



# Effectiveness of a self-regulation intervention for weight loss: A randomized controlled trial

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**Objectives.** To evaluate effectiveness and acceptability of a novel intervention, based on self-regulation theory, for weight loss.

**Design.** A two-arm parallel group design was employed.

**Methods.** Adult participants with a BMI  $\geq 30$  kg/m<sup>2</sup> and the aim to lose weight were recruited and randomized to either a control or intervention group. Both groups were asked to weigh themselves daily for eight weeks. The intervention group was encouraged to use a weight tracking app, and complete daily and weekly questionnaires to prompt action planning, reflection, and evaluation of actions. Participants chose daily actions from a menu of 53 behaviours. The primary outcome was weight change after 8 weeks, assessed using linear mixed effects models. At follow-up, 20 intervention group participants were interviewed regarding their experiences in the trial.

**Results.** 100 participants were recruited, and 98% were followed up at 8 weeks. Mean weight loss was  $-4.18$  kg ( $SD = 3.84$ ) in the intervention compared to  $-1.01$  kg ( $SD = 2.67$ ) in the control group; the adjusted difference was  $-3.20$  kg (95% CI  $-4.49$ ,  $-1.92$ ). Participants rated the intervention's usefulness as 8.25 ( $SD = 2.04$ ) on a scale from 1 to 10. Adherence was a significant independent predictor of weight loss success ( $-1.54$  kg per one  $SD$ , 95% CI  $-2.16$ ,  $-0.93$ ), but not a mediator of the intervention effect. Participants reported that the intervention enabled them to experiment with and identify effective weight loss actions.

**Conclusions.** Guiding participants through the self-regulation process was feasible, acceptable to participants, and led to significantly greater short-term weight loss than unguided self-weighing.

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## Statement of Contribution

### **What is already known on this subject?**

- Self-regulation does not occur automatically when individuals self-monitor their weight.
- Existing interventions employing self-regulation components do not optimally harness the potential of this strategy.

### **What does this study add?**

- An intervention guiding individuals through the whole iterative self-regulation process is effective for weight loss.
- High adherence rates and positive intervention ratings demonstrate that such an intervention is feasible and acceptable.
- Daily action planning and weekly reflection enable participants to identify their personal set of effective weight loss actions.

It is hypothesized that self-monitoring of weight is effective for weight loss because it triggers self-regulation of behaviour (Burke, Wang, & Sevcik, 2011; Kanfer & Karoly, 1972). That is, individuals are thought to contextualize weight measurements, reflect on weight changes and plan, and perform weight loss actions after self-weighing. The process is hypothesized to occur iteratively, until the goal weight is reached (Carver & Scheier, 1982; Kanfer & Karoly, 1972). However, in a qualitative analysis investigating natural self-regulation after self-weighing, individuals reflected on previous behaviour only half of the time, and the planning of weight loss actions was rare (Frie, Hartmann-Boyce, Pilbeam, Jebb, & Aveyard, 2019). Nonetheless, the frequency of making specific action plans significantly predicted weight loss success. The study therefore suggested that individuals may need support in performing self-regulation, but that successful self-regulation may lead to weight loss.

Several interventions have sought to move beyond self-monitoring of weight by incorporating other components of the self-regulation process (Bennett *et al.*, 2018; Benyamini *et al.*, 2013; Dombrowski, Endevelt, Steinberg, & Benyamini, 2016; Huisman *et al.*, 2009; LaRose, Gorin, & Wing, 2009; Leahey *et al.*, 2014; Lin *et al.*, 2015; Lin *et al.*, 2014; Mann, Palmisano, & Lin, 2016; Pacanowski & Levitsky, 2015; Steinberg, Levine, Askew, Foley, & Bennett, 2013; Steinberg, Tate, *et al.*, 2013). The majority of these interventions have led to significant weight loss, supporting the value of self-regulation for weight loss. However, these interventions have arguably not optimally harnessed the potential of the self-regulation strategy, as they either fail to prompt the planning of actions, do not incorporate action planning as an iterative element, or dictate the actions to be planned. Moreover, some of the interventions guiding participants through iterative action planning are delivered face-to-face, which is resource-intensive and difficult to deliver at large scale. In order to elicit the full benefits of self-regulation as a self-help tool, we developed a new weight loss intervention aiming to guide people through an iterative self-regulation process (Frie, Hartmann-Boyce, Jebb, & Aveyard, (2019). The PREVAIL intervention (People REGulating themselves to Achieve weight Loss) encourages users to self-monitor their weight, self-experiment with different weight loss approaches, and use the self-regulation mechanism to identify a set of effective strategies. To the best of our knowledge, it is the first intervention to prompt users to plan weight loss actions on a daily basis. The aim of this trial was to test the early effectiveness of this novel intervention against daily weighing only. A secondary objective of the trial was to conduct a process evaluation of the PREVAIL intervention to assess its feasibility and acceptability to inform any future trial. Moderators and mediators of the effect were also assessed. We

investigated a potential moderation by educational attainment, as education is strongly associated with executive control (Liew, 2012; Rose, Feldman, & Jankowski, 2011; Titz & Karbach, 2014). Another potential moderator related to the participant's liking of self-weighing, given the centrality of this component to the intervention. A potential mediating effect of adherence was investigated, since it is a common predictor of the success of weight loss interventions (Acharya *et al.*, 2009; Webber, Tate, Ward, & Bowling, 2010).

## Methods

### Study design and setting

An individually 1:1 randomized, two-arm, parallel group design was employed to compare the effectiveness of the self-regulation intervention against daily self-weighing alone. Participation lasted eight weeks from baseline to follow-up. The study took place in Oxfordshire, UK, between April and October 2019. The trial was reviewed and approved by the NHS National Research Ethics Committee and the Health Research Authority (reference number: 18/SC/0482). A protocol of the trial was registered prospectively (Frie, Hartmann-Boyce, Jebb, & Aveyard, (2018) and published (Frie *et al.*, 2019).

### Recruitment

Based on an assumed difference of 1.5 kg between groups, an estimated standard deviation of 2.13 kg (taken from another study with 2 months follow-up (Lally, Chipperfield, & Wardle, 2008)), 90% power, and a 5% type I error rate, a sample size of 88 participants was required. Including a 10% dropout rate increased the sample size to 97 participants. We rounded this figure up to 100 participants.

Four primary care practices searched their health records to identify suitable patients for the trial (age  $\geq 18$  years, BMI  $\geq 30$  kg/m<sup>2</sup>). They excluded patients who would have been inappropriate to invite, such as the terminally ill. Suitable patients were sent an invitation letter from their GP. GPs also identified suitable patients during routine consultations. People who were interested in taking part contacted the research team by email or telephone. A researcher provided further information about the study and screened individuals to determine eligibility. Participants had to be willing and able to give informed consent, be aged 18 years or above, have a BMI  $\geq 30$  kg/m<sup>2</sup>, and own an Apple or Android smartphone. People were excluded if they were unable to understand English, were currently weighing themselves more than once a week, had taken part in a weight management programme or other weight loss study in the last three months, had lost more than 5% of their current body weight in the last six months, had received or were scheduled for bariatric surgery, were pregnant or planning to become pregnant during the course of the study, or had ever been diagnosed with an eating disorder. Individuals could also not take part if they foresaw that they would be unable to follow all intervention procedures for a period of more than four consecutive days. If the person appeared to be eligible, a baseline appointment was scheduled and the participant information sheet was emailed. GPs were notified of recruitment and requested not to refer patients to formal weight loss programmes, other obesity clinics, or bariatric surgery, while they were enrolled as participants in this trial.

