ORIGINAL ARTICLE

A pilot randomized controlled trial testing the effects of a routine-based intervention on outcomes in a behavioural weight loss programme

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Summary

Background

Structured routines aimed at eating and sleep have been successfully employed in weight loss interventions for children. Although such routines are discussed in lifestyle modification programmes for adults, they are not a primary focus.

Purpose

The purpose of this study is to determine if establishing healthy eating and sleep routines may improve outcomes in a behavioural weight loss (BWL) intervention.

Methods

Twenty-five overweight/obese participants (age = 52.4 ± 9.8; body mass index = 33.5 ± 4.1) were randomly assigned to either a 4-week routine-based intervention (ROU) targeting regular eating and sleep or an education control before beginning an 18-week BWL intervention.

Results

Routine-based intervention participants reported adhering to eating routines, with increased 'on-schedule' eating ($p = 0.007$) and decreased 'off-schedule' eating ($p = 0.002$) but showed no change in 'on-schedule' sleep ($p = 0.74$). However, contrary to our hypothesis, ROU participants lost less weight than controls after 6 weeks of BWL (2.3 ± 2.5 vs. 4.6 ± 2.6 kg, $p = 0.04$) and achieved only modest weight loss over the full 18 weeks (ROU: 3.2 ± 4.6 vs. education control: 5.8 ± 5.7 kg, $p = 0.23$).

Conclusions

Focusing initially on establishing healthy sleep and eating routines led to poorer, rather than better, subsequent weight loss outcomes. Further studies using a longer initial intervention period or focusing on only sleep or eating behaviour are needed to determine whether establishing routines for eating and sleep behaviours can enhance weight loss in adults.

Keywords: Behavioural weight loss intervention, multiple behaviour change, obesity, weight loss.

Introduction

Establishing and adhering to a healthy routine is beneficial for many health-related behaviours (1-3). Routines may serve to help make behaviours such as healthy eating, sleep and activity habitual and part of one's lifestyle and may assist in regulating biological rhythms. Regulation of biological rhythms is central to healthy functioning and may be necessary to avoid potential negative outcomes such as obesity (4). Routines may be particularly beneficial in regulation of circadian (i.e. daily) rhythms such as sleep–wake and feeding cycles that are thought to play a role in obesity (5). Thus, routines are a promising strategy for obesity treatment.

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Paediatric studies demonstrate the potential utility of routine-based approaches related to the circadian cycle for weight regulation, including planning family meal times, working on sleep schedules and achieving adequate sleep and limiting daily screen time (6,7). In these studies, routines have been shown to be beneficial for weight outcomes (8-10). Given that eating regularly and following a consistent sleep routine are also associated with body weight in adults (11-13), addressing routines in adults may similarly promote weight loss; however, this has not previously been tested.

Eating regularly (i.e. following a consistent pattern of meal/snack times), and following a consistent sleep schedule (i.e. consistent bedtimes and wake times that promote adequate sleep), may contribute to weight control by helping to regulate circadian rhythms as well as through psychological and physiological mechanisms. For example, research suggests that skipping meals or reduced meal frequency (less than three meals per day) negatively affects appetite control (14). Perceived hunger and desire to eat have been shown to increase, while perceived satiety decreases when individuals wait to consume all calories in one dinner meal rather than eating at regularly spaced meals throughout the day, even when the same total calories are consumed (15). Therefore, by scheduling eating episodes at set intervals throughout the day, obese individuals may be able to better regulate hunger and appetite. Moreover, research with animals suggests that keeping a regular feeding schedule may aid metabolism and contribute to weight control (16,17). In one particular study, even when keeping caloric intake equal between two groups, those animals who ate on an irregular schedule gained weight compared with those on a more regimented routine (17). In humans, irregular meal frequency has been shown to disturb energy metabolism in lean (18,19) and obese women (20) and can disrupt glucose regulation (21). Thus, establishing a routine in which obese participants eat at pre-specified times of day may reduce the negative appetite consequences and suboptimal metabolism that can occur with meal skipping or irregular meal frequency and consequently enhance outcomes in a behavioural weight loss (BWL) programme.

