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# BMJ Open

## Third-wave cognitive behaviour therapies for weight management: Systematic review and network meta-analysis protocol.

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Manuscripts

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3 **Third-wave cognitive behaviour therapies for weight management: Systematic**  
4 **review and network meta-analysis protocol.**  
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7

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## ABSTRACT

**Introduction:** Behavioural and cognitive behavioural programmes are commonly used to assist with weight management, but there is considerable scope to improve their effectiveness, particularly in the longer term. Third-wave cognitive behaviour therapies (CBT) have this potential and are increasingly used. This systematic review will assess the effect of third-wave CBTs for weight management on weight, psychological and physical health outcomes in adults with overweight or obesity.

**Methods and analysis:** The systematic review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidance. We will include studies of any third-wave CBTs focusing on weight loss or weight maintenance for adults with a body mass index (BMI)  $\geq 25\text{kg/m}^2$ . Eligible study designs will be randomised control trials (RCTs), non-randomised trials, prospective cohort and case series. Outcomes of interest will be body weight/BMI, psychological and physical health, and adherence. We will search the following databases from inception to 16<sup>th</sup> January 2018: MEDLINE, CINHAL, EMBASE, Cochrane database (CENTRAL), PsycINFO, AMED, ASSIA and Web of Science. The search strategy will be based on the concepts: 1) third-wave CBTs 2) overweight, obesity or weight management. No restrictions will be applied. We will search reference lists of relevant reviews and included articles. Two independent reviewers will screen articles for eligibility using a two-stage process. Two independent reviewers will extract data from studies, and assess risk of bias using the Critical Appraisal Skills Programme checklist. A random-effects network meta-analysis of outcomes, and sub-group analyses and meta-regression will be conducted, where the data permit. If not appropriate, a narrative synthesis will be undertaken.

1  
2  
3 **Ethics and dissemination:** Ethical approval is not required as no primary  
4  
5 data will be collected. The completed systematic review will be disseminated  
6  
7 in a peer-reviewed journal, presented at conferences and used to inform the  
8  
9 development a weight management programme.  
10

11  
12  
13 **PROSPERO registration:** CRD42018088255  
14

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16 **Keywords:** Third-wave cognitive behaviour therapy, Weight management, Weight  
17  
18 loss, Weight maintenance, Overweight, Obesity  
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## 24 **ARTICLE SUMMARY**

### 25 **Strengths and limitations of this study**

- 26  
27 • Different third wave CBT modalities and delivery methods will be  
28  
29 distinguished enabling investigation into their comparative effectiveness.  
30  
31
- 32 • In addition to the direct treatment effects, indirect treatment effects will be  
33  
34 analysed using a random-effects network meta-analysis.  
35  
36
- 37 • A comprehensive search strategy will be used with a large number of  
38  
39 databases searched, no limitations applied and all prospective study designs  
40  
41 included.  
42  
43
- 44 • A description of the intervention content, duration and delivery mode will be  
45  
46 provided.  
47  
48
- 49 • It is anticipated that many papers will not provide sufficient details on all  
50  
51 variables of interest and we will be reliant on communication with  
52  
53 corresponding authors for additional information.  
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## INTRODUCTION

Overweight and obesity is a major public health challenge, due to its high prevalence<sup>1,2</sup> and associations with reduced physical and psychological health,<sup>3-5</sup> as well as negative social and economic consequences.<sup>6-8</sup> Supporting people with overweight and obesity to achieve and maintain a healthier weight is an international priority. Most treatment approaches for overweight and obesity combine diet and physical activity advice with psychological support to make behavioural changes. Most commonly, this is a standalone treatment, although it is also an accompaniment to surgery or pharmacotherapy.<sup>9</sup>

There are a number of behavioural programmes that are effective for weight management in the short term, but there is substantial room for improvement in reach and effectiveness – particularly in terms of long term outcomes.<sup>10-12</sup> Whilst many people are able to apply behavioural strategies in order to lose weight, it is hard to sustain these in the face of obesogenic physical and social environments, the biological drive to maintain body weight, and the habitual nature of key behaviours.

One way that the effectiveness of behavioural programmes might be improved is to identify new strategies that target psychological processes associated with better long term weight loss and weight loss maintenance. Key amongst these is sustained motivation and the healthy and adaptive self-regulation of eating behaviour and emotions.<sup>13-15</sup> Third-wave cognitive behaviour therapies (CBTs) have been identified as a potentially useful treatment to address these important factors.

### Third-wave CBTs

Third-wave CBTs have a number of core components that distinguish these approaches from first wave behaviour therapy and second wave cognitive behaviour

1  
2  
3 therapy; specifically an emphasis on openness, awareness, and action.<sup>16</sup> Types of  
4  
5 third-wave CBTs include dialectical behavioural therapy (DBT), schema therapy  
6  
7 (ST), acceptance and commitment therapy (ACT), acceptance-based behavioural  
8  
9 treatment (ABBT), mindfulness-based cognitive behavioural treatment (MBCT) or  
10  
11 compassion-focussed therapy (CFT).<sup>16–18</sup> These treatments have been associated  
12  
13 with adaptive self-regulation and sustained motivation across a number of health  
14  
15 domains, for example, in depression and addiction.<sup>19–21</sup>  
16  
17

18  
19 There are a number of ways in which these treatments could support successful  
20  
21 weight management. For example, fostering non-judgemental awareness of  
22  
23 thoughts, feelings and behaviour, could enable people to reduce overeating and to  
24  
25 limit the influence of internal and external cues. Encouraging patients to experience  
26  
27 potentially aversive internal experiences (cravings, anxiety, behavioural fatigue) and  
28  
29 to pursue behaviour that is congruent with their goals and values could support them  
30  
31 in adhering to a weight management plan – even when weight loss has plateaued.  
32  
33 Fostering a compassionate attitude toward the self could help prevent  
34  
35 discouragement following minor lapses. Mindfulness and acceptance-based  
36  
37 therapies have also been associated with improvements in psychological outcomes  
38  
39 related to long term weight management, including self-regulation, dietary restraint,  
40  
41 emotional eating, body satisfaction and mood.<sup>22–26</sup>  
42  
43  
44

### 45 **Evidence to date**

46  
47  
48 Previous systematic reviews have investigated the effect of third-wave CBTs on  
49  
50 weight management.<sup>22–28</sup>  
51  
52

53  
54 Although these reviews have consistently reported improvements for obesity related  
55  
56 eating behaviours and psychological outcomes, results for weight loss have been  
57  
58  
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1  
2  
3 mixed. Only three reviews of interventions in people with overweight and obesity  
4 included a meta-analysis of weight or BMI outcomes.<sup>22,25,26</sup> Rogers et al.'s<sup>25</sup> meta-  
5 analysis of eight studies reported a small but significant reduction in BMI, and the 16  
6 studies included in Carrière et al.'s<sup>22</sup> meta-analysis reported a significant moderate  
7 effect on weight loss. However, no significant effect was found for BMI in Ruffault et  
8 al.'s<sup>26</sup> meta-analysis of nine studies. These differences may be attributable to  
9 variation in inclusion criteria and methods across the reviews.  
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18 In addition to mixed findings, there are a number of methodological limitations that  
19 constrain conclusions on the effectiveness of third-wave CBT for weight  
20 management. The majority of reviews utilised a small number of databases,<sup>24–27</sup>  
21 lacked a comprehensive search strategy,<sup>26</sup> and conducted their database searches  
22 during, or prior to 2016,<sup>23,25–28</sup> meaning that existing reviews will not have captured  
23 all relevant research. In addition, there has been an emphasis on mindfulness, with  
24 some reviews excluding other therapy types<sup>22,23</sup> and others using the term  
25 'mindfulness' to encompass a range of third-wave CBTs. There has been a general  
26 failure in reviews to distinguish between different types of third-wave CBT or different  
27 methods of delivery, and detail on intervention content, delivery mode and intensity  
28 is lacking. This causes difficulties in assessing the comparative effectiveness of  
29 different approaches and limits their potential to inform future studies. Furthermore,  
30 little is known regarding participant adherence and attrition as only Olson and  
31 Emery<sup>28</sup> provided detail on this outcome. This would provide important insights into  
32 intervention fidelity and acceptability.  
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51 The present systematic review will provide a more comprehensive review of the  
52 range of third-wave CBTs that have been utilised for weight management. It will  
53 interrogate a large number of databases and include all prospective study designs,  
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1  
2  
3 while acknowledging the strength of randomised controlled trials. Importantly, it will  
4 distinguish between different treatment modalities and delivery methods, by pulling  
5 both the direct head-to-head comparisons reported in earlier studies, and the indirect  
6 and mixed effects within a random-effects network meta-analysis framework. Meta-  
7 regression methods will be applied to identify and/or adjust for potential source(s) of  
8 heterogeneity. While change in weight is the primary outcome, this review will also  
9 capture a range of physical and psychological health outcomes and will summarise  
10 data on intervention adherence. This review will provide important information with  
11 which to inform the development and refinement of third-wave CBTs for weight  
12 management.

