotional eating, intuitive eating and body food-choice congruence

Model	0 (57)	Regression coefficients	95% confidence interval		P value
			Lower bound	Upper bound	
1	(constant)	0.4	0.08	0.6	0.02
	Change in uncontrolled eating	-0.02	-0.04	-0.01	0.001
2	(Constant)	0.1	-0.2	0.4	0.4
	Change in Uncontrolled eating	-0.02	-0.03	-0.01	0.003
	Change in Emotional Eating	-0.02	-0.03	-0.008	0.004

Reliance on Hunger Cues

Reliance on hunger increased by a mean of 0.8 units, as measured on a scale ranging from 1 to 5.

The regression model found change in spiritual well-being was significantly associated with reliance on hunger cues. This change in reliance on hunger was significantly associated with spiritual well-being such that, as spiritual well-being on a scale of 20 to 120 increased by one unit reliance on hunger cues also increased by 0.1 units (Table 20).

Table 20: Linear regression analysis to explore the association between changes in reliance on hunger with: spiritual well-being

Model		Regression	95% confid	ence interval	P value
1 (constant) Change in Spiritual well-being	coefficients	Lower bound	Upper bound		
	(constant)	0.7	0.2	1.1	0.01
	Change in Spiritual well-being	0.1	0.0001	0.1	0.04

Body Food-Choice Congruence

Body Food-Choice Congruence increased by a mean of 0.4 units, measured on a scale ranging from 1 to 5. Changes in dietary intake of sugar and MUFA, uncontrolled eating, cognitive restrained eating and eating for physical reasons

rather than emotional, were entered into the regression model, a two-step model was produced.

In the first step uncontrolled eating behaviour was added, as uncontrolled eating behaviour increased by one unit on a scale of 0 to 100, participant's body food-choice congruence score decreased by 0.3 units. In the second step, cognitive restrained eating behaviour was added, as cognitive restrained eating behaviour increased by one unit on a scale of 0 to 100, participant's body food-choice congruence score increased by 0.01 units (Table 21).

Table 21: Linear regression analysis to explore the association between changes in body food-choice congruence with; dietary intake of sugar and MUFA, and uncontrolled eating, cognitive restrained eating and eating for physical reasons rather than emotional reasons.

Model	-	Regression	95% confid	ence interval	P value
		coefficients	Lower bound	Upper bound	
1	(constant)	0.1	-0.1	0.4	0.3
	Change in Uncontrolled Eating	-0.03	-0.04	-0.02	0.001
2	(Constant)	0.3	-0.2	0.3	8.0
	Change in Uncontrolled Eating	-0.03	-0.03	-0.02	0.001
	Change in Cognitive Restrained	0.01	0.001	0.02	0.03
	Eating				

Mental Well-Being

Mental well-being increased by a mean of 3.9, as measured on a scale ranging from 14 to 70.

When changes in dietary intake of fat, saturated fat, QOL VAS, uncontrolled eating and anxiety were entered into a stepwise multiple regression, only anxiety was significantly associated with change in mental well-being. Such that as participant's anxiety scores increased by one unit on a scale of 0 to 21, participants mental well-being scores decreased by 1.7 units (Table 22).

Table 22: Linear regression analysis to explore the association between changes in mental well-being and dietary intake of fat, saturated fat, OOL VAS, uncontrolled eating and anxiety

Model		Regression	95% confidence interval		P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	1	-1.8	3.8	0.5
	Change in anxiety	-1.7	-2.7	-0.8	0.001

Anxiety

Anxiety reduced by a mean of 1.6 units, as measured on a scale ranging from 0 to 21. When changes in dietary intake of sodium and calcium and uncontrolled eating behaviour, mental well-being, and religious love were entered into the regression model, a two-step model was produced.

In the first step, mental well-being was added, as participant's mental well-being score increased by one unit on a scale of 14-70, anxiety decreased by 0.3 units. In the second step sodium was added, and this showed that as participants sodium intake increased by one unit, anxiety decreased by 0.003 units (Table 23).

Table 23: Linear regression analysis to explore the association between change in anxiety with; nutritional intake of sodium and calcium and uncontrolled eating behaviour, mental well-being, and

religious love

Model		Regression	95% confidence interval		P value
		coefficients	Lower Bound	Upper	
			Bound		
1	(constant)	-0.4	-1.6	0.7	0.4
	Change in Mental Well-being	-0.3	-0.5	-0.1	0.001
	(Constant)	-0.8	-1.8	0.1	0.09
	Change in Mental Well-being	-0.2	0.4	-0.1	0.004
	Change in Sodium intake	-0.003	-0.01	-0.001	0.01

In this chapter I have presented the quantitative findings of this PhD, in the following chapter I will present the qualitative findings of this PhD. The qualitative findings illuminate the main quantitative findings, which will be demonstrated in the quotes used, and discussed further in the discussion.

5 Results of the Embedded Qualitative Studies

Introduction to Chapter 5

This chapter will present the results of the embedded qualitative studies. It is presented through the following two sections.

In the first section (5.1) I present the results of the qualitative study exploring the facilitator's experiences. In the second section (5.2) I present the qualitative findings of the participant's engagement with and acceptability of the programme.

5.1 Embedded Qualitative Study (Facilitator Acceptability)

Three facilitators volunteered to deliver the intervention. One facilitator was a church minister of pastoral care and two facilitators were school teachers by profession. Each facilitator had good interpersonal and leadership skills. This was evidenced by their own professional training and by previous volunteer work within the church, particularly with respect to facilitating small groups. The lay facilitators were not from a healthcare background and their experience in dealing with people who had significant weight and food issues was limited. The lay facilitators were trained around programme content, the importance of listening and supporting participants' own behaviour change solutions rather than providing advice, and when to signpost individuals to healthcare professionals. Initially, sessions were demonstrated by myself and the PI, however facilitators took on more responsibility for delivery as the programme progressed. The PI and I were available during the rest of the programme to support facilitators and check fidelity through observation.

5.1.1 Results of Facilitator Acceptability

Following close engagement with the data, two super-ordinate themes were identified: 'facilitating the group was not always easy' and 'developing more thorough training resources.' Both super-ordinate themes encapsulate sub-themes and are illustrated with extracts from the transcripts (Figure 6).

5.1.1.1 Theme 1: Facilitating the Group Was Not Always Easy

All facilitators had previous experience facilitating church groups, for example bible studies, and felt they understood what facilitating involved. However, when facilitators tried to translate their skills and experiences to facilitate participants on the Taste & See programme, facilitators discussed they struggled at times throughout the programme. Facilitator's struggles were captured through the following two sub-themes.

Subtheme 1: *The need to define the facilitator role*

All facilitators expressed a level of uncertainty around what the facilitator role actually is, in the context of Taste & See. Facilitators discussed whilst they were managing to support group discussions, they felt they needed further clarity around what they should be focusing on.

"I think generally it would have been good to have some advice on...what the facilitators were supposed to do, what they were supposed to ask."

[Extract 1, Facilitator 1]

"A little bit more clarity [around] the role you wanted us to play. I think that would have been the most helpful. I mean all the stuff is in the book or hand-outs and we have them in advance and we can read through and understand that stuff, but what do we do with it? How do we actually put it into practice?"

[Extract 2, Facilitator 2]

Facilitators felt some of the problems came from a lack of clarity around the objectives of the individual sessions. The objectives did not always provide enough direction for the facilitators to be able to guide discussions towards an end goal.

"What were the real objectives in that conversation? Was there a real objective or was it just an open time? If there were objectives, how are we going to get there... how much were we to be just somebody chatting within the group or [how much were we] actually pulling people towards an objective?

[Extract 3, Facilitator 2]

Subtheme 2: Challenges of identity: a facilitator or a participant?

Two of the facilitators on the programme also engaged with the materials as a participant. This created dissonance in the way they fulfilled the role of a facilitator, as balancing the two roles was not always easily achieved and it became hard to remain objective. This particular challenge again may have stemmed from not having a clear definition of the facilitator role.

"Yeah I was unsure what my role was, whether I'm supposed to be just part of it [and] encourage conversation or actually be the example setter or be the teacher."

[Extract 4, Facilitator 2]

"I think on one week I felt in reflection that I probably should have been more encouraging and practicing it than actually bringing my personal opinion."

[Extract 5, Facilitator 2]

5.1.1.2 Theme 2: Developing More Thorough Training Resources

The most dominant discourse that persisted across the facilitator interviews was around the need for more thorough training resources. This particular theme closely coincides with the first theme, as well as needing to clarify the role of the facilitator, facilitators highlighted several training needs they felt were unmet. The data for this theme has been presented through three sub themes.