Similarly, consistent sleep schedules that promote adequate sleep may also enhance weight loss outcomes. Short sleep is associated with increased obesity risk (22–26). This association may be mediated by the effect of sleep duration on the regulation of hunger-signalling and satiety-signalling hormones ghrelin and leptin (27,28) and/or through glucose regulation (29). Recent reports in children and older adults suggest that variability in sleep schedule is also associated with obesity, independent of total sleep duration (30–32). Moreover, short sleep is related to reductions in cognitive function and declines in mood (33,34), which may both contribute to difficulties in carrying out necessary weight management behaviours. Although several studies have suggested this connection between short sleep and obesity, studies investigating the effects of intervening on sleep behaviours to enhance weight loss in adults are needed. To date, one pilot study in overweight/obese adults has examined how an intervention focused on sleep and weight behaviours compares with a standard BWL intervention in a primary care setting (35). Findings suggest a potential benefit to addressing sleep behaviours as participants in the joint sleep and weight intervention lost weight at a faster rate than those in the control group (35).

Given the potential for a consistent healthy sleep and eating schedule to aid in weight control efforts, we examined whether establishing a regular sleep and eating schedule prior to beginning a standard BWL intervention would improve weight loss outcomes. In this pilot randomized controlled trial, participants were randomly assigned to either a novel 4-week routine-based intervention (ROU) to work towards (i) eating at regular intervals throughout the day and (ii) following a consistent sleep schedule to achieve 8 h of sleep each night or to a 4-week education control (EDU) group. The ROU and EDU interventions were limited to 4 weeks duration to allow participants to quickly begin the 18-week BWL programme. We hypothesized that participants assigned to ROU would achieve better weight losses in the subsequent weight loss programme than those in EDU.