## 23 24 25 **Objectives**

26  
27  
28 We aim to evaluate the effectiveness of third-wave CBTs for weight management in  
29 adults with overweight or obesity.

### 30 31 32 33 Primary objective

- 34  
35  
36 • To evaluate the effectiveness of third-wave CBTs for weight loss and weight  
37 loss maintenance in adults with overweight and obesity.

### 38 39 40 41 Secondary Objectives

- 42  
43  
44 • To evaluate the effect of third-wave CBTs for weight loss and weight loss  
45 maintenance on psychological and physical health outcomes in adults with  
46 overweight and obesity.
- 47  
48  
49 • To provide a detailed description of the content, duration, and delivery of  
50 interventions.

- To identify the intervention characteristics that are associated with better outcomes and adherence.

## **METHODS AND ANALYSIS**

### **Eligibility criteria**

Studies will be selected according to the criteria outlined below.

#### *Study designs*

We will include original research articles, theses and dissertations reporting randomised control trials (RCTs), non-RCTs, prospective cohort (PC) and case series studies that report an outcome measure pre- and post-intervention. No restrictions will be placed upon language, year of publication or publication status.

#### *Participants*

We will include studies of community dwelling adult human participants (aged  $\geq 18$  years) with overweight or obesity (BMI  $\geq 25$  kg/m<sup>2</sup>). Participants must be seeking assistance with weight loss or weight loss maintenance. No further restrictions will be made on gender, age, recruitment method, or co-morbid conditions.

#### *Interventions*

Studies will be included if they evaluated a third-wave CBT for the purpose of weight loss or weight loss maintenance. In terms of defining third-wave CBTs, they must be described as using DBT, ST, ACT, ABBT, MBCT or CFT. As these approaches are sometimes delivered as part of a multi-component intervention, no restriction will be placed on the proportion of the intervention using the technique, although this may

1  
2  
3 be considered in secondary-analyses. Interventions will be of any duration or  
4 delivery mode. There will be no restriction placed on who delivers the intervention. If  
5 multiple arms are included in a study, any arm that meets the inclusion criteria will be  
6 included in the review. We will exclude studies that do not state that weight  
7 management is an aim of the intervention.  
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### 13 14 *Comparators*

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17 For the meta-analysis, we will include studies with no comparator i.e., single-arm  
18 pre-post studies with no control arms. We will also compare third-wave CBTs to (i)  
19 no intervention or minimal intervention, and (ii) other behavioural programme(s), as  
20 reported in the studies.  
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### 26 27 *Outcomes*

28  
29 The primary outcomes will be:

- 30  
31
- 32 • Body weight
- 33 • BMI
- 34  
35  
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37

38 The secondary outcomes will be:

- 39  
40
- 41 • Stress
- 42 • Anxiety
- 43 • Depression
- 44 • Meta-cognition
- 45 • Eating attitudes
- 46 • Eating behaviours
- 47 • Body satisfaction
- 48  
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- Quality of life
- Blood pressure
- Lipids
- Glycaemia
- Adherence to treatment

### *Timing*

We will include studies that report one or more of the primary or secondary outcome measures pre- and post-intervention. We will exclude studies in which the follow up measures are less than 12 weeks from baseline, because of the identified need to find new approaches to improve long-term weight loss and weight loss maintenance.

### *Setting*

No laboratory based interventions will be included. All other settings are eligible for inclusion.

### *Language*

There will be no language restrictions.

## **Information sources and search strategy**

### *Electronic searches*

We will search the following databases: CINHAL, MEDLINE, EMBASE, Cochrane database (CENTRAL), PsycINFO, AMED, ASSIA and Web of Science. No restrictions to the search strategies will be applied, and databases will be searched from inception to the 16<sup>th</sup> of January 2018. For studies published in a non-English

1  
2  
3 language, appropriate employees of the university will be contacted to request a  
4  
5 translation.  
6  
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8 To identify studies for inclusion in this review, detailed search strategies will be  
9  
10 developed for each electronic database by ERL, who has previous experience  
11  
12 conducting systematic reviews, with input from a medical librarian. Other members of  
13  
14 the systematic review team will also be consulted to ensure appropriateness of  
15  
16 terminology and that no terms have been overlooked. The search strategy will  
17  
18 include a number of key word and subject heading searches relating to the concepts:  
19  
20 (1) Third-wave CBTs AND (2) Overweight, obesity or weight management. Searches  
21  
22 in the other databases will be based upon the MEDLINE search strategy (see  
23  
24 supplementary additional file), with modification when appropriate to take into  
25  
26 consideration database-specific terms. Search terms for the third-wave CBTs  
27  
28 concept will be based upon a systematic review of third-wave CBTs for eating  
29  
30 disorders by Linardon et al.<sup>18</sup>  
31  
32  
33

### 34 *Other search methods*

35  
36  
37 To enhance literature saturation, we will manually search reference lists of all  
38  
39 primary studies identified as eligible for inclusion in the review and previous relevant  
40  
41 reviews. Authors of abstracts that were identified in the database searches will be  
42  
43 contacted to identify whether the study findings have been published elsewhere or  
44  
45 accepted for publication. A bibliography of the included studies will be circulated to  
46  
47 the systematic review team to ensure no other studies they are aware of are  
48  
49 excluded.  
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### 53 **Study records**

### *Data management and selection process*

We will import results from the searches into a Microsoft Excel spreadsheet and duplicates will be removed. We will screen the study titles and abstracts to eliminate articles which clearly do not meet the inclusion criteria. There will be an initial piloting of this screening with an identical 10% of articles independently screened by two researchers to ensure consistency. If a high degree of disagreement occurs, the inclusion and exclusion criteria of the studies will be clarified through discussion with a third reviewer. Once piloting is completed, all article titles and abstracts will be independently screened by two researchers. We will obtain full text papers where titles and abstracts are deemed to be relevant or where eligibility is unclear. The obtained full text articles will then be independently screened by two researchers and their eligibility will be discussed to gain consensus. Where necessary, we will seek additional information from study authors to resolve any questions about eligibility. Reasons for exclusion of articles at the full text screening stage will be recorded. A third reviewer will resolve disagreements, if required. Reviewers will not be blinded to authors, institution or journal when screening articles. In the case of multiple articles pertaining to the same study, all articles will be included and then collated to make best use of the data. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)<sup>29</sup> flow-chart will be presented showing the process of study selection.