Subtheme 1: *Managing difficult and dominant group members:*

One of the key training needs facilitators identified were around managing difficult and dominant group members. The majority of the facilitators identified they had individuals in their groups who took over discussions, leaving little time for others to speak.

"I was just thinking earlier about some difficult people. There was a difficult person in my group who I [found] difficult to manage because they weren't allowing other people to speak. I really had to put in some more tactics for that group, but perhaps that goes back to the initial facilitators training."

[Extract 6, Facilitator 1]

Dominant members made it difficult for facilitators to manage the groups. All of the facilitators noted whilst they tried to manage issues with group members the best way they could during sessions, they would like more support with this issue, if they were to facilitate the programme again.

Subtheme 2: Being more prepared for the range of issues that arise.

All the facilitators had no clinical experience, and so the range of issues that came up during sessions were unexpected. Facilitators felt they needed to be better prepared for the range of issues they could encounter as they learned about issues they never thought could be relevant to weight management during their experiences of facilitating the programme.

"I didn't think people were going to have such massive issues. I thought it was basically well, just stop eating so much... but I've discovered it's more complicated than that."

[Extract 7, Facilitator 1]

"Another thing I was thinking was having advice or information on the sorts of issues people are going to have... I had someone in my group who had eating disorder issues and I didn't know and I didn't know what to do about it..."

[Extract 8, Facilitator 1]

Subtheme 3: More advice about boundaries to ensure beneficence.

Facilitators also highlighted the need for advice around boundaries when listening to and supporting others, particularly during sessions like 'facing the past' where issues like adverse childhood experiences were discussed.

"What I'm just wary of is going digging, which is what we were doing really and then digging something up that is a lot bigger. [We need to] make sure that [the] person is in a position where they can handle [it, and] take it to a counsellor."

[Extract 9, Facilitator 3]

Related to this, facilitators also acknowledged the importance of staying non-judgemental, and being sensitive to participants but at times they found this difficult to achieve.

"I think one of the challenges is staying completely non-judgemental, even if you think you're [not] judging it's easy to say something that someone else can then feel they're being judged."

[Extract 10, Facilitator 3]

Facilitators identified that they were consistently remaining mindful of what they were saying, but this was still an area they felt they wanted more support with.

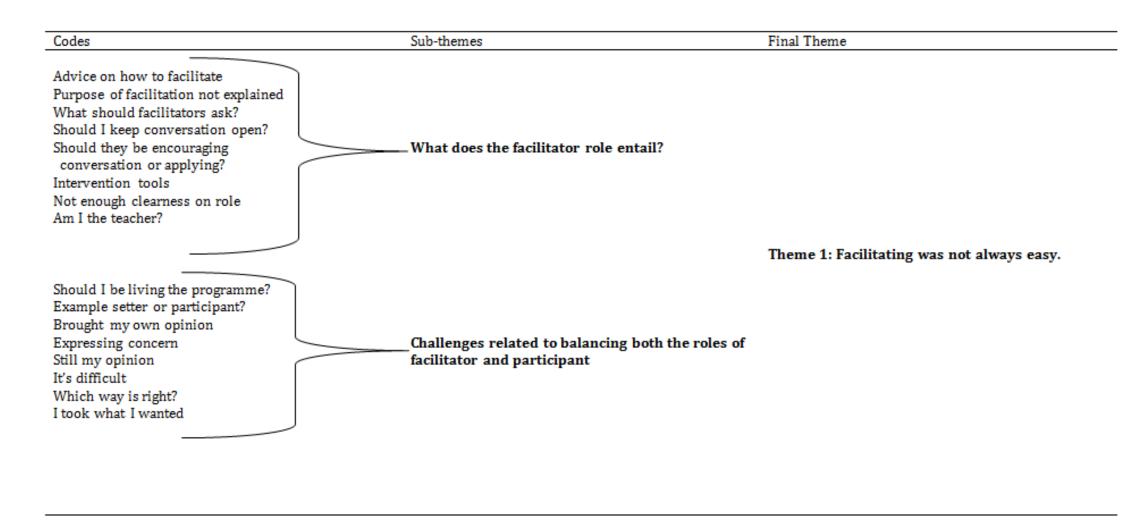


Figure 6: Thematic map of the analysis process; displaying how codes were translated to themes

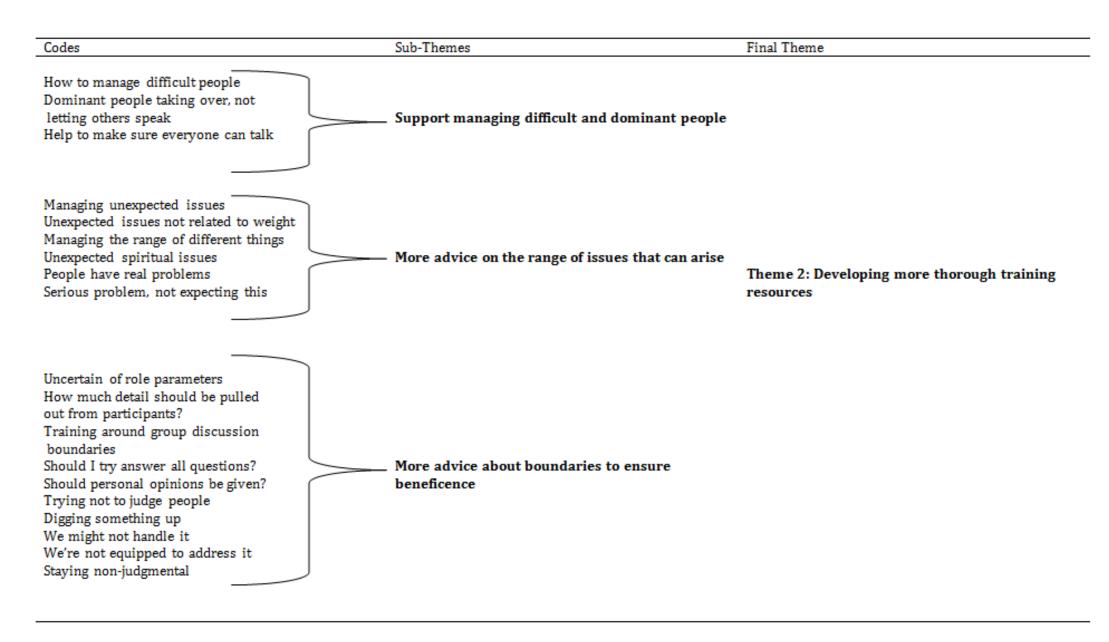


Figure 6: Thematic map of the analysis process; displaying how codes were translated to themes

5.2 Embedded Qualitative Study (Participant Acceptability and Engagement)

This section presents the qualitative findings of participant's acceptability of and engagement with the programme materials and contents.

5.2.1 Participants

Participants were purposively recruited, where all those who had taken part in the feasibility trial of Taste & See were invited to participate in the interview. A total of 15 participants took part in the semi-structured interviews post intervention during July –August 2015. Three participants could not participate in interviews due to time commitments involved. The interviews typically lasted between 30-40mins.

5.2.2 Participant Acceptability and Engagement Results

Following close engagement with the data, seven super-ordinate themes were identified: 'God and food issues had been kept separate', 'beginning to use faith as a resource', 'eating freely was a challenge', 'there is empowerment and enjoyment in freedom', 'addressing more than just a weight problem', 'coping with other group members', and 'journeying towards a healthier relationship with food'. All super-ordinate themes encapsulate sub-themes, and are illustrated with supporting extracts from the transcripts (Figure 7).

5.2.2.1 Theme 1: God and Food Issues Had Been Kept Separate

The religious component of this weight loss programme was a novel and salient experience for participants. The theme 'God and food issues were separate' illustrates the initial stages of participants' engagement with the religious component. This theme captures participants' initial thoughts and feelings about where God and their spirituality fit within their eating behaviour. The data for this theme has been organised into three sub-themes.

Subtheme 1: Food issues had never been taken to God before

Participants described how their faith was central to their lives; most of the participants actively engaged with their faith on a daily basis. At the start of the course, the idea of spirituality in relation to eating was a new concept that needed to be worked through as bringing God into their eating was not something participants had previously considered.