### Randomization

Four randomization sequences, one for each GP practice, were created by an independent researcher using a computer algorithm ([www.randomization.com](http://www.randomization.com)). The sequences were created using block randomization with randomly varying block sizes of 2 and 4. Allocation information for each participant was concealed by the independent researcher in sealed, opaque envelopes. The lead researcher took the envelopes to baseline meetings and revealed allocation following the eligibility assessment. Participants were kept blinded to their allocation throughout the study.

### Intervention and control

#### Intervention

The PREVAIL intervention and its development are explained in detail elsewhere (Frie *et al.*, 2019). The intervention aimed to guide individuals through iterative self-regulation following daily weighing on standard body scales (Etekcity Corporation, Anaheim, CA, USA). To foster contextualization of weight measurements, participants were asked to track their weight measurements daily using an app called 'Weight Loss Tracker, BMI' by aktiWir GmbH. This allowed them to review their weight loss progress in a graph and receive positive feedback on weight loss successes. Participants were also encouraged to plan a weight loss action on a daily basis using a questionnaire (using Qualtrics, Seattle, WA, USA). Participants could choose from a list of 53 weight loss actions, which covered diet and physical activity-related activities and were grouped into seven categories (see Figure 1 for Category Orange: Avoiding or swapping specific foods). At the start of each week, participants chose one of the categories and planned one action of this category each day for the rest of the week. A weekly progress report gave information about the weekly weight loss trend, and prompted participants to complete a questionnaire to reflect on and evaluate the category of actions they had tried out. By doing so, participants were encouraged to identify which actions they found particularly useful and wanted to continue with, thus creating a set of personal weight loss tools. An optional A3-sized action diary helped participants track their implementation of action plans. Participants received a manual explaining the experimental nature of the intervention in detail at the baseline meeting. A researcher from the study team called participants at the end of the 1st and 4th week to clarify the process and solve technical problems that may have arisen.

<p>Category orange: Avoiding or swapping specific foods</p> <ol style="list-style-type: none"> <li>1. Don't eat between meals</li> <li>2. Cut out crisps, biscuits, cakes and sweets</li> <li>3. Cut out fried food</li> <li>4. Have only one course at meal-times</li> <li>5. Cut out carbs</li> <li>6. Swap unhealthy snacks for fruits and vegetables</li> <li>7. Swap rice/potatoes/pasta for extra vegetables</li> <li>8. Use meal replacement products</li> <li>9. Swap unhealthy snacks with 6-8 individual nuts</li> </ol>
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**Figure 1.** Category orange: avoiding or swapping specific foods. [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

### *Control*

Participants in the control group were asked to self-weigh daily, which previous research found to be ineffective for weight loss (Madigan, Jolly, Lewis, Aveyard, & Daley, 2014). We chose this comparator task in order to test whether the self-regulation process could enhance self-weighing to be an effective weight loss tool. Participants were provided with smart scales, which were equipped with a SIM card and automatically transferred weight measurements to a secure server via the 3G/4G network (BodyTrace, Inc., New York, NY, USA). Whenever participants noticed that the synchronization function failed, they kept a written record of their weight measurement.

### **Procedure**

Participants met the lead researcher from the study team at baseline and follow-up.

At baseline, the researcher sought informed consent and measured participants' height and weight. Eligible participants were asked to complete an online questionnaire capturing demographic information and previous experiences with self-weighing. Participants were randomized and provided with instructions for the assigned intervention. They received a body scale for the duration of the trial. A follow-up appointment was scheduled for the week after completion of the eight-week intervention period. A week in advance of the second meeting, a reminder email was sent. In the intervention group, this email also contained a link to a final questionnaire, asking participants about the usefulness of the intervention. At the meeting, participants were asked to return the weighing scales, and in the intervention group, also the action diary. Body weight was measured, and the researcher invited participants to discuss their experiences in the study. For 20 participants in the intervention group, this was an audio-recorded qualitative interview. Before ending the meeting, participants were asked two questions to assess blinding: What they thought the aim of the trial was and what task they thought the parallel group had followed. Afterwards, participants were debriefed, thanked for their participation, and provided with a £35 voucher as compensation for their time and effort.

### **Outcome measures**

#### *Primary outcome measures*

The primary outcome was weight change from baseline to follow-up. Participants' weight was measured using a digital scale (SC-240 MA; Tanita, Tokyo, Japan).

#### *Secondary outcome measures*

*Quantitative process measures.* In the control group, adherence to self-weighing was assessed by the proportion of days for which a weight was recorded. For the intervention group, self-weighing was assessed based on the proportion of days for which a weight was recorded in the weight-tracking app or in the daily action-planning questionnaire. The adherence to the self-regulation step 'contextualization with previous weight measurements' was assessed as the proportion of days for which a weight measurement was recorded in the weight-tracking app. Adherence to the 'action planning' and 'reflection/evaluation' steps of self-regulation were measured by calculating the proportion of days for which the respective questionnaires were

completed. In the final questionnaire, participants in the intervention group rated each intervention component and the overall intervention programme on a scale from 1 (not useful) to 10 (very useful).

*Qualitative process evaluation.* We qualitatively assessed participants' views on the acceptability and feasibility of the intervention, and identified barriers and unmet needs in the interviews at the follow-up meeting. Interviewees were purposefully sampled from the intervention group to reflect different levels of adherence, weight change, and responses to the final questionnaire.

#### *Moderation*

We examined whether educational attainment or liking of self-weighing (both measured in the baseline questionnaire) moderated the effect of the intervention. Liking of self-weighing was assessed on a scale from 1 (dislike it a great deal) to 5 (like it a great deal).

#### *Mediation*

We assessed whether adherence to all respective tasks of the intervention and control arm mediated the effectiveness of the intervention.

#### **Statistical analyses**

A statistical analysis plan was published on ISRCTN preceding the analyses (Frie *et al.*, 2018). Quantitative analysis was carried out using SPSS (IBM, version 24) and R (version 3.4.1, using the integrated development environment R Studio, version 1.0.153). All analyses were conducted at a 5% two-sided significance level.

The effectiveness of the intervention for weight loss was tested both on the basis of intention-to-treat (ITT) and per-protocol (PP). For the ITT analysis, participants were analysed according to their allocated intervention group. We endeavoured to obtain full follow-up data on every participant to allow full ITT analysis. Where this was not possible, we sought self-reported weight by telephone or email and otherwise carried forward baseline observations (BOCF). Sensitivity of the analysis to assumptions about missing data was assessed by also running an analysis imputing the last home-measured weight (last observation carried forward, LOCF) for people who did not attend the final meeting and did not self-report their weight at eight-week follow-up, as well as an analysis restricted to participants completing follow-up or self-reporting weight at follow-up (in the following called completer analysis). For the PP analysis, participants were excluded if they stopped following their allocated intervention before the final follow-up. For both the ITT and PP analyses, linear mixed effects models, predicting weight at follow-up while adjusting for baseline weight (fixed effect) and GP practice (random effect), assessed the effect of trial arm (fixed effect). To test the robustness of the models to departures from normality, we reran all analyses using generalized estimating equations.