### *Data collection process*

For studies that fulfil the inclusion criteria, we will extract data from articles onto a data collection form. This form will be based upon the Cochrane data extraction form,<sup>30</sup> the Consolidated Standards of Reporting Trials (CONSORT) 2010

statement<sup>31</sup> and the Template for Intervention Description and Replication (TIDieR) checklist.<sup>32</sup> This will ensure that an appropriate breadth and depth of detail will be captured. The data extraction form will be piloted on three articles before it is finalised. Data will be independently extracted by two researchers and any discrepancies will be resolved by a third reviewer. Data analysis will be conducted using statistical program Stata version 14.2 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.).

### Data items

Data to be extracted from the studies will include:

- General information (e.g. study authors, publication year, country, source of funding)
- Study aim
- Population description
- Study characteristics (e.g. study design, randomisation, blinding, allocation concealment)
- Participants (e.g. age, sex, race/ethnicity, socioeconomic status, diagnosed condition(s), recruitment methods, sample size, weight)
- Intervention characteristics (e.g. therapy type/content, mode of delivery, group or individual delivery, dose of intervention, duration of session, setting, profession who delivered the intervention, theoretical framework)
- Comparator intervention characteristics (e.g. therapy type/content, mode of delivery, group or individual delivery, dose of intervention, duration of session, setting, profession who delivered the intervention, theoretical framework)

- Outcomes (e.g. outcome(s) studied, whether self-reported or objectively measured, duration of follow-up, statistical analysis, intervention effect sizes,)
- Adherence and attrition (e.g. total number of participants at baseline and at follow-up measurements, reasons for attrition, attendance, adherence to intervention)

If studies provide data for multiple follow-up time points, data will be extracted for all time points. If multiple arms are included in a study, data from any arm that meets the inclusion criteria will be extracted.

Due to the objective of this study to provide detailed descriptions of the content of the interventions, attempts will be made to contact the corresponding author of the study to retrieve further information not provided in the article, or in related publications. Study authors will also be contacted if there are any uncertainties regarding the study or missing data. If there is no response, authors will receive two email reminders. Authors will be given a two month timeframe to reply to this request for further information.

### **Outcomes and prioritisation**

The primary outcomes of interest are body weight and BMI as the aim of our review is to evaluate the effect of the third-wave CBTs on weight management. Body weight will be reported as kg. BMI will be defined as body weight (kg) divided by height (m) squared, and will be reported as kg/m<sup>2</sup>. We will record whether these measurements have been objectively assessed or have been obtained through participant self-report or other means.



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2  
3 Secondary outcomes are stress, anxiety, depression, meta-cognition, eating  
4 attitudes, eating behaviours, body satisfaction, quality of life, blood pressure, lipids,  
5 glycaemia and adherence to the third-wave CBT.  
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9

10 Psychosocial outcomes that have been associated with successful weight  
11 management have been included in order to understand the potential of third wave  
12 CBTs to target these potential determinants of longer term weight control. Data for  
13 these outcomes will be extracted as reported in the study. It will be noted if a  
14 validated instrument has been used.  
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20 For blood pressure, data for systolic and diastolic blood pressure will be extracted  
21 separately, and it will be reported using the unit mmHg. For lipids, data will be  
22 extracted for total cholesterol, low-density lipoproteins (LDL) and high-density  
23 lipoproteins (HDL) and reported using the unit mmol/l. If the ratio of total cholesterol  
24 to HDL has been presented, if possible, this will be converted into the separate  
25 outcomes for total cholesterol and HDL, or the study author will be contacted for raw  
26 data. Glycaemia may be reported as glycated haemoglobin (HbA<sub>1c</sub>; mmol/mol or %) or  
27 glucose (random, fasting or 2hr; mmol/l). These outcomes are important as they  
28 are closely associated with weight and are risk factors for a range of chronic  
29 diseases.  
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44 Information relevant to adherence to treatment will include number of sessions  
45 attended, length and number of times practicing skills, use of resources, and  
46 deviations from intervention instructions. Any information regarding participant  
47 attrition/retention, reasons for attrition and attendance at sessions will also be  
48 collected. This is important as it will enable investigation into the effect of intensity of  
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3 interventions on weight management, and also give insight into the acceptability of  
4  
5 the intervention.  
6

### 7 8 **Risk of bias of individual studies** 9

10  
11 Two researchers will independently assess the included studies for risk of bias. Any  
12  
13 discrepancies will be discussed with a third reviewer to gain consensus. We will pilot  
14  
15 this approach with three studies. Risk of bias and methodological quality will be  
16  
17 assessed in accordance with the appropriate Critical Appraisal Skills Programme  
18  
19 (CASP) checklist.<sup>33,34</sup> It is felt that this choice of assessment would be most  
20  
21 appropriate due to the study designs eligible for inclusion e.g. non-RCTs, PC and  
22  
23 case series. Choice of CASP checklist will be dependent on the study design. The  
24  
25 majority of criteria within the checklist will be answered with 'yes', 'no' or 'can't tell'  
26  
27 responses. Based on these criteria, studies will be classified as being of 'high', 'low'  
28  
29 or 'unclear' risk of bias. Any other potential sources of risk of bias not covered by the  
30  
31 CASP checklist will be noted. Reviewers will not be blinded to study authors, journal  
32  
33 or institution. Results will be presented in a summary table.  
34  
35

### 36 37 **Meta-biases** 38

39  
40 To assess for selective outcome reporting, if a study protocol is available, the  
41  
42 outcomes reported in the protocol and the article will be compared. If not available,  
43  
44 the methods and results section of the article will be compared to check for any  
45  
46 inconsistencies.  
47  
48

### 49 50 **Data synthesis** 51

52  
53 *Intervention comparisons: Direct*  
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3 Standard pairwise random-effects meta-analysis will be conducted where the  
4  
5 homogeneity of data and intervention permit, using Stata version 14.2. The head-to-  
6  
7 head comparisons will be conducted on the outcome measures reported at specific  
8  
9 time-points of follow-up (e.g., 3 months, 6 months, 12 months). Studies that have  
10  
11 outcomes that fall between these time-points will be combined with the closest time-  
12  
13 point. Mean differences (for continuous data) and odds ratio (for categorical data),  
14  
15 and their 95% confidence intervals will be estimated and reported.  
16  
17

### 18 *Intervention comparisons: Indirect and mixed*

19  
20  
21 Random-effects network meta-analysis will be conducted to estimate the indirect and  
22  
23 mixed effects using the Stata suite of commands for network meta-analysis, along  
24  
25 with commands for visualisation and reporting of results.  
26  
27

### 28 *Sensitivity analyses*

29  
30  
31 Sensitivity analysis will be conducted to see the potential impact on the effect  
32  
33 estimates of different study designs (e.g., RCTs, cohort studies) by restricting the  
34  
35 analysis to specific study types and/or by excluding one study designs at a time.  
36  
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38  
39 In the case of studies with two or more eligible intervention arms, dependent on the  
40  
41 similarity of the interventions, results may be combined or be split into different  
42  
43 groups. If different measures have been used to assess the same outcome and are  
44  
45 sufficiently similar, they may be pooled or harmonised. If the effect measures are  
46  
47 reported in different scales, meta-analysis will use standardised mean differences  
48  
49 (standardised by the baseline SD value).  
50  
51

### 52 *Statistical heterogeneity*

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2  
3 The statistical heterogeneity (the portion of the variability that cannot be attributed to  
4 random error) of the studies will be tested using the  $I^2$  statistic along with its 95% CI.  
5  
6 Forest plots showing the overlap of the confidence intervals will also be provided to  
7 enable visual inspection. For the network meta-analysis, we will also report a total  $I^2$   
8  
9 statistic, and the heterogeneity variance parameter ( $\tau^2$ ) estimated from the network  
10  
11 meta-analysis models.  
12  
13  
14