"When it comes to . . . eating healthy and all of that, no, I'd never attached that [to] God"

[Extract 1, Participant 1]

Subtheme 2: Food issues were considered too trivial for God

When participants started to consider the role God played in their food-related struggles, many participants believed the issues they experienced were too trivial for God to be interested in. Participants identified how they felt their eating behaviour was something they had to deal with by themselves, illustrating a reason why issues associated with food were not previously taken to God.

"At the beginning I did find it difficult . . . I felt it was trivial for God . . . taking things about eating and dieting and weight to Him."

[Extract 2, Participant 2]

"Previously I would have thought [issues related to weight] are just too trivial for God to be bothered about, [and] actually it was my responsibility to sort them out."

[Extract 3, Participant 3]

Subtheme 3: Shame prevented participants from bringing God into their eating

For many participants, the issues they had with food and the problems they faced represented great failures in their lives, whereas their relationship with God was viewed positively. Accounts from the participants suggested feelings of guilt and shame meant they deliberately kept God separate from their eating behaviour.

"I never brought them together because as far as I'm concerned my eating is a big, well, a failed area of my life; whereas my faith and my relationship with God has just gone from strength to strength. I always speak to God about how I'm feeling

emotionally and pray for help and support with all other areas; it [my eating] is one of those areas that I've kept very separate."

[Extract 4, Participant 4]

Some participants felt the problems they have with food and eating should be something they attempt to deal with themselves first before they take it to God, which further illustrates shame and the deliberate attempt to keep this issue away from God.

"I've always had the mind-set I'll take it to God, I'll pray about it, but I have to lose weight first."

[Extract 5, Participant 5]

5.2.2.2 Theme 2: Beginning To Use Faith as a Resource

The theme 'beginning to use faith as a resource' encompasses the next part of the participants' journey. It begins to show how participants engaged with the religious element as they progressed through the course; this has been captured through four sub-themes.

Subtheme 1: Realising God does want to help

From having never relinquished their weight-related struggles to God, participants transitioned to a place where they acknowledged God does want to help them with their weight-related struggles.

"I... found the fact that God does want to help me in this [overcoming emotional eating] helpful, because... it [was] something which I thought was trivial, really not something necessarily that God would be interested in."

[Extract 6, Participant 2]

This acknowledgement meant participants started to ask God for help with their issues related to food.

Subtheme 2: Drawing on faith to achieve a healthier relationship with food

As participants started to understand God wanted to help them, participants began drawing on their faith and applying their faith in different ways to help them. Some of the participants identified they were no longer just praying for weight loss,

rather they were praying specifically about certain areas they wanted help with. Participants noted how they were drawing on strength from God to help them.

"But obviously, it [weight loss] was not simple as just praying and it happens. Now I realise it's praying for the strength to be able to do [and] fulfil what it [is] that I actually want to happen; so I need the strength to be able to . . . make sure I . . . exercise regularly [and] make sure I'm content with [the] food I'm eating."

[Extract 7, Participant 6]

Some participants noted how perceiving their relationship with food through the lens of their faith meant they were reading and applying Bible verses in a whole new context. Interpreting their eating behaviours through what Bible scriptures teach, led participants to be more mindful about their motives behind eating.

"God's given us a brain and it's for understanding His word. Overindulgence, selfishness, greed, gluttony, those are things I didn't actually think about when you grew up and have at sort of meals."

[Extract 8, Participant 7]

"Everything is permissible but not everything is beneficial' that's given me... a clearer understanding of how I can stop, think, before I act, consider it, reflect on things, then go do it."

[Extract 9, Participant 7]

Subtheme 3: God's love as a catalyst for self-love

The content of the programme that considered God's love and acceptance led participants on a journey towards self-love and self-care. The quotes below demonstrate as participants began to see and love themselves the way God sees and loves them, they experienced a change in their motivation to manage their food and weight.

"This experience has taught me how to love myself, the love God has for me, and how precious my body is in all aspects—inside and out—so what I put in it is really important."

[Extract 10, Participant 1]

"God loves me as I am but wants me to love myself and lose some weight to be healthy"

[Extract 11, Participant 2]

Subtheme 4: No discomfort with, and applicability of, Christian spirituality

Some participants described despite not belonging to the Christian faith, the Christian spirituality discussed on the programme did not isolate them or pose as a barrier preventing them from participating. Participants reported they were comfortable with this element and it was not forced on them.

"I didn't feel pressured, no, I could take it or leave it. If I didn't want to pray—I didn't pray."

[Extract 12, Participant 8]

'I mean I felt even though I'm a non-Christian it was still . . . very applicable...there [was] very general well-being, good stuff . . . I didn't find that a barrier at all."

[Extract 13, Participant 6]

Participants felt they could identify with Christian spirituality despite not belonging to the Christian faith and they could still apply and relate the messages of this element to their eating behaviours.

"A lot the Bible readings were common sense, I mean there were a couple of times when I thought... I'm not sure of that one, but I don't think I was the only person, you know, and sometimes we thought, well, actually, no [I] don't really relate to that, and other times you just think, well, actually, you know, that's common sense whether you believe it comes from a God or a universe or whatever—for me it still makes sense."

[Extract 14, Participant 8]

5.2.2.3 Theme 3: Eating Freely Was a Challenge

Freedom from dietary restrictions formed another novel aspect of Taste & See. The theme 'eating freely was a challenge' explores participants' initial encounter with the 'unconditional permission to eat' element of intuitive eating. The data for this theme was captured using the three sub-themes presented below.

Subtheme 1: *Freedom felt dangerous*

When participants described their early thoughts about the freedom component of the intervention, participants used phrases like "playing with fire" and "a license to indulge" describing how freedom felt like a temptation to eat everything, which seemed counterintuitive to their reasons for joining the programme.

"It was really almost like opening the floodgates and saying right, okay, you can have everything; go and empty Tesco's."

[Extract 15, Participant 8]

Subtheme 2: *Freedom felt too good to be true*

For many participants, their initial thoughts about dietary freedom raised scepticism, because it was going against their existing beliefs about how to lose weight.

"Initially I was a bit sceptical, because it just seems like one of those diets that you see in the Daily Mail, like 'oh eat what you want and still lose 5 stone'. . . . It just seemed a bit too good to be true."

[Extract 16, Participant 6]

"Cos to me, losing weight is deprivation of something; you know, I didn't really see to begin with how you could not do that and lose weight."

[Extract 17, Participant 5]

Subtheme 3: Freedom gave rise to feelings of uncertainty about the programme's success

Whilst practicing intuitive eating, some of the interviews suggested freedom gave rise to feelings of uncertainty about successful weight loss. As participants ate intuitively, they were convinced they had gained weight, and their accounts suggested this stemmed from their initial struggles with freedom from dietary restriction.

"I felt like I was eating less but I didn't necessarily feel like I'd lost weight. I weighed myself and I got a real shock because I had actually lost some weight, and I've been trying to lose that weight for 10 years."

[Extract 18, Participant 9]

"That [eating freely] was difficult at the beginning, and of course when you're making free choices about what you're eating you just assume you're going to be putting weight on. So I didn't stand on the scales because I just thought that would stop me and I'd just want to go on a diet again."

[Extract 19, Participant 4]

To address this in the future, one participant suggested a form of accountability be developed where participants can check in with someone or are provided with an option to weigh themselves to help alleviate these concerns.

5.2.2.4 Theme 4: There is Empowerment and Enjoyment in Freedom

This theme highlights the positive experiences of participants' engagement with freedom. When engaging with the unconditional permission to eat element, participants started to experience empowerment and enjoyment, which was achieved through liberating themselves from dietary restrictions. This theme is presented through two sub-themes.

Subtheme 1: Freedom teaches you to think for yourself

As participants began to understand the ethos of the freedom message, there was a realisation amongst all the participants that freedom is "teaching you to think for yourself". Participants developed a sense of empowerment when engaging with this element as they began thinking of their own ways to manage their eating behaviours. Participants were finding out what worked for them and employing strategies they wanted to use rather than obeying dietary rules that had been provided for them by others.

"I think I was taking responsibility for what I was doing, a little bit more than somebody imposing on me."

[Extract 20, Participant 4]

"It [freedom] teaches you how to think for yourself and not to stick to a schedule."

[Extract 21, Participant 1]

Subtheme 2: Freedom diminishes the negative emotions associated with eating

Throughout the course engaging with the freedom element led participants to feel liberated from negative emotions; there was a realisation that "food is not the enemy". Participants expressed how the removal of dietary restrictions allowed them to begin to enjoy the foods they previously would have experienced guilt about eating.