For the quantitative process outcomes, means and standard deviations of intervention ratings from the final questionnaire and adherence rates to the intervention components were calculated. A linear mixed effects model, adjusting for baseline weight (fixed effect) and GP practice (random effect), assessed the effect of the overall

intervention rating on weight at follow-up in the intervention group. Adherence rates for daily weighing in the control and intervention groups were compared using independent samples *t*-tests.

For the moderation analyses, we assessed whether educational qualification moderated the effectiveness of the intervention. To this end, the binary measure educational qualification (with or without university degree) and the interaction term educational qualification  $\times$  trial arm were added to the linear mixed effects model of the primary analysis. Similarly, we tested whether liking of weighing moderated the intervention effect by adding the variable liking of weighing and the interaction term liking of weighing  $\times$  trial arm to the model. For both moderation analyses, estimated marginal means (EMMs) of follow-up weight were calculated (see Appendix B).

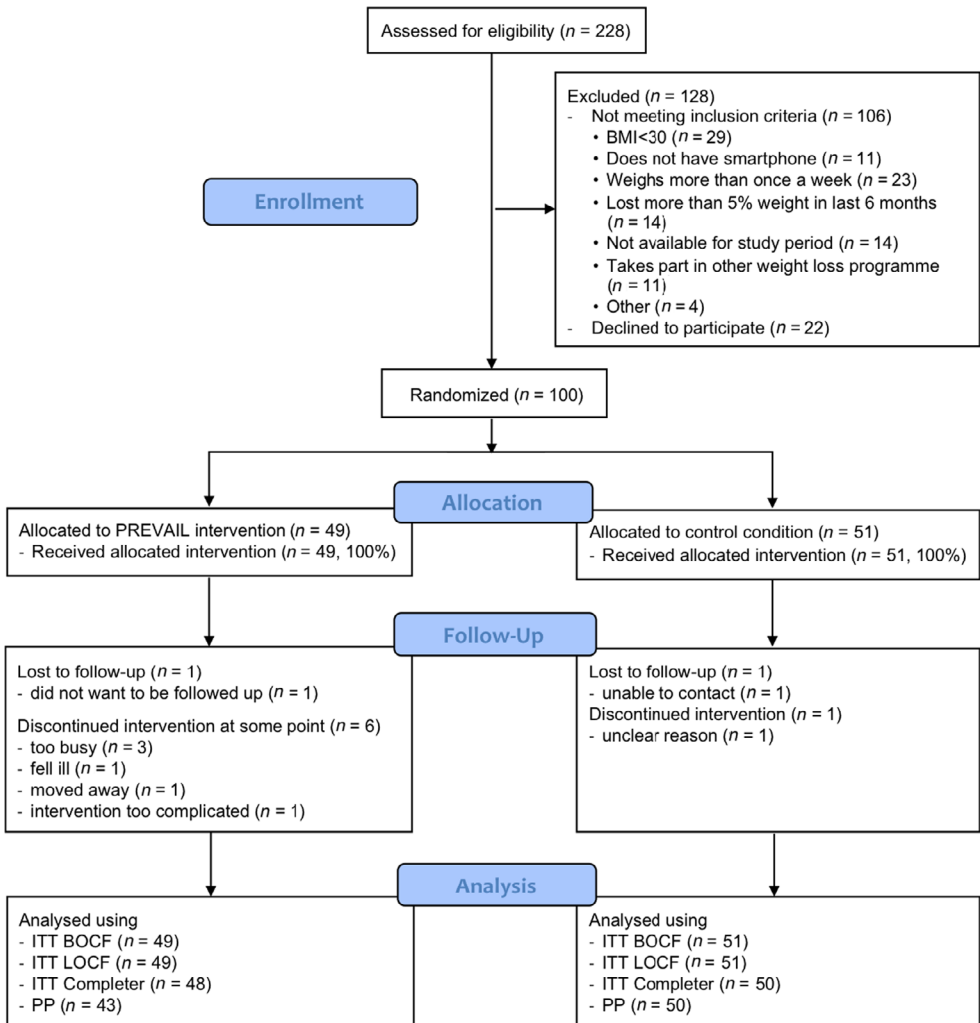
We tested whether adherence mediated the effect of trial arm on weight change.<sup>1</sup> A composite adherence score was calculated by averaging the adherence measures for daily weighing, weight-tracking, action planning, and reflection/evaluation in the intervention group. In the control group, the composite adherence score was equal to daily weighing adherence. Missing data for adherence were not imputed, and respective cases were excluded. Following the methodology of Baron and Kenny (1986), the mediation analysis first repeated the primary analysis, but excluded participants for whom adherence data were not available. Step 2 of the mediation analysis tested whether trial arm significantly predicted composite adherence while adjusting for GP practice. For steps 3 and 4, the linear mixed effects model of step 1 was repeated, this time adding the composite adherence score as a predictor to assess whether adherence significantly predicted weight change and whether the effect of trial arm turned non-significant in the presence of the adherence measure. The indirect effect and proportion of total effect were calculated.

### **Qualitative analyses**

All interview audio-recordings were transcribed and entered into NVivo (QSR International, version 11.4.2) for qualitative data analysis. One researcher performed all analyses. Framework analysis according to Ritchie and Spencer (2002) was used to assess participants' experiences and perceptions of the intervention. An a priori framework covering the different intervention components, that is, weighing, weight-tracking, action planning, weekly progress reports, reflection, and evaluation, was created. Emerging themes surrounding the intervention components were added inductively throughout the coding process. Inductive thematic analysis (Braun & Clarke, 2012) was used to explore additional themes, including acceptability, barriers, and unmet needs. No a priori framework or ideas were imposed onto the data for this second analysis, and only themes that emerged directly from the data were recorded. Axial coding techniques, adapted from the grounded theory approach, were employed to identify overarching themes and linkages between themes (Simmons, 2017).

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<sup>1</sup> In the statistical analysis plan we stated that we would run a moderation analysis. However, it made more theoretical sense to assess whether adherence was a mediator as engaging with the intervention could be a necessary precursor for effectiveness.



**Figure 2.** CONSORT flow diagram. [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

## Results

### Sample

Between April and August 2019, 261 people expressed initial interest in the study and 228 were screened for eligibility, 128 of whom were excluded due to various criteria, most commonly for having a BMI < 30 kg/m<sup>2</sup> or weighing more than once a week. Twenty-two people declined participation (see Figure 2 for CONSORT flow diagram). One hundred participants were recruited and randomized to the control ( $n = 51$ ) and intervention groups ( $n = 49$ ). The average BMI at baseline was 35.1 kg/m<sup>2</sup>, 62/99 participants who reported their gender were female, and mean age was 53.2 years (Table 1).

