

# A brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: a RCT

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## Scientific summary

### RCT intervention preventing weight regain

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# Scientific summary

## Background

In the UK, the rates of obesity have more than doubled in the last 25 years, and being overweight has become the norm for adults. Over one-quarter of adults in the UK are obese, and > 63% are either overweight or obese. Obesity is associated with a reduced life expectancy of up to 14 years and substantial health-care costs in terms of treatment.

Although many behavioural weight loss treatments are effective, long-term maintenance remains a challenge. The period after initial weight loss is when people are at the highest risk of weight regain. Few people (about 1 in 10) recover from even minor lapses of 1–2 kg of regain in weight. Therefore, preventing small regains from turning into larger relapses is critical to recovery among people who have successfully lost weight. This is because the clinical and economic benefits of weight loss interventions depend strongly on how long the effects can be maintained. On average, people will regain one-third to half of their lost weight within the first year following treatment and will return to their baseline weight within 3–5 years after treatment. These data clearly indicate that weight regain is common, and efforts are needed to prevent it. Given the large numbers of people who need to lose weight and then who need to maintain this weight loss, there is a critical need for low-cost, practical and scalable interventions that effectively maintain weight loss. Compared with weight loss trials, very few studies have focused on weight loss maintenance, and those trials that do exist have tended to evaluate intensive interventions that typically have high associated costs. Over time, it becomes increasingly difficult for individuals to continue to follow the weight loss strategies learnt during attendance at a weight loss programme. Therefore, interventions are required that can successfully help adults to manage their weight throughout their lives. The strategies required for weight loss may be different from those required for weight loss maintenance and the prevention of weight gain, and research is required to establish what these particular strategies or interventions might be for adults. The UK government and US health agencies have recognised the vital role played by third-sector and social enterprise providers in tackling obesity, and, as public health funds are being reduced, using alternative providers is an innovative way in which to engage the population in behavioural change to improve health outcomes.

## Objectives

The primary objective of this study was to examine the effect of a brief weight maintenance intervention. The intervention focused on encouraging participants to set a target weight that they should not exceed, and to return to their weight loss plan if they did, monitoring progress with daily self-weighing and recording of weight. This was implemented through three brief telephone calls and regular text messages. The comparator was usual care, which usually means no intervention, but to maintain blindness the usual-care group was provided with a leaflet about following a healthy lifestyle. The primary outcome was the measured change in mean weight at the 12-month follow-up. The secondary objectives included the assessment of mean weight change at 3 months, and a comparison of the proportion of participants in the intervention and usual-care groups who gained < 1 kg of their baseline weight at 3 and 12 months. The effect of the intervention on potential mediators and indicators of psychological harm was also assessed. A number of process evaluation objectives were also addressed, including assessment of intervention fidelity, intervention delivery, assessment of participants' adherence to daily self-weighing and assessment of the degree to which participants developed automaticity or habitual self-weighing.

## Methods

### Study design

Two-group, individually randomised controlled trial with stratification by whether or not participants intended to continue with their weight loss programme.

### Participant recruitment

We recruited participants principally from the Birmingham Lighten Up service; this provided NHS patients who were obese with a free course of weight loss treatment for 3 months, mainly by attending Weight Watchers® (Maidenhead, UK; [www.weightwatchers.com/uk](http://www.weightwatchers.com/uk)), Rosemary Conley (Tharston, UK; [www.rosemaryconley.com](http://www.rosemaryconley.com)) or Slimming World® (Alfreton, UK; [www.slimmingworld.co.uk](http://www.slimmingworld.co.uk)). Adults who took part in the Lighten Up weight loss programmes were sent an invitation letter and information leaflet about the study when they reached week 9 of their weight loss programme. The Lighten Up programme was administered by a third-sector organisation, Gateway Family Services, and Gateway staff telephoned participants at the end of the programme and asked them their current weight and the amount of weight they had lost since starting their weight loss programme. Those individuals who had lost at least 5% of their starting weight were asked to participate in this study about maintaining weight loss. Weight loss during the programme was measured during a baseline home visit to ensure that the study eligibility criteria were met. In other local public health-funded weight management services (in Dudley and Solihull) that were used for recruitment, participants were sent a letter, an information sheet and a reply form, and the research team contacted these participants on receipt of the reply form to assess their eligibility and book a home visit for assessment.

### Trial intervention

The intervention was based on our pilot study and designed such that it would offer support at a time when people are at the highest risk of weight regain. The intervention was designed to be simple, able to address the practical challenges of delivery, affordable and easy to implement if effective. For these reasons, the intervention was delivered not by behavioural specialists but by call centre staff working for a third-sector, not-for-profit community organisation. The aim of the intervention was to prevent people abandoning their weight control by minimising the size of any lapse and, therefore, prevent their motivation to continue weight control from being undermined. The intervention was based on self-regulatory theory, the relapse prevention model and the theory of habit formation. When applied to weight loss maintenance in the context of this study, a key focus of these models was to help participants appreciate and understand the benefits of their weight loss thus far, set a target above which they would take action by returning to their weight loss plan, and develop a self-weighing habit and record this on a record card detailing their weight target.