Methods

Participants

A total of 25 individuals participated in this pilot study (Figure 1). To be eligible for the study, participants had to be 21–65 years, have a body mass index (BMI) within 25–45 kg/m^2, be weight stable (within 5% of their current reported body weight over the past 6 months), not currently on any weight loss medications or enrolled in other weight loss programmes and report no history of eating disorders, schizophrenia, bipolar disorder or substance abuse. Given the focus on sleep in the routine intervention, those who self-reported sleeping more than 7 h per night based on typical bedtimes and wake times across the week or those who were shift workers were also excluded. All assessments and treatment sessions were conducted at the Weight Control and Diabetes Research Center in Providence, RI. All participants provided informed consent in accordance with The Miriam Hospital
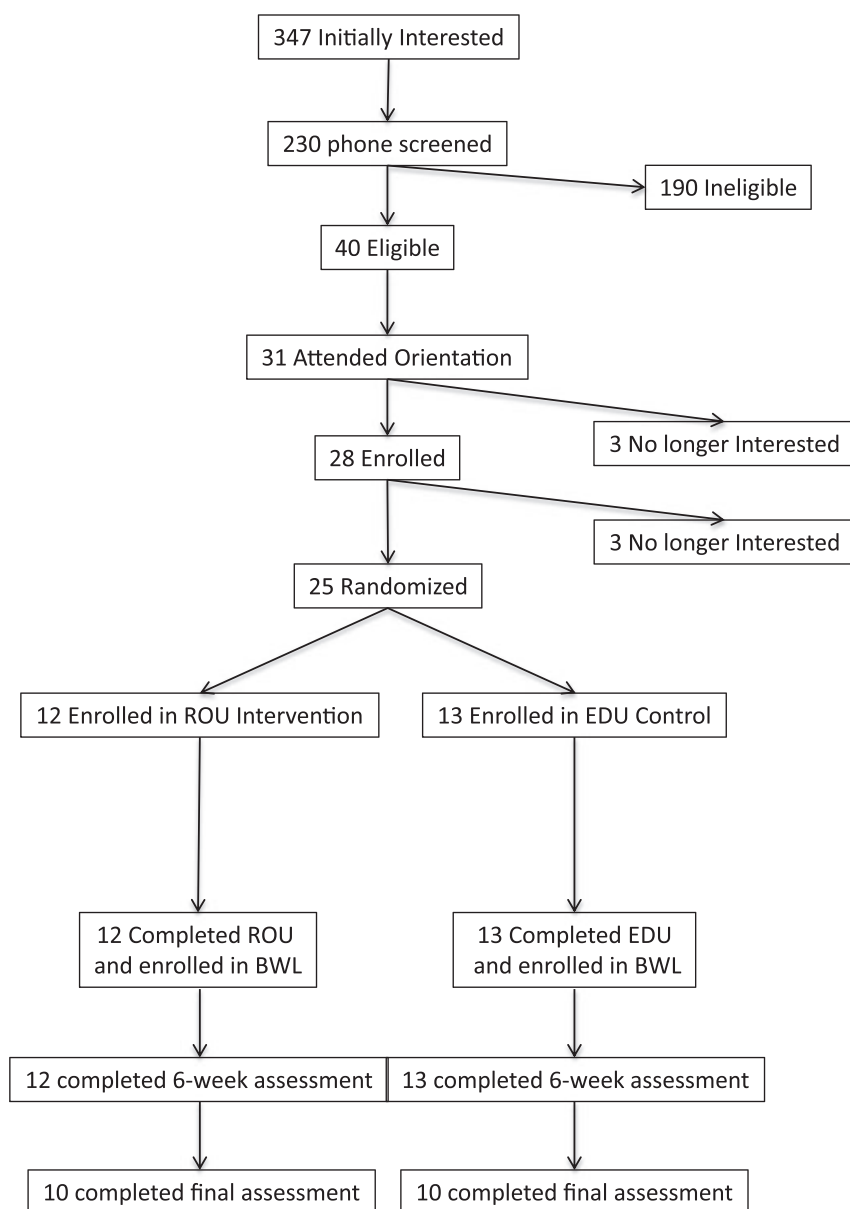
Figure 1 Consort diagram depicting the flow of participants in this randomized controlled study. Common reasons for ineligibility included self-reported sleep >7 h, inability to attend group sessions, and medication usage.

Internal Review Board. This study was registered at clinicaltrials.gov (NCT01428687).

Study design

Subjects completed baseline assessments (described later) and were then randomly assigned within gender to the routine intervention (ROU; $N = 12$) or an education only control (EDU; $N = 13$). Both groups attended weekly 1-h group sessions for 4 weeks that provided the ROU or EDU content (described later). They were asked not to lose weight during this time. Following the 4-week ROU intervention or EDU, assessments were repeated. All subjects then went on to participate in an 18-week BWL intervention with six weekly meetings, followed by six biweekly meetings. After the first 6 weeks of BWL,

participants completed an assessment that included weight measurements only. Final weight assessments were conducted after week 18 of BWL (Figure 2). Participants were paid $25 for completing the assessments at the end of the 4-week intervention and the end of the 18-week BWL programme (total = $50).

Clinical intervention

ROU (weeks 1–4)

Participants in the ROU group practiced establishing and following routines around two specific behaviours associated with weight regulation – namely, only eating at five pre-specified times each day (three meals and two snacks) and following a consistent bedtime and wake time schedule to achieve 8 h of sleep per night. Beginning at week 1 of the intervention, the ROU group worked with interventionists to develop a schedule for eating episodes such that they never went for more than four waking hours without eating. During group sessions, ROU participants scheduled their eating episodes for each day of the following week in food diaries. A consistent sleep schedule was developed for each participant beginning at week 2 of the intervention. Given constraints of weekday schedules (i.e. needing to wake at a certain time for work), typical weekday wake times were maintained, and bedtimes were adjusted to promote 8 h time in bed each night. Further, given normal variability in weekday and weekend sleep schedules, participants were allowed to delay bedtimes and wake times by up to 1 hour on weekends as long as the 8-h time in bed schedule was maintained. Participants planned ahead when they would go to bed and recorded their actual bedtime and wake time in their diary. Self-regulation skills (goal setting, self-monitoring, self-evaluation and self-reinforcement) were taught to help participants increase these two behaviours and inhibit incompatible behaviours (e.g. unplanned eating episodes or staying up late). The ROU group was instructed to continue adhering to these routines throughout the 18-week BWL programme.