Two participants in each group did not attend the follow-up appointment, but one in each group reported their weight at this time point, resulting in a sample of 98 participants for the completer analysis. Forty-three (88%) participants in the intervention group and 50 (98%) in the control group completed the allocated intervention and

**Table 1.** Baseline demographic characteristics

Demographic	Control ( <i>n</i> = 51)	Intervention ( <i>n</i> = 49)	Total ( <i>n</i> = 100)
Age: years, mean (SD)	52.1 (15.0)	54.4 (15.7)	53.2 (15.3)
Gender female: count, % <sup>a</sup>	31, 60.8% <sup>a</sup>	31, 63.3% <sup>a</sup>	62, 62.6% <sup>a</sup>
BMI: kg/m <sup>2</sup> , mean (SD)	35.1 (4.8)	35.1 (3.4)	35.1 (4.1)
Ethnicity, <i>n</i> (%)			
White	44 (86.3%)	45 (91.8%)	89 (89.0%)
Asian or Asian British	4 (7.8%)	2 (4.1%)	6 (6.0%)
Black or Black British	2 (3.9%)	1 (2.0%)	3 (3.0%)
Mixed/other	1 (2.0%)	1 (2.0%)	2 (2.0%)
Highest educational qualification, <i>n</i> (%)			
No formal qualifications	2 (3.9%)	4 (8.2%)	6 (6.0%)
Vocational/work qualifications	2 (3.9%)	1 (2.0%)	3 (3.0%)
GCSE, NVQ level 1	6 (11.8%)	6 (12.2%)	12 (12.0%)
Apprenticeship	3 (5.9%)	1 (2.0%)	4 (4.0%)
A' levels, NVQ level 2–3	5 (9.8%)	6 (12.2%)	11 (11.0%)
Other post-high school qualifications	2 (3.9%)	1 (2.0%)	3 (3.0%)
University Degree, NVQ level 4+	31 (60.8%)	30 (61.2%)	61 (61.0%)
Employment status <sup>b</sup> , <i>n</i> (%)			
Employed	34 (66.7%)	25 (51.0%)	59 (59.0%)
Self-employed	8 (15.7%)	5 (10.2%)	13 (13.0%)
Unemployed	1 (2.0%)	1 (2.0%)	2 (2.0%)
Looking after home and family	2 (3.9%)	2 (4.1%)	4 (4.0%)
Student	1 (2.0%)	1 (2.0%)	2 (2.0%)
Retired	9 (17.6%)	16 (32.7%)	25 (25.0%)
Long-term sick or disabled	1 (2.0%)	0 (0.0%)	1 (1.0%)

Note. <sup>a</sup>One participant in the control group preferred not to indicate their gender, the percentage for female gender is therefore based on 99 participants in total.; <sup>b</sup>Participants were able to select several if applicable.

were included in the PP analysis. At follow-up, 18 participants indicated being aware of their allocation to control (*n* = 5) or treatment (*n* = 13) group. Follow-up was completed in October 2019.

### Primary outcome

Participants in the intervention group had lost 4.2 kg at 8-week follow-up, compared with 1.0 kg in the control group, a difference of 3.2 kg (95% CI −4.49, −1.92). Similar results were found in the LOCF and completer analyses (Table 2). In the PP analysis, there was a 3.65 kg difference between the two groups (95% CI −4.98, −2.33). Model residuals were not normally distributed. GEE sensitivity analyses replicated the effect of trial arm on weight change for each analysis type (Table 3).

### Process evaluation

#### Adherence

Data on adherence from five participants in the control group were lost due to technical issues with synchronization of the scales. Adherence to daily weighing did not differ

**Table 2.** Results of the linear mixed effects models of the primary analysis

Analysis type	Mean (SD) weight change		Adjusted difference (95% CI)	p
	Intervention	Control		
ITT				
BOCF (N = 100)	-4.18 (3.84; n = 49)	-1.01 (2.67; n = 51)	-3.20 (-4.49, -1.92)	<.001
LOCF (N = 100)	-4.18 (3.84; n = 49)	-1.03 (2.67; n = 51)	-3.18 (-4.47, -1.90)	<.001
Completer (N = 98)	-4.26 (3.84; n = 48)	-1.03 (2.69; n = 50)	-3.27 (-4.57, -1.97)	<.001
PP (N = 93)	-4.70 (3.81; n = 43)	-1.03 (2.69; n = 50)	-3.65 (-4.98, -2.33)	<.001

Note. Adjusted for: GP practice (random effect), baseline weight (fixed effect).

**Table 3.** Results of the GEE sensitivity analysis of the primary analysis

Analysis type	GEE sensitivity analysis	
	Adjusted difference (95% CI)	p
ITT		
BOCF (N = 100)	-3.20 (-4.93, -1.47)	<.001
LOCF (N = 100)	-3.18 (-4.93, -1.43)	<.001
Completer (N = 98)	-3.27 (-5.04, -1.50)	<.001
PP (N = 93)	-3.65 (-5.39, -1.92)	<.001

Note. Adjusted for: GP practice (random effect), baseline weight (fixed effect).

significantly between the control ( $M = 84.9\%$ ,  $SD = 14.8\%$ ) and intervention groups ( $M = 81.7\%$ ,  $SD = 30.1\%$ ; mean difference =  $3.1\%$ ,  $t(70.8) = 0.65$ , 95% CI  $-6.5\%$ ,  $12.8\%$ ; Table 4).

#### Intervention component rating

Forty-five (92%) intervention group participants completed the final questionnaire (Table 5). The average overall rating of the intervention was 8.3 on a scale from 1 (not useful) to 10 (very useful). Participants in the intervention group lost 1.1 kg more per one-unit increase in the overall intervention rating (95% CI =  $-1.56$ ,  $-0.65$ ).

**Table 4.** Adherence to intervention components

Trial arm	Intervention component	Mean % (SD)
Control	Daily weighing (n = 46)	84.9% (14.8)
Intervention	Daily weighing (n = 49)	81.7% (30.1)
	Weight-tracking (n = 40)	75.0% (36.3)
	Daily Action-Planning Questionnaires (n = 49)	79.9% (30.4)
	Weekly Reflection/Evaluation Questionnaires (n = 49)	70.4% (35.8)
	Composite adherence (n = 49)	76.6% (30.7)
	Action diary (optional, n = 47)	47.9% (41.3)

**Table 5.** Average ratings of the intervention components in the final questionnaire

Question	Mean (SD)
How do you feel about weighing yourself overall?	7.6 (2.6)
How useful did you find the intervention for controlling your weight overall?	8.3 (2.0)
How useful did you find tracking your weight for controlling your weight?	8.0 (2.7)
How useful did you find planning weight loss actions for controlling your weight?	8.1 (1.9)
How useful did you find reflecting on the reasons for weight changes for controlling your weight?	7.1 (2.3)
How useful did you find the weekly action evaluation for controlling your weight?	6.9 (2.2)

*Note.* Questions were completed by participants who followed the intervention for at least one week and attended the follow-up meeting. The first question was rated on a scale from 1 (very negative) to 10 (very positive). The other questions were rated on a scale from 1 (not useful) to 10 (very useful).