### 15 16 *Analysis of subgroups or subsets*

17  
18  
19 If sufficient data are available, subgroup analysis will compare:  
20

- 21 • Type of intervention (e.g. therapy type, duration, delivery, intensity)
- 22
- 23 • Comparator intervention (e.g. minimal intervention or other behavioural
- 24 intervention)
- 25
- 26 • Health condition of participants (e.g. type 2 diabetes)
- 27
- 28 • Length of follow up (e.g. 12 weeks, 6 months, 12 months)
- 29
- 30 • Study design (e.g. RCT, quasi-RCTs, PC, case series)
- 31
- 32 • Study quality (e.g. risk of bias)
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39 If sufficient data on important covariates are reported in the studies, meta-  
40 regression techniques will be applied to identify and/or adjust for potential  
41 sources of heterogeneity, if applicable.  
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### 46 *Narrative analysis*

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49 If meta-analysis is determined not to be appropriate due to substantial heterogeneity  
50 of studies and outcome measures that cannot be pooled, a narrative synthesis will  
51 be completed. This will be provided in the text and tables to summarise and explain  
52 the characteristics and findings of the studies.  
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### *Missing data*

It is anticipated that rates of attrition and missing data for outcome measurements may be relatively high, and that studies will adopt a variety of methods for handling missing data, including using only complete cases, using all observed data, multiple imputation, baseline observation carried forward, and last observation carried forward. The details of the missing data and data analysis approach will be described in the review. Our main analyses will use whichever analysis is reported in the paper. Where multiple approaches are reported, preference will be given to multiple imputation and all observed data methods. We will conduct a sensitivity analysis to evaluate whether the approach to missing data impacts on the primary outcome.

### **Confidence in cumulative estimate**

The quality of evidence will be assessed using the appropriate CASP checklist. This will be used to judge studies for any methodological flaws. This assessment is suitable due to our inclusion of non-RCTs, PCs and case series design studies. Other assessments more appropriate for RCT design studies may misjudge the quality of studies using these designs.

### **ETHICS AND DISSEMINATION**

The potential of third wave CBTs in weight management has been recently recognised, especially for long-term outcomes. However, evidence of their effectiveness on weight is mixed, and previous reviews have a number of limitations; our review will address these weaknesses.

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3 Our review will distinguish between the different therapies and delivery modes,  
4 enabling investigation into their comparative effectiveness. A detailed description of  
5 the intervention content, duration and delivery mode will be provided and where  
6 possible, meta-regression will be used to identify (and/or to adjust for) the source of  
7 heterogeneity across the studies. Besides direct treatment effects using standard  
8 random effects pairwise meta-analysis, we will also estimate the indirect treatment  
9 effects using random-effects network meta-analysis. This will allow us to include data  
10 from a range of prospective studies, not only randomised controlled trials.  
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21 Ethical approval is not required as no primary data will be collected. This systematic  
22 review will follow the Preferred Reporting for Systematic Reviews and Meta-  
23 Analyses (PRISMA) checklist.<sup>29</sup> It is planned that this systematic review will be  
24 published in a scientific journal, presented at relevant conferences and will be used  
25 in the development of a new weight management programme to help adults with  
26 overweight and obesity to reduce weight regain following weight loss. The findings of  
27 this review will be of interest to health professionals working with adults with  
28 overweight or obesity, researchers involved in the development, evaluation and  
29 implementation of weight management interventions, and policy makers and those  
30 responsible for commissioning weight management services.  
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## 46 **AUTHOR CONTRIBUTORS**

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49 ALA, AJH and SJG conceived the study, participated in the study design, provided  
50 input on methods, participated in the development of the initial search strategy and  
51 contributed to the drafting of the manuscript. ERL participated in the study design,  
52 provided input on methods, developed the initial search strategy and was  
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3 responsible for drafting the manuscript. NI provided input on methods, participated in  
4 the preparation of the initial manuscript draft and reviewed drafts. CH contributed to  
5 the drafting of the manuscript. All authors critically reviewed the manuscript and  
6 approved the final version submitted for publication.  
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16 Medicine librarian Eleanor Barker for assistance developing the search strategy.  
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## 20 **COMPETING INTERESTS**

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23 None declared  
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## 26 **DATA STATEMENT**

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29 Not applicable  
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33  
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## Supplementary file: Medline search strategy

1	exp Obesity/
2	exp Overweight/
3	exp Body Weight/
4	exp Body Mass Index/
5	exp Waist Circumference/
6	exp Feeding Behavior/
7	exp Body Weight Changes/
8	exp Caloric Restriction/
9	exp Weight Loss/
10	obes*.mp.
11	(overweight or over-weight).mp.
12	(weight adj3 (body or chang* or loss* or maint* or manag* or control* or reduct*)).mp.
13	(food adj3 (intake or habit*)).mp.
14	(body mass index or bmi).mp.
15	body adj3 mass.mp.
16	(calori* adj3 (restrict* or restrain* or reduc*)).mp.
17	feeding adj3 behavio*.mp.
18	(diet* adj3 (restrict* or restrain* or reduc*)).mp.
19	(waist* adj3 circumferenc*).mp.
20	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
21	((3rd or third) adj3 wave).mp.
22	(acceptance* adj3 (commit* or mind* or base* or focus* or intervention* or therap* or treat*)).mp.
23	exp Mindfulness/
24	(mindful* or mind-ful*).mp.
25	(compassion* adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.

26	(behav* adj3 activation).mp.
27	((meta-cognit* or metacognit*) adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.
28	(dialectic* adj3 (behavio* or mind* or base* or focus* or intervention* or therap* or treat*)).mp.
29	(schema* adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.
30	(function* adj3 analyt*).mp.
31	(relation* adj3 frame*).mp.
32	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
33	20 and 32

Search terms 21 to 31 based upon Linardon et al.'s<sup>18</sup> search strategy. No database search restrictions will be applied.

## PRISMA- P 2015 Checklist

Section and topic	Item number	Checklist item	Criteria location within manuscript
<b>ADMINISTRATIVE INFORMATION</b>			
Title			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Page 1
Authors			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pages 1, 20 & 21
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support			
Sources	5a	Indicate sources of financial or other support for the review	Page 21
Sponsor	5b	Provide name for the review funder and/or sponsor	Page 21
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Page 21
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pages 4 - 7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pages 7 & 8
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pages 8 - 10
Information sources	9	Describe all intended information sources (such as electronic databases, contact	Pages 10 & 11

		with study authors, trial registers or other grey literature sources) with planned dates of coverage	
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file
<b>Study records</b>			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Page 12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Page 12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Page 12 & 13
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Pages 13 & 14
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Page 14 -16
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Page 16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Pages 16 & 17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	Pages 16 -18
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Pages 17 & 18
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Page 18
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Page 16
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Page 19



# BMJ Open

## Third-wave cognitive behaviour therapies for weight management: Systematic review and network meta-analysis protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023425.R1
Article Type:	Protocol
Date Submitted by the Author:	29-May-2018
Complete List of Authors:	Lawlor, Emma; MRC Epidemiology Unit, University of Cambridge Islam, Nazrul; MRC Epidemiology Unit, University of Cambridge Griffin, Simon; The Primary Care Unit, Institute of Public Health Hill, Andrew; University of Leeds, Division of Psychological and Social Medicine, School of Medicine Hughes, Carly; Fakenham Medical Practice; University of East Anglia Faculty of Medicine and Health Sciences Ahern, Amy; MRC Epidemiology Unit, University of Cambridge
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Public health
Keywords:	Third-wave cognitive behaviour therapy, Weight management, Weight loss, Weight maintenance, Overweight, Obesity

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Manuscripts

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3 **Third-wave cognitive behaviour therapies for weight management: Systematic**  
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5 **review and network meta-analysis protocol.**  
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8 Emma R Lawlor<sup>1</sup>, Nazrul Islam<sup>1</sup>, Simon J Griffin<sup>1,2</sup>, Andrew J Hill<sup>3</sup>, Carly Hughes<sup>4,5</sup>,  
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41 Word count: 3840  
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## ABSTRACT

**Introduction:** Behavioural and cognitive behavioural programmes are commonly used to assist with weight management, but there is considerable scope to improve their effectiveness, particularly in the longer term. Third-wave cognitive behaviour therapies (CBT) have this potential and are increasingly used. This systematic review will assess the effect of third-wave CBTs for weight management on weight, psychological and physical health outcomes in adults with overweight or obesity.

