

**Psychological factors associated with obesity**

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## Declaration

This thesis has been submitted for the award of a Doctorate in Clinical Psychology. I declare that this work is my own and has not been submitted to any other institution or for any other qualification or degree.

Laura Jackson

**Word Counts**

<b>Section 1:</b>	<b>Literature Review</b>	7855 words
	With references	9708 words
<b>Section 2:</b>	<b>Empirical Report</b>	11999 words
	With references	13785 words
<b>Section 3:</b>	<b>Appendices</b>	6501 words
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	Including references and appendices	29994 words

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## **Psychological factors associated with obesity**

### Abstract

Due to the increasing prevalence of obesity and its high associated costs, research has focused on investigating factors related to obesity in the hope of providing insight into prevention and intervention.

Research into psychological variables associated with obesity has included consideration of fundamental, schema-level core beliefs held by obese people. Section one consists of a systematic literature review, which critically appraises the findings from eight studies investigating schemas amongst overweight/obese people. The schemas of social isolation, failure to achieve, defectiveness/shame, subjugation and emotional deprivation appear to be held more strongly by obese people compared to people of a normal weight. However, variation in schemas exist within the overweight/obese population, associated with whether individuals experienced childhood sexual abuse, binge eating or a loss of control when eating.

Research into psychological characteristics associated with successful weight loss amongst obese people has produced inconsistent findings. The research report, in section two, examines whether personality, psychopathology, patient activation, quality of life or physical symptom burden are associated with the magnitude of weight loss or attrition in a weight management programme. The results, based on 49 obese participants, show that psychosocial factors do not predict how much weight was lost or whether someone remained in treatment. While there is psychological change following the programme, it is not associated with the magnitude of weight loss.

Lifestyle interventions appear suitable for all individuals wanting to lose weight, regardless of psychological profile. Additional therapeutic interventions could be offered to people who are obese to help address maladaptive schemas.

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## Section one: Literature Review

A systematic review of schema-level core beliefs in people who are overweight or obese

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# **A systematic review of schema-level core beliefs in people who are overweight or obese**

## **Abstract**

### **Objectives**

Research into core beliefs held by obese and overweight people is in its infancy, with most literature focusing on automatic thoughts about shape, weight and eating. The aim of this literature review is to present and systematically appraise the existing literature into schema-level core beliefs held by people who are obese or overweight. Specifically, it aims to investigate the association of schema levels with weight status, and whether a core set of schemas characterise obese people.

### **Methods**

Eight papers investigating core beliefs amongst people who are obese/overweight were identified following a systematic search of PubMed and Web of Science databases. The search terms used were “obes\*” or “overweight” and “schema” or “schemas” or “schemata” or “core beliefs” or “core belief”.

### **Results**

Obese/overweight people appear to hold some core beliefs more strongly than people who are of a normal weight. These are the schemas of social isolation, failure to achieve, defectiveness/shame, subjugation and emotional deprivation. However, there is also a lot of variation in schemas within the obese/overweight population, related to whether participants binge ate, experienced childhood sexual abuse or lost control when eating.

## **Conclusions**

Due to the current lack of research in the field, it is not currently possible to determine the direction of the relationship between obesity and core beliefs. However, the current literature provides scope for future investigations and recommendations for clinical practice, such as offering therapeutic interventions aimed at addressing core beliefs amongst the obese population.

## **Practitioner points**

- Patients attending weight management programmes might benefit from an assessment for maladaptive schemas, using clinical interviews and appropriate measures.
- Obesity treatment, in general, could benefit from incorporating psychological strategies aimed at addressing emotional deprivation, defectiveness/shame, failure to achieve, social isolation, and subjugation schemas.
- It might be useful to monitor schemas throughout treatment, to identify whether they are maintaining obesity and reducing the effectiveness of weight management programmes.

## **Cautions**

- The limitations of the reviewed studies weaken the conclusions. Weaknesses in the sampling methods used resulted in participants who might not fully represent the entire population of people who are obese/overweight.
- All studies except one rely on self-report, which introduces bias, particularly in obese individuals who have been found to respond in socially desirable ways.

## **A systematic review of schema-level core beliefs in people who are overweight or obese**

### **Obesity**

Obesity is defined as the accumulation of excess fat, with the potential to impair health. It is the result of an imbalance between energy intake and expenditure, leading to the consumption of more calories than are burned off during physical activity (World Health Organisation; WHO, 2000). In adults, obesity is classified using the body mass index (BMI). A BMI score is a method of measuring the weight status of an adult based on weight in kilograms (kg) divided by the square of height in metres (m) ( $\text{kg}/\text{m}^2$ ). Someone would be classified as being overweight with a BMI between 25 and 29.9, and obese with a BMI over 30 (National Institute for Health and Care Excellence; NICE, 2014). It is more difficult to classify the weight of a child or adolescent due to their continually increasing height and changing body composition (WHO, 2000). Therefore adjusted BMI scores can be used ( $[\text{actual BMI}/\text{percentile 50 for age and gender}] \times 100$ ).

The reported European prevalence of obesity, as defined by BMI, ranges from 6.0% (Lithuania, 1997) to 36.5% (Poland, 1992-1993) of women and 4% (France, 1994-1996) to 30.0% (Czech Republic, 2002-2005) of men (Berghöfer et al., 2008). The prevalence of obesity increased worldwide from 5% to 10% of men and from 8% to 14% of women between 1980 and 2008 (WHO, 2014). The growth of obesity has been linked to social factors such as reduction in industries requiring physically active labour and the availability of cheap, high calorie foods (Cawley, 2015; Hamilton, Hamilton, & Zderic, 2007; Tillotson, 2004).

Obesity as a result of an unhealthy lifestyle increases the risk of non-communicable diseases. Non-communicable diseases caused 38 million of the 56 million deaths worldwide in 2012 (WHO, 2015). Obesity was estimated to cost the

NHS in England £6.3 billion in 2015 (Butland et al., 2007). The cost associated with the indirect effects of obesity, such as loss of productivity, was estimated at £27 billion in the UK, in the same year (Butland et al., 2007). Additionally, social consequences include exclusion, discrimination and reduced earnings (Morgan, & Dent, 2010). However, despite the high costs associated with obesity, its prevalence is rising.

Bariatric surgery, lifestyle programmes aimed at weight management and Cognitive Behavioural Therapy (CBT) for obesity have limited success at reducing weight in the long term (Cooper et al., 2010; Rusch, & Andris, 2007; Teixeira et al., 2004). It is possible that factors associated with obesity prevent such treatment being effective. Research has focused on the biological and social factors associated with obesity (Parsons, Power, Logan, & Summerbell, 1999). However, until recently little research has examined the psychological factors related to obesity. The most commonly investigated psychological correlates of obesity are quality of life (e.g., Minet Kinge, & Morris, 2010) and eating-, exercise- and food-related cognitions (e.g., Morgan et al, 2012). Unsuccessful therapy for any difficulty has been suggested to be due to unchanging core beliefs (Young, Klosko, & Weishaar, 2003). However, research into cognitions at the core belief level amongst people who are obese is limited.

### **Schemas**

Schema-level core beliefs have been described in a number of ways. Markus (1977) described schemas as “cognitive generalizations about the self, derived from past experience, that organize and guide the processing of the self-related information contained in an individual’s social experiences” (p.64). Beck and colleagues (e.g., Beck, Davis, & Freeman, 2014) defined schemas as cognitive frameworks, consisting of rules, attitudes and beliefs, which structure experiences and influence feelings, thoughts and actions. Beck (1976) divided cognitions into automatic thoughts and their triggering underlying schemas (unconditional beliefs about the self, others and the world).



Young and colleagues (2003) proposed a model of early maladaptive schemas. This model suggests that maladaptive schemas develop early in life in response to childhood events such as trauma, victimisation and excessive gratification or frustration of needs, such as emotional expression. Maladaptive schemas are proposed to provide a framework for viewing the self and others and are elaborated through life. Early experiences result in the individual being convinced that their core beliefs are the truth (unconditional). As infants code experiences emotionally rather than verbally, their capacity to question core beliefs is limited. It is only when later experiences challenge core beliefs that their validity is queried. However, it is a commonly held assumption that schemas cannot be changed (Riso et al., 2006), though there is some evidence that they are mood-dependent (Stopa, & Waters, 2005).

For this review, schemas are defined as broad cognitive structures that incorporate core beliefs (unconditional levels of belief about who we are) and influence perceptions, emotions and behaviours, including problematic behaviours such as overeating. People who identify with certain schemas will attend to, process and respond to related information (including that pertaining to weight and appearance) differently to people who do not identify with having that schema. Core beliefs are contained within schemas and researchers use both terms to mean fundamental thoughts about the self. Therefore, from this point forward 'schema' and 'core belief' will be used inter-changeably to refer to schema-level core beliefs.

There are various questionnaires that measure schemas. In its different forms, the Young Schema Questionnaire (YSQ; Young, & Brown, 1990) is the most widely used measure of cognitions at the schema level. The Eating Disorders Belief Questionnaire (EDBQ) investigates negative core beliefs in addition to specific disordered eating beliefs (Cooper, Cohen-Tovée, Todd, Wells, & Tovée, 1997). Some general measures of mental health also include specific items outlining individual core

beliefs (e.g., Beck Depression Inventory; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

It is important to look at schemas in the overweight and obese population as it is possible that dysfunctional schemas drive their weight problem, are maintained by the weight problem, or adversely affect the effectiveness of weight management programmes. Overeating could be a method of avoiding the negative affect associated with maladaptive schemas. Activated schemas, such as the failure to achieve schema, might also predict failure at weight loss treatment and therefore result in poorer intervention outcomes (Byrne, 2002).

Schema-level core beliefs have been investigated within eating disorders. More pathological core beliefs were present amongst people with binge eating disorder (schemas related to inability to express emotions or function independently and needing to sacrifice their own needs) and bulimia nervosa (schemas related to fear of abandonment) compared to BMI-matched controls (Waller, 2003). People with anorexia nervosa report more negative self-beliefs than those on a diet and non-dieting controls (Cooper, & Turner, 2000). Therefore, characteristic patterns of schemas appear to be present in people with eating disorders.

As people with disorders of eating have been found to have characteristic patterns of negative core beliefs, it is possible that schemas leading to overeating exist in overweight and obese populations. A review of research into schemas amongst the obese/overweight population could find out whether there are any patterns of core beliefs that characterise obesity or are associated with obesity's severity or presence. This could help inform clinicians about the most effective way to treat obesity. Reviewing the literature could also provide indications about which model of maladaptive schemas best explains the relationship between schemas and obesity, and has the most relevance in obesity research.

## **Aims**

This review aimed to investigate the existing literature into which schemas are present in overweight and obese individuals and to critically appraise the employed methods. The specific aims of this review were as follows:

1. To investigate the association of schema levels with weight status
2. To examine whether a core set of schemas characterises obese people

## **Method**

### **Design**

A systematic method was chosen to address the questions posed by this review. A systematic review is a methodical way of clearly selecting, critically appraising and summarising the available research (Moher, Liberati, Tezlaff, & Altman, 2009). This approach was appropriate, given the transparency and reduced risk of bias inherent in the methodology and the current limited scope of the topic in the literature. This review followed the “preferred reporting items for systematic reviews and meta-analyses” (PRISMA; Moher et al., 2009) guidance. As such, the review used clear search terms, inclusion and exclusion criteria and quality assessment measures to reduce the risk of bias in the selection and synthesis of the research. Ethical approval was not required due to the study being a review.

### **Search strategy**

To explore schema-level core beliefs in people who are obese or overweight, literature was searched for using PubMed and Web of Science databases. As a review had not been conducted in this topic area previously, all the available literature from the databases until 04/12/2015 were searched to ensure any relevant published paper was found. Search terms and Boolean operators were used to search the databases for relevant papers:

“Obes\*” or “Overweight” and “Schema”  
or “Schemas”  
or “Schemata”  
or “Core beliefs”  
or “Core belief”

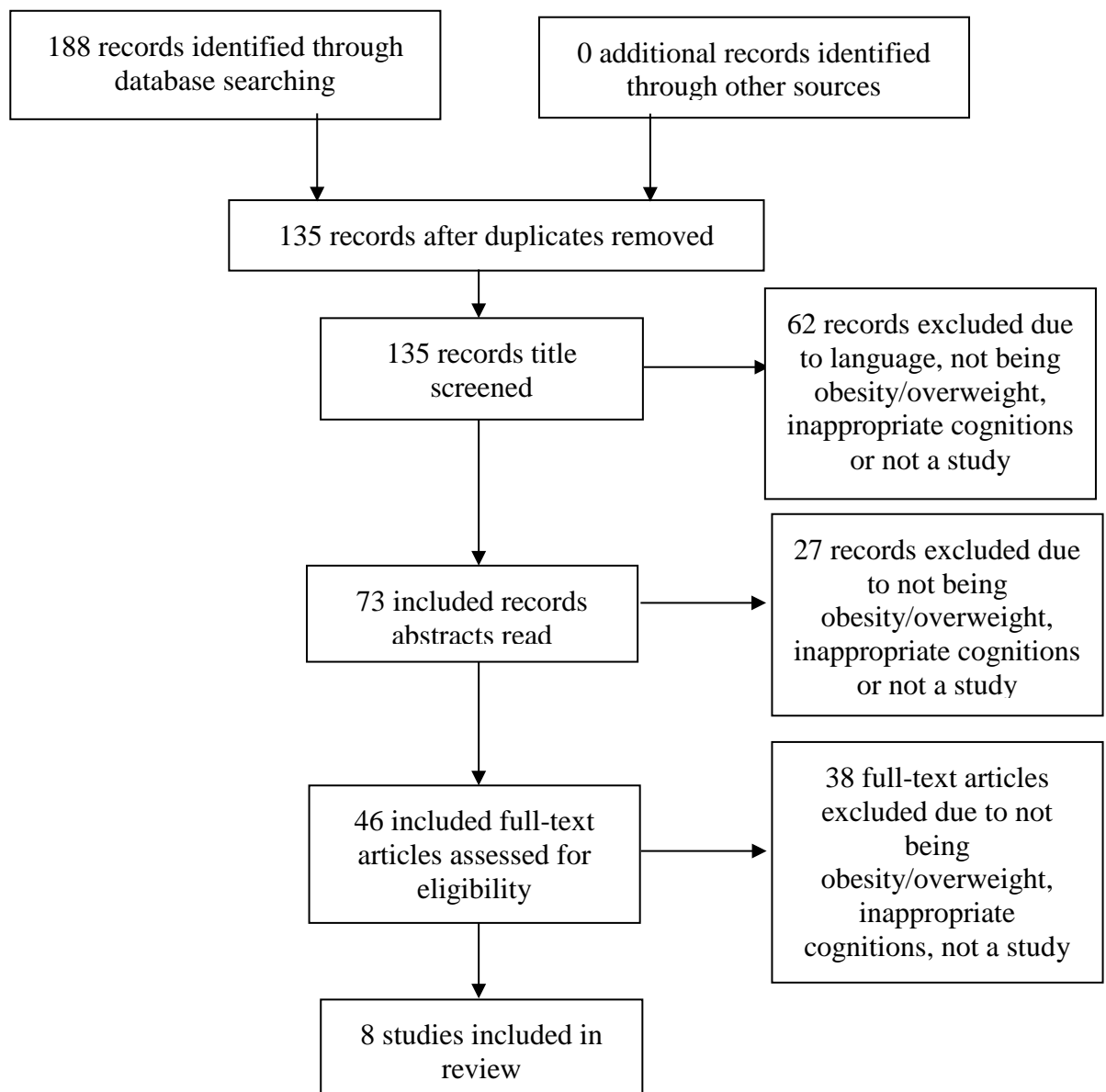
Preliminary searches were conducted using the search terms “cognitive content” and “cognitions”. However, this identified a wealth of papers relating to more superficial cognitions. Comparison of the resulting papers from searches with and without these terms showed that these additional terms were not necessary to locate the relevant papers. Therefore, those search terms were excluded from the final search strategy (see Appendix 1 for full search history).

The search terms were intended to include papers investigating core beliefs amongst overweight participants in addition to obese participants to discover whether any differences exist amongst the weight categories. However, definitions of obesity varied between studies but all reliably included overweight participants and no studies compared obese participants with overweight participants. Consequently, resulting findings have been reported to reflect the “obese/overweight population” rather than “obese population”. To ensure all relevant papers were included in the review even if they had not been identified through the databases, reference list searches were performed on all included studies.

### **Inclusion and exclusion criteria**

Studies were identified as eligible for review through a process of title screening followed by abstract screening, and finally full article screening. This process is shown in Figure 1, using a PRISMA diagram (Moher et al., 2009).

Figure 1 PRISMA diagram showing how studies were selected for review



Studies were included for review if participants, other than the control group, were defined as obese or overweight by the authors or described as attending or waiting for weight loss treatment. Additionally, to be included in the review, the cognitions studied must be at the core belief level.

Initially, the only exclusion criteria were conference papers and publication not in the English language. All papers including questionnaires with items relating to core beliefs were read in full. However, papers including total scores rather than data on individual scales were not included in the review, as they did not provide enough

information about the specific schemas present amongst the obese population. When papers were published using the same data set, only the paper that included the data most relevant to the review aims was included.

Initial consideration of the review findings resulted in exclusion of papers relating to one measure. The EDBQ contains only one negative self-belief scale which does not provide a diverse enough pattern of core beliefs to build a profile of schemas amongst the obese population (Cooper et al., 1997). Therefore, papers solely using the EDBQ as a measure of schema dysfunction were excluded from the review. The process of conducting a systematic review is iterative (Moher et al., 2009). Therefore, this exclusion criterion evolved throughout the process of data selection through supervision consultation, and appraisal of the limited utility of these papers to contribute meaningful information to achieving the aims. The screening process was repeated with this additional exclusion criterion and Figure 1 incorporates this iteration.

### **Quality of studies**

Providing an indication of the quality of studies in the area allowed the interpretation of the findings to be weighted based on the quality of the research, if necessary. Study quality was appraised using an adapted version of Downs and Black's checklist (1998). This quality appraisal checklist was chosen due to having good reported internal consistency and reliability. The checklist items includes a scoring system that quantifies the quality of each reviewed paper. The checklist was adapted to remove criteria that were not applicable to the cross-sectional methods used by the included studies. Sixteen relevant criteria were selected and items relating to interventions and follow up were removed (see Appendix 2 for the adjusted checklist).

Following Downs and Black's (1998) checklist created a consistent approach to quality appraisal considering the following criteria:

- Reporting (aims, outcomes, participant characteristics, confounders, findings, variability estimates and probability values)
- External validity (representativeness of participants)
- Internal validity – bias (data-dredging, statistical tests and measures)
- Internal validity – confounding (selection bias and confounding adjustment)
- Statistical power

Studies were rated from 0-21 based on 16 criteria. When it was impossible to determine whether the quality criteria had been met, a score of 0 was given. A higher score indicated greater quality. Papers were included in the review if they reached a score of 10.5 (50% of the total possible). This score was an arbitrary cut-off, chosen to include only papers of sufficient quality. See Appendix 3 for the individual item and total scores for each paper.

The first author conducted the quality assessment for all eight papers and a second person appraised the quality of 50% of the papers (the first and third paper alphabetically from each of the four papers that covered each aim) using the same criteria. The second appraiser was also a third year Doctor of Clinical Psychology student. This process resulted in 87.5% agreement. Cohen's kappa was 0.68 ( $p < .001$ ; SPSS version 22) suggesting substantial agreement between the appraisers (Landis, & Koch, 1977). Taken together, these statistics provide support for the reliability of the quality ratings completed by the first researcher. The inter-rater reliability was as good as could be expected, as the checklist has a natural degree of inter-rater disagreement (Downs, & Black, 1998). When a difference in opinion occurred, discussion between the two appraisers resulted in an agreed total quality rating, as included in Table 1 in the

Results section. There were between one and four items for each paper that the quality appraisers initially disagreed upon. Whether the second person allocated a higher or lower score for the item varied. See Appendix 3 for individual scores from both appraisers for the studies.