"I do eat chocolate still, but I don't crave it, I don't think about it from morning 'til night, which is what I've always done, the whole of my life. It's been almost an obsessive compulsion, so even when I'm dieting successfully I would have that bar of chocolate. I would put it in the cupboard and I would know where it is and I would fixate on it the whole day 'til I was allowed to have it. [Now] days go by when I don't

eat chocolate, some days I do, sometimes I eat too much, but it's not [with] that awful guilty [feeling]. I can actually enjoy it whilst I eat it."

[Extract 22, Participant 3]

Some felt they were in a failing battle, with feelings of failure triggering emotional eating. Dietary freedom helped participants to be released from feelings of failure.

"I just have whatever I want really. Today I had 2 pieces of toast and honey without too much guilt attached to it, so they weren't horrendous breakfasts but it was really nice to be released from that, because I'm not going through all morning feeling that I've failed already, which is kind of the norm."

[Extract 23, Participant 4]

5.2.2.5 Theme 5: Addressing More Than Just a Weight Problem

Most of the participants were very much aware of their current weight issues, and the implications these have on their wider health. However, for most of the participants their weight was not the only issue that required addressing. This theme captures how the programme was an opportunity to address more than just their weight as a quantitative measure. The data for this theme has been captured through the three sub-themes presented below.

Subtheme 1: An opportunity to address other issues

As previously described, the course delved into a range of issues associated with a poor relationship with food (e.g., eating in response to emotion, childhood habits). This provided participants with the opportunity to tackle issues they had not faced before.

"I think things that I've never fully accepted or I've found too difficult and I've just hidden, put to one side, thinking it's all about just losing weight but it's the big thing [about] why I've got myself overweight."

[Extract 24, Participant 5]

"I've found that the week where we were writing letters and kind of really dealing with issues [around] why we have weight gain issues. For me [that] was quite important, it gave me the opportunity to deal with something quite major."

[Extract 25, Participant 3]

Exploring the different issues contributing to weight gain gave participants the opportunity to start understanding their eating behaviours. Some participants had previously identified themselves as emotional eaters. However, following the

session around understanding motivations behind eating, they realised they were not emotional eaters but ate in response to feelings of boredom or tiredness. Other participants identified how they had never experienced real physiological hunger and as a result were overeating. Additionally, other individuals realised their issues with food were down to a lack of discipline, which they were now trying to address.

"The biggest thing for me for was the fact that I thought I was an emotional eater, and I'm not. The reason I'm eating isn't, well it is slightly linked to emotion[s] but it's not linked to me being upset or anxious or stressed, which was what was confusing me. I don't feel that my life is controlled by anxiety and stress at the moment; I'm not in a crisis stage at any point. I'm actually going along quite happily. So, my eating is coming from my boredom and maybe slightly loneliness. I'm used to being surrounded by adults and now I'm at home with the kids and that's a different type of thing. My husband works long hours and quite often long days. [So] I eat 'cos I get bored and fed up and it's something that passes the time. The choices of jobs that need doing aren't necessarily things that interest me or I want to do, [so] it actually hasn't got anything to do with being anxious or stressed or emotionally upset, which is good."

[Extract 26, Participant 4]

Subtheme 2: *Different from previous weight loss attempts*

The importance of having the opportunity to address other issues was further emphasised when participants reflected on their previous weight loss attempts. Participants discussed during previous weight loss attempts, their focus was on reducing their body weight. Through this they would experience short-term success, but the real issues they had with food remain unaddressed. Participants' accounts illustrated exploring these issues further and beginning to them, in some ways more important than weight loss, which was key to participants' journey through the programme.

"What I've found with all other diets and everything else [is that they've] helped in the short term, but I haven't dealt with the underlying reasons why. I've needed to do that."

[Extract 27, Participant 5]

"I think what's important to me [is that] all the way through my life I've gone to diet clubs or followed a diet or whatever. I haven't ever addressed the mindset that I'm in about food, and how I deal with that, and how I feel about it. You've only got to open my fridge [and] realise it's a healthier fridge. You go to my bedroom there isn't a

stash, there's nothing to binge on in my bedroom, which is sort of my secret place. That to me at the moment is almost more important than losing the weight; does that make sense?"

[Extract 28, Participant 8]

As participants continued to reflect on their previous weight loss attempts, they described how addressing these problems was valuable in moving forward and developing a more realistic approach to weight management.

"I've learned things about how I'm eating, and the psychological bit of how I am eating, which in some ways is more important because I can't go through life constantly measuring, weighing, adding up points and all the rest of it. It's got to come from somewhere else and that's gonna take time."

[Extract 29, Participant 10]

Subtheme 3: At times there was too much to take in

Whilst participants credited the intervention with helping them address these complex issues, it was also evident at times the content of the course could be too much for participants to take in. As participants progressed through the sessions, they found the course challenged their existing behaviours, provoking them to form new cognitions and attitudes towards food. Whilst this was considered helpful and necessary, this process was described as overwhelming at times.

"We've already had an awful lot of information. You've learned all this, you know what you've been doing wrong, [and] there's going to be more added to it before you get to the end. I found it piled up a bit, you're uncovering some of your weaknesses, and some of the areas that you're not good at...causing you to reflect on your lifestyle."

[Extract 30, Participant 7]

Additionally, a few participants suggested the content of the intervention was overwhelming because the solutions were not given to them. There was an expectation among most of the participants that they would be provided with rules to follow, akin to other weight management programmes. The aim of the course was to assist participants with finding their own solutions. Whilst most participants could engage with this, some participants would have preferred solutions from the facilitators.

"Sometimes I felt perhaps it was a lot without giving us all the answers, but I realise that's not gonna happen, and that shouldn't happen, [it] can't happen, you've got to do it yourself."

5.2.2.6 Theme 6: Coping With Other Group Members

During each session participants were split into smaller groups of three or four, where they shared their thoughts, feelings and stories. This theme demonstrates how participants felt about this element of the intervention, with participants reporting mixed experiences across their interviews. This has been captured through four sub-themes.

Subtheme 1: *The benefits of being in smaller groups*

All the participants agreed separating into small groups of three or four people was beneficial. Being in smaller groups helped to create solidarity, provided a safe environment for discussion and sharing ideas and was a good support system for participants.

"It helps to know that other people go through the same problems [and] the same challenges as you do, and in fact some of them [have] worse challenges."

[Extract 32, Participant 10]

"Yeah I just enjoyed it, it was nice in the discussions to hear how other people were getting on and get other people's input on things, so it was all good."

[Extract 33, Participant 4]

Subtheme 2: People who have bigger issues with eating took over group discussions

Whilst there were benefits to separating into smaller groups, some participants felt group members who had bigger or deeper issues associated with eating had the tendency to dominate the group discussion.

"Some people have a lot of . . . problems and for me that's not particularly helpful. I'm a very selfish person, it has to be said, not wanting to listen to other people's problems.

[Extract 34, Participant 10]

When participants found they could not relate to the discussion, they felt they had to hold back from sharing their experiences, which meant their own issues were not always addressed.

"I felt sometimes there were people with much bigger issues, so I [held] back a little bit with my issues. I think maybe it would have been better to be [in] more similar

groups, because I think some people with bigger issues took over the discussion and I felt it didn't really speak to me."

[Extract 35, Participant 11]

Subtheme 3: *Different opinions about group consistency*

Participants also discussed the consistency of groups and their thoughts on what was most comfortable for them. There were mixed responses on what participants found helpful. For some, keeping groups consistent all the way through was important, as a shared understanding was established and rapport had been built between the group members. By not keeping groups consistent, some participants considered this element was lost.

"When I came in late, I actually sat with a group [where] I didn't know anybody. I really think it's important that if you're going to do a group that the people that you sit with you kind of develop a rapport with and you understand them because they've talked about their past and their problems with food."

[Extract 36, Participant 12]

As well as keeping groups consistent, some participants also felt participants should be matched according to the issues they have with food, as this gave further common ground for participants to develop rapport.

"I felt the groups needed to be smaller, better or specifically matched together."

[Extract 37, Participant 13]

However, for other participants mixing around across different groups was better for them. For some this was to prevent cliques developing and for others it was so they could get different ideas and perspectives.

"I would have liked to be in different groups... 'cos otherwise it gets a bit cliquey. You get different ideas off people and where they're coming from and some people are worse than you and you think, 'oh gosh I thought I had problems'."

[Extract 38, Participant 14]

5.2.2.7 Theme 7: Journeying Towards a Healthier Relationship with Food

This theme captures participants' overall experience of the programme and the next part of their journey. This theme has been captured through three subthemes.