**Methods and analysis:** The systematic review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidance. We will include studies of any third-wave CBTs focusing on weight loss or weight maintenance for adults with a body mass index (BMI)  $\geq 25\text{kg/m}^2$ . Eligible study designs will be randomised control trials, non-randomised trials, prospective cohort and case series. Outcomes of interest will be body weight/BMI, psychological and physical health, and adherence. We will search the following databases from inception to 16<sup>th</sup> January 2018: MEDLINE, CINHAL, EMBASE, Cochrane database (CENTRAL), PsycINFO, AMED, ASSIA and Web of Science. The search strategy will be based on the concepts: 1) third-wave CBTs 2) overweight, obesity or weight management. No restrictions will be applied. We will search reference lists of relevant reviews and included articles. Two independent reviewers will screen articles for eligibility using a two-stage process. Two independent reviewers will extract data, assess risk of bias using RoB 2.0, ROBINS-I or ROBINS-E checklist and assess quality using GRADE. A random-effects network meta-analysis of outcomes, and sub-group analyses and meta-regression will be conducted, where data permit. If not appropriate, a narrative synthesis will be undertaken.

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3 **Ethics and dissemination:** Ethical approval is not required as no primary data will  
4 be collected. The completed systematic review will be disseminated in a peer-  
5 reviewed journal, presented at conferences and used to inform the development a  
6 weight management programme.  
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12 **PROSPERO registration:** CRD42018088255  
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15 **Keywords:** Third-wave cognitive behaviour therapy, Weight management, Weight  
16 loss, Weight maintenance, Overweight, Obesity  
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## 20 21 22 23 **ARTICLE SUMMARY**

### 24 25 26 **Strengths and limitations of this study**

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29 • Different third wave CBT modalities and delivery methods will be  
30 distinguished enabling investigation into their comparative effectiveness.  
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- 33 • In addition to the direct treatment effects, indirect treatment effects will be  
34 analysed using a random-effects network meta-analysis.  
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- 37 • A comprehensive search strategy will be used with a large number of  
38 databases searched, no limitations applied and all prospective study designs  
39 included.  
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- 42 • A description of the intervention content, duration and delivery mode will be  
43 provided.  
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- 46 • It is anticipated that many papers will not provide sufficient details on all  
47 variables of interest and we will be reliant on communication with  
48 corresponding authors for additional information.  
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## INTRODUCTION

Overweight and obesity is a major public health challenge, due to its high prevalence<sup>1,2</sup> and associations with reduced physical and psychological health,<sup>3-5</sup> as well as negative social and economic consequences.<sup>6-8</sup> Supporting people with overweight and obesity to achieve and maintain a healthier weight is an international priority. Most treatment approaches for overweight and obesity combine diet and physical activity advice with psychological support to make behavioural changes. Most commonly, this is a standalone treatment, although it is also an accompaniment to surgery or pharmacotherapy.<sup>9</sup>

There are a number of behavioural programmes that are effective for weight management in the short term, but there is substantial room for improvement in reach and effectiveness – particularly in terms of long term outcomes.<sup>10-12</sup> Whilst many people are able to apply behavioural strategies in order to lose weight, it is hard to sustain these in the face of obesogenic physical and social environments, the biological drive to maintain body weight, and the habitual nature of key behaviours.

One way that the effectiveness of behavioural programmes might be improved is to identify new strategies that target psychological processes associated with better long term weight loss and weight loss maintenance. Key amongst these is sustained motivation and the healthy and adaptive self-regulation of eating behaviour and emotions.<sup>13-15</sup> Third-wave cognitive behaviour therapies (CBTs) have been identified as a potentially useful treatment to address these important factors.

### Third-wave CBTs

Third-wave CBTs have a number of core components that distinguish these approaches from first wave behaviour therapy and second wave cognitive behaviour

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2  
3 therapy; specifically an emphasis on openness, awareness, and action.<sup>16</sup> Types of  
4  
5 third-wave CBTs include dialectical behavioural therapy (DBT), schema therapy  
6  
7 (ST), acceptance and commitment therapy (ACT), acceptance-based behavioural  
8  
9 treatment (ABBT), mindfulness-based cognitive behavioural treatment (MBCT) or  
10  
11 compassion-focussed therapy (CFT).<sup>16–18</sup> These treatments have been associated  
12  
13 with adaptive self-regulation and sustained motivation across a number of health  
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15 domains, for example, in depression and addiction.<sup>19–21</sup>  
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18  
19 There are a number of ways in which these treatments could support successful  
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21 weight management. For example, fostering non-judgemental awareness of  
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23 thoughts, feelings and behaviour, could enable people to reduce overeating and to  
24  
25 limit the influence of internal and external cues. Encouraging patients to experience  
26  
27 potentially aversive internal experiences (cravings, anxiety, behavioural fatigue) and  
28  
29 to pursue behaviour that is congruent with their goals and values could support them  
30  
31 in adhering to a weight management plan – even when weight loss has plateaued.  
32  
33 Fostering a compassionate attitude toward the self could help prevent  
34  
35 discouragement following minor lapses. Mindfulness and acceptance-based  
36  
37 therapies have also been associated with improvements in psychological outcomes  
38  
39 related to long term weight management, including self-regulation, dietary restraint,  
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41 emotional eating, body satisfaction and mood.<sup>22–26</sup>  
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### 45 **Evidence to date**

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48 Previous systematic reviews have investigated the effect of third-wave CBTs on  
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50 weight management.<sup>22–28</sup>  
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54 Although these reviews have consistently reported improvements for obesity related  
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56 eating behaviours and psychological outcomes, results for weight loss have been  
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3 mixed. Only three reviews of interventions in people with overweight and obesity  
4 included a meta-analysis of weight or BMI outcomes.<sup>22,25,26</sup> Rogers et al.'s<sup>25</sup> meta-  
5 analysis of eight studies reported a small but significant reduction in BMI, and the 16  
6 studies included in Carrière et al.'s<sup>22</sup> meta-analysis reported a significant moderate  
7 effect on weight loss. However, no significant effect was found for BMI in Ruffault et  
8 al.'s<sup>26</sup> meta-analysis of nine studies. These differences may be attributable to  
9 variation in inclusion criteria and methods across the reviews.  
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18 In addition to mixed findings, there are a number of methodological limitations that  
19 constrain conclusions on the effectiveness of third-wave CBT for weight  
20 management. The majority of reviews utilised a small number of databases,<sup>24–27</sup>  
21 lacked a comprehensive search strategy,<sup>26</sup> and conducted their database searches  
22 during, or prior to 2016,<sup>23,25–28</sup> meaning that existing reviews will not have captured  
23 all relevant research. In addition, there has been an emphasis on mindfulness, with  
24 some reviews excluding other therapy types<sup>22,23</sup> and others using the term  
25 'mindfulness' to encompass a range of third-wave CBTs. There has been a general  
26 failure in reviews to distinguish between different types of third-wave CBT or different  
27 methods of delivery, and detail on intervention content, delivery mode and intensity  
28 is lacking. This causes difficulties in assessing the comparative effectiveness of  
29 different approaches and limits their potential to inform future studies. Furthermore,  
30 little is known regarding participant adherence and attrition as only Olson and  
31 Emery<sup>28</sup> provided detail on this outcome. This would provide important insights into  
32 intervention fidelity and acceptability.  
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51 The present systematic review will provide a more comprehensive review of the  
52 range of third-wave CBTs that have been utilised for weight management. It will  
53 interrogate a large number of databases and include all prospective study designs,  
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3 while acknowledging the strength of randomised controlled trials. Importantly, it will  
4 distinguish between different treatment modalities and delivery methods, by pulling  
5 both the direct head-to-head comparisons reported in earlier studies, and the indirect  
6 and mixed effects within a random-effects network meta-analysis framework. Meta-  
7 regression methods will be applied to identify and/or adjust for potential source(s) of  
8 heterogeneity. While change in weight is the primary outcome, this review will also  
9 capture a range of physical and psychological health outcomes and will summarise  
10 data on intervention adherence. This review will provide important information with  
11 which to inform the development and refinement of third-wave CBTs for weight  
12 management.  
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## 25 **Objectives**