It might be assumed that the quality of research improves over time. Therefore, a Pearson's correlation was conducted (SPSS, version 22) between years since publication and total quality rating. There was no significant correlation of time since publication with quality ratings ( $r = -.252$ ;  $p = .547$ ). Therefore, it can be concluded that the quality of papers was similar regardless of when they were published.

## Results

Table 1 summarises the characteristics of the reviewed papers, which are presented in order of descending quality. Despite the plan to weight conclusions based on the quality of the papers, they all achieved an acceptable level and most were comparable (within four points of each other). However, one paper was of a considerably lower quality than the others (Bidadian, Bahramizadeh, & Poursharifi 2011).

The findings from papers investigating the association of schema levels with weight status are considered first. Table 2 displays the results relevant to this aim. This is followed by research investigating whether a core set of schemas characterise obese people (see Table 3).



Table 1.  
*Characteristics of all reviewed studies*

Author (Date)	Participants	Measures	Strengths	Limitations	Quality rating
Van Vlierberghe, Braet, & Goossens (2009)	64 overweight adolescents (38/64 treatment seekers, 42/64 females). Adjusted BMI 120%+. Mean age 14.97 (SD = 1.52, range 12-18)	ChEDE, YSQ-S, CDI	Use of a structured clinical interview to assess eating disorders. Non-treatment seekers included so generalisability is increased. Males and females sampled. Matching of participants on demographics reduced potential for confounding effects. Measured weight. Used validated schema measure.	Small sample size. Cross-sectional design limits ability to make temporal conclusions or suggestions of mechanisms by which schemas lead to binge eating. Self-report measure open to bias.	18
Anderson, Rieger, & Caterson (2006)	52 obese adults (BMI 30+) new attendees of group weight loss sessions 9/52 with clinical/subclinical BED. 39 normal weight adult control participants (BMI = 18.5-24.9). Age 18+	YSQ-S, QEWP-R, BES, POMS-A, BIDR	Relatively large sample size. Comparison group used. Weight of obese group measured improving accuracy. Validated measure used. Males and females sampled. Measure to control for desirable responses.	Treatment seeking obese participants only. Comparison group differed on age and household income - potential confounding variables. Self-report weight of normal weight controls could be inaccurate. Retrospective data. Opportunity sampling for control. Self-report measure open to bias.	17

Table 1 continued.

Author (Date)	Participants	Measures	Strengths	Limitations	Quality rating
Fereidouni et al. (2015)	60 obese female candidates for bariatric surgery (BMI 40+ or 35+ with comorbidity). Mean age 35.83. 60 normal weight females (BMI 18-24.9). Mean age 33.38. 23 overweight female adolescents (BMI 25+). Mean BMI = 27.8 (S.D. = 2.6), age 17.6 years (S.D. = 0.42); 23 normal weight female adolescents. Mean BMI = 20.2 (S.D. = 0.1), age 17.7 years (S.D. = 0.43)	YSQ-S, DERS, BES	Large sample size. Matched control group on age and years of education. Used validated measures.	Bariatric surgery candidates and females only therefore generalisability to all obese people is limited. Self-report questionnaires vulnerable to bias. Obese group treated as homogenous and didn't investigate differences between those with BED and not.	17
Turner, Rose, & Cooper (2005)	74 obese females (BMI 27-45.2, mean 33.4, SD=4.2). 37/74 with BED. Mean age 38.4 (SD=7.1, range 21-49). 1 removed from analysis (final n = 73)	YSQ-S, EAT, EDBQ, BDI, PBI	Comparison group included. Used two measures of schemas – increases validity. Standardised measures used.	Small samples size. All females. Small age range (17-18) sampled. All non-treatment seekers. All sampling issues limit generalisability. Weight was self-report - could be inaccurate. Self-report measures vulnerable to bias.	16
Nauta, Hospers, Jansen, & Kok (2000)		RES, BDI, EDE-Q and interview	Interview to gather cognitions. Relatively large sample size. Clinician measured BMI – increases accuracy.	All female participants. Advert offered treatment for eating problems, unclear if this was provided. No comparison group. Interview relies on accessible cognitions only. All participants defined as obese but not all BMI>30	14

Table 1 continued .

Author (Date)	Participants	Measures	Strengths	Limitations	Quality rating
Van Hanswijck, Waller, Fiennes, Rashid, & Lacey, (2003)	30 morbidly obese adults (BMI 40+) waiting for gastric surgery as a weight loss treatment. 24 females. Mean BMI = 55.5 (S.D. = 10.1, range = 40.8-73.5). Mean age = 42.3 (S.D. = 9.12, range = 27-61)	CATS, YSQ-S	Weight measured by clinicians. Validated measure used.	Small sample size. Mainly female sample. Clinical population only. Retrospective data. No control group of normal weight participants for comparison. Self-report vulnerable to bias.	14
Van Vlierberghe & Braet (2007)	91 obese adolescents referred for weight loss treatment (mean adjusted BMI = 183.25, S.D. = 26.75, range 132.88-273.92, all over 95th percentile). 53/91 females. Mean age = 14.91 (S.D. = 1.53). 91 normal weight controls from two secondary schools (mean adjusted BMI 99.93, S.D. = 10.41, range 78.90-119.39, below 85th percentile). 52/91 females. Mean age 15.02 (S.D. = 1.68)	Adolescents ; Corresponding items from the YSQ & YSR Parents: CBCL	Large sample size. Males and females studied. Matched normal weight control group on age, gender and SES to obese group.	Obese adolescents studied so not able to generalise to obese adults. Only treatment-seeking obese people. Comparison group recruited differently. There could be a self-report bias. Questionable validity and reliability of the YSQ measure used.	14

Table 1 continued .

Author (Date)	Participants	Measures	Strengths	Limitations	Quality rating
Bidadian, Bahramizadeh, & Poursharifi (2011)	60 patients from a Weight Loss Clinic (19-37 years old, mean age = 24.62 (S.D. = 2.91), mean male age = 25.71 (S.D. = 2.63) and female = 23.4 (S.D. = 2.75)	YSQ-S, WHOQOL-BREF	Relatively large sample size. Participants were not coerced. Used validated measures	Participant BMI not reported. Aims and participant characteristics not clearly described. Treatment seeking participants only and volunteer participants limits generalisability. Cross-sectional design unable to infer causation.	12

Note. All studies were cross-sectional. BES-Binge Eating Scale (Gormally, Black, Daston, & Rardin, 1982); BDR-Balanced Inventory of Desirable Responding (Paulhus, 1991); BDI-Beck Depression Inventory (Beck, Ward, Mendelson, Mock, Erbaugh, 1961); CBCL-Child Behaviour Checklist (Achenbach 1991a); CATS-Childhood Abuse and Trauma Scale (Sanders, & Becker-Lausen, 1995); CDI-Children's Depression Index (Kovacs, 1992); EAT-Eating Attitudes Test (Garner, & Garfinkel, 1979); EDBQ-Eating Disorder Belief Questionnaire (Cooper, Cohen-Tovée, Todd, Wells, & Tovée, 1997); ChEDE-Eating Disorder Examination-Child version (Bryant-Waugh, Cooper, Taylor, & Lask, 1996); EDE-Q-Eating Disorder Examination Questionnaire (Fairburn, & Beglin, 2008); DERS-Difficulties in emotional regulation scale (Gratz, & Roemer, 2004); PBI-Parental Bonding Instrument (Parker, Tupling, & Brown, 1979); POMS-A-Profile of Mood States-Adolescents (Terry, Lane, & Foggarty, 2003); QEWPR-Questionnaire on Eating and Weight Patterns-Revised (Spitzer et al., 1992); RES-Rosenberg self-esteem scale (Rosenberg, 1965); WHOQOL-BREF quality of life assessment (World Health Organization, 1998); YSQ-S-Young Schema Questionnaire-Short Form (Young, & Brown, 1998), Dutch YSQ-Corresponding items from the Young Schema Questionnaire-long version (Van Vlierberghe, Rijkeboer, Hamers, & Braet, 2004); YSR-Youth self-report (Achenbach 1991b).

## The association of schema levels with weight status

Of the eight studies reviewed, four investigated the strength of core beliefs according to whether someone is obese/overweight or not. Table 2 shows the results of these four papers, ordered alphabetically according to the first author.

Table 2.

### *Findings from the four studies investigating core beliefs according to weight status*

Author (Year published)	Results
Anderson, Rieger, & Caterson (2006)	Obese adults had a greater severity of maladaptive schemas than normal weight adults. Higher social isolation, defectiveness/shame and failure to achieve schema scores were significantly related to obesity status. Amongst the obese participants, greater severity of maladaptive schema was significantly associated with more mood disturbance and problematic eating.
Fereidouni et al. (2015)	Obese females had significantly higher scores on emotional deprivation, enmeshment, dependency, mistrust, failure, self-sacrifice, abandonment, social isolation/alienation, subjugation, vulnerability and self-control schemas compared to the normal weight females. Obese females reported more binge eating and goal, impulse and strategy emotional regulation difficulties than normal weight females.
Turner, Rose, & Cooper (2005)	Overweight female adolescents scored significantly higher on the negative self-belief scale and schemas relating to subjugation, emotional deprivation, abandonment and self-control than normal weight female adolescents. In the overweight group BMI correlated negatively with the insufficient self-control schema and maternal care negatively correlated with all schema. Overweight females perceived their fathers as less caring and more overprotective.
Van Vlierberghe & Braet (2007)	Obese adolescents who have been referred for weight loss treatment report more severe levels of maladaptive schemas than adolescents of normal weight especially social isolation/alienation, defectiveness/shame, failure to achieve, emotional deprivation, subjugation and dependence/incompetence schemas. Social isolation and vulnerability schemas were related to internalising symptoms. Dependence and entitlement schemas were related to externalising symptoms.

Table 2 shows that in the populations studied, obesity appears to be associated with a greater severity of maladaptive schemas. Out of the 15 maladaptive schemas, five

were found to be held more strongly amongst the obese/overweight population in more than one study. Those schemas are social isolation and failure to achieve (Anderson, Rieger, & Caterson, 2006; Fereidouni et al., 2015; Van Vlierberghe, & Braet, 2007), subjugation and emotional deprivation (Fereidouni et al., 2015; Turner, Rose, & Cooper, 2005; Van Vlierberghe, & Braet, 2007) and defectiveness/shame (Anderson et al., 2006; Van Vlierberghe, & Braet, 2007). There appears to be a cluster of maladaptive schemas held more strongly by people who are obese/overweight. However, as shown in Table 1, problems with sampling in all reviewed studies limits the ability to generalise this finding to the whole population of obese/overweight people.

### **Schema patterns within the obese/overweight population**

Of the eight included studies, four investigated the second aim – whether a core set of schemas characterises obese people. Table 3 shows the results of these four studies ordered alphabetically according to first author.

Table 3 shows that all the reviewed studies investigating schemas within the obese/overweight population found variation in schema profiles or severity amongst the group. However, the studies did have sampling problems, as shown in Table 1. The pattern of schemas varied dependent upon whether participants binge ate (Nauta, Hospers, Jansen, & Kok, 2000), experienced childhood sexual abuse (Van Hanswijck de Jonge, Waller, Fiennes, Rashid, & Lacey, 2003), or lost control over eating (Van Vlierberghe, Braet, & Goossens, 2009), and varied with their quality of life (Bidadian, Bahramizadeh, & Poursharifi, 2011). Regardless of participants' age range or quality of research, there did not appear to be a consistent pattern of schemas present among the obese/overweight population.

It is important to note that Bidadian and colleagues' (2011) produced a poorer quality paper relative to the others included in this review. Therefore, the finding that

obese people's core beliefs differ according to quality of life experienced should be interpreted with caution.

Table 3.

*Findings from the four studies investigating patterns of core beliefs within obesity*

Author (Date)	Results
Bidadian, Bahramizadeh, & Poursharifi, (2011)	In patients attending a weight loss clinic, emotional deprivation, defectiveness/shame, failure, dependence, enmeshment, unrelenting standards, entitlement and insufficient self-control schemas negatively correlated with quality of life. Emotional deprivation, insufficient self-control and mistrust/abuse schemas predicted 90% of the variance in quality of life. Insufficient self-control was related to total health and physical health.
Nauta, Hospers, Jansen, & Kok, (2000)	All the obese females identified with schemas relating to a lack of willpower, rejection and unworthiness. People who were obese and binge ate mentioned rejection and unworthiness schemas more often whilst in the obese non-binge eaters the lack of willpower schemas were predominant. Only in the group of obese binge-eaters were weight, shape and eating concerns combined with negative self-generalisations.
Van Hanswijck, Waller, Fiennes, Rashid, & Lacey, (2003)	Amongst the obese population, those who had experienced childhood sexual abuse exhibited a greater severity of maladaptive schema, in particular social isolation, defectiveness/shame, vulnerability to harm and subjugation schemas than those who had not experienced childhood sexual abuse. BMI was associated with dependence and entitlement schemas in the non-abused group and emotional deprivation, mistrust/abuse, social isolation, abandonment, unrelenting standards and subjugation in the abused group. Weight fluctuations were associated with dependence, enmeshment and entitlement in the non-abused group of participants and abandonment and social isolation in participants who had been abused.
Van Vlierberghe, Braet, & Goossens(2009)	Overweight adolescents experiencing a loss of control over eating report a greater severity of maladaptive schema, in particular: social isolation, subjugation, failure to achieve, abandonment, unrelenting standards and mistrust/abuse schemas. Some schemas were associated with eating, shape, restraint concerns and depression.

## Discussion

### Summary

This review aimed to investigate the association of schema levels with weight status (whether someone is obese/overweight or not) and to examine whether a core set of schemas can characterise obese/overweight people. Considering the first aim of whether obese/overweight people have different schemas to people who are of a normal weight, the literature shows that there appears to be a cluster of critical schemas associated with being obese or overweight. People who were obese/overweight held social isolation, failure to achieve, defectiveness/shame, subjugation and emotional deprivation schemas more strongly than people of a normal weight.

The second aim related to whether there are schema differences within the obese/overweight population. Investigating whether all obese people hold the same schemas as strongly when other factors, such as life experience, quality of life, degree of binge eating and control over eating, differ shows that there does not appear to be a consistent pattern of core beliefs within the obese/overweight population. Therefore, it is not possible to characterise the obese/overweight population based on their schemas. This pattern suggests that a complex relationship exists between schemas and obesity. Appraisal of the research highlights that there are limitations associated with the available literature. Therefore these findings must be interpreted with caution.

### **The relationship between obesity and schemas**

It could be argued that the current cultural climate creates a tendency towards obesity increasing in prevalence, due to social and genetic factors (e.g., Tillotson, 2004). Therefore, a psychological explanation for the relationship between obesity and schemas must sit amongst these factors to explain why some people, rather than others, become and remain obese.

One hypothesis is that aversive childhood environments lead to obesity and maladaptive schemas concurrently. For example, a parent might be insensitive to the



child's appetite cues and therefore not effectively regulate their food intake, as well as providing conditions for dysfunctional schemas to develop. Another possibility is that aversive childhood environments leads an individual to develop maladaptive schemas, activation of which results in primary, compensatory behaviours to reduce the possibility of negative affect occurring (Waller, Kennerley, & Ohanian, 2007). For obese people, this could maintain their weight by predicting failure of weight loss interventions (Byrne, 2002). Therefore, to avoid activating the failure to achieve schema, they do not attempt to lose weight and their current weight is maintained. Another alternative is a model of central and compensatory schemas (Waller et al., 2007), which is proposed as a potential mechanism linking schemas and obesity.

**Central and compensatory schemas.** Five core beliefs appeared to be held more strongly amongst obese/overweight people than people who are of a normal weight. These core beliefs were social isolation, failure to achieve, defectiveness/shame, subjugation and emotional deprivation. A model of obesity is proposed which categorises core beliefs as central (emotional deprivation, defectiveness/shame and failure to achieve) or compensatory (social isolation and subjugation). The model suggests that *central schemas* develop in response to aversive childhood experiences and compensatory schemas develop to cope with the effects of the central schemas. For example, a variety of childhood incidents could occur (e.g., neglect, excessive criticism or traumatic experiences) that might lead someone to develop central schemas of emotional deprivation, defectiveness/shame and failure to achieve. These schemas were three of the five identified in the review as being more elevated amongst the obese/overweight populations.

Van Hanswijck de Jonge and colleagues' (2003) finding that obese adults who experienced childhood sexual abuse exhibited a greater severity of maladaptive schema than those who had not experienced childhood sexual abuse supports the assertion that

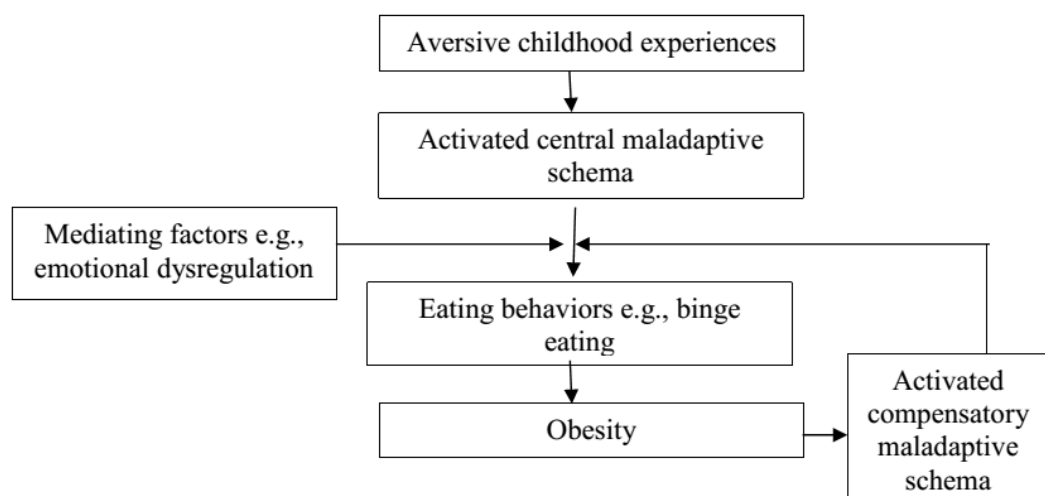
maladaptive schema develop as a result of early life experiences. As obese/overweight people exhibit a greater severity of maladaptive schemas than people of a normal weight, it is possible that obese/overweight people have experienced more negative early life events. Further supporting research highlights that obese individuals report more instances of maltreatment in childhood than people of a normal weight (Grilo, Masheb, Brody, Burke-Martindale, & Rothschild, 2005; Rohde et al., 2008).

The resulting negative affect experienced by activation of the emotional deprivation, defectiveness/shame and failure to achieve schemas might be intolerable for some due to a variety of mediating and moderating factors. These could be emotion regulation difficulties, lack of problem solving ability or hypersensitivity to emotions. Eating in response to schema activation allows the individual to replace the emotion with a more acceptable emotion (e.g., satiation, fullness or nausea) and could result in avoidance of the negative affect. The resulting negatively reinforcing effect of removing the aversive experience leads to the behaviour (eating) being more likely to occur when the stimulus (negative emotion) is re-experienced. Consequently, if these central schemas are activated frequently and a person responds by eating, they are at risk of becoming obese. This model could also explain the variation in schema severity according to binge eating severity, losing control over eating and aversive early life experiences found in the papers investigating schema differences within the obese populations.

Along with elevated maladaptive schemas, more emotional dysregulation, binge eating and mood disturbance were present amongst people who were obese compared to people who were normal weight (Anderson et al., 2006; Fereidouni et al., 2015; Van Vlierberghe, & Braet, 2007). These findings offer support to the notion that negative central schemas cause binge eating in individuals unable to tolerate negative affect.