Education control (weeks 1–4)

Participants in the EDU group received educational sessions on the prevalence and health consequences of obesity, the importance of fruit and vegetable intake, and common myths about diet and exercise. No behaviour modification strategies were taught or promoted during the 4-week period in the EDU group.

Behavioural weight loss

After the initial 4-week programme, all participants received an 18-week (12-session) group BWL intervention that involved 6 weeks of weekly meetings followed by 12 weeks of biweekly meetings incorporating diet, exercise and behavioural therapy. All participants were placed on a standard caloric and fat restricted diet (e.g. 1,200–1,500 kcal day depending on initial weight, with ≤30% calories from fat) and were encouraged to increase their physical activity gradually to at least 200 min week (using activities similar in intensity to brisk walking and bouts of at least 10 min). They received a fat/calorie guidebook and a diary to record all the food they consumed and their physical activity. Clinicians continually reviewed participant diaries in order to provide patients with written feedback about calorie and fat goals and their eating and exercise behaviour. Prior to each group session, each participant was weighed privately with an interventionist. In addition to information on nutrition and physical activity, specific behavioural strategies addressed during the
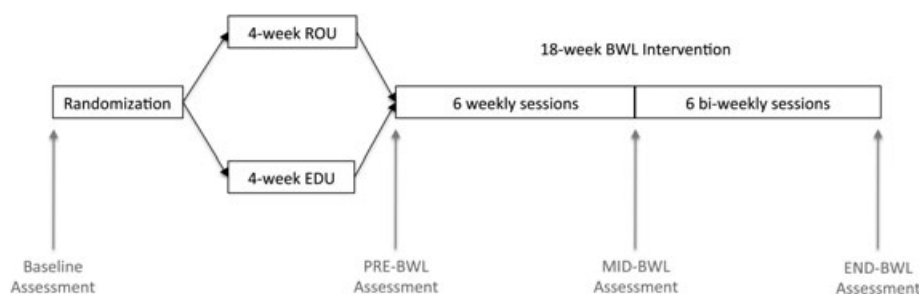
Figure 2 Study design: following baseline assessments participants were randomized to either the 4-week ROU intervention or 4 weeks of the EDU control group sessions. They were assessed at the end of the 4 weeks, and then all participants began an 18-week BWL intervention that met weekly for six sessions (with assessments after week 6), and then biweekly for six sessions (with assessments at the end of the 18-week programme).

Table 1 Baseline characteristics (mean ± standard deviation)

	Education control	Routine intervention	*T*-value	*p*-value
N	13	12		
Gender	69% female	75% female	0.1 (X^2)	0.75
Age	50.4 (±11.4)	54.5 (±7.6)	0.31	0.76
Race/ethnicity	77% White	100% White	3.15 (X^2)	0.08
Baseline body mass index	34.0 (±3.7)	32.8 (±4.6)	0.72	0.48
Baseline sleep hours (armband)	6.7 (±1.0)	6.8 (±0.7)	1.58	0.13

programme included self-monitoring, goal setting, stimulus control and problem solving. During the BWL programme, participants in the ROU arm also received regular reminders to keep to their consistent 8-h per night sleep schedule and to eat regularly according to their pre-specified schedule.