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28 We aim to evaluate the effectiveness of third-wave CBTs for weight management in  
29 adults with overweight or obesity.  
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### 33 Primary objective

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36 • To evaluate the effectiveness of third-wave CBTs for weight loss and weight  
37 loss maintenance in adults with overweight and obesity.  
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### 41 Secondary Objectives

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44 • To evaluate the effect of third-wave CBTs for weight loss and weight loss  
45 maintenance on psychological and physical health outcomes in adults with  
46 overweight and obesity.  
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51 • To provide a detailed description of the content, duration, and delivery of  
52 interventions.  
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- To identify the intervention characteristics that are associated with better outcomes and adherence.

## **METHODS AND ANALYSIS**

### **Eligibility criteria**

Studies will be selected according to the criteria outlined below.

#### *Study designs*

We will include original research articles, theses and dissertations reporting randomised control trials (RCTs), non-RCTs, prospective cohort (PC) and case series studies that report an outcome measure pre- and post-intervention. No restrictions will be placed upon language, year of publication or publication status.

#### *Participants*

We will include studies of community dwelling adult human participants (aged  $\geq 18$  years) with overweight or obesity ( $\text{BMI} \geq 25 \text{ kg/m}^2$ ). Participants must be seeking assistance with weight loss or weight loss maintenance. No further restrictions will be made on gender, age, recruitment method, or co-morbid conditions.

#### *Interventions*

Studies will be included if they evaluated a third-wave CBT for the purpose of weight loss or weight loss maintenance. In terms of defining third-wave CBTs, they must be described as using DBT, ST, ACT, ABBT, MBCT or CFT. As these approaches are sometimes delivered as part of a multi-component intervention, no restriction will be placed on the proportion of the intervention using the technique, although this may

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2  
3 be considered in secondary-analyses. Interventions will be of any duration or  
4 delivery mode. There will be no restriction placed on who delivers the intervention. If  
5 multiple arms are included in a study, any arm that meets the inclusion criteria will be  
6 included in the review. We will exclude studies that do not state that weight  
7 management is an aim of the intervention.  
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### 13 14 *Comparators*

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17 For the meta-analysis, we will include studies with no comparator i.e., single-arm  
18 pre-post studies with no control arms. We will also compare third-wave CBTs to (i)  
19 no intervention or minimal intervention, and (ii) other behavioural programme(s), as  
20 reported in the studies.  
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### 26 27 *Outcomes*

28  
29 The primary outcomes will be:

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32 • Body weight
- 33  
34 • BMI

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37 The secondary outcomes will be:

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39 • Stress
  - 40  
41 • Anxiety
  - 42  
43 • Depression
  - 44  
45 • Meta-cognition
  - 46  
47 • Eating attitudes
  - 48  
49 • Eating behaviours
  - 50  
51 • Body satisfaction
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- Quality of life
- Blood pressure
- Lipids
- Glycaemia
- Adherence to treatment

### *Timing*

We will include studies that report one or more of the primary or secondary outcome measures pre- and post-intervention. We will exclude studies in which the follow up measures are less than 3 months from baseline, because of the identified need to find new approaches to improve long-term weight loss and weight loss maintenance.

### *Setting*

No laboratory based interventions will be included. All other settings are eligible for inclusion.

### *Language*

There will be no language restrictions.

## **Information sources and search strategy**

### *Electronic searches*

We will search the following databases: CINHAL, MEDLINE, EMBASE, Cochrane database (CENTRAL), PsycINFO, AMED, ASSIA and Web of Science. No restrictions to the search strategies will be applied, and databases will be searched from inception to the 16<sup>th</sup> of January 2018. For studies published in a non-English

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2  
3 language, appropriate employees of the university will be contacted to request a  
4  
5 translation.  
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8 To identify studies for inclusion in this review, detailed search strategies will be  
9  
10 developed for each electronic database by ERL, who has previous experience  
11  
12 conducting systematic reviews, with input from a medical librarian. Other members of  
13  
14 the systematic review team will also be consulted to ensure appropriateness of  
15  
16 terminology and that no terms have been overlooked. The search strategy will  
17  
18 include a number of key word and subject heading searches relating to the concepts:  
19  
20 (1) Third-wave CBTs AND (2) Overweight, obesity or weight management. Searches  
21  
22 in the other databases will be based upon the MEDLINE search strategy (see  
23  
24 supplementary additional file), with modification when appropriate to take into  
25  
26 consideration database-specific terms. Search terms for the third-wave CBTs  
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28 concept will be based upon a systematic review of third-wave CBTs for eating  
29  
30 disorders by Linardon et al.<sup>18</sup>  
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### 34 *Other search methods*

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37 To enhance literature saturation, we will manually search reference lists of all  
38  
39 primary studies identified as eligible for inclusion in the review and previous relevant  
40  
41 reviews. Authors of abstracts that were identified in the database searches will be  
42  
43 contacted to identify whether the study findings have been published elsewhere or  
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45 accepted for publication. A bibliography of the included studies will be circulated to  
46  
47 the systematic review team to ensure no other studies they are aware of are  
48  
49 excluded.  
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### 53 **Study records**

### *Data management and selection process*

We will import results from the searches into a Microsoft Excel spreadsheet and duplicates will be removed. We will screen the study titles and abstracts to eliminate articles which clearly do not meet the inclusion criteria. There will be an initial piloting of this screening with an identical 10% of articles independently screened by two researchers to ensure consistency. If a high degree of disagreement occurs, the inclusion and exclusion criteria of the studies will be clarified through discussion with a third reviewer. Once piloting is completed, all article titles and abstracts will be independently screened by two researchers. We will obtain full text papers where titles and abstracts are deemed to be relevant or where eligibility is unclear. The obtained full text articles will then be independently screened by two researchers and their eligibility will be discussed to gain consensus. Where necessary, we will seek additional information from study authors to resolve any questions about eligibility. Reasons for exclusion of articles at the full text screening stage will be recorded. A third reviewer will resolve disagreements, if required. Reviewers will not be blinded to authors, institution or journal when screening articles. In the case of multiple articles pertaining to the same study, all articles will be included and then collated to make best use of the data. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)<sup>29</sup> flow-chart will be presented showing the process of study selection.

### *Data collection process*

For studies that fulfil the inclusion criteria, we will extract data from articles onto a data collection form. This form will be based upon the Cochrane data extraction form,<sup>30</sup> the Consolidated Standards of Reporting Trials (CONSORT) 2010

statement<sup>31</sup> and the Template for Intervention Description and Replication (TIDieR) checklist.<sup>32</sup> This will ensure that an appropriate breadth and depth of detail will be captured. The data extraction form will be piloted on three articles before it is finalised. Data will be independently extracted by two researchers and any discrepancies will be resolved by a third reviewer. Data analysis will be conducted using statistical program Stata version 14.2 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.).