Living life as an obese person can lead to additional problems, such as experiencing the effects of social stigma (Lee, & Shapiro, 2003) and low self-esteem (Pila, Sabiston, Brunet, Castonguay, & O’Loughlin, 2015). *Compensatory schemas* are hypothesised to develop to cope with the effects of the central schemas. Obesity is proposed to be one of the effects of the central schemas. The final two schemas found to be held more strongly amongst the obese/overweight population (social isolation and subjugation) could have developed to cope with obesity. Isolating themselves and putting the needs of others before their own could be a way of people who are obese/overweight making themselves feel more acceptable, improve their self-esteem and reduce the possibility of encountering stigma. As a way of avoiding the associated negative emotion that occurs when these compensatory schemas are activated, the individual uses the strategy they have found to work, and eat to feel a different sensation, and thus obesity is maintained. Figure 2 shows how this model of central and compensatory schemas could lead to and maintain obesity.

Figure 2 A model of the role of central and compensatory maladaptive schemas in obesity



## **Critique of the literature**

There are limitations associated with all the reviewed studies that weaken the conclusions that can be drawn. Firstly, there are limitations in the samples obtained by the researchers, which limit the generalisability of the findings to all obese/overweight people. The obese samples obtained in six of the reviewed papers only included people seeking support for weight loss. Obese people seeking treatment have been found to experience higher levels of psychopathology, binge eating and emotional eating than obese people not seeking treatment (Fitzgibbon, Stolley, & Kirschenbaum, 1993). Therefore, it is possible that differences in schemas also exist between the two groups of people. Consequently, the findings could be reflective of people seeking treatment rather than people who are obese. The schemas in common between the samples who sought treatment and those not seeking treatment – subjugation and emotional deprivation (Turner et al., 2005) – are the schemas most likely to represent the core beliefs held by the obese/overweight population as a whole.

In a few studies (Fereidouni et al., 2015; Nauta et al.; 2000; Turner et al., 2005), all participants were female, which limits the ability to generalise the findings to all obese/overweight people. Research suggests that females hold most maladaptive schemas more strongly than males (e.g., El-Gilany, El-Bilsha, & Ibrahim, 2013). As differences in schemas exist between the genders, the review findings might not be applicable to obese/overweight males. Consequently, the proposed model might only reflect how schemas link to obesity in obese/overweight females seeking treatment.

Turner and colleagues (2005) used the EDBQ (Cooper et al., 1997) in addition to the YSQ-S (Young, & Brown, 1998). As this measure replicated the finding that elevated negative self-beliefs exist in the overweight participants, it provides strength to the assertion that the higher scoring on the YSQ-S was due to the greater presence of those schemas amongst the obese/overweight population, and not due to something

inherent in the measure itself. Therefore, the results found are likely to represent differences in core beliefs between the populations.

However all studies, with the exclusion of Nauta et al. (2000), relied on self-report which is known to introduce bias. Research has found that obese people respond to questionnaires in socially desirable ways in an effort to reduce the appearance of psychological problems, which avoids increasing the stigmatising effect associated with obesity (Lee, & Shapiro, 2003). Only Anderson and colleagues' (2006) considered the tendency for obese people to provide socially desirable responses. Maladaptive schema were found to be present despite the possibility that obese/overweight participants were responding in socially desirable ways, which strengthens the idea that obese/overweight people do hold certain schema more strongly than people of normal weight.

A final limitation of the studies is their use of a cross-sectional design. These methods involve retrospective data collection at one time point. This reflects the infancy of the research but limits the conclusions that can be drawn. Subsequently, it is possible to propose a model but not be certain whether maladaptive schemas are a cause, consequence or mediating factor in the development of obesity.

In summary, it is likely that the results found reflect reliable differences in core beliefs in the populations studied. However, the populations studied might not be reflective of the entire population of people who are obese/overweight, reducing the ecological validity of the review findings.

### **Limitations of the review**

The limitations associated with this review begin with the methodological weaknesses of the included studies. Although the review aimed to reduce bias in the literature selection and synthesis, there are some limitations in the review itself.

First, the search strategy focussed on published literature. Therefore, a publication bias could have occurred, as unpublished studies are known to have

approximately 9% smaller effects (Hopewell, McDonald, Clarke, & Egger, 2007). This review focussed on eight papers that found significant differences in schemas. It is unknown how many studies were conducted into obesity and schemas that might have found no associations and gone unpublished. Additionally, the use of only two databases and the search terms possibly not being exhaustive could have led to the omission of some relevant studies. If unpublished and additional published studies were included, the review might have reached different conclusions.

The exclusion of papers that solely used the EDBQ (Cooper et al., 1997) as a measure of schemas could also be a weakness. This exclusion criterion was decided due to the limited ability of this measure to provide information about the differing schemas that exist. However, removing this criterion could have led to different results or more information about the mechanisms by which maladaptive schemas are associated with obesity.

There are also potential limitations in the interpretation process. Although attempts were made to remain impartial, the author's interest in the field could have impacted upon the interpretation of study results. This is particularly important in the quality appraisal process, and could have led to higher scores indicating greater quality. However, the acceptable level of inter-rater reliability suggests this might not have occurred. Additionally, the arbitrary cut-off point for inclusion in the review, based on achieving 50% of the total possible quality rating, adds further subjectivity into the process and could have led to the inclusion of some poorer quality studies.

There is also a limitation in the use of the Downs and Black (1998) checklist as, due to the limited research designs reviewed, some items were not relevant and were therefore removed. This process of item omission could have affected the validity of the use of the checklist as a quality control measure. An alternative quality control measure

requiring fewer adaptations with an objective cut off point could have been used (e.g., Kmet, Lee, & Cook, 2004).

Earlier in this review, the concept of building a profile of obese people was considered. The results show that a profile of overweight/obese people is not possible to obtain due to variation between individuals. However, the differences found between overweight/obese people and people of a normal weight suggest that further investigation into schemas in this population is warranted.

It is useful to consider whether there is a tendency towards obesity in people with a certain set of schemas, as found by this review, with the acknowledgement that some people with the same schema pattern will never go on to develop obesity. With this knowledge, suggestions for clinical practice emerge. For example, assessing whether the five core schemas found in this review are held by individuals might be helpful. If individuals identify with these schemas, investigating whether they contribute to the maintenance of the weight problem could provide different directions for weight loss treatment such as monitoring or addressing schemas. Consequently, it is useful to consider the psychological characteristics that overweight/obese people have in common, even if it is not feasible to construct a profile of obese people's cognitions.

### **Future research**

Future research could help elucidate the model of schemas and obesity. Longitudinal research with younger participants, comparing those who develop obesity with those who remain a normal weight, could provide information about how maladaptive schemas are associated with obesity. Research could investigate whether different schemas develop at different points in life, providing information about the existence of central and compensatory schemas.

Such research could also investigate the mechanisms by which maladaptive schemas are associated with obesity to provide further support for the model proposed

by this review. Investigating the relationship between differences in maladaptive schemas and other psychological variables (e.g., depression and emotion regulation) could provide information about factors that mediate or moderate the relationship between maladaptive schemas and obesity.

Prospective studies could provide information about whether maladaptive schemas predict the amount of weight lost or regained following weight loss interventions, to investigate whether maladaptive schemas contribute to the limited success of obesity treatment. Research investigating the impact of weight loss on schemas and psychosocial factors could provide useful insights into the relationship between schemas and obesity. As maladaptive schemas are thought to increase negative affect, a reduction in psychopathology following weight loss could indicate that reducing obesity has an effect upon maladaptive schemas. Therefore, this research could provide useful insights into the nature of the relationship between maladaptive schema and obesity. Future research could also compare schemas in the obese population with those of people with eating disorders, to investigate whether any commonalities exist.

Any future research should address the limitations of the current literature to increase the applicability of findings to the whole population of overweight/obese people. This could include research using stratified sampling to include non-treatment seekers and more males. The use of experimental conditions (e.g., the Stroop task) to investigate the activation of schemas could overcome the limitations of the self-report measures used by most reviewed studies. The Stroop task has been used to investigate attentional bias in eating disorders and other clinical conditions (Cooper, Anastasiades, & Fairburn, 1992).

### **Clinical implications**

The review suggests that obese people presenting for treatment might have more dysfunctional core beliefs than the normal weight population. Additionally, the severity



of these maladaptive schema is associated with childhood sexual abuse, losing control over eating and degree of binge eating. Therefore, psychological therapy might be required in the treatment of obesity in some cases. NICE (2014) recommend psychological support and cognitive restructuring, but currently therapy to address core beliefs is not included in the guidance.

When patients attend assessment for weight loss, it might be beneficial to assess for maladaptive schemas using clinical interviews and appropriate validated assessment measures, such as the YSQ-S (Young, & Brown, 1998). Patients might benefit from a flexible approach, where their needs at referral are responded to – whether that is lifestyle management through reducing dietary intake and increasing exercise, surgery, or challenging core beliefs through a therapeutic intervention. Even if therapy is not chosen, it could still be useful to use the YSQ-S to monitor schemas as treatment progresses, to highlight whether some schemas are maintaining obesity and require addressing in addition to the agreed programme, or whether they are reduced by weight loss per se. It is possible that targeting only the weight might neglect factors that maintain obesity, and therefore lead to relapse and weight gain, as found in the literature (Barte et al., 2010).

Formulating a specific therapeutic package based on assessment of schemas would be ideal. To begin with, however, obesity treatment could incorporate psychological strategies aimed at addressing the core five schemas most relevant to obesity as identified in this review (emotional deprivation, defectiveness/shame, failure to achieve, social isolation, subjugation), as detailed by Young (1990).

### **Conclusion**

This systematic review of the available literature has found that a group of maladaptive schemas appear to be held more strongly amongst people who are

obese/overweight than people who are normal weight. These schemas were social isolation, failure to achieve, defectiveness/shame, subjugation, and emotional deprivation. However, there is no one consistent pattern of schemas amongst people who are obese/overweight. Therefore, it is not possible to characterise the obese population based on their core beliefs. It is not known whether maladaptive schemas cause, are a consequence of, or mediate/moderate the development of obesity. Whether schemas affect successful weight loss, and the precise mechanisms defining the relationship between schemas and obesity, are unclear at this stage of the research and require further investigation. However, it could still be useful to consider assessing for core beliefs and offering therapy to challenge those cognitions amongst people who are obese.

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## Section two: Research report

The relationship between psychosocial characteristics and weight loss in a weight management programme

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## **The relationship between psychosocial characteristics and weight loss in a weight management programme**

### Abstract

#### **Objectives**

Despite the severity of the health risks associated with obesity, the effectiveness of weight loss interventions is limited. Therefore, understanding factors associated with weight loss could be useful to help improve outcomes. Previous research has produced weak and inconsistent findings regarding the association between psychosocial characteristics and weight loss during lifestyle interventions. Therefore, this study aimed to investigate the association of personality, psychopathology, patient activation, quality of life and physical symptom burden with the amount of weight lost (and rate of attrition) during participation in a weight management programme.

#### **Methods**

Data on psychosocial variables and weight were collected from 49 participants during the first 12 weeks of a routine clinical intervention for weight loss. The resulting data were analysed using a combination of comparative and associative statistical tests.

**Design.** A within-groups correlational longitudinal design with naturalistic data was employed.

#### **Results**

Psychosocial characteristics did not predict the amount of weight lost by participants or their ability to remain in treatment. Mental health, quality of life and physical symptom burden improved during the first 12 weeks of the intervention. However, only the improvements in symptom burden were significantly associated with the amount of weight lost.

## **Conclusions**

There does not appear to be a direct relationship between magnitude of weight loss and psychosocial characteristics. The lifestyle intervention is suitable for all obese people wanting to lose weight. Additionally, improvements in physical symptom burden could reinforce additional weight loss.

## **Practitioner points**

- It is not advisable to have referral criteria excluding anyone on the basis of their psychological characteristics, as the intervention appears suitable for all.
- As psychosocial characteristics were unable to predict how much weight was lost, there is no recommendation to adapt current clinical practices to focus on psychological change.
- When setting expectations of change, clinicians might benefit from considering the small amount of proportional weight lost during the first 12 weeks of a weight management programme.
- The finding that the amount of weight lost was associated with physical improvements could be used by clinicians to motivate people to lose more weight.

## **Cautions**

- It is possible that a selection bias occurred, resulting in participants who were not reflective of all attending the weight management programme. Therefore, it might not be possible to generalise the findings to all obese people losing weight.
- Missing data resulted in some pro-rated final scores, which increased the possibility of measurement error. Therefore, the results might not be a valid representation of participants' psychosocial characteristics.



## **The relationship between psychosocial characteristics and weight loss in a weight management programme**

### **Obesity treatment**

Obesity is a worldwide problem. A body mass index (BMI) score classifies the weight status of an adult and is calculated by dividing weight in kilograms (kg) by the square of height in metres (m) (i.e., kg/m<sup>2</sup>). The worldwide prevalence of obesity (BMI  $\geq 30$ ; National Institute for Health and Care Excellence; NICE, 2014) has increased from 5% of men and 8% of women in 1980 to 10% and 14% respectively in 2008 (World Health Organization; WHO, 2014). In 2008, 35% of adults aged 20 years or over were overweight with a BMI over 25 (WHO, 2014).

Obesity is one of the top five risk factors for death (WHO, 2009). Consequently, the healthcare burden of obesity is comparable to that caused by tuberculosis and HIV/AIDS (WHO, 2009). Obesity is associated with mental and physical health problems. Obesity increases the risk of depression (Luppino et al., 2010), heart disease, high blood pressure, type 2 diabetes mellitus, stroke and cancer (Wellman, & Friedberg, 2002). Therefore, effective treatment for obesity is vital.

For obese people with a BMI 30-39.9, NICE (2006) recommends lifestyle weight management programmes. These programmes advise eating a balanced diet and increasing physical activity. For people with a BMI of 40 or above, lifestyle weight management programmes or bariatric surgery are recommended. The goal for weight management programmes is usually around 5-10% weight loss, as this results in physical benefits (Klein, 2001).

The term 'lifestyle intervention' has been used in the literature to describe many different weight loss interventions with the exclusion of pharmacological and surgical

interventions. Lifestyle interventions include nutritional counselling, exercise and diet programmes, rehabilitation centres and therapeutic support.

**Success of weight loss interventions.** Despite the high cost associated with being obese, the success of lifestyle weight management interventions is limited and could be influenced by many variables (Teixeira et al., 2004). For example, in one study the greatest predictor of weight loss during a lifestyle intervention was initial weight loss of at least a kilogram (Elfhag, & Rössner, 2010).

Studies investigating the effectiveness of lifestyle weight management interventions at maintaining the weight loss show varying results (Gilmartin, & Murphy, 2015). Additionally, there does not appear to be an association between the amount of weight lost and the percentage of the loss maintained following the end of an intervention, with an average across studies of 54% of a 9.5% weight loss being maintained (Barte et al., 2010). One suggestion for the variable success of the programmes is that other factors contribute to weight loss and maintenance. As psychological and social variables differ between individuals, these factors could be the reason some people lose weight, whilst others do not. Understanding the relationship between weight loss and psychosocial variables could provide insight into the varying success of weight management programmes.

### **Psychosocial variables and weight**

There is a wealth of research investigating the impact of psychosocial characteristics on adherence to weight management treatment and the amount of weight lost but findings are inconsistent. In order to understand the relationship between two variables, studying the impact upon one factor when the other changes helps indicate whether a causative relationship exists. However, few studies investigate the impact of weight loss upon psychosocial characteristics. The following section will summarise the findings so far, focusing upon weight loss in lifestyle management programmes.

**The impact of psychosocial factors on weight loss.** Previous research investigating the impact of personality on weight loss has found varying results. A meta-analysis showed high conscientiousness to be associated with a greater chance of return to non-obese from obese (Jokela et al., 2013). Some studies have investigated whether personality is associated with the amount of weight lost. Weight loss has been found to be associated with low novelty seeking (Dalle Grave et al., 2015) and, in participants undergoing a ‘very low energy diet’, negatively associated with facets of conscientiousness and positively associated with neuroticism (Munro, Bore, Munro, & Garg, 2011). An earlier study found no association between personality and weight loss following an eight week weight loss program (Poston et al., 1999).

Research findings into the effects of psychopathology on successful weight loss are also inconsistent. Whether weight was lost in pharmacological and lifestyle interventions was associated with lower baseline depression symptoms (Fabricatore et al., 2009). In another study, patients with depression and anxiety did not lose less weight than patients without these diagnoses in a lifestyle intervention (Legenbauer et al., 2009). In another lifestyle intervention study, psychopathology did not appear to predict the amount of weight lost (Currey, Holt, & Waller, submitted).

Similarly, research into the association of quality of life with amount of weight lost following a lifestyle intervention has produced variable results. Losing a larger amount of weight one year after a lifestyle intervention was predicted by lower mental health-related quality of life (Karlsen, Sohagen, & Hjelmesaeth, 2013). In a different study, poorer health-related quality of life in women was related to less weight lost (Teixera et al., 2004). Research into the effects of physical symptom burden on how much weight is lost following a weight loss intervention is lacking.

Patient activation (how prepared and skilled someone is at managing their own healthcare) is related to healthy diet and regular exercise (Greene, & Hibbard, 2012;

Hibbard, Mahoney, Stock, & Tusler, 2007). Therefore, as a poor diet and lack of exercise are associated with obesity, it is likely that being overweight or obese is related to low activation. However, there was no association between level of patient activation and successful weight loss in a financial incentive-based health intervention for obese people (Becker et al., 2015). It has not been possible to locate any published research investigating the effect of the level of patient activation on the amount of weight lost in a lifestyle intervention. Preliminary research does suggest, however, that greater patient activation is associated with current healthy weight management behaviours, stronger intentions to lose weight and greater self-efficacy in a group of obese participants (Moore, Jay, Rhee, Gillespie, & Coldiron, 2010).

To summarise, findings from research into the effects of psychosocial factors on weight loss are inconsistent. Some research suggests personality affects the amount of weight lost. Other research indicates no relationship between the amount of weight lost and personality or psychopathology. In the available literature, different facets of quality of life have been shown to be associated with the amount of weight lost. Research into the effects of patient activation and physical symptom burden on magnitude of weight loss is lacking.

**Psychosocial variables and treatment adherence.** Despite the associated health risks increasing as BMI rises beyond being a normal weight (e.g., Hsu, McCulloch, Iribarren, Darbinian, & Go, 2006), the likelihood an individual will remain in a weight loss programme to reduce these risks decreases as BMI rises. Goode and colleagues (2016) found the odds of attrition to increase by 11% for every unit increase in BMI. Other studies suggest that poorer initial responses to weight loss interventions also increases the chance of individual exiting treatment prematurely (e.g., Colombo, et al., 2014).

The relationship between psychosocial variables and attrition in weight loss interventions has also been studied. People were more likely to drop out of a behavioural weight loss programme if they were low in reward dependence (De Panfilis et al., 2008). Conversely, using the same personality measure, Dalle Grave and colleagues (2015) found personality traits not to be associated with attrition in lifestyle weight loss interventions.

Greater identification with being angry or hostile was associated with attrition in a behavioural weight loss intervention (Colombo et al., 2014). Attrition in guided self-help for binge eating was predicted by negative affect but not depression (Masheb, & Grilo, 2008). However, in a clinical trial, having more baseline depression symptoms was associated with attrition in pharmacological and psychological interventions for weight loss (Fabricatore et al, 2009).

Baseline depression was also significantly associated with poorer attendance at lifestyle modification sessions for weight loss (Mazzeschi et al., 2012). In addition to depression symptoms, health-related quality of life predicted poor adherence to the exercise and educational sessions included in the lifestyle programme (Mazzeschi et al., 2012). Teixeira and colleagues (2004) also found poorer health-related quality of life to be related to treatment attrition.