**Table 6.** Linear mixed effects models testing moderators of effectiveness

Moderators	Adjusted difference (95% CI); <i>p</i>		
	Trial arm	Additional variable	Additional variable × trial arm
University degree ( <i>N</i> = 100) <sup>a</sup>	−5.69 (−10.13, −1.24), <i>p</i> = .01	−2.01 (−6.15, 2.14), <i>p</i> = .35	1.54 (−1.10, 4.19), <i>p</i> = .25
Liking of weighing ( <i>N</i> = 100) <sup>b</sup>	−3.71 (−7.77, 0.35), <i>p</i> = .08	−0.84 (−3.29, 1.61), <i>p</i> = .50	0.22 (−1.31, 1.74), <i>p</i> = .78

*Note.* Outcome: Weight Change (BOCF); adjusted for: GP practice (random effect), baseline weight (fixed effect).

<sup>a</sup>Coded as 1 = has a degree, 0 = not got one.; <sup>b</sup>Scale from 1 (dislike it a great deal) to 5 (like it a great deal).

### **Moderation by educational status or liking of weighing**

There was no evidence of a moderation of the intervention's effect on weight change by educational status. There was also no main effect for educational status (all *p* > .1, Table 6 and Appendix B).

There was no evidence of neither a moderation, nor a main effect of liking of weighing on weight change (all *p* > .1, Table 6 and Appendix B).

**Table 7.** Results of the mediation analysis

Outcome	Adjusted difference (95% CI)	
	Trial arm	Adherence
Step 1: Weight Change ( <i>n</i> = 95) <sup>a</sup>	−3.30 (−4.63, −1.98)	
Step 2: Adherence ( <i>n</i> = 95) <sup>b</sup>	−0.083 (−0.18, 0.02)	
Step 3 + 4: Weight Change ( <i>n</i> = 95) <sup>c</sup>	−3.81 (−5.01, −2.61)	−1.54 <sup>d</sup> (−2.16, −0.93)

*Note.* <sup>a</sup>Effect of trial arm on weight change, adjusted for: GP practice (random effect), baseline weight (fixed effect).; <sup>b</sup>Association between trial arm and adherence, adjusted for: GP practice (random effect).; <sup>c</sup>Effect of trial arm adjusted for adherence.; <sup>d</sup>Presented per 1 SD increase in adherence.

### **Mediation by adherence**

There was no evidence that adherence mediated the effect of trial arm on weight loss. The indirect effect was  $-0.13$  kg, and the proportion of total effect was 3.2%. Higher adherence was independently associated with weight loss ( $-1.54$  kg per 1 *SD* increase in adherence, 95% CI  $-2.16$ ,  $-0.93$ ; Table 7).

### **Qualitative analysis**

Participants chosen for the follow-up interview had an adherence score ranging between 21% and 100%. Their average weight loss was  $-4.6$  kg (range =  $-18.7$  to  $+0.9$  kg, *SD* = 4.9). The overall intervention rating ranged between 3 and 10 points on a 10-point scale (*M* = 7.9, *SD* = 2.31). The key themes and data are presented in Appendix A.

Most participants evaluated the intervention positively. Many described their experience as a success and positively noted that the intervention had allowed them to experiment with different weight loss approaches and identify which ones were most effective for them. The daily frequency of action planning was thought to be particularly useful in this context, as it encouraged people to try out more difficult weight loss actions. Many participants did not require the full eight weeks of experimentation to identify their personal set of effective actions and simply repeated their preferred actions towards the end of the trial. The intervention was perceived as a good start to the weight loss endeavour, and many participants intended to continue with their new-found approaches. A common barrier to the intervention was that participants felt social and leisure time activities clashed and created unexpected hindrances to their weight loss plans. Because of this, participants found that they were more able to stick to their plans on weekdays than on weekends. Some participants experienced difficulties identifying a cause and effect relationship between their behaviour and daily weight changes, hindering their ability to evaluate their progress. In this context, a few participants talked about experiencing emotional reactions to weighing. Strong negative emotions could constitute a barrier to further self-regulation.

## **Discussion**

An intervention encouraging users to self-experiment with different weight loss approaches and use the self-regulation mechanism to identify their personal set of effective strategies led to significantly greater weight loss than daily weighing alone. Adherence to both treatments was high, and there was no evidence of a difference between groups. Adherence was an independent, positive predictor of weight loss, but did not mediate the intervention's effectiveness. On average, participants in the PREVAIL trial arm rated the intervention favourably. Participants felt that the intervention had allowed them to identify their personal set of effective weight loss actions. The interviews revealed that social and leisure time activities were a common hindrance to performing planned weight loss actions.

### **Self-regulation is effective for weight loss**

Several trials have shown that interventions which include self-regulation components are effective for weight loss (Bennett *et al.*, 2018; Benyamini *et al.*, 2013; LaRose *et al.*, 2009; Leahey *et al.*, 2014; Lin *et al.*, 2015; Lin *et al.*, 2014; Pacanowski & Levitsky, 2015; Steinberg, Tate, *et al.*, 2013). A meta-analysis of 101 studies examined the impact of self-

regulatory intervention components on diet and exercise. Their findings suggested that combining self-monitoring with at least one other component of the self-regulatory cycle, including goal setting, specific action planning, feedback on the effect of actions, and the evaluation of actions, was significantly more effective than interventions using self-monitoring only (Michie, Abraham, Whittington, McAteer, & Gupta, 2009). Similarly, a meta-analysis on the effectiveness of monitoring goal progress found that larger effects were elicited when the technique was combined with explicit goal setting, feedback on goal progress, and the planning of actions (Harkin *et al.*, 2016). These systematic reviews thus indicate that self-monitoring techniques should be provided in context with other self-regulation components in order to elicit the full potential of self-regulation. The present trial contributes to this literature by showing that coaching individuals through all steps of the self-regulatory cycle significantly enhances weight loss over self-monitoring alone. To the best of our knowledge, it is the first trial testing iterative, daily self-regulation in this way and thus provides the first direct evidence that this approach is effective in the short term. Since the intervention was delivered remotely, it could be classified as a self-help programme. A previous meta-analysis found that self-help interventions generally elicit significantly more weight loss than minimal controls (Hartmann-Boyce, Jebb, Fletcher, & Aveyard, 2015), supporting the development of further interventions of this kind. Our results show that self-help interventions employing the self-regulation principle have the potential to be effective.

### **Action planning may be the key to weight loss success**

The PREVAIL intervention guided participants through specific action planning using principles based on implementation intention research (de Vet, Oenema, & Brug, 2011; Gollwitzer & Sheeran, 2006; Hagger & Luszczynska, 2014). In line with this previous research, the action-planning task helped participants to plan and enact relevant behaviours, resulting in weight loss. A novel aspect of the PREVAIL intervention was the daily frequency of action-planning. Typically, weight loss studies including an action-planning component help participants create one plan for the whole duration of the intervention (Bennett *et al.*, 2018; Dombrowski *et al.*, 2016; Lin *et al.*, 2015), or dictate which actions are to be performed (Bennett *et al.*, 2018; Lin *et al.*, 2014; Steinberg, Levine, *et al.*, 2013). Few allow for the iterative reformulation of personally chosen action plans, and when they do, the action plans are usually set for at least a week at a time (Benyamini *et al.*, 2013; Yardley *et al.*, 2014). Planning the actions daily was feasible, acceptable and seemed beneficial to participants. The adherence to action planning was nearly 80%, and action planning had the highest rating in terms of usefulness of all intervention components at 8.1/10 points. Daily planning allowed participants to adapt their actions flexibly to their day and experiment with more approaches. Possibly, daily action planning may have also increased a sense of goal ownership, a significant predictor of goal engagement and attrition (Deci & Ryan, 2000; Huisman, Maes, De Gucht, Chatrou, & Haak, 2010). Daily action planning may thus have played a key role in the effectiveness of the intervention. Future research may wish to compare a self-regulation intervention employing daily action planning with one prompting action planning on a less regular basis, in order to test the superiority of the daily action-planning approach.