### Data items

Data to be extracted from the studies will include:

- General information (e.g. study authors, publication year, country, source of funding)
- Study aim
- Population description
- Study characteristics (e.g. study design, randomisation, blinding, allocation concealment)
- Participants (e.g. age, sex, race/ethnicity, socioeconomic status, diagnosed condition(s), recruitment methods, sample size, weight)
- Intervention characteristics (e.g. therapy type/content, mode of delivery, group or individual delivery, dose of intervention, duration of session, setting, profession who delivered the intervention, theoretical framework)
- Comparator intervention characteristics (e.g. therapy type/content, mode of delivery, group or individual delivery, dose of intervention, duration of session, setting, profession who delivered the intervention, theoretical framework)

- Outcomes (e.g. outcome(s) studied, whether self-reported or objectively measured, duration of follow-up, statistical analysis, intervention effect sizes,)
- Adherence and attrition (e.g. total number of participants at baseline and at follow-up measurements, reasons for attrition, attendance, adherence to intervention)

If studies provide data for multiple follow-up time points, data will be extracted for all time points. If multiple arms are included in a study, data from any arm that meets the inclusion criteria will be extracted.

Due to the objective of this study to provide detailed descriptions of the content of the interventions, attempts will be made to contact the corresponding author of the study to retrieve further information not provided in the article, or in related publications. Study authors will also be contacted if there are any uncertainties regarding the study or missing data. If there is no response, authors will receive two email reminders. Authors will be given a two month timeframe to reply to this request for further information.

### **Outcomes and prioritisation**

The primary outcomes of interest are body weight and BMI as the aim of our review is to evaluate the effect of the third-wave CBTs on weight management. Body weight will be reported as kg. BMI will be defined as body weight (kg) divided by height (m) squared, and will be reported as kg/m<sup>2</sup>. We will record whether these measurements have been objectively assessed or have been obtained through participant self-report or other means.

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3 Secondary outcomes are stress, anxiety, depression, meta-cognition, eating  
4 attitudes, eating behaviours, body satisfaction, quality of life, blood pressure, lipids,  
5 glycaemia and adherence to the third-wave CBT.  
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10 Psychosocial outcomes that have been associated with successful weight  
11 management have been included in order to understand the potential of third wave  
12 CBTs to target these potential determinants of longer term weight control. Data for  
13 these outcomes will be extracted as reported in the study. It will be noted if a  
14 validated instrument has been used.  
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20 For blood pressure, data for systolic and diastolic blood pressure will be extracted  
21 separately, and it will be reported using the unit mmHg. For lipids, data will be  
22 extracted for total cholesterol, low-density lipoproteins (LDL) and high-density  
23 lipoproteins (HDL) and reported using the unit mmol/l. If the ratio of total cholesterol  
24 to HDL has been presented, if possible, this will be converted into the separate  
25 outcomes for total cholesterol and HDL, or the study author will be contacted for raw  
26 data. Glycaemia may be reported as glycated haemoglobin (HbA<sub>1c</sub>; mmol/mol or %) or  
27 glucose (random, fasting or 2hr; mmol/l). These outcomes are important as they  
28 are closely associated with weight and are risk factors for a range of chronic  
29 diseases.  
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44 Information relevant to adherence to treatment will include number of sessions  
45 attended, length and number of times practicing skills, use of resources, and  
46 deviations from intervention instructions. Any information regarding participant  
47 attrition/retention, reasons for attrition and attendance at sessions will also be  
48 collected. This is important as it will enable investigation into the effect of intensity of  
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3 interventions on weight management, and also give insight into the acceptability of  
4  
5 the intervention.  
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### 8 **Risk of bias of individual studies**

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10 Two researchers will independently assess the included studies for risk of bias. Any  
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12 discrepancies will be discussed with a third reviewer to gain consensus. We will pilot  
13  
14 this approach with three studies. Risk of bias will be assessed using the Risk of Bias  
15  
16 2.0 (RoB 2.0) tool,<sup>33</sup> the Risk of Bias in Non-randomised studies of Interventions  
17  
18 (ROBINS-I) tool<sup>34</sup> or Risk of Bias in Non-randomised Studies of Exposures  
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20 (ROBINS-E)<sup>35</sup> Choice of tool will be dependent on the study design. Any other  
21  
22 potential sources of risk of bias not covered by the tools will be noted. Reviewers will  
23  
24 not be blinded to study authors, journal or institution. Results will be presented in a  
25  
26 summary table.  
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### 30 **Meta-biases**

31  
32 To assess for selective outcome reporting, if a study protocol is available, the  
33  
34 outcomes reported in the protocol and the article will be compared. If not available,  
35  
36 the methods and results section of the article will be compared to check for any  
37  
38 inconsistencies.  
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### 43 **Data synthesis**

#### 44 *Intervention comparisons: Direct*

45  
46  
47 Standard pairwise random-effects meta-analysis will be conducted where the  
48  
49 homogeneity of data and intervention permit, using Stata version 14.2. The head-to-  
50  
51 head comparisons will be conducted on the outcome measures reported at specific  
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53 time-points of follow-up (e.g., 3 months, 6 months, 12 months). Studies that have  
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3 outcomes that fall between these time-points will be combined with the closest time-  
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5 point. Mean differences (for continuous data) and odds ratio (for categorical data),  
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7 and their 95% confidence intervals will be estimated and reported.  
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#### 10 *Intervention comparisons: Indirect and mixed*

11  
12 Random-effects network meta-analysis will be conducted to estimate the indirect and  
13  
14 mixed effects using the Stata suite of commands for network meta-analysis, along  
15  
16 with commands for visualisation and reporting of results.  
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#### 20 *Sensitivity analyses*

21  
22 Sensitivity analysis will be conducted to see the potential impact on the effect  
23  
24 estimates of different study designs (e.g., RCTs, cohort studies) by restricting the  
25  
26 analysis to specific study types and/or by excluding one study designs at a time.  
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31 In the case of studies with two or more eligible intervention arms, dependent on the  
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33 similarity of the interventions, results may be combined or be split into different  
34  
35 groups. If different measures have been used to assess the same outcome and are  
36  
37 sufficiently similar, they may be pooled or harmonised. If the effect measures are  
38  
39 reported in different scales, meta-analysis will use standardised mean differences  
40  
41 (standardised by the baseline SD value).  
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#### 44 *Statistical heterogeneity*

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46 The statistical heterogeneity (the portion of the variability that cannot be attributed to  
47  
48 random error) of the studies will be tested using the  $I^2$  statistic along with its 95% CI.  
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50 Forest plots showing the overlap of the confidence intervals will also be provided to  
51  
52 enable visual inspection. For the network meta-analysis, we will also report a total  $I^2$   
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3 statistic, and the heterogeneity variance parameter ( $\tau^2$ ) estimated from the network  
4  
5 meta-analysis models.  
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### 7 8 *Analysis of subgroups or subsets* 9

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11 If sufficient data are available, subgroup analysis will compare:  
12

- 13 • Type of intervention (e.g. therapy type, duration, delivery, intensity)
- 14 • Comparator intervention (e.g. minimal intervention or other behavioural  
15 intervention)
- 16 • Health condition of participants (e.g. type 2 diabetes)
- 17 • Length of follow up (e.g. 3 months, 6 months, 12 months)
- 18 • Study design (e.g. RCT, quasi-RCTs, PC, case series)
- 19 • Study quality (e.g. risk of bias)

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22 If sufficient data on important covariates are reported in the studies, meta-  
23 regression techniques will be applied to identify and/or adjust for potential  
24 sources of heterogeneity, if applicable.  
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### 27 28 29 30 31 32 33 34 35 36 37 *Narrative analysis* 38