Patient activation (how committed an individual is to managing their own healthcare) is related to treatment adherence (e.g., Skolasky, Mackenzie, Wegener, & Riley, 2008). However, patient activation has not been investigated in weight management programmes. Additionally, being of a poor physical health is expected to reduce ability to attend appointments and engage in recommended physical activities. However, research investigating this appears to be lacking.

To summarise, whether someone adheres to a weight loss programme appears associated with whether the individual has a poor health-related quality of life. In some

studies, psychopathology and personality characteristics were related to attrition and in other studies psychopathology and personality were not associated with attrition.

Research into the effects of patient activation and physical symptom burden on adherence to weight management programmes is lacking.

**The impact of weight loss on psychosocial characteristics.** Few studies have considered psychosocial change following weight loss in obese people. A review found significant associations between whether weight was lost and physical health-related quality of life but not mental health-related or overall health-related quality of life (Warkentin, Das, Majumdar, Johnson, & Padwal, 2014). Quality of life appears to improve following lifestyle modification programmes for weight loss (Faulconbridge et al., 2013). Sarwer and colleagues (2013) found a correlation between the magnitude of weight loss and improvements in mental but not physical quality of life 12 months after a primary-care weight loss programme.

Weight loss one year after beginning pharmacological and/or psychological interventions (lifestyle modification or therapy) was significantly associated with improvements in patients' mean depression symptomology (Faulconbridge et al., 2009). This study also found that 13.9% of patients noticed a discernible increase in depression symptoms during the programme and that these patients also lost significantly less weight than the rest of the patients. Conversely, no statistically significant changes in mental health were found following a 10 week very-low-energy diet and behaviour modification programme (Kaukua, Pekkarinen, Sane, & Mustajoki, 2002).

Weight loss during a lifestyle intervention could be positively associated with patients' capabilities for self-managing their health-care, due to greater access to health-care knowledge and developing skills to manage their weight. In support, Desouza and colleagues (2012) found patient activation to improve following weight loss after a lifestyle intervention.

Weight loss also leads to improvements in physical functioning, perceived health (Kaukua et al., 2002) and the degree of bothersome caused by physical disablement due to obesity (Patrick, Bushnell, & Rothman, 2004). It appears that positive change in other domains might also occur along with a reduction in weight as a result of weight loss interventions. However, it is not known whether the changes in physical symptom burden or patient activation are associated with how much weight is lost.

Recent literature shows that personality might not be as stable as once thought (McCrae, & Costa, 1982), given that scores on a personality measure changed throughout life (Roberts, Walton, & Viechtbauer, 2006). Therefore, it is possible that personality could also change, along with quality of life, psychopathology, level of patient activation and physical disablement, as a result of weight loss. However, whether personality changes following weight loss has not yet been investigated.

In sum, quality of life appears to be associated with the amount of weight lost and treatment adherence. However, the literature shows an unclear picture of whether personality and psychopathology are associated with adherence to weight management programmes and weight loss. In addition, there is a lack of research investigating whether patient activation and physical disablement affect the adherence to weight management programmes and the amount of weight lost. Additionally, there have not been many studies investigating whether psychosocial improvements, following weight loss interventions, are directly associated with the amount of weight lost.

### **Mechanisms of weight loss**

Behavioural change theories consider how attitudes (Schifter, & Ajzen, 1985) and motivation (Edmunds, Ntoumanis, & Duda, 2007) lead to the required behavioural changes (eat less and exercise more) to effect weight loss. Social cognitive theory postulates that a combination of intrapersonal, behavioural and environmental factors

results in behavioural change (Bandura, 1998). Consequently, any difference in these factors between individuals could lead to differences in the ability to make the changes required to lose weight. As described above, currently the research is mixed as to whether the research into the intrapersonal variables supports this theory of weight loss.

It is possible that relationships between psychosocial characteristics and weight loss have been found by some researchers and not others due to some studies having samples with weaker identification with psychosocial characteristics, therefore finding no effect of psychosocial variables on weight loss. In contrast, studies using samples who identify more with the investigated psychosocial characteristics might find an effect of the characteristics on weight loss. Investigating the association between psychosocial characteristics and the amount of weight lost will provide indications whether this explains the divergent findings.

Despite the infancy of the literature, with the exceptions of personality (which is yet to be investigated) and psychopathology (which has produced inconsistent findings), losing weight appears to be associated with positive improvements in quality of life, level of activation and physical disablement. However, it is unclear whether these benefits are associated with the amount of weight lost. The question that remains is whether the act of losing weight, regardless of how much, leads to psychosocial change. This link could be due to realising that is possible to lose weight, or identification with being in control of their weight. Alternatively, a dimensional relationship between weight loss and psychosocial characteristics could exist. More weight lost could lead to, for example, greater improvements in mental health which reinforces the behavioural changes and leads to further weight loss (Skinner, 1938). Investigating whether there is a categorical or dimensional association between weight loss and changes in psychosocial characteristics could provide some indication of the answer to this question.



## **Rationale**

Despite the high cost associated with obesity and the positive changes that can occur when weight is lost, outcomes in lifestyle management programmes are variable. Many participants do not respond fully (or at all) to lifestyle management (e.g., Teixeira, Going, Sardinha, & Lohman, 2005). This lack of response is enhanced by the practical difficulties and high attrition rates in treatment (Grossi et al., 2006). Therefore, identifying who succeeds, defined by their psychosocial features as well as their weight loss, might help target treatments appropriately in the future. The majority of the available research focuses on whether psychosocial characteristics predict whether weight is lost rather than how much weight is lost. Therefore, this study will investigate the association between the amount of weight lost and psychosocial characteristics to see whether this provides any further information about whether and how psychosocial factors affect weight loss.

Additionally, investigating whether psychosocial change following a weight management programme is associated with the magnitude of weight loss could provide additional information about mechanisms of change resulting in weight loss. Findings could indicate whether weight loss creates psychological improvements that reinforce the behavioral changes, leading to more weight lost or whether there is a categorical effect of losing some weight improves psychosocial functioning.

## **Aims**

This study aimed to investigate the association between psychosocial characteristics and the amount of weight lost (and rate of attrition) during a lifestyle weight management programme. The specific aims of this study were as follows:

1. To investigate whether pre-treatment psychosocial variables are associated with the amount of weight lost during the first 12 weeks of a weight management programme.

Hypothesis one – Pre-treatment psychosocial variables will predict the amount of weight lost.

2. To investigate whether pre-treatment psychosocial variables are associated with the rate of attrition with initial weight included as a variable.

Hypothesis two – Pre-treatment psychosocial variables will predict the rate of attrition.

3. To examine whether the amount of weight lost is associated with psychosocial change, over and above any association with the psychosocial variables at the outset of treatment.

Hypothesis three – The amount of weight lost will correlate with psychosocial change.

4. To investigate whether people attending a weight management programme lose weight, whilst controlling for initial weight. Whether early weight loss correlates with weight loss later in the programme was also examined.

Hypothesis four – People attending a weight management programme will lose weight.

Hypothesis five – Early weight loss will correlate with weight loss later in the programme.

## **Method**

### **Design**

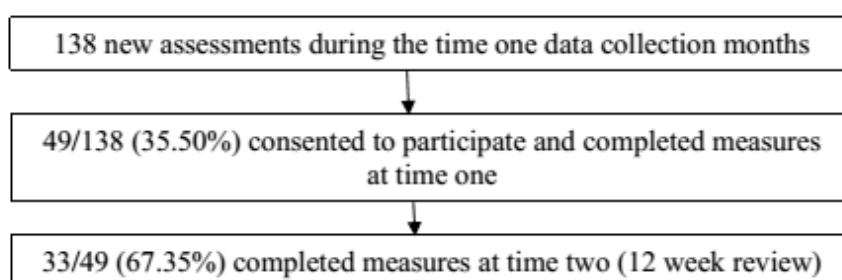
A within-groups correlational, longitudinal design with naturalistic data was employed. Data were collected at the beginning of and after 12 weeks of a routine clinical intervention for weight loss. This practice-based study involved investigating the impact of psychological variables (personality, mental health, quality of life, level of health-care activation, and physical symptom burden) on the amount of weight lost and

rate of attrition. Additionally, whether there was an association between the amount of weight loss and change in the psychological variables was investigated. Where appropriate, initial weight was controlled for in the analyses.

### Participants

A total of 49 patients attending the weight loss clinic for an initial assessment between August 2015 and January 2016 consented to participate in the research. A further 12 people were invited to participate but declined. Seventy-seven people were assessed by the service during the time data was collected for time one, but were not recorded as consenting to or declining participation in the study. It is not possible to be certain why this information was not recorded, but it could include clinicians neglecting to ask clients to participate, the measures not being completed, or inappropriate referrals leading to discharge after the initial assessment. Figure 1 shows the flow of participants through assessment to 12 week review.

Figure 1 Participant flow through the service



**Inclusion and exclusion criteria.** Participants were included in the study if they consented to participate, could read in English, were obese (BMI  $\geq 30$  kg/m<sup>2</sup>) or receiving treatment to prevent obesity, and were 18 years old or over. People were excluded from the study if they had a medical complication that would make it difficult for them to complete the weight management programme. People who had been prescribed novel anti-psychotic medications were also excluded from the research because of the potential weight gain associated with their use. However, people with

such medical complications or taking medication were still accepted into the weight management programme but excluded from the research in case either affected the results.

**Sample size.** The number of participants required for the multiple regression analyses was calculated using the system devised by Green (1991). Green suggests a 'rule of thumb' for calculating a sample size based on 50 participants plus the number of predictors multiplied by eight. Using this formula ( $50+(8*11)$ ), 138 participants would be required for the multiple regression to have enough statistical power be viable.

A correlational method was used to investigate the association between the amount of weight lost and changes in psychosocial variables. The number of participants required for the correlation analyses was calculated using Cohen's (1969) calculation. Assuming a medium effect size of 0.30, a statistical power of 0.8 and a two-tailed  $p$  value of 0.05, 85 participants were required (Appendix A). The  $p$ -value was not adjusted as a significant finding would be contrary to expectations. Using the same method, but assuming an effect size of 0.4 (found by Currey et al, submitted), that number would have been 47.

## **Materials**

To address the aims, five self-report questionnaires were given to participants at the start of treatment and at 12-week review. Each questionnaire assessed a different psychosocial characteristic.

**The Clinical Outcomes of Routine Evaluation (CORE-10).** The CORE-10 was designed as a measure of psychopathology (Barkham et al., 2013, Appendix B). The CORE-10 is a 10-item general measure of the frequency of clinical symptoms over the previous week and a shortened version of the 34-item Clinical Outcomes of Routine Evaluation – Outcome Measure (CORE-OM; Evans, et al., 2002). The service routinely gathered information from the CORE-OM from participants. Therefore, the

corresponding items that formed the CORE-10 were extracted from the completed CORE-OM forms.

The CORE-10 includes items relating to anxiety, depression, trauma, close relationships, social relationships, physical symptoms, general functioning and risk. Participants are asked to select how often they have had a particular difficulty over the previous week from five options: 'not at all', 'only occasionally', 'sometimes', 'often' and 'most of the time'. For eight items indicating a symptom of distress (e.g., 'I have felt tense, anxious or nervous') the scale ascends from 0 (not at all) to 4 (most of the time). For two items indicating positive coping (e.g., 'I have felt able to cope when things go wrong'), this scale is reversed from 4 (not at all) to 0 (most of the time). A clinical score was created by adding together the item scores, dividing by the number of questions completed then multiplying by 10. Higher scores indicate greater psychological distress.

The CORE-10 has good internal reliability ( $\alpha = 0.90$ ), and correlates highly with the CORE-OM (0.94 in a clinical sample and 0.92 in a non-clinical sample; Barkham et al., 2013). In this study the internal consistency of the CORE-10 items was 0.77 denoting acceptable consistency. The clinical cut off indicating psychological distress is 11, with a reliable change index of 6 (90% confidence intervals; Barkham et al., 2013).

#### **The Obesity and Weight-Loss Quality Of Life Measure (OWLQOL).**

OWLQOL is a measure of quality of life specific to obesity and weight-loss (Patrick et al, 2004, Appendix B). It was included for replication purposes, as Currey et al. (submitted) found it to be associated with weight loss. The OWLQOL was already routinely collected from patients in the participating service. The mean completion time for the OWLQOL is five minutes (range, 3-8 minutes; Patrick et al., 2004).

Participants were asked to rate their agreement with a series of 17 statements about quality of life and weight (e.g., 'my weight prevents me from doing what I want to do') on a seven-point scale from 'not at all' (0) to 'a very great deal' (6). An overall score is derived from reversing all 17 item scores, totaling the resulting scores and transforming the score to a 0-100 scale (by dividing the total of the reversed scores by 102 then multiplying by 100). Higher scores indicate a better obesity-related quality of life.

The OWLQOL has good internal consistency ( $\alpha > 0.90$ ), convergent validity and test-retest reliability (0.95; Patrick et al., 2004). In this study, the internal consistency of the OWLQOL was excellent ( $\alpha > 0.94$ ). The European community obese population mean is 64.9 (SD = 23.7; Patrick et al., 2004).

**The Weight Related Symptom Measure (WRSM).** The WRSM is a 20-item measure of physical disablement (Patrick et al., 2004, Appendix B). The WRSM provides an index of health-related problems. The participant is asked to rate the presence and severity of a range of symptoms common among overweight and obese individuals (e.g., back pain) over the past four weeks. The WRSM was already routinely collected from participants in the service. The mean completion time for the WRSM is two minutes (range, 1-4 minutes; Patrick et al., 2004)

Symptom presence is indicated by a 'yes'/'no' response to whether a symptom has been experienced. The degree of bothersomeness this symptom causes the participant is then measured based on their response to a seven-point scale from 0 ('not at all') to 6 ('a very great deal'). A total score is calculated by totaling the degree of bothersomeness each symptom causes, resulting in a score from 0 to 120. High scores indicate a worse symptom burden.

The WRSM has good internal consistency ( $\alpha = 0.87$ ) and an intra-class correlation coefficient of 0.83 (Patrick et al., 2004). The internal consistency of the

WRSM in this study was also good ( $\alpha = 0.86$ ). The European community obese population mean is 21.0 (SD = 18.1; Patrick et al., 2004).

**The Ten Item Personality Inventory (TIPI).** Participants were already required to complete a large number of questionnaires in routine clinical practice. Therefore, in the interests of brevity, a brief personality measure was chosen to reduce further demand on participants. The TIPI was designed as a brief measure of personality, and takes approximately one minute to complete (Gosling, Rentfrow, & Swann, 2003, Appendix B).

The TIPI measures the Big Five personality dimensions: extraversion, emotional stability, agreeableness, openness and conscientiousness. The TIPI includes two items corresponding to each personality dimension, one of which is reverse-scored. Each item consists of two personality descriptors rated on a seven-point scale, where the participant indicates how much the descriptors apply to them from 1 ('disagree strongly') to 7 ('agree strongly'). For example, the extraversion dimension includes items where the participant has to indicate the extent to which they consider themselves as 'extraverted, enthusiastic' and 'reserved, quiet'. A score for each personality dimension is created by calculating the mean of the standard and reversed item corresponding to that trait. Higher scores on each dimension indicate a greater identification with that personality trait. The TIPI has adequate levels of convergence with more comprehensive personality measures (mean  $r = 0.77$ ), test-retest reliability (0.72) and external correlates ( $> 0.90$ ; Gosling et al., 2003). Due to only two items corresponding to each personality measure, it has not been possible to calculate the internal consistency of the TIPI personality dimensions in this study.

**The Patient Activation Measure (PAM-13).** The PAM-13 was designed as a measure of knowledge, skill and confidence in self-management of overall health

(Hibbard, Mahoney, Stockhard, & Tusler, 2005, Appendix B). A license for the use of the PAM-13 for research purposes was obtained from Insignia Health (Appendix C).

The PAM-13 has 13 items, consisting of self-statements (e.g., 'taking an active role in my own health care is the most important factor in determining my health and ability to function'). Participants were asked to indicate how much they agree or disagree with a statement about their health by selecting from the following options: 'disagree strongly' (1), 'disagree' (2), 'agree' (3), 'agree strongly' (4) or 'not applicable' (5). For a valid score on the PAM, 10 of the 13 items require completion. A scoring spreadsheet was provided with the license. For each participant, the scoring sheet transformed individual item scores to a total score out of 100 using calibration tables. A higher total score indicates greater activation, more confidence and motivation to actively manage healthcare. This total score can also be used to indicate the level of activation the participant is currently operating at, where total scores up to 47 indicates level one, 47.1-55.1 denotes level 2, 55.2-67 denotes level 3, and level four is 67.1 and above.

Thus, the PAM assesses four levels of activation. These levels are: having a belief that an active role is important but being passive and lacking understanding of their role in managing their own healthcare (1); having the confidence and knowledge to take action (2); taking action (3); and adopting many of the behaviours needed to manage their own health and staying the course under stress (4) (Hibbard, & Gilbert, 2014). High levels of activation indicate a greater level of self-management.

The PAM is a reliable measure and has good construct validity (Hibbard et al., 2005). The PAM-13 has excellent divergent ( $r$  range = 0.007-0.125) and convergent validity ( $r = 0.4$ ) and relatively good person ( $r = 0.85$ ) and item reliability ( $r = 0.99$ ; Hung et al., 2013). In this study, the internal consistency of the PAM was excellent ( $\alpha = 0.93$ ).



**Demographics.** Participants' age, gender, weight and height were gathered from the service records. Weight management advisors measured participants' height and weight using the Leicester height measure and calibrated scales respectively. Height and weight recordings were used to calculate the participants' Body Mass Index (BMI) and percentage BMI lost.

### **Procedure**

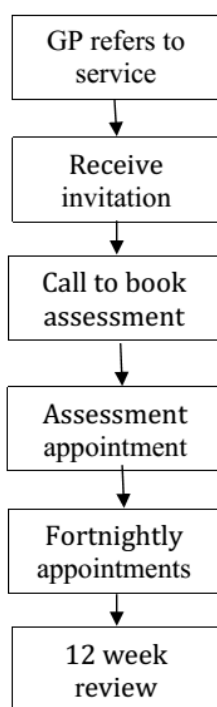
**The clinical setting.** Two NHS weight management services for adults who are obese expressed a willingness to participate. One service had an intake of 16 eligible individuals for group interventions per week. Assuming that the number who agreed to participate was eight per week (a conservative estimate based on Currey et al, submitted), and an attrition rate of 33%, there should have been five completers recruited each week. Thus, the necessary sample size of 44 should have been reached within approximately 10 weeks of recruitment. During the research this service went to tender and was not recommissioned, resulting in only one service for recruitment. This service supported the needs of a smaller population and offered one-to-one appointments rather than groups. Additionally, the service was going through a period of restructuring, involving merging with a larger health promotion service, when the research took place, which could have affected the referral rate. Consequently, the intake per week was smaller and recruitment took longer than anticipated.

**The treatment.** The service participants were recruited from was a specialist weight management service, led by Clinical psychologists. The service offered a programme of support delivered by Clinical psychologists, Weight management advisors and Dietitians, and accepted referrals from Primary care practitioners. The service were flexible in their referral criteria, and acceptance is decided on a case by case basis. The referral criteria accepted people with a BMI of 45 or above or people with a lower BMI with additional complexities or if they had attempted tier two services

without success. The programme aimed to help people to make lasting lifestyle changes (regarding diet and exercise) and overcome their difficulties in reducing and maintaining their weight.

Figure 2 shows a typical patient journey. Following referral, patients are sent a letter asking whether they wish to opt into the service. Once patients decided to opt in they telephoned the service to book an assessment appointment with a Clinical psychologist and Weight management advisor.

Figure 2 Patient experience during the first 12 weeks of the weight loss service



The assessment appointment lasted approximately an hour and a half. During the initial appointment the Clinical psychologist assessed patient needs using a semi-structured interview, and designed an individualised package of care. The Clinical psychologist held a reviewing and consultancy role. Therefore, at the initial appointment the patient was also introduced to their allocated Weight management advisor who would meet them approximately fortnightly, for outreach appointments

during the first 12 weeks. Patients also meet with the Dietitian to gather individual advice on nutritional intake.