Sub theme 1: *Taste & See has equipped me with tools*

Participants acknowledged the programme had not brought around an instant change but rather equipped them with tools to begin developing a better relationship with food. Many of the participants recognised they were still at the start of their weight loss journey but moving forward in the right direction.

"What it's given me is [an] understanding [of] the dynamics of eating. Why we eat, what are the triggers, what are the internal triggers, and the external triggers and [how] those influences can negatively affect you and how you can make the wrong choices. [The Bible verse] 'Everything is permissible but not everything is beneficial' [has] given me a clearer understanding of how I can stop [and] think before I act, consider it, reflect on things then go do it. It doesn't always work, I'll be honest, it's something you get caught out [with] so it's still breaking those engrained habits and they take time."

[Extract 39, Participant 7]

Subtheme 2: *Starting to move forward*

Throughout the course participants learned about their own eating behaviours. At the end of the course, participants identified themselves to be at the next stage of their journey where they are beginning to use their tools and apply the things they have learned from the intervention.

"I'm trying not to eat between meals but I haven't got to grips . . . with this"

[Extract 40, Participant 12]

"[I learned that] there is another way out there and that the way I look at food is not necessarily a healthy way of looking at food. I had my eyes opened to a new way of looking at eating and food that I need to grasp and make it become my way of thinking. Does that make sense?"

[Extract 41, Participant 10]

Some participants wanted to repeat the course so they could better consolidate the knowledge they had developed, and make incorporating the intervention into their daily lives easier.

"I really like it and I would love to do it again because I think having got the concept of it, doing it again I'd get a lot more out of it, if that makes any sense? I think it's one of these things you need to do more than once."

[Extract 42, Participant 10]

Sub-theme 3: *Final thoughts on the Taste & See programme*

Overall participants highly commended the programme, meriting the use of religiosity and intuitive eating as approaches towards weight management. The following quotes illustrate participants' final thoughts about the programme.

"I would say I would recommend it to everyone; yeah, I would recommend it to everyone"

[Extract 43, Participant 14]

"I was in a much worse place than I actually really thought I was, and I recognise that I needed to address it [and] I found it hard to address it . . . Spirituality and education about healthy eating works."

[Extract 44, Participant 15]

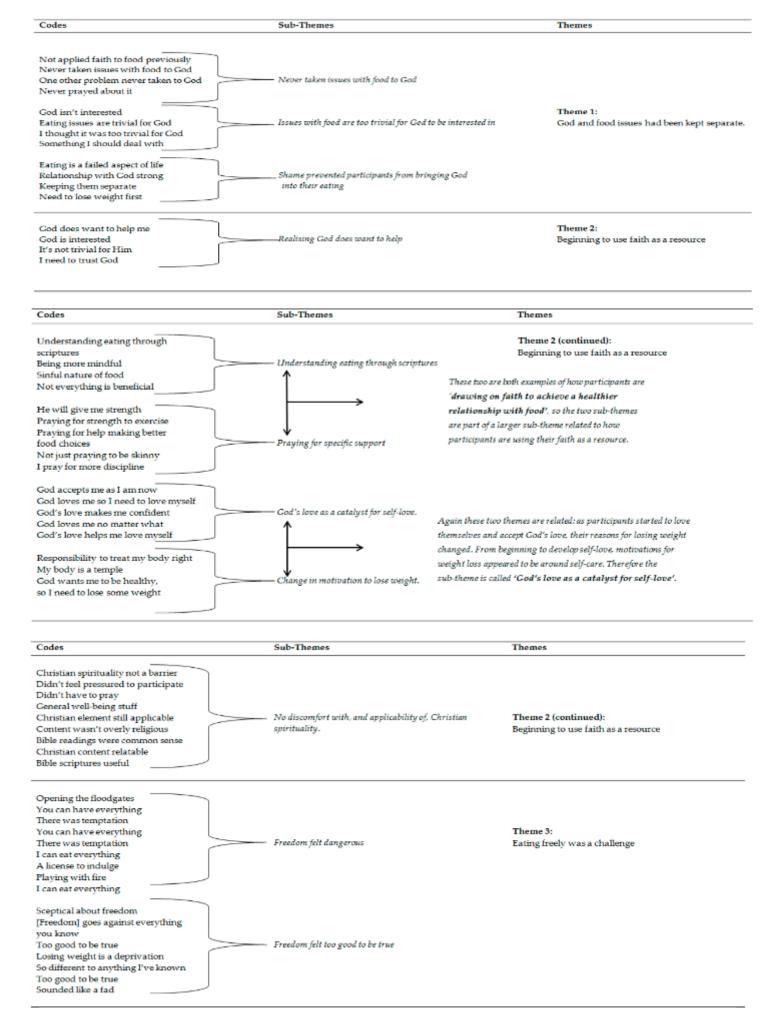
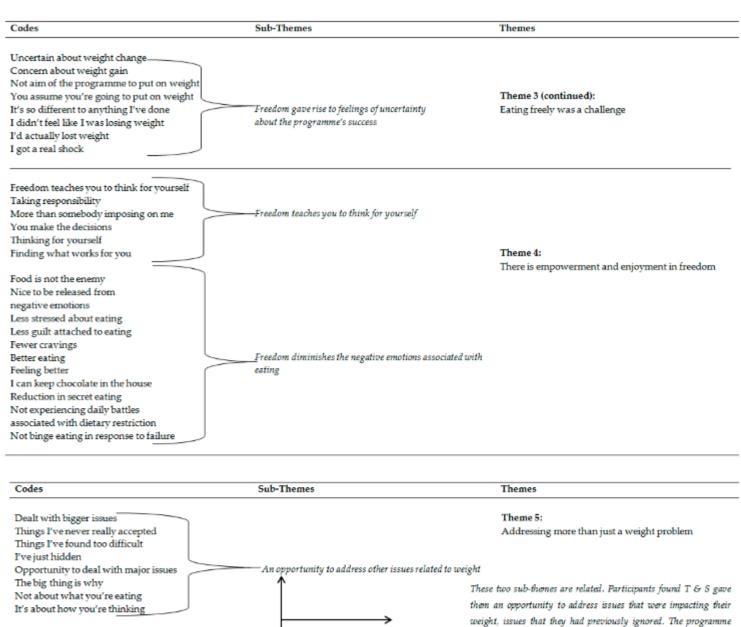


Figure 7: Thematic map of the analysis process; displaying how codes were translated to themes



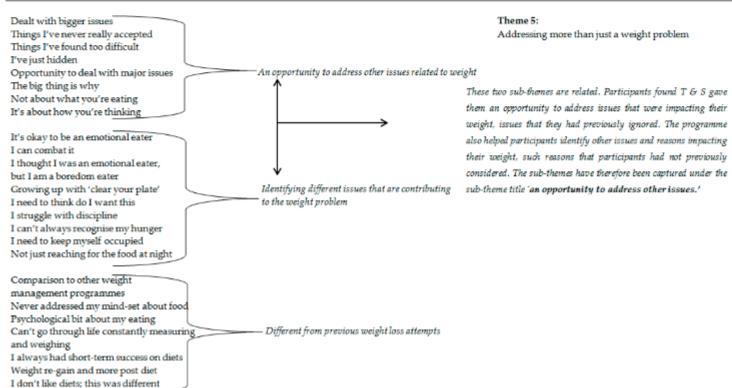


Figure 7: Thematic map of the analysis process; displaying how codes were translated to themes