The goal of the intervention was for participants, at a minimum, to avoid regaining > 1 kg of their baseline weight (i.e. prevention of relapse). Studies have shown that the habituation of daily health behaviour occurs after an average of 3 months; thus, the intervention lasted 12 weeks. The main element of the intervention delivery was support telephone calls at weeks 0, 2 and 4, which encouraged target-setting, daily self-weighing and recording of weight on a record card, together with reminder text messages every other day for the first 4 weeks, reducing to twice weekly thereafter. We designed the intervention such that the telephone contacts and most frequent texts messages occurred in the first 4 weeks because the period after initial weight loss is when people are at the highest risk of weight regain. Daily weighing was encouraged to maximise the possibility that participants would develop the habit of regularly weighing themselves. Text messages were sent three times per week for the first 4 weeks (i.e. every other day) and twice per month for the next 8 weeks until the end of the weight maintenance intervention phase. Thereafter, participants continued to receive text messages twice per month until the 12-month follow-up. The full trial protocol has been published [Madigan CD, Jolly K, Roalfe A, Lewis AL, Webber L, Aveyard P, Daley AJ. Study protocol: the effectiveness and cost effectiveness of a brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: randomised controlled trial (The LIMIT Study). *BMC Public Health* 2015;**15**:530].

### Data collection and main outcome measures

The primary outcome of change in weight between the start of the maintenance intervention (baseline) and 12 months after randomisation was objectively assessed during a home visit appointment. Change in weight from baseline to the 3-month follow-up was also assessed. Maintenance of weight loss was defined as successful when participants' weight at the 12-month follow-up was  $\leq 1$  kg of their weight at baseline. The secondary outcomes, therefore, included the proportion of participants in the intervention and usual-care groups who had regained  $< 1$  kg in weight at the 3- and 12-month follow-up points. As an objective measure of adherence to daily self-weighing, the intervention group received a set of real-time weight-tracking scales (BodyTrace scales BT003; © BodyTrace Inc., [www.bodytrace.com](http://www.bodytrace.com)) that recorded every time participants weighed themselves, the data from which were sent to the research team via wireless cellular data transfer. We used questionnaires at baseline and at each follow-up point to examine how the programme affected conscious cognitive restraint, the aim of the intervention, and whether or not it led to an unhealthy focus on weight or disturbed eating patterns. We also planned a cost-effectiveness analysis with modelling of the long-term health consequences that may follow successful weight maintenance.

### Results

The primary analysis was intention to treat and included all participants who were randomised to a study group with imputation for those who were missing. We imputed self-reported weight at follow-up, or, if that was missing, assumed that participants had gained 0.3 kg per month since baseline. The primary outcome was assessed by an analysis of covariance to compare weight change between the groups, with adjustment for baseline weight, and the stratification variable, intention (or not) at baseline to continue attending a weight loss programme. A total of 813 potential participants were screened, of whom 583 were eligible and randomised (usual care,  $n = 292$ ; intervention,  $n = 291$ ). A total of 94% and 89.1% of participants completed follow-up at 3 and 12 months, respectively. At 12 months, the mean unadjusted weight change was +0.39 kg for the intervention group and -0.17 kg for the usual-care group, an adjusted difference of 0.53 kg [95% confidence interval (CI) -0.64 to 1.71 kg]. At 12 months, 134 (45.9%) and 130 (44.7%) participants in the usual-care and intervention groups, respectively, regained  $\leq 1$  kg of their baseline weight (odds ratio 0.96, 95% CI 0.69 to 1.33). A total of 235 (80.8%) and 234 (80.1%) participants regained  $\leq 1$  kg at 3 months (odds ratio 1.05, 95% CI 0.69 to 1.58). Conscious energy restraint scores were not significantly different between the groups. Intervention delivery was very high: 86.2% of participants received all three intervention calls and 93% of participants in the intervention group elected to receive all of the support text messages. Objective weight recording showed that, on average, the intervention group weighed themselves on 57% of the 365 days that they were involved in the study. Self-report data showed that 168 (57.7%) of the intervention group and 37 (12.7%) of the usual-care group weighed themselves daily at 3 months, and 88 (30.2%) and 23 (7.9%) did so at 12 months. There was no evidence that the intervention caused harm. The groups had low, and similar, rates of uncontrolled eating, emotional eating, body image concerns and binge eating. As the intervention was ineffective, we did not complete the cost-effectiveness analysis.

### Limitations

A high level of continued engagement with weight loss programmes during the study may have meant that participants received mixed messages about self-weighing, as commercial weight loss programmes discourage self-weighing between the weekly classes.

## Conclusions

The intervention was delivered as intended and participants mostly adhered to setting a target and weighing themselves frequently. However, this had no effect on conscious cognitive restraint and, consequently, the intervention was not effective at preventing weight regain. There was no evidence that it caused psychological harm.

## Future research

In this study, regular self-weighing was ineffective in promoting cognitive restraint of eating. Studies that aim to test other strategies to engage people in long-term conscious cognitive control over energy balance would be very useful.

## Trial registration

This trial is registered as ISRCTN52341938.

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