Following the initial meetings patients could access therapy with a Clinical psychologist if required at any time during treatment. Psychological intervention included Cognitive Behavioural Therapy, Compassion-Focused Therapy, Solution Focused Therapy and Person-Centred Psychotherapy.

This study focused only on the initial 12 weeks of treatment. However, patients could remain within the care of the service for up to two years, with support gradually reducing. Reviews were held after the first 12 weeks then every six months before discharge.

**Ethical procedures.** The study received approval from a NHS Research Ethics Committee and the local NHS Research and Development Department, and adhered to national and local governance policies (Appendix D).

In the information sheet (Appendix E) participants were made aware of the anonymity of their responses and their right to withdraw their data at any point in the research. Once scanned into the secure electronic system, the paper questionnaires were shredded and placed in the confidential waste. Responses to the questionnaires were coded for anonymity when added to the database. The code and corresponding participant details were stored separate to the data analysis file.

There was no deception or invasion of participant privacy in this study, and participants were fully informed of the aims of the study at the outset in the information sheet and invitation letter (Appendices E & F). Therefore, informed consent was gained from all participants using the consent form (Appendix G). Participants were given a point of contact should they wish to access the outcomes of the study.

Given that the measures were taken during routine clinical practice, no harm was expected to come to the participants as a result of the research. Participants were made

aware of this in the information sheet and an adverse incident/complaint form (Appendix H) was available should it be required. Risk was monitored within routine clinical practice, following service procedures. To protect the involved parties a research contract (Appendix I) was agreed.

**Project recruitment.** Clinicians working at the weight loss service were consulted in a team meeting about the potential for a project investigating psychosocial variables and weight loss to take place within the service. Clinicians were provided with information about the project and introduced to the TIPI (Gosling et al., 2003) and PAM (Hibbard et al., 2005) questionnaires. This meeting allowed clinicians to discuss the research and for any initial queries to be dealt with appropriately.

Prior to recruitment, patients from the service where the data was due to be collected were consulted about the feasibility of the study and acceptability of the questionnaires. No issues were highlighted by those patients, who accepted the study to be feasible for their peers to complete.

All patients attending assessment appointments at the weight management programme between August 2015 and January 2016, who met the inclusion criteria, were potential participants. The patient files of all new accepted referrals were updated to include copies of the participant invitation letter, information sheet, consent form, TIPI and PAM. All patients were sent paper copies of the questionnaires measured for routine practice (measuring psychopathology, weight related physical symptoms and quality of life) to complete and bring with them at assessment appointment.

At the assessment appointment, clinicians explained to all eligible patients that the service was collaborating on a research study. Potential participants were provided with the information sheet (Appendix E) and invitation letter (Appendix F). Clinicians discussed the research with the patients and invited their participation in the study. Participants were informed that they would be required to complete an additional two

measures designed to investigate personality variables and level of activation for responsibility for their own healthcare. Participants were informed that this would involve them completing an additional 23 questions which would take approximately five minutes to complete. Clinicians were provided with the lead researcher's email address to contact for more information should they feel unsure how to respond to participant queries. Consent was gained by participants signing a consent form (Appendix G). The study information was removed from the patient file of patients who declined to participate and their treatment proceeded as usual.

**Data collection.** Once the consent form was received by the clinician, participants were provided with two additional questionnaires to complete (PAM and TIPI). The order by which the questionnaires were provided to the participants was not specified and was subject to the individual clinician's own preferences.

Once the paper questionnaires for all five measures were completed, clinicians scanned and uploaded them, along with the signed consent form, onto the electronic, secure, password protected NHS clinical recording system. This decision was made in collaboration with the NHS supervisor for ease of administration as it did not involve a great deviation from routine practice, and as such reduced the demand on the involved clinicians. Following the assessment appointment, Weight management advisors made a note of which patients were participating in the research to ensure the extra measures (TIPI and PAM) were collected at the 12-week review.

Data collection occurred in each participant's first 12 weeks of the weight management programme. Twelve weeks was chosen as the fixed time period as some services do not impose an end to treatment. Currey et al. (submitted) showed that such programmes result in a mean weight loss of 5% within that time frame (an adequate amount to result in meaningful psychological and physical health improvements - e.g., Vidal, 2002).

At the 12-week review, participants completed the three routine measures (CORE, OWLQOL, and WRSM) and the additional two measures (TIPI and PAM). The paper copies were then scanned onto the electronic patient recording system and shredded by the clinicians. If treatment terminated before 12 weeks, measures could be taken earlier with clinician agreement that the patient has achieved a satisfactory level of weight loss.

Data collection lasted nine months. Phase one, which involved recruiting all participants and taking the initial measures (at time one), lasted six months. The second phase began three months into recruitment when the initial participants had their 12-week reviews (time two). The second phase also lasted six months and the two phases of data collection were concurrent for the middle three months. After phase one ended, three months of the second phase of data collection remained to gather measures at time two for the more recently recruited participants.

Weight management advisors measured participants' height before the intervention. Weight was measured by Weight management advisors pre-intervention and approximately fortnightly for the following 12 weeks. Participants' height and weight were recorded on the online system. For this study, only the weight measurements pre-intervention, after four weeks, after eight weeks and at the 12-week review were recorded to reduce the impact of natural weight fluctuations on the results. When the appointment did not occur on exactly at the four week timeframe, the measurement taken on the closest date was recorded. Clinicians aimed to conduct the routine 12-week review within a two week timeframe either side of this date.

## **Data Analysis**

**Data preparation.** The raw data were transferred to a Microsoft Excel file for preparation. Dummy coding was used on the categorical variables of gender (1 = male; 2 = female) and drop out (1 = dropped out of treatment; 2 = remained). As data were

gathered within clinical practice, rather than a research trial, it was anticipated that some information would be missing and errors would be present. Where clinicians had been unable to repeat measures on participants during their 12 week review, assessment scores were used for analysis (intention-to-treat).

Psychosocial variables were personality (TIPI scores), health-care behaviour activation (PAM scores), mental health (CORE-10 score), quality of life (OWLQOL score) and physical disablement (WRSM score). The raw scores on each of the measures were converted into total, clinical or transformed scores as described in the materials section. This resulted in two sets of scores for each participant from the assessment (time one) and 12-week review (time two) appointments. From each time point there was a total score for each of the five personality variables from the TIPI, a PAM total transformed score and activation level, a CORE-10 clinical score, an OWLQOL transformed score and a degree of bothersomeness score for WRSM.

The scoring keys for each measure were checked to determine the maximum number of missing items allowed to pro-rate the scores whilst reducing the chance of measurement error. The official PAM spreadsheet computed PAM scores if up to three items were missing. However, it is noted that the chance of measurement error of the total score increases as the number of missing items increases (Linden, 2015). The CORE-10 measure advised that pro-rating the final score (the mean value multiplied by 10) when more than one item (10%) was missing should only be done with caution. Therefore, when one item was missing the final score was pro-rated. When two or more items were missing, the data from that participant was removed from the analysis. It was not possible to locate any guidance on how many missing items the OWLQOL, WRSM and TIPI allowed for. Therefore, it was decided, based on the CORE-10 criteria, to pro-rate the OWLQOL and WRSM only if up to 10% of the items were missing. This allowed for one item to be missed on the OWLQOL and two items on the WRSM. It

was decided that the TIPI would not be pro-rated because only two items contributed to each personality dimension so prorating would be based on only one item. If more items were missing than recommended for pro-rating, data from that participant pertaining to that total score or personality dimension only were removed from further analyses. This process resulted in different total numbers of participants for different analyses.

The amount of weight lost was calculated using the percentage change in BMI/weight ( $\text{kg}/\text{m}^2$ ) from baseline to 12-week review, or using the last available score for participants who dropped out of treatment.

**Descriptive statistics.** Means and standard deviations of changes in BMI, weight, and the psychosocial measures (TIPI, PAM, CORE-10, OWLQOL and WRSM) over 12 weeks were calculated using SPSS (version 22).

**Inferential analysis.** Data were analysed using SPSS (version 22). Completer analyses were conducted for all participants who remained in treatment for 12 weeks. Intention-to-treat analyses were also conducted using the last available scores of participants who dropped out of treatment in the final analyses.

As the resulting data was well enough distributed, parametric tests were used. Multiple regression was used to determine whether pre-treatment personality and psychosocial scores predict the amount of weight lost (the dependent variable). Logistic regression was used to investigate whether pre-treatment psychosocial scores predict attrition. The independent variables in both analyses were the scores on TIPI, CORE-10, OWLQOL, PAM and WRSM.

Pearson's correlations were used to investigate the association between weight loss and change in scores on TIPI, CORE-10, OWLQOL, PAM and WRSM, partialing out the effects of any association with the psychosocial variables at the outset of treatment.



Paired t-tests were used to compare baseline with post intervention weight. A repeated measures ANOVA was used to determine where weight change occurs over the 12 weeks.

Pearson's correlations were used to determine whether weight lost after the first month of the intervention is associated with weight lost over the remaining period of the intervention.

## **Results**

The following results are the findings from associative and comparative statistical tests, on the data provided by the participants of a lifestyle intervention at assessment and 12-week review, investigating the association between weight loss and psychosocial characteristics. Where relevant in addition to completer analysis, intention-to-treat analysis was performed taking the last available score for each of the variables if participants prematurely terminated treatment. Effect sizes were computed but, following convention, were only reported for significant findings.

### **Participant characteristics**

Table 1 shows characteristics of the group of participants. Most participants were classified as obese, with only one participant with a BMI slightly below 30. In addition, of the 49 participants 26.5% were male and 73.5% female.

Sixteen participants (32.7%) terminated treatment before reaching their 12 week review. Independent t-tests found no significant difference between participants who remained in treatment and those who ended treatment early in terms of age ( $t(47) = 0.06, p = 0.95$ ), initial BMI ( $t(47) = 1.28, p = 0.21$ ) or scores on the measures for all psychosocial variables at assessment.

Table 1.

*Participant characteristics*

	M	SD	Minimum	Maximum
Age	45.53	11.95	21	75
Initial weight (kg)	143.77	26.65	88.4	201.4
Initial height (m)	1.66	0.12	1.15	1.92
Initial BMI	51.48	9.06	29.22	76.59

Note. BMI - Body Mass Index; M - mean; SD - standard deviation; kg – kilogram; m – metres.

**Intervention effectiveness**

**The effectiveness of the intervention at helping people lose weight.** Post intervention BMI was significantly lower than the baseline BMI in the completer analysis ( $t(33) = 5.14, p < 0.01$ ) and intention-to-treat analysis ( $t(48) = 4.71, p < 0.01$ ). Table 2 shows the cumulative totals of the amount of weight lost after one, two and three months as a percentage of total initial weight. On average the most weight is lost, as a percentage of initial BMI, in the first month of a lifestyle intervention. The amount of further weight loss, as a percentage of initial BMI, gradually reduces incrementally over the following two months. In the ITT analyses a further 0.54% is lost in the second month and 0.09% in the third. The completer analysis shows that an additional 0.66% and 0.43% is lost in the second and third months of the weight loss programme.

There is some weight loss achieved by attenders of the lifestyle intervention programme. However, the amount of weight lost is proportionally small given the participants' high initial BMI, resulting in non-significant findings as displayed in Table 3. Out of the 33 participants who completed the initial 12 weeks of treatment, 25 (75.76%) lost up to 5% of their initial BMI and five (15.15%) lost more than 5% of their original BMI.

Table 2.

*The amount of weight lost as a percentage of total initial weight calculated using BMI*

BMI loss as a percentage of initial BMI	M (%)	SD	Minimum	Maximum
ITT analysis				
One month	1.18	1.48	-1.05	4.93
Two months	1.72	2.1	-1.97	7.56
Three months	1.81	2.66	-6.89	9.08
Completer analysis				
One month	1.34	1.51	-1.05	4.93
Two months	2	2.17	-1.97	7.56
Three months	2.43	2.64	-6.89	9.08

Note. BMI – body mass index; M - mean; SD - standard deviation; ITT – intention-to-treat. N = 43 after 1 month, 41 after two months and 34 after three months.

Among participants who completed 12 weeks of the intervention, weight loss in the first month correlated with weight loss in the second month ( $r = 0.70$ ,  $p < 0.01$ ) and third month ( $r = 0.40$ ,  $p = 0.02$ ). The intention-to-treat analysis also showed this association - early weight loss correlated with weight loss during the second ( $r = 0.73$ ,  $p < 0.01$ ) and third months ( $r = 0.53$ ,  $p < 0.01$ ).

Table 3.

*The results of ANCOVAs (intention-to-treat and completer analyses), investigating whether a significant proportion of weight is lost when controlling for initial weight*

		Time one	Time two	Time three	Time four	Main effect		Covariate	
						F	<i>p</i>	F	<i>P</i>
Intention-to-treat analysis									
BMI	M	51.48	50.85	50.57	50.54				
	SD	9.06	8.89	8.79	9.00				
						0.63	NS	1.74	NS
Completer analysis									
BMI	M	51.48	51.41	51.56	51.22				
	SD	9.06	8.9	8.7	8.87				
						0.73	NS	1.79	NS

Note. BMI - Body Mass Index; M - mean; SD - standard deviation; NS - not significant

### **The effectiveness of the intervention at improving psychosocial functioning.**

Table 4 shows that there were significant differences between the scores on the CORE-10, OWLQOL and WRSM measures at assessment and 12 weeks later. This effect was significant for completer and intention-to-treat analysis with moderate to large effect sizes (Cohen's *d*). The mean initial CORE-10 score was 14.97 (SD = 7.42). This score reduced to a mean of 11.84 (SD = 7.81) in the intention-to-treat analysis and 9.44 (SD = 6.93) in the completer analysis. Twelve of the 33 participants who remained in the service for 12 weeks achieved a reliable change score of at least six points on the CORE-10, and 11 moved out of the clinical range, denoting clinically significant change. The mean OWLQOL scores improved from 23.71 (SD = 21.78) to 31.69 (SD = 21.79) in the intention-to-treat analysis and 35.53 (SD = 21.33) in the completer analysis. Finally the WRSM scores reduced from an initial mean of 59.80 (SD = 23.01)

to 50.27 (SD = 23.09 intention-to-treat) and 45.06 (SD = 22.79; completer analysis). No other variables reached significant change over the 12 weeks.

Table 4.

*The results of paired t-tests investigating psychosocial change between assessment and 12 weeks. Effect sizes (Cohen's d) are shown for significant effects only.*

Psychosocial variable	Intention-to-treat		Effect size <i>d</i>	Completer		Effect size <i>d</i>
	<i>t</i>	<i>p</i>		<i>t</i>	<i>P</i>	
Extraversion	1.3	0.2		1.31	0.2	
Agreeableness	0.69	0.49		0.69	0.50	
Conscientiousness	0.69	0.49		0.69	0.5	
Emotional Stability	1.3	0.19		1.33	0.19	
Openness	0.00	1.00		0.00	1.00	
PAM	1.60	0.12		1.62	0.12	
CORE-10	3.74	< 0.01	0.54	4.06	< 0.01	0.72
OWLQOL	3.61	< 0.01	-0.52	3.87	< 0.01	-0.68
WRSM	3.38	< 0.01	0.48	3.58	< 0.01	0.62

Note. PAM - Patient activation measure; CORE -10 Clinical Outcomes of Routine Evaluation; OWLQOL – Obesity and weight loss quality of life measure; WRSM -Weight related symptom measure.

### **The ability of pre-treatment psychosocial variables to predict the amount of weight lost**

Table 5 shows the results of a multiple regression on the ability of pre-treatment characteristics to predict weight loss. There was no overall effect and none of the individual variables approached significance in the intention-to-treat or completer analysis.

Table 5.

*Regression analyses showing the ability of the psychosocial variables to predict the amount of weight lost*

Dependent variable	F	p	% Variance explained	Independent variables	T	p	b
<i>ITT analysis</i>							
BMI loss after three months	0.95	0.51	1.50%	Age	0.79	0.44	0.14
				Initial BMI	0.40	0.70	-0.09
				Extraversion	0.39	0.70	0.1
				Agreeableness	0.98	0.34	-0.19
				Conscientiousness	0.41	0.68	0.1
				Emotional Stability	0.37	0.72	0.1
				Openness	0.36	0.72	0.1
				PAM	0.83	0.42	0.16
				CORE-10	1.90	0.07	0.48
				OWLQOL	0.81	0.43	0.17
				WRSM	0.14	0.89	-0.03
<i>Completer analysis</i>							
BMI loss after three months	1.21	0.35	7.8%	Age	1.09	0.29	0.23
				Initial BMI	0.18	0.86	-0.05
				Extraversion	0.44	0.67	-0.14
				Agreeableness	1.26	0.23	-0.26
				Conscientiousness	0.06	0.95	-0.3
				Emotional Stability	0.11	0.91	-0.03
				Openness	1.48	0.16	0.6
				PAM	0.68	0.5	-0.16
				CORE-10	1.69	0.11	0.55
				OWLQOL	1.60	0.13	0.6
				WRSM	0.18	0.86	0.05

Note. ITT – intention-to-treat, BMI – body mass index, PAM - Patient activation measure; CORE -10 Clinical Outcomes of Routine Evaluation; OWLQOL – Obesity and weight loss quality of life measure; WRSM -Weight related symptom measure.

In addition, the amount of weight lost by males and females was compared. The average amount of weight lost after 12 weeks (as measured by BMI) by males was

2.01% (SD = 3.47) of initial BMI and the amount of weight lost by females was 2.60% (SD = 2.28). These figures were based on 10 males and 24 females remaining in treatment to be weighed after 12 weeks. There was no significant difference between the amount of weight lost between males and females ( $t = 0.59$ ,  $p = 0.56$ ). Intention-to-treat analysis showed that males lost on average 2.27% (SD = 3.45) of the initial BMI and females lost 1.66% (SD = 2.35;  $t = 0.71$ ,  $p = 0.48$ ).

Therefore, psychosocial characteristics do not predict the magnitude of weight loss achieved by participants. The lifestyle management programme can be seen as suitable for all, as it was equally effective at achieving weight loss amongst people with differing characteristics.

#### **The ability of pre-treatment psychosocial variables to predict rate of attrition**

In order to determine whether any of the psychosocial variables predicted attrition, a bivariate logistic regression was used to predict retention or dropout. The outcome was that there was no significant overall effect ( $\chi^2 = 8.47$ ,  $p = 0.49$ ). This indicates that taken together the pre-treatment variables were not able to predict whether somebody remained in treatment. Most of the individual variables did not approach significance. However, conscientiousness did significantly predict whether someone remained in treatment ( $p = 0.04$ ). However, this effect was not significant when initial BMI was added into the regression, suggesting a relationship between initial BMI and conscientiousness accounting for this finding.

#### **The association between the amount of weight lost and changes in psychosocial characteristics**

Table 6 shows that there were no significant associations between the amount of weight lost and changes in most psychosocial variables. There was a significant correlation between the amount of weight lost (as measured by percentage change in

BMI) and change in WRSM score. Therefore, as more weight is lost the severity of the burden caused by physical symptoms associated with obesity reduces.

Table 6.

*Partial correlations between the change in BMI and psychosocial variables*

Change in measure/dimension	Intention-to-treat analysis		Completer analysis	
	Change in BMI	Significance	Change in BMI	Significance
PAM	0.08	0.61	0.14	0.45
CORE-10	-0.14	0.34	-0.09	0.62
OWLQOL	0.26	0.08	0.10	0.60
WRSM	-0.45	< 0.01	-0.37	0.04
Extraversion	0.01	0.54	0.02	0.90
Agreeableness	0.09	0.59	0.12	0.54
Conscientiousness	0.06	0.69	-0.06	0.74
Emotional Stability	0.16	0.31	0.14	0.45
Openness	-0.1	0.53	-0.15	0.42

Note. BMI - Body Mass Index; PAM - Patient activation measure; CORE -10 Clinical Outcomes of Routine Evaluation; OWLQOL – Obesity and weight loss quality of life measure; WRSM -Weight related symptom measure.