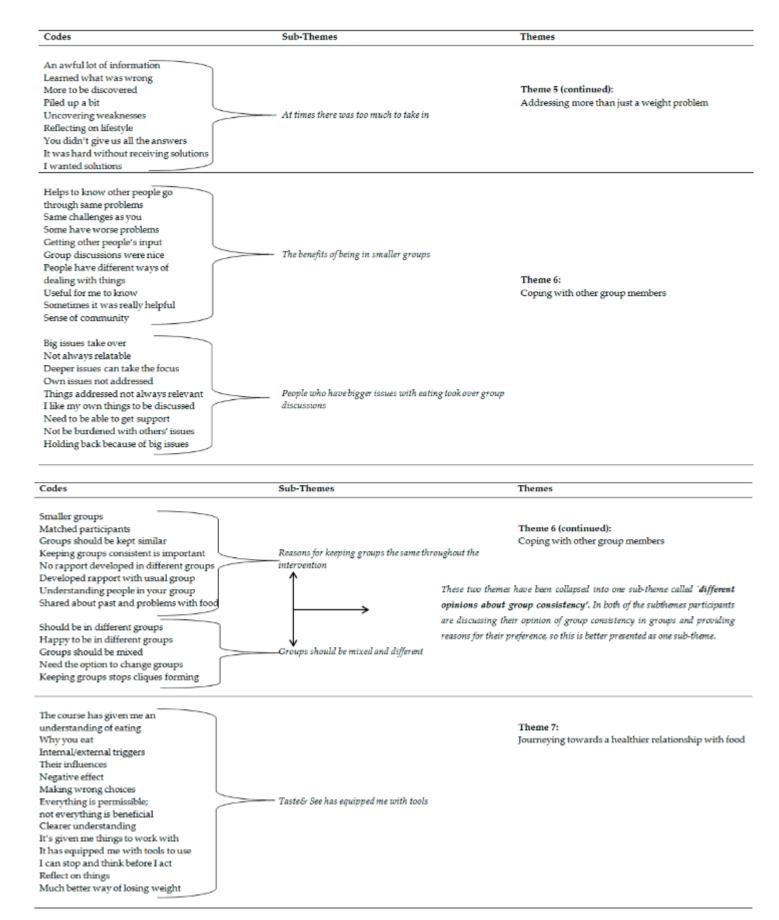


Figure 7: Thematic map of the analysis process; displaying how codes were translated to themes

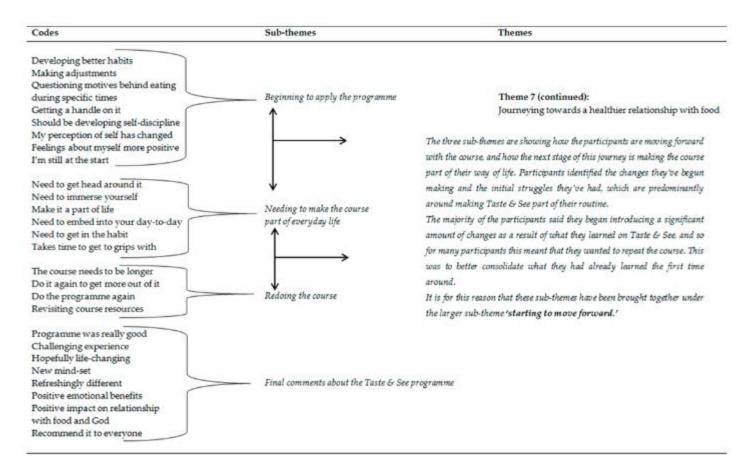


Figure 7: Thematic map of the analysis process; displaying how codes were translated to themes

6 Discussion

Introduction to Chapter 6

This is the final chapter of this thesis, I have organised this chapter into four sections. In section 6.1 I discuss the results of the feasibility study that were presented in chapter four. In section 6.2 I discuss the results of the embedded qualitative study that explored facilitator feasibility in section 5.1.1. In section 6.3 I discuss the results of the qualitative study that explored participant acceptability of and engagement with the programme. Each of these sections are presented as follows; a summary of findings, strengths and limitations of the study, and a discussion of the results in relation to the existing literature. The final section (6.4) is an overall conclusion which discusses the overall findings, and the implications of the findings, alongside the future developments of the programme.

6.1 Discussion of Feasibility Study

6.1.1 Summary of the Results

The feasibility study found it was feasible to recruit 18 participants over a period of two weeks. It was also feasible to deliver and evaluate this programme within a church setting. The recruitment process of the study found face-to-face recruitment through the church was the most effective strategy. Attendance during the programme declined over time, with reasons for non-attendance being reported as previous evening commitments and booked holidays. Only one participant was lost to follow-up at the end of the intervention (three-months from baseline); at nine months (six-month follow-up), only three participants were lost to follow-up, demonstrating good participant retention. Where follow-up data could not be collected, ITT was performed using BOCF at both time points.

At the end of the intervention (three-months from baseline); there were significant increases in mental well-being, cognitive restrained eating, QOL VAS and the intuitive eating dimensions of eating for physical rather than emotional reasons and reliance on hunger cues. There were also significant decreases in EQ-5D5L pain/discomfort, BMI, uncontrolled eating, emotional eating, anxiety and depression. There was a mean reduction in energy intake, total fat, saturated fat and there was a mean increase in spiritual well-being, although these were not statistically significant. Changes at six-month follow-up (nine-months from baseline) showed a partial reversal in the improvement in mean scores of uncontrolled eating, emotional eating, cognitive restrained eating, anxiety, depression, mental well-being and spiritual well-being. Nonetheless, the figures for uncontrolled eating, emotional eating, mental well-being and anxiety were still significantly improved, at this time point, in comparison to their baseline values. The mean change in weight, energy intake and BMI returned to baseline levels, this increase in energy came from polysaccharides and protein, while total fat, saturated fat and sugar intake was further reduced during this time period, thereby indicating positive ongoing dietary change after the end of the intervention even though these values did not reach statistical significance. The significant improvements in intuitive eating behaviour seen at the end of the

intervention were virtually unchanged during the following six-months, such that the same significant improvements as at the end of the intervention were sustained nine months after baseline.

6.1.2 Strengths and Limitations of the Study

There are several strengths to this feasibility study; Taste & See is the first programme to be trialled within a UK Church setting incorporating both Christian Spirituality and intuitive eating principles into a weight management programme. This small pre-and-post-study was adequate to show the feasibility of evaluating this programme within a church setting and gain information of likely mean change and standard deviation of outcome variables to inform a RCT. To detect change in all our variables, standardised and validated measures, previously validated for this purpose were used meriting this study further.

Limitations of this feasibility study include the nature of the study design and small sample size, although adequate to test feasibility, only limited conclusions can be drawn from the data analysis. There was no control group to allow for testing of comparative effectiveness. Improvements were only observed during the times when participants underwent the intervention; without a randomised control group the results cannot prove that the findings were due to the intervention and not due to a 'placebo effect' or, more specifically in this situation, the effect of time and raised awareness or other confounding factors. The sample size was also too small to provide precise estimates of outcomes as shown by the wide confidence intervals.

Despite using tried and tested methods, some participants reported difficulty completing some questions which may have led to a degree of inaccuracy. Not all data was available at follow-up, although BOCF was conservatively used to replace missing values, improvements in the mean scores of outcomes were still seen.

Additionally, underreporting of energy intake is well known in populations who struggle with weight control (Schoeller 1990). However the values did not fall below the cut-off for implausibility as determined by the validated Goldberg cut-

offs (Tooze et al. 2012). Underreporting is a consistent phenomenon and so is unlikely to be responsible for the changes in dietary intake that were observed over time. Indeed, the change in energy intake over time was in line with expected values for the degree of weight change observed here. These results so far would be poorly generalisable, not only in light of the small sample size but because the sample demographics were relatively homogeneous. Most of the sample participants were Christian, had degree-level education status, female, and White in ethnicity. Taste & See—was also only tested in one church, and so whether this type of intervention would be acceptable across all Christian denomination churches needs investigating. Additionally, there was high clinical variability among the sample in relation to eating behaviour and BMI. As such, individuals' aims for the programme may have been different, and could have diluted effects in some outcomes. For example, not all individuals were seeking to lose weight, and so a lower mean weight loss across this sample, compared to that in weight-loss-focussed programmes, should not be taken as a lack of efficacy.

6.1.3 Consistency with Other Findings

The feasibility of conducting this type of programme within a church is consistent with findings from the US where pre- and post-studies of faith-based interventions (Dodani & Fields 2010, Yeary et al. 2011, Murrock & Gary 2010), as well as RCTs (Resincow et al. 2005, Wilcox et al. 2013) have been successfully conducted. This trial reported on many outcome variables, but the most consistently reported outcome in other faith-based weight management programmes is weight. Participants lost a mean of 1.6kg at three-months, and returned to baseline levels of weight at nine-months after baseline. In comparison to other intuitive eating programmes, the findings at three-months are consistent with previous systematic review findings showing participants who learn to eat intuitively achieve significant decreases in weight and BMI (Schaefer & Magnuson 2014, Clifford et al. 2015). More specifically, the magnitude of the weight loss observed at three months is consistent with 1.4kg weight loss seen for intuitive eaters previously at the end of a 14-week intervention in comparison to the social support and wait list control group who lost 0.6kg and 0.4kg respectively post-intervention (Gagnon-

Girouard et al. 2010). Other studies have reported greater weight loss; 7.9kg (Mellin, Croughan-Minihane & Dickey 1997); 3.1kg, (Roughan, Seddon, and Vernon-Roberts 1990); 4.9kg (Tanco, Wolfgang & Earle 1988); or no weight loss at all (Provencher et al. 2009, Leblanc et al. 2012, Cole & Haracek 2010) at this time point. Some studies have shown this weight loss is maintained at one year in intuitive eating interventions (Rapoport, Clark & Wardle 2000, Sbrocco et al 1999). This finding was not found in this trial, however, whether weight loss would have followed and been evident one year after baseline in this study is possible. The sixmonth follow-up period fell during the winter months, and so seasonal variations in weight change could account for some weight regain. Longitudinal prospective study evidence found a small significant increase of 0.48kg in body weight during the winter amongst a sample of 593 predominantly overweight participants. This was attributed to an increased caloric intake of 86 kcal a day across the sample during the winter season (Ma et al. 2006).

