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"Say No": a feasibility trial of a brief intervention to reduce instances of indulgent

energy intake episodes

Running title: "Say No" Trial

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Conflicts of interest

Professor Caterson reports grants from SFI, NovoNordisk, Pfizer and BMS outside of the submitted work; and speakers fees from Novo Nordisk, Servier Laboratories and Ache Pharmaceuticals. Professor Hill has received payment as an advisor for Slimming World. The other authors declared no conflict of interest.

Author Contributions

CM initiated the study idea with input from IDC and AH. All authors were involved in the

design of the study. CM, JB, CH delivered and managed the trial. CM and CH completed

data entry. CM completed the analysis and drafted the manuscript. All authors had input into

the manuscript.

What is already known about this subject?

- Energy dense foods that are high in fat and sugar contribute to weight gain.
- There are a small number of short duration experimental studies that have examined reducing snacks and indulgences.

What does this study add?

- This study found that people wanted to reduce their indulgences, the brief intervention was feasible and there was a reduction in the number of indulgences consumed.
- Twenty-seven indulgences per week were being consumed at baseline and on average each indulgence was 800 kJ, suggesting intervention is needed.

Abstract

Objective: To examine the feasibility of a brief intervention to reduce instances of indulgent energy intake.

Methods: Forty-five participants with a BMI ≥ 25 kg/m² were randomised to one of three groups for eight weeks. The control group was asked to complete a questionnaire every four days, the self-monitoring group was given the same instructions but also asked to "Say No" to indulgences. The self-monitoring and feedback group was asked to do the same but in addition to send a photograph or description of that to which they had 'said no' and were then provided with feedback. All participants reported on indulgences for seven days prospectively at baseline and eight-week follow-up.

Results: The follow-up rate was 80%; completion of questionnaires was 63% and 87 text messages were sent. The control group reduced their indulgences by 4.1 (SD 10.0), the self-monitoring group by 13.8 (SD 16.8) and self-monitoring and feedback group by 9.0 (SD

11.7) per week. All bar one, feasibility progression criteria were met and this was the return of the indulgence diaries during the intervention period.

Conclusions: The study demonstrates the feasibility of a brief intervention to reduce the number of indulgences people ate. The progression criteria were met and areas of improvement are highlighted.

Key words: self-monitoring, behaviour change, diet

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Introduction

The current environment is one where food temptations and opportunities to eat are frequent, and food is readily available and cheap (1). Thus the environment greatly influences food and beverage consumption (1, 2). Food cues, which emphasise the immediate pleasure of eating foods high in energy, especially those high in sugar and fat, can over-ride the desire to control eating to reach weight loss goals (3). To maintain a healthy weight or reduce weight in the current environment self-regulation of energy intake is necessary.

A strong predictor of weight gain is the consumption of indulgent foods and beverages (high energy) (4-6). This is because additional energy is consumed when indulgences are eaten on top of daily meals (7). We have defined an indulgence in this study as an energy dense, high sugar/high fat food or beverage that would negatively affect a person's weight control attempt. Such indulgences are often called discretionary foods, however the general public may not understand this term (8). These types of foods and beverages account for approximately 35% of total energy intake in American and Australian diets (9, 10). Furthermore, people report snacking (often an indulgence) an average of 14 times per week,

with the energy composition of these snacks ranging from 1368 to 1690 kJ (11-13). Portion sizes of discretionary foods have significantly increased between 1995 and 2011 by between 17-66% for foods such as pizza, cake, sausage, processed meat, ice cream, cereal bars and wine. Evidence for the increased risk of weight gain and obesity due to energy dense food, presented in the World Health Organisation's 'Diet, Nutrition and the Prevention of Chronic Disease' report, was rated as 'convincing'(14). Thus an intervention to reduce consumption of indulgences may help in weight control/management (15).