## Discussion

### Summary

This study aimed to investigate the association between psychosocial characteristics and the amount of weight lost in a lifestyle weight management intervention. To address the first aim, the effects of pre-treatment psychosocial variables on the amount of weight lost, during the first 12 weeks of a weight management programme, was investigated. There was no significant effect of personality, patient activation, quality of life, mental health or physical symptom burden on how much weight was lost by participants. Second, the association between pre-treatment psychosocial variables and the rate of attrition was investigated. Similarly, the psychosocial variables were unable to predict whether a participant remained or prematurely exited treatment.



The third aim was to examine whether the amount of weight lost was associated with change in psychosocial characteristics. Whilst losing more weight appears to improve the burden associated with physical symptoms, there does not appear to be a psychological effect associated with the amount of weight lost. The obesity programme did significantly improve mental health and quality of life. However, these changes were not associated with the amount of weight lost.

Finally, the results showed that people attending the weight management programme lost weight. However, this effect lost statistical significance when initial BMI was controlled for. Weight loss during the first month of the intervention was, however, associated with later weight loss.

This replication and extension study showed that there does not appear to be a direct correlational relationship between the amount of weight lost and psychosocial variables. However, the limitations of the study, as outlined below, must be considered when interpreting these findings.

### **The relationship between psychosocial characteristics and weight loss**

The existing literature investigating predictors of weight loss in weight management programmes was inconclusive. The present study contributes to the research firstly by supporting the notion that lifestyle weight management programmes have limited success, as found by Teixeira and colleagues (2004).

**The impact of psychosocial factors on weight loss.** The findings in this study support Poston and colleagues' (1999) results who also found that there was not an association between personality and the amount of weight lost. The results also provide a challenge to findings suggesting that personality is associated with weight loss (Dalle Grave et al., 2015 & Munro, Bore, Munro, & Garg, 2011). However, it is possible that the different measures of personality used in these studies could account for the divergent results.

Despite the level of health-care activation being related to stronger intentions to lose weight in obese participants (Moore et al., 2010), Becker and colleagues (2015) found no association between patient activation and weight loss in an intervention for obese people. The current study supports these findings. It appears that commitment and ability to self-manage healthcare is not associated with how much weight is lost during a weight management intervention. This might be due to the research taking place in a clinical setting. All participants in a weight loss intervention are requesting help from a healthcare provider for their weight problems. It is possible that people choosing to lose weight independently or with a group such as Slimming World have different levels of activation which could be associated with how much weight they lose.

Similarly to the current study, Currey and colleagues (submitted) found that initial psychopathology did not predict the amount of weight lost. This replication study provides further support for mental health not affecting magnitude of weight loss in a lifestyle intervention.

Previous literature had found successful weight loss in lifestyle interventions to be associated with quality of life (Karlsen et al., 2013; Teixeira et al., 2004). This study found that quality of life did not predict the amount of weight lost. As the previous literature was divided with some finding poorer quality of life predicted more weight lost and others concluding that a better quality of life was associated with weight loss, the finding that there is no association is not surprising. It is possible that the quality of life measures used do not accurately reflect the experiences of obese people leading to varying results when analyses are repeated.

**Psychosocial variables and treatment adherence.** This study found that none of the psychosocial variables measured predicted whether someone remained in the weight management intervention. This finding supports previous literature that also

found there to be no association between attrition and personality (Dalle Grave et al., 2015) or psychopathology (Masheb, & Grilo, 2008).

Some previous research has found that the chance of patients prematurely exiting treatment increased if participants were low in reward dependence (De Panfilis et al., 2008), were identified as being angry or hostile (Colombo, et al., 2014), had more symptoms of depression (Fabricatore, et al, 2009), or had a poorer health-related quality of life (Teixera et al., 2004). De Panfilis and colleagues (2008) used a different classification system for personality and the two studies who found mental health to be related with attrition measured specific problems rather than using a general measure as the current study did. This could suggest that general psychopathology does not predict a premature exit from treatment but having a specific difficulty does. Additionally, the method of classifying personality could have led to differences being missed in the current study. Finally, Teixeira and colleagues (2004) only studied females. This could suggest that life quality affects drop out in females more, and that the inclusion of males in this study diluted this effect.

Taken together, this study's findings suggest that the ability of the lifestyle intervention to help people lose weight and remain in treatment are not affected by the psychosocial factors studied. The programme is suitable for all regardless of mental health, personality, quality of life, patient activation or physical symptom burden.

**The impact of weight loss on psychosocial characteristics.** The present study failed to replicate the previous finding that the amount of weight lost was directly associated with improvements in mental health (Currey et al., submitted). The current findings also contradicts previous literature that found the amount of weight loss to be associated with improvements in mental health (e.g., Faulconbridge et al., 2009).

The findings obtained by Currey and colleagues (submitted) were based on a much larger sample but who had a similar mean age and initial BMI and were studied

over the same time period in the weight loss programme. The sample in the current study had a slightly higher attrition rate with 32.7% exiting the intervention before 12 weeks whilst only 27.2% of participants in Currey et al.'s (submitted) study dropped out of treatment prior to the 12 week review. This could have skewed the intention to treat results towards finding no effect due to a greater proportion of participant data being from time one. The main difference between the studies was the method of data collection. Currey, et al.'s (submitted) study contained data from all participants entering the service, whereas the current study relied on patients being asked about participation and agreeing to participate. This has implications for the representativeness of the current sample. Another possibility for the differing results between the studies is a difference between the samples in factors that were not measured by either study, such as the length of time participants had been obese.

Previous studies found losing weight to be associated with improvements in patient activation (Desouza et al., 2012) and quality of life (Faulconbridge et al., 2013) but did not specifically look at whether these changes correlated with the amount of weight lost. Consequently, the finding that patient activation did not change following weight loss challenges the previous findings. However, this study supports Faulconbridge and colleagues' (2013) findings that quality of life improves following a weight loss intervention, but suggests that this change is not proportionate to the amount of weight that is lost. The finding that personality does not change following the weight loss intervention offers support to the argument for the stability of personality throughout life (McCrae, & Costa, 1982).

The amount of weight lost was associated with improvements in the burden experienced as a result of the physical symptoms of obesity. This finding supports previous literature which found improvements in physical functioning and perceived health to be associated with weight loss (Kaukua et al., 2002; Patrick et al., 2004).

Improvements in quality of life and psychopathology following the first 12 weeks of a lifestyle weight management intervention appear to occur regardless of the amount of weight lost. This finding suggests that it is not the amount of weight that is lost that determines the psychological benefits of the programme but the act of losing weight as a whole or being enrolled in a weight loss programme.

### **Theoretical implications**

The variation in psychological and social factors between individuals could account for the limited success of weight loss programmes (Teixeira et al., 2005). The interaction of intrapersonal, behavioural and environmental factors with learning, as suggested by social cognitive theory, offers some explanation as to why some people make and maintain the required behavioural changes to lose weight and some do not (Bandura, 1998). This study has contributed to this understanding by suggesting that the intrapersonal or psychosocial differences investigated in this study do not account for differences in the amount of weight lost or whether someone remains in a weight loss programme.

This study also investigated the relationship between the amount of weight loss and psychosocial change and found that a reduction in physical symptom burden, following 12 weeks of a weight management programme, correlated with the magnitude of weight loss. Therefore, the improvement in physical symptoms as a result of losing weight appeared to negatively reinforce further weight loss, through the removal of the aversive physical symptoms (Skinner, 1938). Thus a dimensional relationship between physical symptoms and weight loss exists.

The improvement in quality of life and mental health following the programme was not associated with the amount of weight lost. This finding suggests that a categorical relationship exists between weight loss and psychosocial change. Learned helplessness, which occurs when adaptive responding is disrupted by having no

perceived control over negative occurrences, could help understand these findings (Seligman, 1972). It is possible that obese individuals have experienced many weight loss attempts with little success, resulting in discouragement, depression and learned helplessness about their ability to lose weight and change their lives. The weight management service provides individuals with an alternative (diet and exercise modifications) and they begin to lose weight. Thus, the experience of some weight loss might lead to the realisation of having control over their weight - learned mastery. It is possible that the realisation of control, irrespective of how much weight is lost, leads to mental health and quality of life improvements.

### **Study limitations**

Caution has to be exercised when interpreting the findings as the desired sample size of 138 for the regression and 85 for the correlation were not achieved. Even when the higher effect size was assumed for the correlations, the target of 47 participants was still not quite reached. Consequently, the study was underpowered. Therefore, there were not enough participants sampled to be certain of the null findings in relation to the association of psychosocial characteristics and the amount of weight loss or programme attrition. Future studies investigating predictors of success and other associated changes in weight loss programmes need to ensure they have a large enough sample size.

As data were gathered within routine clinical practice, this practice-based study reduces the effect of highly selected participants biasing the findings. Practice-based studies have the benefit of providing an indication of what happens in real clinical situations. However, a selection bias was still possible.

Clinicians were asked to invite all eligible people attending an assessment to participate. However, there was a possibility that participants were approached in a more subjective manner, as more assessments were conducted during the data collection months than people recorded as participating or declining participation. Clinicians

might be more likely to enquire about participation if patients display certain characteristics, such as appearing more motivated and engaged. If motivation rather than the measured psychosocial characteristics determined the weight loss outcomes in these participants, any effect of psychosocial characteristics could be masked. Consequently, the data might reflect the results of a select population of weight loss treatment seekers, and not reliably reflect the obese population as a whole. This potential limitation has implications for the ability of the results to be generalised beyond the sample obtained. Ethically, it has not been possible to compare the characteristics of participating and non-participating patients. Therefore, it is impossible to know whether patients asked to participate differ to those who clinicians were unable to ask.

Gathering data within a clinical service meant that all participants would be defined as 'treatment seekers'. Consequently, the sample was not reflective of all obese people losing weight (i.e., people dieting independently or through a slimming club). It is possible that people attempting to lose weight without healthcare intervention have different psychosocial characteristics, which could be associated with how much weight is lost. Therefore, it is not possible to generalise the findings to all obese people losing weight.

Obese people have been found to respond in ways they perceive to be socially desirable (Lee, & Shapiro, 2003). It is not known whether this occurred in the current study as a test for socially desirable responding was not administered. Finally, as rigorous procedures for data collection were not followed some data were missing. This led to fewer participant data for some analyses and some of the measure scores requiring pro-rating, which increased the chance of measurement error. Consequently the scores obtained might not be a valid representation of participants' psychosocial characteristics.

## **Future research**

Further research into the limited success of lifestyle weight management programmes is required. This research could provide information that would improve the success rate of weight management programmes, given the high costs associated with obesity. Perhaps the lack of success is due to social or psychological factors not measured by this study such as self-efficacy, motivation, social support or attitudes towards weight loss. For example, Liebl, Barnason and Brage Hudson (2016) found that people saw the positive influence of friends and family as the reason for maintaining weight loss after a surgical intervention.

As the weight loss programme resulted in mental health and quality of life improvements that were not associated with the amount of weight lost, further research to explain this finding is warranted. Research could elucidate whether the psychosocial improvements are due to an attitude shift or sense of having control once people begin losing weight, following a period of learned helplessness. Additionally, follow up studies could investigate whether this pattern extends beyond the initial 12 weeks, or following this there is a different relationship between weight loss and psychosocial change.

Research in the future could investigate the association between psychosocial characteristics and weight loss in obese people attempting to lose weight in non-clinical settings such as Slimming World or among independent dieters. It would also be interesting to investigate people with lower body weights to see if the same patterns exist. It is possible that the categorical relationship between weight loss and psychosocial change only occurs amongst people with a high BMI, due to a greater chance of experiencing learned helplessness through repeated weight loss failures.



## **Clinical implications**

NICE (2006) recommends lifestyle weight management programmes for people with a BMI 30 and above, aiming for 5-10% weight loss due to the physical benefits associated with this loss (Klein, 2001). This study found participants lost on average 2.43% of their weight in the first 12 weeks of a lifestyle intervention. Therefore, it is advisable that clinicians consider this when setting out patient expectations, as only a small amount of weight is lost, proportional to the initial BMI, and the level of this weight loss is not associated with the level of psychological change.

This study did, however, find this small amount of weight loss to be associated with improvements in physical symptoms. Therefore, a desire to improve the burden of the physical symptoms associated with obesity could be used by weight loss interventions to motivate people to lose more weight. Additionally, the act of losing weight, regardless of how much, appears to lead to improvements in quality of life and mental health. This finding could be used to further motivate people to lose weight.

As no psychosocial variables predicted the amount of weight lost, there is no recommendation to change current clinical practices to focus on psychological change. It is advised that lifestyle interventions continue with the approach they already adopt, focusing on losing weight through behavioural change (diet and exercise). Clinicians can consider increasing input during the initial four weeks, as the amount of weight lost during this time was found to be related to later weight loss. It is also advised that referral criteria are not adapted to exclude anyone on the basis of their psychological characteristics as the intervention appears suitable for all.

## **Conclusion**

The first 12 weeks of the weight management programme helped obese people to lose weight. However, the amount of weight lost was not a significant amount

proportionate to the large initial BMI of the sample. The amount of weight lost or whether participants remained in treatment were not predicted by psychosocial characteristics, suggesting the intervention is suitable for all. The intervention also had positive effects on participants' quality of life, mental health and the burden caused by the physical symptoms of obesity. However, unlike the improvements in physical health, the quality of life and mental health improvements were independent of the amount of weight lost.

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<sup>1</sup> Note. The ethical approvals were gained whilst using my maiden name, Green.

## Appendix 1: Search history (Web of Science and PubMed)

Table 1A.

*Full search history*

Core concept – obesity		Core concept - core beliefs	Core concept	Results
Obese Overweight Fat Corpulent	AND	"cognitive content" "think" "core beliefs" schema* "core belief" Believe Perceive Imagine		30407
Obese Overweight	AND	"cognitive content" "think" "core beliefs" schema* "core belief" Believe Perceive Imagine		14166
Obese Overweight	AND	"cognitive content" "think" "core beliefs" schema* "core belief"		645
obes* Overweight	AND	"cognitive content" "think" "core beliefs" schema* "core belief"		1937
obes* Overweight	AND	"cognitive content" "core beliefs" schema* "core belief"		1377
obes* Overweight	AND	"cognitive content" "core beliefs" schema* "core belief" "cognitions"		1598
obes* Overweight	AND	"core beliefs" schema* "core belief"		1377

obes* Overweight	AND	"core beliefs" "core belief" schema*	psychology Theory	41
obes* Overweight	AND	"core beliefs" "core belief" schema* Young YSQ "Young Schema Questionnaire"		89581
obes* Overweight	AND	"core beliefs" "core belief" schema* YSQ "Young Schema Questionnaire"		
obes* Overweight	AND	"core beliefs" "core belief" schema schemas schemata		128

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## Appendix 2: The amended quality checklist (Downs &amp; Black, 1998)

Table 2A.

*The amended quality checklist*

Question	Possible scores
<b>Reporting</b>	
1. Is the hypothesis/aim/objective of the study clearly described?	0 or 1
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section? If the main outcomes are first mentioned in the Results section, the question should be answered no.	0 or 1
3. Are the characteristics of the patients included in the study clearly described? In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.	0 or 1
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described? A list of principal confounders is provided	0, 1 or 2
6. Are the main findings of the study clearly described? Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (this question does not cover statistical tests which are considered below).	0 or 1
7. Does the study provide estimates of the random variability in the data for the main outcomes? In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes	0 or 1
10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001? External validity: All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.	0 or 1
11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.	0 or 1
12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited? The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.	0 or 1
16. If any of the results of the study were based on "data dredging", was this made clear? Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.	0 or 1
18. Were the statistical tests used to assess the main outcomes appropriate? The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.	0 or 1
20. Were the main outcome measures used accurate (valid and reliable)? For studies where the outcome measures are clearly described, the question should be	0 or 1

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answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.	
Internal validity - confounding (selection bias)	
21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.	0 or 1
22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.	0 or 1
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.	0 or 1
Power	
27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance <5%. Sample sizes have been calculated to detect a difference of x% and y%.	0, 1, 2, 3, 4 or 5

---

## Appendix 3: Individual item scores for the quality checklist by both quality appraisers

Table 3A.  
Downs and Black's quality checklist items scores for papers in alphabetical order

Downs and Black criteria	1	2	3	5	6	7	10	11	12	16	18	20	21	22	25	27	Total
Anderson, Rieger, & Caterson (2006)	1	1	1	2	1	1	1	0	0	1	1	1	0	0	1	5	17
Bidadian, Bahramizadeh, & Poursharifi (2011)	0	1	0	0	1	0	0	0	0	1	1	1	1	1	0	5	12
Fereidouni et al. (2015)	1	1	1	2	1	1	1	0	0	1	1	1	0	0	1	5	17
Nauta et al. (2000)	1	1	1	1	1	0	0	0	0	0	1	1	1	1	0	5	14
Turner, Rose, & Cooper (2005)	1	1	1	0	1	1	1	0	0	1	1	1	1	0	1	5	16
van Hanswijck et al. (2003)	1	1	0	0	1	1	0	0	0	1	1	1	1	1	0	5	14
Van Vlierberghe & Braet (2007)	1	1	1	1	1	1	0	0	0	0	1	1	0	0	1	5	14
Van Vlierberghe, Braet & Goossens (2009)	1	1	1	2	1	1	0	0	0	1	1	1	1	1	1	5	18

Note. The numbers provided above are answers to the questions for the items in the quality checklist where 0 - no or unable to determine; 1 - yes for all criteria excluding criteria 5 (where 2 - yes, 1 - partially and 0 - no) and criteria 27 (where 0 was assigned if there were no participants, 1 if the sample size was 1-2, 2 if the sample size was 3-4, 3 if the sample size was 5-6, 4 if the sample size was 7-8 and 5 if there were more than 8 participants). N/A resulted in a score of 0 being given for that item.



Table 3B.

*The first and second quality appraisers scoring using Downs and Black's checklist*

Downs and Black criteria	1	2	3	5	6	7	10	11	12	16	18	20	21	22	25	27
Rater	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Anderson, Rieger, & Caterson (2006)	1	1	1	2	1	1	1	1	0	0	0	1	1	0	0	0
Bidadian, Bahramizadeh, & Poursharif (2011)	0	0	1	0	0	1	0	0	0	0	1	1	1	1	0	0
Turner, Rose, & Cooper (2005)	1	1	1	0	1	1	1	1	0	1	1	1	1	1	0	0
Van Vlierberghe, Braet & Goossens (2009)	1	1	1	2	2	1	1	0	0	1	1	1	1	0	1	1

Note. Rater A was the first author; rater B rated the above 50% of the studies

## Appendix A: Sample size calculations

$$\alpha \text{ (two-tailed)} = 0.05$$

$$\beta = 0.2 \text{ (power 0.8)}$$

$$r = 0.3$$

$$\text{The standard normal deviate for } \alpha = Z\alpha = 1.960$$

$$\text{The standard normal deviate for } \beta = Z\beta = 0.842$$

$$C = 0.5 * \ln[(1+r)/(1-r)]$$

$$C = 0.5 * \ln[(1+0.3)/(1-0.3)]$$

$$C = 0.5 * \ln[1.3/0.7]$$

$$C = 0.5 * \ln[1.85714286]$$

$$C = 0.5 * 0.619 = 0.31$$

$$\text{Total sample size} = N = [(Z\alpha + Z\beta)/C]^2 + 3 = 85$$

$$N = [2.8/0.31]^2 + 3$$

$$N = 9.03^2 + 3 = 85$$

## Appendix B: Outcome measures

**TIP**

Here are a number of personality traits that may or may not apply to you. Please tick the box next to each statement to indicate the extent to which you agree or disagree with that statement. You should rate the extent to which the pair of traits applies to you, even if one characteristic applies more strongly than the other.