When the results of weight change at three-months are compared to other weight management faith-based interventions, the magnitude of weight loss was less; Yeary et al. (2011) reported an average weight loss of 2.3kg from baseline to fourmonths, and another study demonstrated an average weight loss of 3.3kg at sixmonths (Kennedy et al 2005). However, previously tested faith-based weight management interventions focus on achieving weight loss through using conventional principals of dieting (Dodani & Fields 2010, Goldfinger et al. 2008, Kim et al. 2008), and not on an intuitive eating approach. When dieting and intuitive eating programmes are compared, greater short-term weight loss is seen with dieting, although the sustainability of this is questionable (Gagnon-Girouard et al. 2010, Van Dyke & Drinkwater 2014).

Additionally the lower rates of weight loss observed in this study maybe a result of not attending the entire programme. Yeary et al. (2011) identified a dose-effect relationship of their faith-based intervention, where participants who engaged with the programme more experienced greater weight loss average (4.4kg) than those who were less engaged (0.29kg). An unexpected result from our study was the significant increase in cognitive restrained eating as measured by the TFEQ-21

which was maintained at nine-months from baseline. A central premise of intuitive eating is to encourage unconditional permission to eat, and so a reduction in this variable is expected (Tylka 2006, Tylka & Kroon van Diest 2013, Bruce & Ricciardelli 2016). Although intuitive eating was taught within this programme freedom was discussed within the context of responsibility where participants were encouraged to adjust to behaviours most helpful to them individually, in this way dietary restriction was not prohibited. We know from interviewing participants that some people became less restrained in their eating but others identified specific areas in which they chose to exercise more restraint than they had done previously and this may have explained the increase we found. Also, in more mindfulness-based programmes, both for weight loss (Dalen et al. 2010) and binge-eating disorder (Kristeller, Wolever & Sheets 2014), an increase in cognitive restrained eating associated with successful outcomes has been seen.

As expected, improvements in various measures of mental health and well-being were associated with improvements in other areas of mental health, such as anxiety and depression. Improvements in mental health and quality of life measures are consistent with improvements in other intuitive eating programmes (Wilcox et al. 2013), but few faith-based studies have reported on these outcomes.

Improvements in relationship with God, as measured by less avoidant attachment and anxious attachment to God were also observed. Cross-sectional evidence has suggested that a secure attachment style with God is associated with reduced psychological symptoms (Granqvist & Kirkpatrick 2013). Less well studied is the association between a relationship with God and eating behaviours, a previous cross-sectional study found intuitive eating negatively correlates with anxious attachment to God in college women (Homan and Cavanaugh 2013). Prospective longitudinal study evidence further suggests that a secure relationship with God serves as a protective role against thin ideals, and that women who have a secure attachment with God are suggested to be more satisfied with their bodies and diet less frequently (Homan & Boyatzis 2010). Findings from the landmark spirituality and health survey support this finding, where an anxious attachment to God is associated with a greater risk of being obese which can attenuated by social

support provided through the church (Krause & Hayward 2016). The association between relationship with God and intuitive eating was explored in the current study however there was no evidence of this association, this may have been due to the inadequate power in this study to detect this.

6.2 Discussion of Facilitator's Acceptability

This section discusses the qualitative findings of facilitator's acceptability of and with delivering the Taste & See programme.

6.2.1 Summary of the Results

Three lay facilitators volunteered and successfully delivered the programme, demonstrating the feasibility of recruiting and training non-clinical facilitators to deliver the Taste & See programme. Qualitative data around their experiences showed whilst facilitators could adequately facilitate, they experienced challenges around understanding the role of the facilitator. There were also challenges associated with balancing facilitator/participant identity, managing participants in the group setting and a need for more advice around the discussions that can arise. Facilitators requested the need for more thorough training resources; this will be addressed and incorporated into the training resources for the planned RCT.

6.2.2 Strengths and Limitations of the Study

This embedded qualitative study enabled facilitators to express more openly their thoughts on the intervention and was a better measure of acceptability than observation and quantitatively measuring acceptability. The strengths are further highlighted when consistency with existing findings is highlighted demonstrating credibility and trustworthiness of the findings.

There were times during individual interviews where facilitators provided their thoughts about others rather than reflections on their own actual experience. For example; they might report participants felt a particular way which was based on assumption rather than having asked participants themselves. This is a potential

limitation, but when this occurred, the researcher tried to guide the discussion back to what actually happened during facilitation.

6.2.3 Interpretation of Findings and Consistency with Other Findings

Qualitative evidence around facilitator acceptability of delivering faith-based interventions and facilitating group sessions is scarce. There have been a number of quantitative studies demonstrating lay non-clinical persons can be recruited from within a church and trained to deliver a healthcare intervention but very few qualitative evaluations exist.

An embedded qualitative study conducted by Kim et al. (2008) of a faith-based weight management programme, explored lay-leaders perceptions of delivering a faith-based intervention in their respective churches. Kim et al. (2008) noted during interviews facilitators described how delivering the programme led facilitators to think about their own health behaviours, in relation to nutrition in particular. In this study, there was evidence of this, Taste & See facilitators experienced changes in their perceptions, understanding of obesity, eating and their faith. The programme caused some facilitators to perceive obesity through a perspective they not previously considered. For one facilitator, there was evidence the intervention caused them to reflect on themselves as an example to the church from a leader perspective. This finding was further evident in a qualitative study conducted as part of a process evaluation by Campbell et al. (2007). When interviewing church leaders involved with delivering the 'Body & Soul' intervention, leaders discussed the changes they had begun making to their diets as a result of their involvement with the intervention.

The findings of Kim et al. (2008) and Yeary et al. (2011) differ from the present study findings. Facilitators on both these interventions felt they were equipped to deliver the intervention, had received enough training and high acceptability of managing the intervention and data collection was demonstrated. When the findings of the current study are considered in light of these findings several factors emerge in explaining the differences in experiences. Kim et al. (2008)

provided their church volunteers with 4 x 2.5hour training sessions, spanning over 4 weeks, and a written manual outlining their roles and responsibilities. Yeary et al. (2011), delivered a 20-hour training programme to their facilitators, and required facilitators to take an examination where a score of at least 80% above needed to be achieved. There are significant differences in training length, resources and session style, with previous studies making their sessions more interactive and activity based.

6.3 Discussion of the Participant's Acceptability of and Engagement with the Programme

The following section discusses the results of the second embedded qualitative study.

6.3.1 Summary of the Results

The embedded qualitative study explored how acceptable participants found the Taste & See intervention, and further explored how they engaged with the different components. The Christian weight management programme was a unique and welcomed experience for the participants. For most of the participants, the idea of bringing God into their eating had not been considered previously despite experiencing considerable struggles with their weight. Participants described how the religious content took them on a journey towards accepting God's help, using their faith as a resource and learning to love themselves the way God loves them. The latter part of the journey formed an important foundation for changing motives to manage their weight post-intervention. Participants found exploring other reasons to eat and how to challenge these behaviours useful, particularly, listening to feelings of hunger and fullness. Similarly, the freedom element also took participants on a journey where early challenges with freedom were related to difficulties in understanding dietary freedom, and fears of weight gain. However freedom eventually helped participants experience release from negative emotions associated with food and eating. Participants identified several benefits to being in smaller groups, which included building rapport and developing solidarity through sharing experiences with one another. However, some participants found small group discussions dominated by those with deeper emotional issues unhelpful. On

the whole, participants felt that the programme helped them take the next step in their journey towards developing a healthier attitude towards food, suggesting acceptance of and engagement with the programme.