By asking participants to stick to one category per week, participants were able to evaluate the effectiveness of actions on the basis of weekly weight trends, thus avoiding problems with interpreting daily fluctuations identified in previous qualitative research (Frie *et al.*, 2019). The intervention foresaw eight weeks of experimentation. However, it

only included seven action categories and participants typically did not find all actions relevant, so it is perhaps not surprising that some participants completed experimentation before the end of the trial. Some participants indicated that the weekly evaluation task reduced in value after experimentation was completed. Further research is needed to identify how the principles of self-regulation could be supported after individuals have completed the experimentation phase.

### ***Influencing factors and barriers to self-regulation***

Our mediation analysis showed no evidence that adherence to the intervention tasks mediated the effect on weight loss, which could be interpreted such that self-regulation did not drive the weight loss effect. However, we would argue that the null-effect is attributable to the fact that adherence assessed different tasks in the control and intervention arm. To properly test whether the intervention leads to weight loss success by facilitating performance of self-regulation, adherence to all self-regulation steps would have had to been measured in both groups. However, in the control group, the only variable we could measure was adherence to self-weighing. A previous study has shown that self-weighing on its own does not lead to complete self-regulation (Frie *et al.*, 2019). Hence, self-weighing adherence in this study was likely not a good indicator of whether individuals actually performed self-regulation. Thus, our data should not be interpreted as showing that self-regulatory activities do not explain the success of the PREVAIL intervention. In support of this, adherence to the self-regulation steps in the intervention arm was still associated with weight loss success. We found that adherence to self-weighing was a significant predictor of weight loss success in the control arm too, and this matches other observational data (Goldstein *et al.*, 2019; LaRose, Lanoye, Tate, & Wing, 2016; Van Wormer, French, Pereira, & Welsh, 2008). Adherence to self-weighing may reflect persistence in weight loss efforts.

Participants reported that external circumstances, such as holidays or leisure time activities with friends or family, hindered the performance of planned actions. Indeed, previous research has shown that holidays are a high-risk time for weight gain (Kaviani, vanDellen, & Cooper, 2019; Yanovski *et al.*, 2000). Moreover, other qualitative research has also found that the social circumstances of food consumption can constitute a barrier to healthy eating (Hammarstrom, Wiklund, Lindahl, Larsson, & Ahlgren, 2014; Porter, Bean, Gerke, & Stern, 2010). Some participants experienced negative emotions regarding unsatisfying weight changes, and this could constitute a barrier to daily weighing and self-regulation. This matches other findings in the literature, indicating that when people expect negative feedback, they stop monitoring the outcome, which has been termed the 'Ostrich Problem' (Chang, Webb, & Benn, 2017; Webb, Chang, & Benn, 2013).

### ***Strengths and limitations***

A strength of this trial is that follow-up was almost complete at 98%. Moreover, nearly 40% of the participants were male, which is a higher proportion than typically present in weight loss studies (Pagoto *et al.*, 2011).

A limitation to this trial is that the follow-up was only eight weeks long. While the trial provided evidence for the short-term effectiveness for weight loss, it was thus not able to investigate whether effects were sustained. A longer-term and larger trial is needed to properly assess the value of the PREVAIL intervention for the treatment of obesity.

Another limitation is that participants were in touch with only one researcher for the full length of the study, which might have created an increased sense of accountability. However, since this applied to both groups, it is unlikely that this drove the weight loss effect found in the primary analyses. Nonetheless, this circumstance might have affected participants' responses in the follow-up interviews, as participants might have aimed to please the researcher with their comments about the intervention. To try to prevent any social desirability bias, the researcher made it clear to participants that the PREVAIL intervention was in its early testing stages, and their honest feedback would be appreciated as it would help to improve the intervention for the future.

A final limitation is that the sample was quite homogenous in terms of educational status and ethnicity, reducing generalizability to the general population. There was no moderation effect of the educational qualification of participants, thus indicating that the intervention effect was independent of educational background. This moderation analysis may, however, have suffered from the restricted variability in the educational attainment variable. A replication of the trial with a more heterogeneous sample is therefore warranted.

## **Conclusion**

This trial provides evidence for the early effectiveness of an intervention that supports people to enact the full cycle of self-regulatory behaviours for weight loss. The positive evaluation of the intervention and high adherence rates show that this approach is both feasible and acceptable to participants. Investigation of long-term effectiveness of the PREVAIL intervention is warranted.

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## **Conflicts of interest**

All authors declare no conflict of interest.

## **Author contributions**

Kerstin Frie: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – original draft; Writing – review &

editing. Jamie Hartmann-Boyce: Conceptualization, Methodology, Supervision, Writing – review & editing. Susan A. Jebb: Conceptualization, Methodology, Supervision, Writing – review & editing. Paul Aveyard: Conceptualization, Funding acquisition, Methodology, Supervision, Writing – review & editing.

## Data availability statement

The data that support the findings of this trial are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy or ethical restrictions.

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## Appendix A:

### Qualitative analysis of follow-up interviews

Theme	Evidence synthesis	Example data
The intervention was a success	<p>Fourteen participants specifically commented on how the intervention had been a success for them. Many went on to recommend the program to friends or family, thinking that it would benefit them as well.</p> <p>Participants positively differentiated the intervention from typical diets, saying that the self-regulation approach was less restrictive, allowed for more flexibility and more active involvement.</p> <p>Reasons for success were plentiful. Several participants commented that the intervention helped them take control over thoughtless eating behaviour. The daily tasks helped participants refresh their motivation and focus on their goal.</p> <p>Participants expressed that they liked the degree of structure, as it allowed them to flexibly make their own decisions, whilst holding them accountable to an overarching goal. Another common reason for weight loss success was that participants had gained important insights into how their body works and how their actions affect their weight.</p> <p>A few participants expressed that they had been sceptical when first starting the program, as the structure and number of tasks seemed daunting. However, most found that the daily intervention tasks quickly became part of their morning routine and soon did not struggle juggling them.</p>	<p>'It's the first time I've lost weight systematically in my life [...] so the program worked wonders for me'. (Male, 48)</p> <p>'I think that the, for me the attractiveness of it was that it wasn't a prohibited diet. [...] It was, you know, much more about choosing what you want to do that worked for you'. (Female, 51)</p> <p>'My thing is emotional eating or I'm bored or something like that. So my attention goes to food and I'm like oh no I'm not doing that because I'm not eating either after this time or in between meals. And that was really helpful just to kind of have that commitment'. (Female, 60)</p> <p>'I think the balance between self-regulating and structure was very good'. (Male, 48)</p> <p>'I've worked out what works best for me and what, sort of helps but doesn't give the good results'. (Female, 55)</p> <p>'When I started I thought 'Oh my God this is gonna be a nightmare' sort of thing, you know, but all of a sudden you get in the little rota'. (Female, 80)</p>
Weighing and weight tracking was useful, but the optimal frequency depends on the participant	<p>Most participants stated that weighing themselves was an important part of the program, whether they enjoyed the process or not.</p> <p>Some participants expressed that the daily frequency of weighing was helpful and necessary, because it kept them</p>	<p>'Thinking about it now I'm starting to feel as though it was absolutely essential weighing myself and monitoring it with an App, otherwise I would have been in the dark regarding my progress'. (Male, 48)</p>