I see myself as	Disagree strongly	Disagree moderately	Disagree a little	Neither agree nor disagree	Agree a little	Agree moderately	Agree strongly
Extraverted, enthusiastic							
Critical, quarrelsome							
Dependable, self-disciplined							
Anxious, easily upset							
Open to new experiences, complex							
Reserved, quiet							
Sympathetic, warm							
Disorganised, careless							
Calm, emotionally stable							
Conventional, uncreative							

**CORE-10**

This form has 10 statements about how you have been OVER THE LAST WEEK.  
Please reach each statement and think about how often you felt that way in the last week.  
Then tick the box which is closest to this.

Over the last week	Not at all	Only occasionally	Sometimes	Often	Most or all of the time
I have felt tense, anxious or nervous					
I have felt I have someone to turn to for support when needed					
I have felt able to cope when things go wrong					
Talking to people has felt too much for me					
I have felt panic or terror					
I made plans to end my life					
I have had difficulty getting to sleep or staying asleep					
I have felt despairing or hopeless					
I have felt unhappy					
Unwanted images or memories have been distressing me					

### OWLQOL

Please read the statements below and put a cross (X) to indicate how much each statement applies to you at the present time.

	Not at all	Hardly	Somewhat	Moderately	A good deal	A great deal	A very great deal
Because of my weight, I try to wear clothes that hide my shape.							
I feel frustrated that I have less energy because of my weight.							
I feel guilty when I eat because of my weight.							
I am bothered by what other people say about my weight.							
Because of my weight, I try to avoid having my photograph taken.							
Because of my weight, I have to pay close attention to personal hygiene.							
My weight prevents me from doing what I want to do.							
I worry about the physical stress that my weight puts on my body.							
I feel frustrated that I am not able to eat what others do because of my weight.							
I feel depressed because of my weight.							
I feel ugly because of my weight.							
I worry about the future because of my weight.							
I envy people who are thin.							
I feel that people stare at me because of my weight.							
I have difficulty accepting my body because of my weight.							
I am afraid that I will gain back any weight that I lose.							
I get discouraged when I try to lose weight.							

**WRSM**

Have you experienced any of the symptoms below in the last four weeks? Please circle Yes or No as appropriate. If Yes, please put a cross (X) to indicate how much this symptom has bothered you.

Symptom		Not at all	Hardly	Somewhat	Moderately	A good deal	A great deal	A very great deal
Shortness of breath	Yes / No							
Tiredness	Yes / No							
Sleep problems	Yes / No							
Sensitivity to cold	Yes / No							
Increased thirst	Yes / No							
Increased irritability	Yes / No							
Back pain	Yes / No							
Frequent urination	Yes / No							
Pain in the joints	Yes / No							
Water retention	Yes / No							
Foot problems	Yes / No							
Sensitivity to heat	Yes / No							
Snoring	Yes / No							
Increased appetite	Yes / No							
Leakage of urine	Yes / No							
Light-headedness	Yes / No							
Increased sweating	Yes / No							
Loss of sexual desire	Yes / No							
Decreased physical stamina	Yes / No							
Skin irritation	Yes / No							

### PAM

Here are a number of statements that may or may not apply to you. Please tick the box next to each statement to indicate the extent to which you agree or disagree with that statement.

	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
When all is said and done, I am the person who is responsible for managing my health condition					
Taking an active role in my own health care is the most important factor in determining my health and ability to function					
I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition					
I know what each of my prescribed medications do					
I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself					
I am confident I can tell my health care provider concerns I have even when he or she does not ask					
I am confident that I can follow through on medical treatments I need to do at home					
I understand the nature and causes of my health condition(s)					
I know the different medical treatment options available for my health condition					
I have been able to maintain the lifestyle changes for my health that I have made					
I know how to prevent further problems with my health condition					
I am confident I can figure out solutions when new situations or problems arise with my health condition					
I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress					

## Appendix C: PAM-13 license for research purposes



### NON-EXCLUSIVE COPYRIGHT LICENSE

**License Fee.** As good and valuable consideration for the license granted herein, you shall pay to Insignia Health, LLC ("Insignia") the payment as shown in your shopping cart above (the "License Fee").

**License Terms.** Subject to the terms of this Agreement, you have the right to administer the PAM Materials (as defined herein) to up to the number of survey participants selected in your shopping cart and as defined below ("Participants"), beginning on the date of your online license purchase ("Effective Date") and ending twelve (12) months thereafter ("End Date").

### DEFINITIONS

"PAM Materials" means the Patient Activation Measure (PAM) survey tool, the PAM survey scoring table; four different levels in which to classify people participating in a PAM survey, guidelines for responding to people in each level, benchmark score and level data and if selected, the Coaching for Activation online nurse/coach guidance, PAM online survey administration tools, and/or online e-learning tools.

A "Participant" is defined as any individual consumer or potential consumer of health care services who is provided access to the PAM Materials, up to the maximum number of participants you selected in your shopping cart.

### TERMS AND CONDITIONS

This Agreement is a grant of a non-exclusive, non-transferrable copyright license to use the PAM Materials for the purpose of assessing and modifying the level of health engagement of Participants, subject to the terms and restrictions set forth herein (the "Agreement"). Use of the PAM Materials for any purpose other than those described herein is expressly prohibited without the written consent of Insignia. For clarity, the rights granted herein DO NOT include the right to:

- Copy, reproduce, publish, disseminate, or otherwise publicly display the PAM Materials or any part thereof outside of the scope of this Agreement;
- create derivative works or make alterations to the PAM Materials or any part thereof;
- use the PAM Materials or any part thereof, including but not limited to the PAM survey, to develop, validate or optimize a new or existing assessment of consumer health engagement, motivation, activation or similar assessment tool;
- sublicense the PAM Materials; or
- reverse engineer, reverse translate, decompile, disassemble or in any manner decode the PAM Materials or any part thereof, or any of the algorithms contained therein.

1. **Rights Granted.** Insignia hereby grants to you a non-exclusive, personal and non-transferable right to reproduce, distribute, and display the PAM Materials for the purpose of administering the PAM survey and collecting information related thereto to no more than the number of Participants defined by your on-line Participant range selection. Using PAM with Participants beyond that Participant range is a violation of this Agreement.

#### 2. Your Obligations.

2.1. You agree not to alter, add, change, or remove any identification marks, including copyright or trademark notices, from the PAM Materials. You further agree that if you reference the PAM Materials to Participants in written materials, publish any studies or findings relating to your use of the PAM Materials, or in any other way publicize your use of the PAM Materials, you shall refer to the PAM survey as the "Patient Activation Measure®" or "PAM®." You further agree to obtain any consents from Participants that are necessary to allow the PAM Materials to be provided to them.

#### 2.2. Reporting; Upon End Date.

(i) You shall provide to Insignia a written report in an electronic format approved by Insignia identifying the number of Participants who were given the PAM survey during the term of this Agreement. You further agree to maintain records supporting such report(s) for at least one (1) year following submission; and





(I) Subject to the confidentiality requirements of Section 3, you agree to share with Insignia non-personally identifiable, individual data ("Data") generated from your use of the PAM Materials. The Data shared shall include individual level data records containing answers to each of the PAM questions, and, if captured, (i) demographic variables, health status and condition variables, (ii) specific outcome variables including health behaviors, self-management behaviors and whether patients using PAM improved the self-management aspects of their health care, and (iii) the PAM Materials' effect on or relationship to patient health care utilization and costs. Such Data shall be reported to Insignia at least annually in the electronic format agreed upon by the parties to this Agreement. You hereby grant Insignia a royalty free, perpetual license to use such Data for its product improvement efforts.

3. **Confidentiality.** Both you and Insignia each acknowledge that either party may receive confidential and proprietary information of the other party including, without limitation, (i) technical information, including functional and technical specifications, analysis, research, processes, computer programs, job control language, communications scripts, methods, ideas, "know how" and the like; (ii) business information, including sales and marketing research, materials, plans, provider and beneficiary demographics, provider-specific information and the like; (iii) electronic media claims data in accordance with the Federal Privacy Act of 1974, as amended; (iv) the PAM Materials and all algorithms utilized by Insignia in the provision of the services set forth in this Agreement; (v) Data; and (vi) other information designated in writing by the owner as confidential at the time of delivery of such information to the recipient (collectively "Confidential Information").

Except for Protected Health Information (as defined by the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA)), Confidential Information of a party hereto shall not include information that: (a) becomes generally available to the public other than as the result of unauthorized disclosure by the recipient; (b) is independently derived by the recipient without the aid, application or use of the disclosing party's Confidential Information; or (c) was received by the recipient on a non-confidential basis prior to receipt from the disclosing party from a third-party lawfully possessing and lawfully entitled to disclose such information.

4. **Covenant Not to Disclose.** Except as provided in Section 2.2, each party receiving Confidential Information from the other party hereby agrees that it shall not use, commercialize or disclose such Confidential Information to any person or entity, without prior written permission of the non-disclosing party. Each party shall use at least the same degree of care in safeguarding the other party's Confidential Information as it uses in safeguarding its own Confidential Information.

5. **Ownership of the PAM Materials.** The State of Oregon, acting by and through the State Board of Higher Education on behalf of the University of Oregon, owns the copyright, title, and other related rights in and to the Patient Activation Measure ("PAM") and related guidance (collectively referred to as the "PAM Guidance") developed by Dr. Judith Hibbard and others. Insignia is the exclusive licensee of certain rights related to the PAM Guidance and is the owner of all trademark rights associated with this technology. All rights not otherwise granted to you in this agreement are reserved by Insignia and/or the University of Oregon.

#### 6. **Indemnification and Limitation of Liability.**

6.1. You agree to indemnify and hold harmless both Insignia and the University of Oregon and their respective members, directors, officers, governing board members, agents, employees, students, volunteers, and assigns against any and all claims, demands, damages, liability, losses, causes of action, costs and expenses arising out of or in any way related to the use, reproduction, distribution or public display of the PAM Materials by you or any of your Participants, or your failure to comply with applicable privacy laws.

6.2. INSIGNIA AND THE UNIVERSITY OF OREGON PROVIDE ACCESS TO THE PAM MATERIALS ON AN "AS IS, WITH ALL DEFECTS" BASIS. NEITHER INSIGNIA NOR THE UNIVERSITY OF OREGON MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED. BY WAY OF EXAMPLE, BUT NOT LIMITATION, INSIGNIA AND THE UNIVERSITY OF OREGON MAKE NO REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE (EVEN IF INSIGNIA OR THE UNIVERSITY OF OREGON KNOW OF SUCH PURPOSE), OR THAT THE USE OF THE PAM MATERIALS WILL NOT INFRINGE ANY PATENTS, COPYRIGHTS, TRADEMARKS OR OTHER RIGHTS OF THIRD PARTIES. YOU HEREBY AGREE TO SAVE, HOLD HARMLESS, DISCHARGE AND RELEASE INSIGNIA AND THE UNIVERSITY OF OREGON AND ALL OF THEIR RESPECTIVE AGENTS, SERVANTS, EMPLOYEES AND VOLUNTEERS, FROM ANY AND ALL LIABILITY, CLAIMS, CAUSES OF ACTIONS, DAMAGES OR DEMANDS OF ANY KIND AND NATURE WHATSOEVER WHICH MAY ARISE FROM OR IN CONNECTION WITH YOUR USE OF THE PAM MATERIALS.



## 7. Term and Termination.

7.1. The term of this Agreement shall commence on the Effective Date and shall continue until the End Date or until terminated in accordance with this Section 7, whichever is earlier ("Term").

7.2. Insignia may terminate this Agreement and the license granted herein for Insignia's convenience, by providing not less than ten (10) days advance written notice to you by electronic communication or otherwise.

7.3. Upon termination or expiration of this Agreement you shall cease using, reproducing, distributing, or publicly displaying any portion of the PAM Materials.

7.4. You acknowledge and agree that termination of Insignia's agreement with the State of Oregon for the right to use and sublicense the PAM survey and PAM Guidance shall terminate this Agreement; provided however that you may request continuation of this Agreement by making written request to the State of Oregon within sixty (60) days of your receipt of written notice of such termination. Such written request for license continuation shall include your agreement to assume with respect to the State of Oregon all obligations (including obligations for payment) contained in this Agreement with Insignia. In such case, the State of Oregon may in its sole discretion agree to accept or decline such request for assignment of this Agreement. Such written request shall be made to Director, Office of Technology Transfer, 1238 University of Oregon, Eugene, Oregon, 97403-1238.

8. Return or Destruction of Information. Except for the Data provided by you pursuant to Section 2.2, upon the expiration or termination of this Agreement, you and Insignia shall, within twenty (20) days, each return or destroy all Confidential Information of the other party; provided, however, that the receiving party may keep one copy of the Confidential Information for archival purposes so long as such archived Confidential Information is safeguarded against disclosure and use prohibited hereunder. In either case, upon request, the recipient shall provide the disclosing party with written certification that all Confidential Information has been returned or destroyed, as the case may be. Despite such a return or destruction, the parties' obligations under this Section shall survive indefinitely.

9. Remedies for Breach of Confidentiality. Each party hereby acknowledges that the violation by it of the restrictions imposed hereunder would cause irreparable harm to the owner of such Confidential Information and that remedies at law would be inadequate to redress any actual or threatened violation of this agreement. Each party agrees that, in addition to other relief that may be available, the foregoing restrictions may be enforced by temporary and permanent injunctive relief. Any award of relief to the owner of such Confidential Information in an action in which the owner substantially prevails shall include recovery of such owner's costs and expenses of enforcement (including attorneys' fees, including attorneys' fees and any costs associated with appeal).

## 10. General Provisions.

10.1. Assignment. The rights granted hereunder and this Agreement may not be assigned, transferred, or sublicensed directly or indirectly, by operation of law, contract or otherwise, by you except with the express written consent of Insignia, which consent may be withheld at Insignia's sole discretion.

10.2. Entire Agreement, Modification, and Waiver. This Agreement replaces and supersedes any prior agreements between the parties and sets forth the entire agreement between the parties with respect to the subject matter hereof, and may not be modified or amended except by written agreement executed by the parties hereto. No waiver, consent, modification, or change of any terms of this Agreement shall be binding unless the same is in writing and signed by both parties and all necessary approvals have been obtained. Such express waiver, consent modification, or change, if made, shall be effective only in the specific instance and for the specific purpose set forth in such signed writing.

10.3. Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Oregon, without giving effect to the conflict of law principles thereof, and applicable federal law. Any action or suit brought by the parties relating to this Agreement shall be brought and conducted solely and exclusively in the state and federal courts in Multnomah County in the State of Oregon in Portland, Oregon. You hereby waive any objection to venue in such courts, and waive any claim that such forum is an inconvenient forum. BY EXECUTION OF THIS AGREEMENT, YOU HEREBY CONSENT TO THE PERSONAL JURISDICTION OF SUCH COURT.

10.4. Notice. Any notice under this Agreement shall be in writing and be delivered in person or by public or private courier service (including U.S. Postal Service Express Mail) or by certified mail with return receipt



requested or by electronic mail. Notice to you shall be addressed to the contact information you provided above, notice to Insignia shall be addressed to the following address or at such other address as Insignia may from time to time direct in writing:

For Insignia:

Insignia Health, LLC  
 Attn: License Department  
 Street: 10900 Wayzata Blvd., Suite 810  
 City, State Zip: Minnetonka, MN 55305  
 Email: [info@insigniahealth.com](mailto:info@insigniahealth.com)

Any notice shall be deemed to have been given on the earlier of: (i) actual delivery or refusal to accept delivery, (ii) the date of mailing by certified mail, (iii) the day facsimile delivery is verified or (iv) if by email the date sent unless an out of office-type reply is received in which case the notice shall be deemed given when the notice indicates the recipient will return to the office. Actual notice, however and from whoever received, shall always be effective.

10.5. Severability. If any one or more provisions of this Agreement shall be adjudicated to be illegal, invalid, or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The parties hereby agree to attempt to substitute for any illegal, invalid, or unenforceable provision a valid or enforceable one, which achieves the economic, legal and commercial objectives of the invalid or unenforceable provision to the greatest extent possible.

10.6. No Third Party Beneficiaries. Nothing in this Agreement gives, is intended to give, or shall be construed to give or provide any benefit or right, whether directly, indirectly, or otherwise, to any other third persons.

10.7. Headings, Drafting, and Counterparts. This Agreement may be executed electronically and in counterparts, each of which may be an original but all of which, when taken together, shall constitute one and the same instrument. Headings included herein are for convenience only and shall not be used to construe this Agreement. The parties agree that they have participated equally in the formation of this Agreement and that the language herein should not be presumptively construed against either of them.

10.8. Audits. You shall create and maintain records as required by this Agreement and you shall grant Insignia reasonable access during normal business hours to examine and take copies of, on no less than ten (10) business days' advance written notice and at Insignia's cost, the records relating to this Agreement, to verify your compliance with the terms and conditions of this Agreement.

10.9. Survival. All terms of this Agreement with the exception of Section 1 shall survive the expiration or termination of this Agreement.

## Appendix D: NHS ethical approval and Research and Development letters

## NHS Health Research Authority favourable opinion letter

**NRES Committee Yorkshire & The Humber - South Yorkshire**

Unit 001  
 Jarrow Business Centre  
 Rolling Mill Road  
 Jarrow  
 Tyne and Wear  
 NE32 3DT

Telephone: 0191 4283563

17 July 2015

Miss Laura Green  
 Trainee Clinical Psychologist  
 Sheffield Health and Social Care NHS Foundation Trust  
 Clinical Psychology Unit, Department of Psychology  
 The University of Sheffield  
 Western Bank  
 Sheffield  
 S10 2TN

Dear Miss Green

**Study title:** The relationship between psychosocial characteristics and weight loss in a weight management programme  
**REC reference:** 15/YH/0198  
**IRAS project ID:** 174240

Thank you for your email of 17 July 2015, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Helen Wilson, [nrescommittee.yorkandhumber-southyorks@nhs.net](mailto:nrescommittee.yorkandhumber-southyorks@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a **favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting

documentation [as revised], subject to the conditions specified below.

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.**

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

#### **Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra\\_studyregistration@nhs.net](mailto:hra_studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### **Ethical review of research sites**

##### **NHS sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management

permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering letter on headed paper [Covering letter]	1	31 March 2015
Covering letter on headed paper [Response Letter from Laura Green]		15 July 2015
IRAS Checklist XML [Checklist_15072015]		15 July 2015
Letters of invitation to participant [Participant invitation letter]	1	12 December 2014
Non-validated questionnaire [PAM questionnaire]	1	12 December 2014
Other [DCHS Letter]		24 June 2015
Participant consent form [consent form]	2	15 July 2015
Participant information sheet (PIS) [Participant Information sheet (clean copy)]	2	15 May 2015
Participant information sheet (PIS) [PIS - Tracked changes]	2	15 May 2015
REC Application Form [REC_Form_31032015]		31 March 2015
REC Application Form [REC_Form_15042015]		15 April 2015
Referee's report or other scientific critique report [Scientific approval]	1	13 February 2015
Research protocol or project proposal [Research proposal]	2	12 December 2014
Summary CV for Chief Investigator (CI) [CI CV]	1	31 March 2015
Summary CV for supervisor (student research) [Supervisor CV]	1	30 June 2014
Validated questionnaire [CORE-10 questionnaire]	1	12 December 2014
Validated questionnaire [OWLQOL questionnaire]	1	12 December 2014
Validated questionnaire [Personality questionnaire]	1	12 December 2014
Validated questionnaire [WRSM questionnaire]	1	12 December 2014
Other [confirmation of R & D]		17 July 2015

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

#### HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

15/YH/0198	Please quote this number on all correspondence
------------	--

With the Committee's best wishes for the success of this project.