Measures

ROU intervention adherence

To verify adherence to the targeted routines, self-reported times for eating and sleeping from participant diaries were used to assess 'on-schedule' and 'off-schedule' episodes for each behaviour. 'On-schedule' eating was defined as consuming a meal or snack within 15 min of the planned time, and eating at all other time points was thus considered 'off schedule'. Similarly, self-reported bedtimes and wake times within 15 min of each participant's planned schedule were considered 'on schedule' and any deviation

beyond that was deemed 'off schedule'. Adherence to the sleep schedule was also assessed objectively and via self-report by determining changes in sleep duration over the initial four-week period. For a one-week period at baseline and the end of the 4-week ROU or EDU intervention, participants wore a BodySense Armband (BodyMedia, Inc., Pittsburgh, PA), and kept a sleep diary (i.e., they self-reported their sleep duration for that same time period). At the end of the week, the armband data were downloaded and reviewed for completeness with the corresponding self-report diary. Sleep duration was calculated based on BodyMedia Inc. software.

Outcomes assessments

All participants completed assessments at baseline, after the initial 4 weeks of ROU or EDU intervention, after the first 6 weeks (intensive phase) of the BWL programme, and at the conclusion of the 18-week BWL treatment. These assessments were conducted by staff members
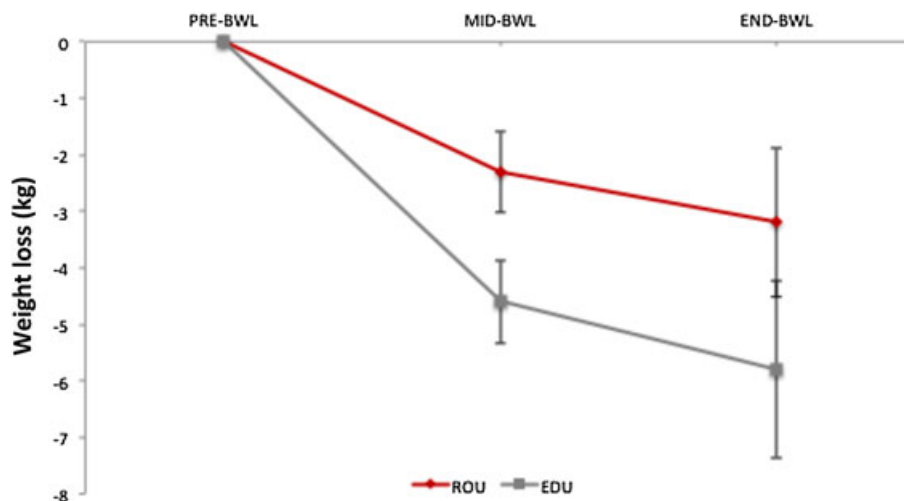
Figure 3 Mean weight loss (kg) in ROU (red) and EDU (grey) groups during the behavioural weight loss intervention. Error bars represent standard error of the mean.

blinded to the participants' treatment condition. At these assessments, weight was measured with Tanita digital scales (TANITA Corporation of America, Inc., Arlington Heights, IL) with the participant in street clothes, without shoes. Height, used for determining BMI, was measured with a wall-mounted stadiometer.

Statistical analysis

To assess adherence within the ROU intervention, the number of on-schedule and off-schedule eating episodes and on-schedule sleep times were compared from the initial week of the target behaviour change (week 1 for eating and week 2 for sleep) to the final week of ROU (week 4). In addition, the ROU and EDU groups were compared on changes in weight, and objective and self-reported sleep assessed at baseline and the end of the 4-week intervention. To assess weight loss during the BWL intervention, we compared changes in weight for ROU and EDU from the start of the weight loss intervention to both the end of the 6-week intensive phase and the end of the full 18-week BWL programme. The weight at the start of BWL was carried forward as the final assessment weight for non-completers.

Descriptive statistics were generated for all variables, including means and standard deviations for continuous variables and percentages for categorical variables. Independent T-tests were conducted to investigate potential differences in each outcome measure between the ROU and EDU arms, and paired samples T-tests were conducted to assess change within group.

Results

Baseline characteristics

At baseline, the two groups did not differ on age ($t(23) = 1.1$, $p = 0.31$), gender ($X^2 = 0.1$, $p = 0.75$), baseline BMI ($t(23) = 0.72$, $p = 0.48$), self-reported sleep ($t(23) = 0.26$, $p = 0.80$) or objectively measured sleep ($t(23) = 1.58$, $p = 0.13$) (Table 1). There was a non-significant trend for a group difference in race/ethnicity ($X^2 = 3.15$, $p = 0.08$).