Continued

**Appendix A** (Continued)

Theme	Evidence synthesis	Example data
	<p>focused and motivated them to continue with their weight loss efforts. Participants explained that the combination of weighing and action planning enhanced the usefulness of weighing, as it gave context to the weight measurement and enabled reflection on cause and effect. The study therefore changed how participants approached and made use of weight measurements.</p> <p>However, participants differed in their ability to interpret day to day changes and some commented on problems with making sense of fluctuations. A few participants talked about experiencing emotional reactions to weighing. When the weight measurements indicated a lack of progress, emotions were negative, and could constitute a barrier to further progress. In these contexts, wanting to weigh less often than daily was discussed. These participants did not want to stop weighing themselves completely, as they still saw value in checking in with their weight on a regular basis. However, they considered that the detrimental effects of daily fluctuations and resulting emotions might be avoidable by weighing on a less frequent basis.</p> <p>Tracking weight measurements using the app was well received. Participants spoke about how seeing their weight loss progress in a graph was motivating. They appreciated that the app was simple and easy to use. Participants wanted to continue using the app to record their weight measurements in the future.</p>	<p>'I've probably used it [the weighing] now more as a sort of actual guide to what works. [...] if you track it you go 'oh actually I spiked and then I lost weight the last three days. Those few days, what did I do then?' (Male, 26)</p> <p>'I did feel it was a bit discouraging when [...] I'd been really good and then your weight would like go up and, I mean I know that's because of like fluid and things [...] it just changes so much doesn't it?' (Female, 39)</p> <p>'Because once I started putting on a little bit of weight then my motivation just really plummeted and I kind of got into a familiar place of oh this never works, nothing will work for me'. (Female, 60)</p> <p>'Maybe on a sort of every two days or every three days kind of basis to keep track. But also to not always have these day to day differences because you do find that that can be a bit demotivating as you, when you don't see the sort of direct cause and effect relationship'. (Female, 49)</p> <p>'I just like looking at the graph [...] That tracking aspect, it's been really motivating'. (Female, 45)</p> <p>'I'm going to continue with the app I've got on my phone because I like it. That actually helps keep me focused'. (Female, 55)</p>
Action planning enabled experimentation and identification of the ideal set of weight loss tools	<p>Participants positively commented on the fact that the action planning task enabled them to experiment with several different weight loss approaches.</p>	<p>'It was quite fun like 'Oh what am I going to do today.' And from an experimenting point of view as well it was, it was good to be able to try different things and to see which [...]</p>

*Continued*

**Appendix A** (Continued)

Theme	Evidence synthesis	Example data
	<p>Which actions were relevant differed per person, and participants actively pre-selected which actions and categories they wished to try. Criteria for this decision were whether the action seemed feasible, whether participants trusted the likely effectiveness of the action and whether adopting the action would make a change to their usual behaviour. On a day-to-day basis, most participants chose actions that would fit well into their schedule to increase feasibility. Some specifically chose those actions that were going to have the most impact on their weight. Finally, there was a group of participants who specifically chose 'easy' actions. Of the 20 participants whom we interviewed, seven had achieved only a little weight loss (&lt;1.5 kg). Of these seven, five reported that they had chosen their actions because they were easy, which might partly explain why they achieved lesser weight loss than other participants.</p> <p>Most participants expressed that they experimented with several actions, at least at the start of the intervention period, and used the reflection and evaluation tasks to identify which actions worked for them. As participants realized which actions were most useful, experimentation decreased and participants repeatedly stuck to their tried and tested set of tools. Some participants therefore expressed that they did not need the full eight weeks of experimentation.</p> <p>The daily aspect of action planning was generally appreciated. Participants reported that it helped them stay focused each day and made the task more exciting as they could switch actions every day. The fact that participants only had to commit to the weight loss action for one day seemed to encourage participants to also give</p>	<p>small things [...] are likely to have an impact and basically focus on those'. (Female, 34)</p> <p>'I looked at all the categories [...] and the actions within them, I knew whether they were good for me to choose. One of them was about drinking. [...] there was nothing in there that would actually [make a difference]. So I'm like forget that category' (Female, 55)</p> <p>'So where it [the action] was easy to be honest. [...] Fasting and things I didn't, I didn't try. Again, I think it's trying to just not get over focused on it, tackle the realistic things'. (Female, 51)</p> <p>'Six weeks would have done it for me. [...] I just felt that I had tried everything I wanted to'. (Female, 45)</p> <p>'Even the ones that seemed difficult, knowing that they were only for a day really helped me to stay on track'. (Female, 31)</p> <p>'It sort of focused your mind for the day. And that you actually sort of thought about what you're going to do and then how you might go about it'. (Male, 26)</p> <p>'And I think actually giving yourself small daily goals to achieve was like it, it kind of gave you a little bit of sense of achievement towards the end of the day'. (Female, 34)</p> <p>'Because I think if you'd have asked me to plan it or plan a week in one go and then leave it alone then I, I may well have done the first two days and then I would have forgotten I think'. (Male, 26)</p>

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**Appendix A** (Continued)

Theme	Evidence synthesis	Example data
Reflection and evaluation enabled identification of useful actions in the first weeks of the study	<p>more difficult actions a try. It also provided participants with a sense of reward when they managed to complete their daily task.</p> <p>Some participants contrasted daily action planning against weekly action planning, and expressed that the daily planning made it more likely for them to adhere to their self-set plans. It also meant that participants could fit their actions flexibly around their daily schedule, which was appreciated.</p> <p>Insight into which actions were effective was enabled by reflecting on weight loss progress. Some participants also evaluated how feasible actions were and whether they had made a difference to behaviour in order to decide which actions worked for them.</p> <p>As participants went through the program, they started to combine weight loss actions that they had found to be useful. By doing this, they built up a set of actions that they continuously performed every day. This allowed them to build new and healthy habits.</p> <p>Since they increasingly stuck to the weight loss actions they had identified as useful, participants found it more and more unnecessary to reflect and evaluate. Therefore, the value of the reflection and evaluation task reduced over time. This might also explain why adherence to the evaluation task was the lowest at 70.4%.</p>	<p>‘Weighing myself daily plus knowing what I had done the day before and was doing that day, I think it actually made me realize what worked instead of just going I think that worked or I think that worked. It was actually, there were facts to back it up so to speak’. (Male, 26)</p> <p>‘It was interesting how it helped me to build, the doing, performing the actions had helped me build habits into my life and because I’d seen a positive change I felt quite positive about continuing with those habits’. (Female, 31)</p> <p>‘Basically yeah once I’d, once I’d established what, what was working, yeah, it didn’t seem like I needed to reflect so much’. (Male, 57)</p>
The intervention was a ‘good start to weight loss’	<p>Having identified their set of tools, participants expressed wanting to continue with these new behaviours to achieve further weight loss. In this context, the intervention was described as a good starter to the weight loss journey.</p>	<p>‘It is very easy, structured [um] it’s a good way of starting your way into weight loss if you really want to do it. It’s, it’s a great beginning’ (Female, 33)</p>
Overall barriers	<p>One of the main barriers to following the intervention was social life and leisure time activities. Participants expressed that, especially on weekends, they often felt their food consumption was out of their control. They struggled to</p>	<p>‘At the weekend when I’m going to a friend’s anything could happen, you know. And I’d feel that I wasn’t in control’. (Female, 72)</p>