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40 If meta-analysis is determined not to be appropriate due to substantial heterogeneity  
41 of studies and outcome measures that cannot be pooled, a narrative synthesis will  
42 be completed. This will be provided in the text and tables to summarise and explain  
43 the characteristics and findings of the studies.  
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### 49 50 *Missing data* 51

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53 It is anticipated that rates of attrition and missing data for outcome measurements  
54 may be relatively high, and that studies will adopt a variety of methods for handling  
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3 missing data, including using only complete cases, using all observed data, multiple  
4 imputation, baseline observation carried forward, and last observation carried  
5 forward. The details of the missing data and data analysis approach will be  
6  
7 described in the review. Our main analyses will use whichever analysis is reported in  
8  
9 the paper. Where multiple approaches are reported, preference will be given to  
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11 multiple imputation and all observed data methods. We will conduct a sensitivity  
12  
13 analysis to evaluate whether the approach to missing data impacts on the primary  
14  
15 outcome.  
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### 21 **Confidence in cumulative estimate**

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23 The quality of evidence will be assessed using the Grading of Recommendations  
24  
25 Assessment, Development and Evaluation (GRADE) approach.<sup>36</sup> This will be used to  
26  
27 judge studies for any methodological flaws. This assessment is suitable due to our  
28  
29 inclusion of non-RCTs, PCs and case series design studies. Other assessments  
30  
31 more appropriate for RCT design studies may misjudge the quality of studies using  
32  
33 these designs.  
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### 38 **Patient and public involvement**

39  
40 This study is part of a larger programme of research funded by an NIHR Programme  
41  
42 Grant for Applied Research. In the development of this research programme we held  
43  
44 a workshop with 22 members of Fakenham Weight Management Service, who  
45  
46 identified the need for support with long term weight management and who felt that  
47  
48 psychological therapies were particularly important. The research proposal was then  
49  
50 reviewed by three members of Fakenham Weight Management Service and the  
51  
52 University of Cambridge PPI Panel prior to submission, then reviewed by PPI  
53  
54 representatives on the funding panel, and revised in light of feedback. A PPI  
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3 representative (Mrs Jennifer Bostock) is a member of our Investigator team for this  
4  
5 research programme, we have two PPI representatives on our programme steering  
6  
7 committee (Mr Graham Rhodes and Mrs Norma Scullion), and we have established  
8  
9 a Patient User Group panel for the programme. Each of these PPI representatives  
10  
11 will contribute to the interpretation and dissemination of findings from this review,  
12  
13 and the translation of these findings into a new weight loss maintenance programme.  
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## 16 17 18 19 **ETHICS AND DISSEMINATION**

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21  
22 The potential of third wave CBTs in weight management has been recently  
23  
24 recognised, especially for long-term outcomes. However, evidence of their  
25  
26 effectiveness on weight is mixed, and previous reviews have a number of limitations;  
27  
28 our review will address these weaknesses.  
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32 Our review will distinguish between the different therapies and delivery modes,  
33  
34 enabling investigation into their comparative effectiveness. A detailed description of  
35  
36 the intervention content, duration and delivery mode will be provided and where  
37  
38 possible, meta-regression will be used to identify (and/or to adjust for) the source of  
39  
40 heterogeneity across the studies. Besides direct treatment effects using standard  
41  
42 random effects pairwise meta-analysis, we will also estimate the indirect treatment  
43  
44 effects using random-effects network meta-analysis. This will allow us to include data  
45  
46 from a range of prospective studies, not only randomised controlled trials.  
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49  
50 Ethical approval is not required as no primary data will be collected. This systematic  
51  
52 review will follow the Preferred Reporting for Systematic Reviews and Meta-  
53  
54 Analyses (PRISMA) checklist.<sup>29</sup> It is planned that this systematic review will be  
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3 published in a scientific journal, presented at relevant conferences and will be used  
4  
5 in the development of a new weight management programme to help adults with  
6  
7 overweight and obesity to reduce weight regain following weight loss. The findings of  
8  
9 this review will be of interest to health professionals working with adults with  
10  
11 overweight or obesity, researchers involved in the development, evaluation and  
12  
13 implementation of weight management interventions, and policy makers and those  
14  
15 responsible for commissioning weight management services.  
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## 21 **AUTHOR CONTRIBUTORS**

22  
23  
24 ALA, AJH and SJG conceived the study, participated in the study design, provided  
25  
26 input on methods, participated in the development of the initial search strategy and  
27  
28 contributed to the drafting of the manuscript. ERL participated in the study design,  
29  
30 provided input on methods, developed the initial search strategy and was  
31  
32 responsible for drafting the manuscript. NI provided input on methods, participated in  
33  
34 the preparation of the initial manuscript draft and reviewed drafts. CH contributed to  
35  
36 the drafting of the manuscript and advising and recruiting patient and public  
37  
38 involvement. All authors critically reviewed the manuscript and approved the final  
39  
40 version submitted for publication.  
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## 45 **ACKNOWLEDGEMENTS**

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## 8 **COMPETING INTERESTS**

9  
10 None declared  
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## 13 **DATA STATEMENT**

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For peer review only

## Supplementary file: Medline search strategy

1	exp Obesity/
2	exp Overweight/
3	exp Body Weight/
4	exp Body Mass Index/
5	exp Waist Circumference/
6	exp Feeding Behavior/
7	exp Body Weight Changes/
8	exp Caloric Restriction/
9	exp Weight Loss/
10	obes*.mp.
11	(overweight or over-weight).mp.
12	(weight adj3 (body or chang* or loss* or maint* or manag* or control* or reduct*)).mp.
13	(food adj3 (intake or habit*)).mp.
14	(body mass index or bmi).mp.
15	body adj3 mass.mp.
16	(calori* adj3 (restrict* or restrain* or reduc*)).mp.
17	feeding adj3 behavio*.mp.
18	(diet* adj3 (restrict* or restrain* or reduc*)).mp.
19	(waist* adj3 circumferenc*).mp.
20	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
21	((3rd or third) adj3 wave).mp.
22	(acceptance* adj3 (commit* or mind* or base* or focus* or intervention* or therap* or treat*)).mp.
23	exp Mindfulness/
24	(mindful* or mind-ful*).mp.
25	(compassion* adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.

26	(behav* adj3 activation).mp.
27	((meta-cognit* or metacognit*) adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.
28	(dialectic* adj3 (behavio* or mind* or base* or focus* or intervention* or therap* or treat*)).mp.
29	(schema* adj3 (mind* or base* or focus* or intervention* or therap* or treat*)).mp.
30	(function* adj3 analyt*).mp.
31	(relation* adj3 frame*).mp.
32	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
33	20 and 32

Search terms 21 to 31 based upon Linardon et al.'s<sup>18</sup> search strategy. No database search restrictions will be applied.

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PRISMA- P 2015 Checklist

Section and topic	Item number	Checklist item	Criteria location within manuscript
<b>ADMINISTRATIVE INFORMATION</b>			
Title			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Page 1
Authors			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pages 1, 20 & 21
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support			
Sources	5a	Indicate sources of financial or other support for the review	Page 21
Sponsor	5b	Provide name for the review funder and/or sponsor	Page 21
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Page 21
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pages 4 - 7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pages 7 & 8
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pages 8 - 10
Information sources	9	Describe all intended information sources (such as electronic databases, contact	Pages 10 & 11



		with study authors, trial registers or other grey literature sources) with planned dates of coverage	
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file
<b>Study records</b>			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Page 12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Page 12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Page 12 & 13
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Pages 13 & 14
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Page 14 -16
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Page 16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Pages 16 & 17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	Pages 16 -18
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Pages 17 & 18
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Page 18
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Page 16
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Page 19