6.3.2 Strengths and Limitations of the Study

Most of the participants from the feasibility trial participated in the interviews. These findings provide unique insights and a fuller understanding of participants' experiences of the programme, as well as illuminating the quantitative findings of the trial. The findings of this study are consistent with previous findings in this area, which increases the credibility of the findings. Thematic analysis was used appropriately to answer the research question, and, as described in the methods, through using peer review, engaging in reflexivity and keeping an audit trail the rigour of this study was enhanced.

The main limitation of the embedded study was the small homogenous sample, which limits the transferability of the findings. The participants knew myself and the PI; this could have introduced an element of social desirability in the responses participants provided during interviews. However, it was emphasized honest feedback was required from the participants and this was crucial for further development of the programme.

6.3.3 Interpretation of Findings and Consistency with Other Findings

Previous studies exploring the acceptability of and engagement with faith-based interventions are scarce. The findings of this qualitative study are, however, consistent with the limited literature within this area. Considering the themes around the intuitive eating component, Kidd, Graor and Murrock (2013) conducted a one-group pre-test/post-test design mixed methods feasibility study of obese women's lived experience of a mindful eating group intervention. This intervention, although broader in its mindfulness approach, encompassed intuitive eating components. The findings of this study echoed the present study, where women highlighted their initial struggles with freedom and being mindful about their eating behaviours. Kidd et al. (2013) identified two themes related to mindful eating: 'feeling the burden, and then the freedom' and 'bringing control back'.

Collectively, these two themes show how participants initially felt burdened by eating mindfully but, as they began practicing it, they gradually felt more in control of their eating behaviours. Participants' accounts reflect how they became more aware of social and environmental cues and how these affect their eating. They also reported feelings of increased self-efficacy and positive emotional gains through eating mindfully. This is similar to the themes 'eating freely was a challenge' and 'there is empowerment and enjoyment in freedom', where freedom was initially met with challenges, but over time participants felt more in control of their eating and experienced enjoyment of their food again. Kidd et al. (2013) also reported findings around the benefits and support of the smaller groups, and how this was a source of encouragement and bonding, which is consistent with the findings of the theme 'coping with other group members'. Kidd et al. (2013) also discussed a theme 'moving from thinking the principles to living the principles'; this particular theme mirrors the final theme, which showed how participants were moving forward with a new way of thinking and taking steps to incorporate Taste & See principals into their daily lives.

Themes around the spiritual element and participants' engagement with this element were similar to those of the participants in Yeary et al. (2011). Yeary et al. (2011) described how the connection between participants' faith and health motivated them to change their health behaviours as a sign of devotion to God. Reicks, Mills and Henry (2003) also showed how women in their study drew on their relationship with God through praying for help to overcome emotional eating and using Biblical scriptures to understand eating behaviour, encouraging women to change their motives for eating. The findings from Seale et al. (2013) further echoed the findings of this study, participants in their study anchored themselves on key scriptures, for example 1 Corinthians 6:19, where the body is described as a temple of the Holy Spirit. Meditating on such scriptures provided participants with a conscious awareness to treat their bodies better, motivating them to maintain the behavioural changes learned on the intervention. Participants in this study also anchored themselves on specific scriptures including this one when navigating through their daily lives post-intervention. For example, certain scriptures served as prompts for participants to think about their eating behaviour motives, whilst other scriptures encouraged participants to make better choices around food. Furthermore, Seale et al. (2013) also found that participants were actively collaborating with God to seek help and find strength beyond their own means to successfully address the struggles they experienced with their weight. This is discussed in the theme 'beginning to use faith as a resource', where participants utilised resources available to them through their faith to achieve lifestyle changes.

Further credibility and trustworthiness of the findings of this study are demonstrated by a qualitative focus group conducted by Kim et al. (2008). The focus group findings reiterated partnering with God and having faith to seek God and access help from Him. Kim et al. (2008) reported participants gained will power from their faith. Knowing God wanted to help them, and anchoring themselves in their faith, participants experienced changes in motivation to maintain healthy lifestyles. These findings echo the findings of this study, in particular the sub-themes 'God does want to help' and 'God's love as a catalyst for self-love.'

Findings unique to this study were the themes around guilt and shame causing participants to hide their struggles with food and eating from God. When faced with health-related struggles including diagnosis of, or adjustment to, a chronic condition, harnessing spiritual beliefs to assist with coping has been observed in the literature (Kristeller et al. 2011, Büssing & Koenig 2010). Participants in this study may not perceive obesity as a chronic condition with an immediate health threat, as for example with T2DM or CVD. Furthermore, it could be suggested these findings are specific to the population under study, as much of the previous research derives from participants of African-American descent, who typically position God centrally in all aspects of their health (DeHaven et al. 2004) and make the church leader the first port of call for health issues (Levin, Chatters & Taylor 2005); in the United Kingdom, the first port of call for most Christians is the NHS.

In addition, while the health message about food and diet is central in certain Christian denominations such as SDA's (Tan et al. 2016), it is considered much less, in many other denominations of Christianity. It has been suggested overindulgence

in food (although not promoted) is overlooked as a 'lesser evil' in comparison to alcohol and smoking (Cline & Ferraro 2006). Many religious functions within the church use food, rather than alcohol, as the celebratory good to be consumed (Sack 2001). Participants in the present study alluded to this, where food was not thought about in relation to overindulgence and gluttony prior to completing the Taste & See programme. Despite this, it is interesting to note guilt, shame and hiding from God characterised many participants' relationship with food; therefore, it may be that the failure to address these aspects of life spiritually is particularly important in the U.K. population.

6.4 Final Conclusions and Implications

This is the first study to incorporate intuitive eating and Christian spirituality and the first study to be conducted in a U.K. context. The findings presented here suggest a complex intervention designed to target religious health as well as physical and psychological health needs in those who are overweight or have an unhealthy relationship with food is feasible to deliver and evaluate in a UK church setting. This feasibility study begins to give some insights into what can be achieved from a 10 to 12 week Christian, church-based healthy intuitive eating programme. This feasibility trial has provided a rich level of evaluation which has been used to improve the intervention design and evaluation process.

There are significant implications of this study, if weight can be reduced, even by a small amount, the impact across communities and on public health could be substantial. Modelling has shown that a 1% reduction in BMI, which is equivalent to a weight loss of approximately 1kg for an adult of average weight, would have a substantial effect on consequent health burdens. Compared with a scenario in which recent trends continue, a 1% BMI reduction across the UK would avoid 179,000–202,000 incident cases of T2DM, 122,000 CVD, and 32,000–33,000 incident cases of cancer with a gain of about 3 million Quality Adjusted Life-Years (QALYs) over 20 years. In addition to improving the healthy, productive life span of the population, this would make a significant dent on the projected additional health-care cost of £1.9–2 billion a year in the UK by 2030 (Wang et al. 2011). The

economic and social costs of mental health problems in England were estimated at £105 billion in 2009–2010; taking into account costs for health and social care, loss of output and human costs.

The economic benefits of mental wellbeing are not as well established as the costs of mental illness; however, improving mental well-being increases psychosocial functioning, lowers healthcare use, and reduces morbidity and premature mortality. With a strong association between obesity and poor mental health an intervention addressing the mental health of those who are obese is particularly important. Using churches enables religious health to be addressed and uses existing social structures with a voluntary workforce that is potentially sustainable and cost effective.

Furthermore while weight management programmes have been shown to be important in African-American churches within the US, this has not been demonstrated elsewhere, the findings of this PhD identify that the holistic nature of this intervention begins to address issues that conventional weight management programmes do not address. Addressing the underlying issues leading to problematic and over-eating is an important factor often overlooked. This PhD has shown positive results can also be achieved through a small feasibility trial. The next steps are now to conduct a larger RCT where the efficacy can be assessed.

The findings of this PhD have further identified important implications used to amend and adapt the Taste & See programme, in preparation for an RCT beyond the scope of this PhD. Based on the facilitators' interviews, a facilitator's manual has been developed and written detailing all the roles, responsibilities, and expectations for the facilitators. It provides the facilitators with all the information they felt they did not receive e.g., examples of issues that participants might discuss during group sessions. The training sessions have been revised to ensure it is better meeting the needs of the potential facilitators. Additionally, a manual for participants has also been developed where participants will have access to all the information related to the sessions, and associated activities that are to be completed with each session. To help facilitate the delivery of the Taste & See

programme without the presence of healthcare professionals and maintain fidelity during a RCT, a DVD containing a recording of each session that will be delivered as part of the Taste & See programme has been developed. The length of the programme has remained the same, as participants all agreed given the content and type of programme Taste & See was, the length was necessary.

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