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**Appendix A** (Continued)

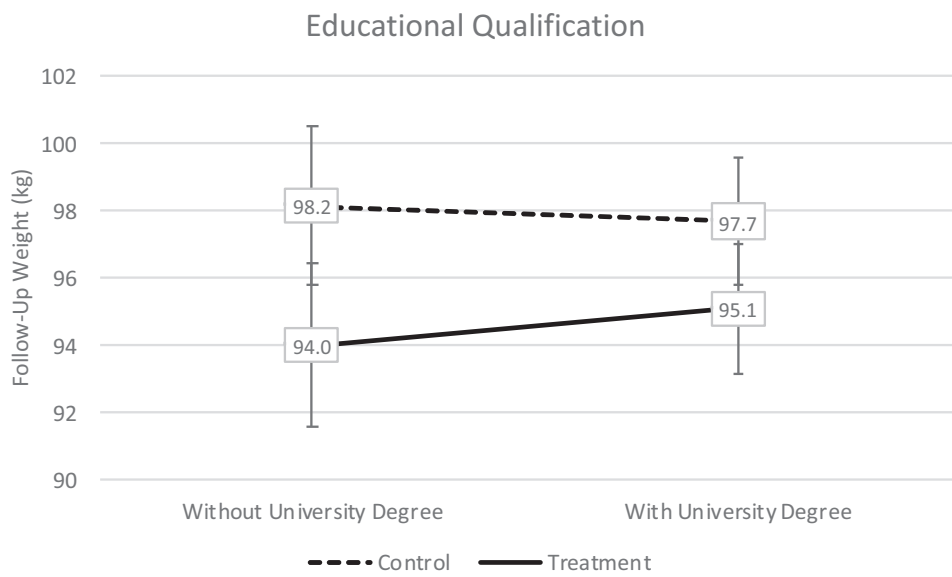
Theme	Evidence synthesis	Example data
	forgo fun activities in order to follow their diet. The same feeling of being out of control also applied to travelling, which was common as the study took place over the summer holiday period.	'You've got to live and I've got a family and I've got friends and I want to do nice things and I don't want to have to say no all the time'. (Female, 45)
	Another barrier related to simply forgetting to perform planned actions. This was usually because participants were busy and lost focus.	'It was to do with being travelling and away and not in a, not in a controllable environment'. (Female, 60)
	Although many participants felt like they got into a routine with the study tasks, a few struggled with managing the multiple aspects of the program and would have liked something simpler.	'I was just forgetful I had stuff on and forgot that I was supposed to be mindful while I was eating my food or whatever because I was just hungry'. (Female, 31)
	Participants felt accountable to the study and wanted the research to go well. While this was not necessarily a barrier to the intervention throughout the study period, it might have affected how well participants carried on with their new habits after the study ended.	'For me it was just a little bit too complicated [. . .] just less, generally less things'. (Female, 51) 'You don't want to let the person down who's giving you a chance to get your wellbeing and it's, and I want your research to go well'. (Male, 48)

**Appendix B:*****Estimated marginal means of moderation analyses******Educational qualification***

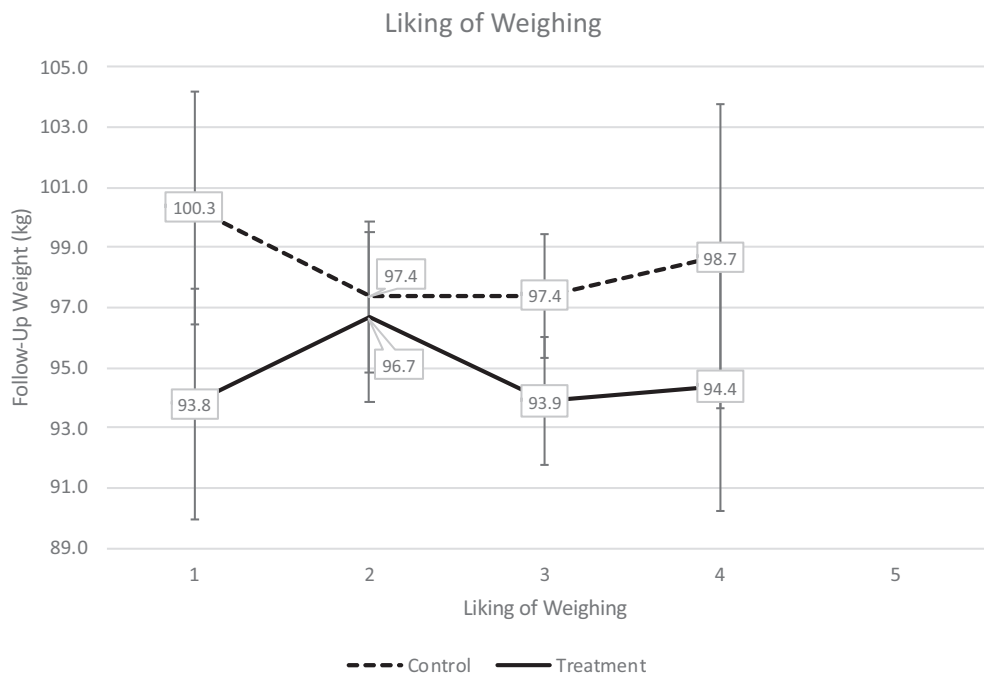
EMMs revealed that in the control group, participants with a university degree lost 0.46 kg more than participants without one, whereas in the intervention group, participants with a university degree lost 1.08 kg less than those without one. There was hence no consistent effect of the university degree variable (see Figure B1).

***Liking of weighing***

No participant rated liking of weighing as 5, meaning that no one 'liked weighing a great deal'. The EMMs of the control group showed that follow-up weight was 1.6 kg lower for those participants who rated weighing at baseline as 4 compared to those who rated it as 1 (scale from 1 = 'dislike it a great deal' to 5 = 'like it a great deal'). In the intervention group, participants who rated weighing as 2 lost more weight than participants who rated weighing as 1, 3, or 4. There was hence no consistent pattern for liking of weighing (see Figure B2).



**Figure B1.** Estimated marginal means and confidence intervals for the interaction term educational qualification × trial arm.



**Figure B2.** Estimated marginal means and confidence intervals for the interaction term liking of weighing × trial arm.