Adherence and outcomes during initial 4-week intervention

All participants in both arms of the study attended 100% of the treatment sessions during weeks 1–4. Weight changes in the two groups during the first 4 weeks of either ROU or EDU were minimal and did not differ from each other (percent weight change ROU: $+0.12 \pm 2.7\%$ [$+0.2 \pm 1.4$ kg]; EDU: $+1.1 \pm 1.3\%$ [$+1.1 \pm 2.4$ kg]; $p = 0.28$). The percentage of reported 'on-schedule' eating episodes increased

significantly from week 1 (when the individual's schedule of eating episodes was developed) to week 4 (mean week $1 = 59.3\%$ and mean week $4 = 79.6\%$; $t(11) = 4.02$, $p = 0.002$). Similarly, the mean number of reported 'off-schedule' eating episodes decreased over time (mean week $1 = 13.3 \pm 5.9$ and mean week $4 = 7.2 \pm 5.9$; $t(11) = 3.31$, $p = 0.007$). However, the percentage of reported 'on-schedule' bed times did not significantly change from week 2 (when the individual's sleep schedule was developed) to week 4 (mean week $2 = 65.3\%$ and week $4 = 60.6\%$; $p = 0.74$). In terms of sleep duration, objectively measured sleep time did not change significantly over the 4 weeks in either ROU (6.8 ± 0.5 h per night at baseline to 7.0 ± 0.7 h per night; $t(11) = 0.99$, $p = 0.35$) or EDU (mean $= 6.3 \pm 1.0$ at baseline to 6.3 ± 0.9 h per night, $p = 0.98$). By contrast, self-reported sleep duration increased from 7.02 ± 1.27 h at baseline to 7.63 ± 0.78 in the ROU group ($p = 0.04$), but there was no change in self-reported sleep duration for the EDU group ($p = 0.79$).

Weight change during behavioural weight loss intervention

As shown in Figure 3, the ROU group lost significantly less weight than the EDU group during the first 6 weeks of the BWL programme (percentage change $= -2.5 \pm 2.5\%$ [-2.3 ± 2.5 kg] in ROU vs. $-4.8 \pm 2.6\%$ [-4.6 ± 2.6 kg] in EDU; $t(23) = 2.3$, $p = 0.029$). There were no significant differences between groups over the full 18-week programme (percent change ROU $= -3.4 \pm 4.7\%$ [-3.2 ± 4.6 kg], EDU $= -6.4 \pm 6.0\%$ [-5.8 ± 5.7 kg]; $t(23) = 1.4$, $p = 0.18$).

Discussion

The hypothesis that working on establishing healthy eating and sleep routines prior to the start of a BWL programme would improve weight loss was not supported. In fact, in this pilot study, those in the routine intervention lost less weight during the first 6 weeks of the BWL programme than those in the educational control group and did not differ significantly in weight loss at the end of the 18-week programme. Although the difference between groups at the conclusion of treatment was not statistically significant with the relatively small sample, this finding represents a medium size effect ($d = .56$) with the routine intervention group losing less weight than EDU overall.

There are several possible explanations for our observed findings. First, providing only 4 weeks for establishment of consistent eating and sleep routines may have been too short for participants to master the changes prescribed (especially in sleep, which was introduced in week 2). Thus,

when they started the weight loss programme, these participants may have been continuing to work on establishing their behavioural routines, while simultaneously taking on the multiple 'new' goals of the BWL programme.