Yours sincerely



pp

**Dr Ian Woollands**  
Chair

Email: [nrescommittee.yorkandhumber-southyorks@nhs.net](mailto:nrescommittee.yorkandhumber-southyorks@nhs.net)

Enclosures: "After ethical review – guidance for researchers"

Copy to: Rachel Holt, Live Life Better Derbyshire

## NHS Derbyshire Community Health Services Trust Research and Development approval letter



Derbyshire Community Health Services **NHS**  
NHS Foundation Trust

**Research and Development Office**  
**TRUST APPROVAL LETTER**

Quality Directorate  
Derbyshire Community Health Services NHS Trust  
Newholme Hospital  
Baslow Road  
Bakewell  
DE45 1AD

Tel: 01629 812525  
Fax: 01629 817890

<http://www.dchs.nhs.uk/>

22<sup>nd</sup> July 2015

Laura Green  
Trainee Clinical Psychologist  
Sheffield Health and Social Care NHS Foundation Trust  
Clinical Psychology Unit, Department of Psychology  
The University of Sheffield  
Western Bank  
Sheffield  
S10 2TN

Dear Laura,

**Re:**

**Ref. DCHS/2015/004 – The relationship between psychosocial characteristics and weight loss in a weight management programme**

Further to the Research Ethics Committee approval for the above study, I am pleased to confirm Derbyshire Community Health Service NHS Trust's management approval for you to proceed in accordance with the agreed protocol, the DCHS's financial procedures for research and development and the Research Governance Framework (which includes the Data Protection Act 1998 and the Health & Safety at Work Act 1974).

Please supply the following to Ramila Patel, Research Governance & Clinical Trials Manager, R&D Office, Derby Hospitals NHS Foundation Trust:

- the actual start and end dates of this study (**before the study commences**).
- details of any publications arising from this research project.
- a final report and a report every six months if the study duration is greater than six months.
- notification of any adverse event or changes to the protocol or if the trial is abandoned.

Chief Executive Tracy Allen

Chair Prem Singh





Derbyshire Community Health Services **NHS**  
NHS Foundation Trust

Please note that approval for this study is dependent on full compliance with all of the above conditions.

I would like to take this opportunity to wish you every success with this study.

Yours sincerely,

**Dr Rick Meredith**  
**Medical Director**

Email [rick.meredith@nhs.net](mailto:rick.meredith@nhs.net)  
Phone 01246 515151

Chief Executive Tracy Allen

Chair Prem Singh

**Short Study Title:** The relationship between psychosocial characteristics and weight loss in a weight management programme

**R&D Ref:** DCHS/2015/004

In accordance with your application and subsequent R&D approval dated 22<sup>nd</sup> July 2015 the following documentation was reviewed and may therefore be used on the above study with Trust approval.

List of reviewed Documents:

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS R&D form		15 April 2015
[Participant invitation letter	1	12 December 2014
Non-validated questionnaire [PAM questionnaire]	1	12 December 2014
Participant consent form	2	15 July 2015
Participant information sheet (PIS)	2	15 May 2015
Research protocol or project proposal	2	12 December 2014
Summary CV for supervisor		11 June 2015
Summary CV for student		23 June 2015
Validated questionnaire [CORE-10 questionnaire] Validated questionnaire [OWLQOL questionnaire] Validated questionnaire [Personaility questionnaire] Validated questionnaire [WRSM questionnaire]	1	12 December 2014
Sponsor Letter/Confirmation of Indemnity		13 February 2015
HRA Ethics Approval letter		17 July 2015
Clinical Psychologist in training contract		22 June 2015

## Appendix E: Participant information sheet



## Department Of Psychology. Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy) Programme  
Clinical supervision training and NHS research training & consultancy.

### **The relationship between psychosocial characteristics and weight loss in a weight management programme - Information sheet**

You are invited to take part in a research project. Before you decide whether to participate, you might want to know why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### **What is the project's purpose?**

The project aims to investigate the relationship between personality and other psychological and social factors with amount of weight loss after taking part in a weight management programme by gathering data over a year.

#### **Why have I been chosen?**

You have been chosen as a recent enroller on the weight management programme. We hope to recruit 90 participants in total.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do not wish to participate or change your mind you will not receive a penalty or lose any benefits you are entitled to as part of the weight management programme. You can decide to stop participating at any time, whilst the study is ongoing, without giving us a reason.

#### **What will happen to me if I take part?**

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Involvement in the study will require completing five questionnaires when you agree to participate and a second set three months into the programme. These questionnaires assess personality, quality of life, physical symptoms, mental health and health related behaviour. Each of the two sets of questionnaires should take approximately 10 minutes of your time. We ask you to try to be as honest as possible in answering the questions and to complete all items. With your permission, we will also gather information about your weight and height from the clinicians running the programme.

Data will be collected from the weight management service for nine months. We will then compare the results from the questionnaires in the beginning with the results three months later to look for differences and relationships with the amount of weight lost.

### **What are the possible disadvantages or risks of taking part?**

We are not expecting any discomforts, disadvantages or risks to occur as a result of your participation. However, any unexpected discomforts, disadvantages and risks, which arise during the research, will be brought immediately to your attention.

### **What are the possible benefits of taking part?**

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will help inform future weight management programmes.

Understanding whether personality, mental health or quality of life impacts upon the amount of weight lost could help services adapt the interventions they provide to help increase the amount of people who benefit from the programmes.

### **What happens if the research study stops earlier than expected?**

If the study stops earlier than expected the reason(s) will be explained to you.

### **What if something goes wrong?**

If you wish to raise a complaint about the research you can contact the Principal Investigator ([lgreen3@sheffield.ac.uk](mailto:lgreen3@sheffield.ac.uk)) or Supervisor ([g.waller@sheffield.ac.uk](mailto:g.waller@sheffield.ac.uk)). However, should you feel that your complaint has not been handled to your satisfaction you can contact the University's 'Registrar and Secretary':

Office of the Registrar and Secretary	Telephone: 0114 222 1100
Firth Court	Fax: 0114 222 1103
Western Bank	email : <a href="mailto:registrar@sheffield.ac.uk">registrar@sheffield.ac.uk</a>
Sheffield S10 2TN	

### **Will my taking part in this project be kept confidential?**

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any reports or publications.

### **What will happen to the results of the research project?**

The results of the research will be submitted as part of a doctoral thesis and are planned to be published late 2016. To obtain a copy of the published results you can contact [g.waller@sheffield.ac.uk](mailto:g.waller@sheffield.ac.uk).

### **Who is organising, funding and ethically reviewing the research?**

This project is funded by and has been ethically approved by The University of Sheffield's clinical psychology department's ethics review procedure. The project has also gained NHS ethical approval.

Thank you for taking the time to read this information sheet and for your participation should you chose to take part.

## Appendix F: Participant invitation letter

**Department Of Psychology.  
Clinical Psychology Unit.**

Doctor of Clinical Psychology (DClin Psy) Programme  
Clinical supervision training and NHS research training & consultancy.

Dear participant,

My name is Laura Green. I am a trainee clinical psychologist at The University of Sheffield supervised by Professor Glenn Waller. You are invited to participate in a research project: The relationship between psychosocial characteristics and weight loss in a weight management programme.

If you choose to participate you will be asked to complete five questionnaires which take approximately 10 minutes. You will be asked to complete these again three months later. These questionnaires assess personality, quality of life, physical symptoms, mental health and health related behaviour. All the information that we collect about you during the study will be kept strictly confidential.

I have enclosed a participant information sheet, which has further details about the study, and a consent form. If you would like to participate please complete and return the consent form.

If you would like any further information please contact me on [lgreen3@sheffield.ac.uk](mailto:lgreen3@sheffield.ac.uk).

Thank you for your consideration. Your participation is greatly appreciated.

Yours faithfully,

Laura Green  
(Trainee clinical psychologist)

Under the supervision of Professor Glenn Waller

Appendix G: Participant consent form  
**Participant Consent Form**

Title of Research Project: The relationship between personality and weight loss in a weight management programme		
Name of Researchers: Laura Green, Glenn Waller		
<b>Participant Identification Number for this project:</b>	<b>Initials:</b>	
1. I confirm that I have read and understand the information sheet dated <i>[insert date]</i> explaining the above research project and I have had the opportunity to ask questions about the project.	<input type="checkbox"/>	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.	<input type="checkbox"/>	
3. I understand that my responses will be kept strictly confidential. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	<input type="checkbox"/>	
4. I give consent for the researchers to access the weight management service records to gather information about my weight and height.	<input type="checkbox"/>	
5. I agree for the data collected from me to be used in future research	<input type="checkbox"/>	
6. I agree to take part in the above research project.	<input type="checkbox"/>	
_____	_____	_____
Name of Participant (or legal representative)	Date	Signature
_____	_____	_____
Name of person taking consent (if different from lead researcher) <i>To be signed and dated in presence of the participant</i>	Date	Signature
_____	_____	_____
Lead Researcher <i>To be signed and dated in presence of the participant</i>	Date	Signature

## Appendix H: Adverse incident form

**Adverse Incident/Complaint Form (Psychology Version) for health care research projects that the University of Sheffield is the research governance sponsor of**

This report form is for use if and when an adverse event incident occurs or a complaint is made relating to a health care research project where the University is the research governance sponsor. It should be completed by the Principal (or Chief) Investigator of the project and agreed with the Chair of the Ethics Committee or if a Clinical Unit project with the Director of Research Training. It will then be discussed with the Head of Department.

Guidance notes are included at the end of the report form (boxes on the form can be expanded).

<b>1. Research Project Title:</b>	
<b>2. 6 digit URMS number (if applicable):</b>	
<b>3. Principal/Chief Investigator:</b>	
<b>4. Supervisor/s:</b>	
<b>5. Who initially discovered the adverse event/Complaint?</b>	
<b>6. When was the adverse event/complaint reported to the Principal/Chief Investigator?</b>	
<b>7. When was the adverse event/complaint reported to the Head of Department/School?</b>	
<b>8. When did the adverse event/complaint actually occur?</b>	
<b>9. Where did it happen?</b>	

<b>10. What actually happened and what was the impact of the adverse event/complaint?</b>
<b>11. Why did the adverse event/complaint occur?</b>

<b>12. Describe what action(s) have been taken to address the impact of this specific adverse event/complaint:</b>	
<b>13. Describe what action(s) have been taken or are planned to limit the risk of a similar event/complaint re-occurring (add any general notes here to qualify the information given elsewhere in the report):</b>	
<b>Agreed and authorised by:</b>	
Name of Principal/Chief Investigator: <i>Insert name here</i>	Date: <i>insert date here</i>
Signature:	
Name of Head of Chair of Ethics Committee/Director of Research Training: <i>Insert name here</i>	Date: <i>insert date here</i>
Signature:	

**Guidance Notes:**

1. Adverse events/complaints should be reported to the Head of Department/School as soon as possible and normally within 5 working days. If the time exceeds this, this should be a consideration in 13.
2. Once complete, this report should be kept in the project's site file for reference and a copy sent to Research and Innovation Services, New Spring House, 231 Glossop Road marked for the attention of the Head of the Planning and Business Support Section (Mrs Deborah McClean).
3. Advice and guidance on completion of the report, analysis of the event and potential actions can be obtained from Research and Innovation Services (Lauren Smaller: ext. 21400).
4. An 'adverse event' is an unexpected event that includes, but is broader than, unintended errors and mistakes which arise as a result of research activity and result in one or more research participants having symptoms or being caused physical or psychological harm or serious distress.

**Examples of this include:**

- A human participant has an adverse reaction to a drug treatment, the use of which had been approved by a Research Ethics Committee.
  - An invasive instrument is used incorrectly, the use of which had been approved by a Research Ethics Committee, and the human participant suffers harm or has an extended stay in hospital.
  - A human participant is asked a series of questions regarding his/her sex life, a line of questioning that a Research Ethics Committee approved. However, for the interviewee, the questions revive painful memories of being abused as a child and the interviewee suffers serious distress such as to warrant therapy.
5. A 'complaint' is any approach made by a research participant to the researcher, their supervisor or collaborator with respect to the conduct of the study



## Appendix I: Research contract



Department Of Psychology.  
**Clinical Psychology Unit.**

Doctor of Clinical Psychology (DClin Psy) Programme  
 Clinical supervision training and NHS research training &  
 consultancy.

## **Clinical Psychologist in Training Research Contract (DClin Psy)**

This contract is to be completed by the trainee, academic supervisor(s), clinical supervisor(s) and other significant individuals (including collaborating clinicians and service users) directly involved in the proposed study. All parties should retain a copy for their records and a copy should be included as a permanent part of the site file held by the principal researcher. The initial contract should be attached to the research proposal.

**This contract covers the responsibilities of all involved in the undertaking of the proposed project and is open to amendment following the review and agreement of all parties concerned. In any event the contract would normally be reviewed annually until submission of the thesis and then quarterly until successful publication.**

**Precise details of research responsibilities and requirements should be obtained through consulting the Course Handbook, the University of Sheffield Guidebook for Research Students and Supervisors, and local NHS Research Governance documentation<sup>2</sup>**

### **Researcher Details**

The principal researcher should be indicated by an asterisk and will normally be the academic supervisor as this is required by ethics. However, it should be clear that the trainee holds the primary responsibility for all aspects of the research. Each supervisor's designation should be described in terms of their occupational title and their role in the proposed study (i.e. academic supervisor, clinical supervisor, collaborator etc.). Continue on a separate sheet if necessary.

#### **1. Trainee Details**

Name: Laura Jackson

Address: Clinical Psychology Unit  
 Department of Psychology

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<sup>2</sup> This is not an exhaustive list and it is the researchers' responsibility to consult additional documentation relating to local responsibilities/requirements.

The University of Sheffield  
 Western Bank  
 Sheffield, S10 2TN, UK

Date: 10/10/2014

Signature: Laura Jackson

Telephone: 07814563333

Email: lgreen3@sheffield.ac.uk

## 2. Academic Supervisor Details

Name: Prof Glenn Waller

Address: Clinical Psychology Unit  
 Department of Psychology  
 The University of Sheffield  
 Western Bank  
 Sheffield, S10 2TN, UK

Designation: Professor

Date: 23<sup>rd</sup> September 2014

Signature: 

Telephone: 0114 22 26568

Email: [g.waller@sheffield.ac.uk](mailto:g.waller@sheffield.ac.uk)

## 3. NHS/Clinical Liaison Supervisor Details – to be confirmed

Name: Dr Rachel Holt

Address: Live Life better Derbyshire, Walton Hospital, Chesterfield

Designation: Clinical Psychologist

Date: 2<sup>nd</sup> December 2015

Signature: (signed)

Email: Rachel.holt@nhs.net

## *Key responsibilities of all involved in the project*

### 1. Trainee

#### **During the course of the research the trainee is responsible for:**

- The overall development of the research
- All practical aspects of the study (including recruitment, data management, analysis, budgeting.)
- Arranging and attending regular meetings with supervisors (It is helpful to arrange in advance a set of meetings for each stage of the research)

- Preparing all research documentation (i.e. the research proposal, ethics form, indemnity forms, etc.)
- Submitting accurate expense claim forms.
- Maintaining and updating the site file and this contract
- Ensuring that the academic supervisor has seen and commented upon all drafts or versions of the proposal prior to it being submitted to the research tutors.
- Ensuring that all supervisors and collaborators are kept informed of the progress of the research. It is envisaged that the trainee will prepare and circulate minutes of key research meetings indicating any actions that have been agreed and the date/s of 2013 meetings. The trainee should ensure that copies of key documents and correspondence are forwarded to all supervisors. The trainee should take responsibility for liaising between supervisors and provide written updates to the research tutors as requested
- Reviewing and updating the research timetable as necessary and planning a research block that enables satisfactory completion of other aspects of the course.
- Ensuring that any documents as required by the course (see course handbook) are submitted to the course administrator in full and on time.
- To ensure that they comply with ethical and professional codes of conduct in carrying out the project including adhering to appropriate personal safety guidelines.
- Ensuring that any data containing personally identifiable information is stored securely.
- Ensuring that any drafts of work that have been agreed to be circulated are provided to supervisors within a sufficient time period to allow a realistic time for review (not usually less than 14 days)

**Following completion of the research the trainee is responsible for:**

- Ensuring that the site file and other documentation/data as necessary are lodged with the supervisor/course.
- Ensuring that local ethics/NRES and governance instructions relating to the completion of the research project are complied with.
- Ensuring that all supervisor(s) are offered a bound copy of the final thesis and appropriate feedback is provided to the collaborating service and if appropriate participants. The nature of the feedback required by the participating service should be negotiated prior to the trainee completing the course.
- Ensuring that data are stored securely, data files are backed up on computer and access to data for publication has been agreed with supervisors.
- Preparing manuscripts for publication in the target journals identified in the thesis<sup>3</sup>

## 2. Academic Supervisor

**During the research the academic supervisor is responsible for:**

- Attending regular meetings with the trainee (It may be helpful to arrange in advance a set of meetings for each stage of the research)
- Advising the trainee in developing a psychologically relevant research proposal and ensuring that this complies with the department's/NHS research plan and is likely to lead to research of a publishable standard.

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<sup>3</sup> Preliminary order of authorship should be indicated in the relevant section of this contract.

- Advise the trainee in considering ethical and professional concerns that may relate to the project including any relevant personal safety issues.
- Supporting the trainee in the preparation of all necessary research documentation.
- Advising the trainee on developing a realistic timetable and planning a research block that enables satisfactory completion of other aspects of the course.
- Monitoring progress and if necessary advising on the revision of the timetable.
- Advising the trainee in addressing any methodological problems as they arise.
- Reading and commenting on a draft (it may be helpful to discuss the format and number of drafts that will be reviewed).

**Following completion of the research the academic supervisor is responsible for:**

- Advising the trainee in preparing manuscripts for publication in the target journals identified in the thesis
- Ensuring the site file and data is stored in a secure place and is accessible for any future audit process.

### 3. Clinical supervisor:

During the research the clinical supervisor is responsible for:

- Attending meetings with supervisors as needed (It may be helpful to arrange in advance a set of meetings for each stage of the research)
- Advising the trainee in developing a realistic timetable for the research and monitoring progress and if necessary assisting in revising the timetable.
- Advise the trainee in considering ethical and professional concerns that may relate to the project.
- Supporting the trainee in being aware of and complying with appropriate local R & D procedures.
- Supporting the trainee in accessing participants.

**Following completion of the research the clinical supervisor is responsible for:**

- Advising the trainee in preparing manuscripts for publication in the target journals identified in the thesis
- Advising on the nature of the feedback required by the participating service.

### *Authorship & dissemination*

Please indicate a working title (or thesis section) for each planned publication and significant presentation/s relating to the thesis. Indicate the rationale for authorship. It is envisaged that the trainee will be the first author on all publications directly arising from the thesis. Additional collaborative publications arising in part from the thesis or data derived from the thesis may have another individual as the first author. It is envisaged that the two primary papers arising from the thesis would normally be submitted by the trainee within 18 months of submission. If this is not the case, the trainee should agree an alternative strategy (e.g. supervisor responsible for publication) with the supervisors concerned.

**1. Proposed title or thesis section (empirical study)**

The relationship between psychosocial characteristics and weight loss in a weight management programme

**Proposed journal / conference presentation / book chapter**

Obesity Research and Clinical Practice

**Proposed order of authorship**

Green, L., Holt., R., & Waller, G.

**Rationale for authorship (including order)**

Based on level of work inputted into the study

**Proposed submission date**

June 2016

**2. Proposed title or thesis section (literature review)**

A systematic review of schema-level core beliefs in people who are overweight or obese

**Proposed journal / conference presentation / book chapter**

Obesity Reviews

**Proposed order of authorship**

Green, L., & Waller, G.

**Rationale for authorship (including order)**

Based on level of work inputted into the review

**Proposed submission date**

June 2016

Continue on a separate sheet if necessary.

**Please update this contract at least once a year and at other times as necessary.**