Behaviourists have long known that attempts to change too many behaviours at once may backfire (36). Basic principles of behaviour modification suggest that making smaller changes gradually may lead to greater long-term success rather than taking on larger, more abrupt changes. Moreover, while in some cases working on multiple behaviours simultaneously may be beneficial (e.g. smoking cessation and physical activity or diet and physical activity) (37–39), this is not always the case, and it may depend on the targeted behaviours themselves and the demands of the changes required (40). Prochaska *et al*. (2008) note that although multiple health behaviour change interventions in individuals may provide a larger impact on overall health, there is a necessary increase in demands and complexity of the intervention, and efforts to make concurrent changes in multiple behaviours may be overwhelming and lead to poor adherence. They suggest sequencing behaviour change goals (as opposed to asking participants to work on more than one change at a time) or assessing participants' readiness to change in each behaviour and matching the strategies accordingly (41). Although standard BWL programmes target eating and exercise behaviours together, additionally requiring specific changes to eating and sleep schedules may have negatively influenced participant attitudes and adherence to BWL goals and may have impacted self-efficacy among ROU participants.

An alternative explanation for the observed effects may be that the level of self-control required to change eating and sleep routines, in addition to the self-control demands of decreasing caloric intake and increasing physical activity, surpassed participants' capabilities. An extensive body of work focusing on self-control has characterized this ability as a 'limited resource'. This model posits that as self-control is used, there will be less available for subsequent tasks; this state of 'ego depletion' increases the likelihood that the individual will fail when exertion of self-control is needed again (42). Applying this model to the current study, our routine-based intervention was designed to increase self-control capacity in two ways. First, the routine-based intervention addressed some of the physiological underpinnings that can deplete self-control, namely sleep deprivation and low blood glucose levels (43,44), and should, as a result, have led to improvements in self-control. Second, the routines intervention provided opportunities to practice self-control. There is evidence suggesting that self-control abilities may be strengthened, as in a muscle, with repeated practice of small acts of self-control (45). Previous studies show that practicing

self-regulatory exercises for 2 weeks that included tracking food eaten, working on improving mood, or improving posture, strengthened self-control and led to less ego depletion (45). Similarly, a 4-month financial monitoring programme has been shown to increase self-regulatory capacity compared with a no-treatment control group (46). Based on these studies, we hypothesized that the routines intervention used in our pilot would likewise provide a chance to practice self-regulation and consequently might enhance self-control capacity. However, in the current study, the acts of self-control required for changing eating and sleep schedules in the routine intervention may have been too difficult, or, perhaps, not practiced for enough time and therefore may have depleted, rather than enhanced, individuals' self-control abilities. In accordance with this, many ROU participants reported being overwhelmed by the behaviour changes required to follow the sleep and eating routines in addition to the demands of BWL.

There are some limitations to this study that must be considered. Because this was a pilot randomized controlled trial, the sample size is relatively small, and a larger cohort may have yielded differing results. Furthermore, as noted earlier, it is possible that the 4-week timeframe for the routine intervention was not adequate to allow for full mastery of the behavioural routines. Although self-reported eating behaviours improved, participants did not make significant changes in their sleep. Other studies in which certain behaviours are targeted prior to the start of a weight loss programme have had a longer timeframe for practicing target behaviours (8 weeks vs. the 4 weeks used in the current study) (47). Thus, a lengthened ROU intervention may have been more effective in the establishment of the desired routines. Additionally, it is not known whether the sleep and/or eating routine behaviours were maintained during the BWL; thus, the present study cannot discern how adherence to sleep and eating schedule routines during actual BWL may impact weight loss. Finally, a design in which participants were randomly assigned to change only their eating routines, only their sleep routines, or both, or a design in which participants addressed these two behaviours in sequence rather than in parallel may have yielded different results.

Despite limitations, this study provides important insight into attempts at health behaviour change. A novel intervention targeting two potentially critical behaviours related to successful weight control, regular eating and consistent sleep, was developed. Participants reported modifying eating and sleep duration; however, self-reported sleep consistency did not improve, and objective measures of sleep did not change. Although the routine intervention did not ultimately improve weight losses, further study with a longer period for establishing the routines or focusing on

eating and sleep routines independently is needed to determine whether establishing healthy routines can improve subsequent weight loss outcomes.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgements

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