A scoping review that examined interventions to reduce energy dense and nutrient poor foods/beverages found that restriction/elimination strategies were consistently beneficial for reducing energy intake (16). Most studies were laboratory experiments with one-off exposure opportunities or field trials lasting only a few weeks. Small-scale intervention studies have investigated reducing intake of these types of foods/beverages or snacking. Verhoeven and colleagues examined the combination of implementation intentions (i.e. self-determined strategies for behaviour change) and self-monitoring (in the form of cue monitoring) to reduce unhealthy snacking behaviours(17). Participants allocated to the cue-monitoring group reported significantly fewer unhealthy snacking situations per day than the controls (1.49 situations, SD 0.75 versus 1.84 situations, SD 0.82). In another short term intervention study using functional imagery training (a method similar to motivational interviewing but focused on mental imagery exercises for achieving goals) found lower snacking intake over a two week period compared to a waiting list control (18). Experimental studies, mostly involving university students, have also shown that social norm and health messages given prior to ad libitum snacks are associated with less energy intake (19). Although the studies have some initial promise it is not known whether such interventions are effective in the longer term and outside an experimental setting.

Accordingly, an intervention that used behaviour change techniques shown to be effective for lifestyle behaviours and that could be easily implemented in routine practice or offered as brief advice was developed (20-22). This intervention focused on "saying no" to indulgent energy intake by means of self-monitoring. Also studied was whether adding feedback and accountability to the intervention produced further benefit. The intervention was based on the self-regulation theory which argues there is a process of conscious personal management which involves monitoring one's behaviour and evaluating it against set goals (23). The aim of self-monitoring is to increase self-awareness and this heightened consciousness may lead to the individual making improvements to their lifestyle (23). It can provide positive reinforcement for weight management and individuals are able to identify lapses in their progress and adjust their behaviour accordingly.

The aim of this study was to examine the feasibility of two brief behavioural interventions to reduce instances of indulgences and therefore reduce energy intake in people who were overweight or with obesity. The main determinants of feasibility were participant recruitment (target 15 per month), follow-up rates of at least 70% at eight weeks, intervention engagement (at least 50% of the intervention group attempted the intervention), and a reduction in indulgences of at least seven per week.

Methods

The design was a three-arm feasibility RCT.

Participants

Forty-five participants were recruited through the Boden Institute Clinical Trial Database, advertisements, and by word of mouth. Interested registrants completed screening by telephone and eligible participants were given an appointment at the Charles Perkins Centre/ Royal Prince Alfred Hospital, Clinic (CPC RPA Clinic) Sydney to discuss the trial in more detail, confirm eligibility, and give written informed consent. Inclusion criteria were: aged \geq 18 years with a BMI \geq 25 kg/m² and wanting to reduce the number of indulgent foods and drinks they consumed. Exclusions were pregnancy or intending to become pregnant within the study time period; poor understanding of English; currently attending a weight management programme or taking part in a clinical weight loss study; taking weight loss medications or other drugs that might affect body weight e.g. anti-psychotics, antidepressants, or corticosteroids; or if they had a history or presence of malignancy. The study was approved by the RPAH Sydney Local Health District Human Research Ethics Committee (X16-0163, HRE/16/RPAH/202).

Outcomes

The following feasibility measures and progression criteria were assessed:

- Number of participants recruited within three months target 15 per month.
- The number of indulgence diaries at baseline and eight weeks completed, as the change in the number of indulgences consumed would be the primary outcome in a future study (at least 80% in those that attend for follow-up) as found in a previous study collecting dietary data (24)).
- Less than 30% drop out rate for participants by eight-week follow-up. This was chosen in comparison to a more conservative 20% rate given the nature of this as a low intensity and broadly unsupported intervention.

- A response rate of at least 50% for the on-line questionnaires as a measure of engagement, given the regularity of required completion (every four days during the intervention period) and the low intensity, unsupported nature of the intervention.
- A mean reduction of seven indulgences per week as an indication of the intervention having an effect. This reduction in indulgences was chosen as evidence suggests people snack (one form of indulgence) approximately 14 times per week and by reducing this by 50% participants may reduce their energy intake by around per kJ per week (11, 13).
- Intervention (self-monitoring groups) only: At least 50% of the intervention group attempted the intervention as measured by text messages and the number of self-monitoring diaries during the intervention completed.

The primary outcome was the change in the number of self-defined indulgences, which would allow estimation of effect sizes for future trials to be powered properly. Secondary outcome measures that might provide information about the mechanisms of the intervention and to assess adherence were assessed. These included changes in self-regulation, control of eating and food cravings.

Outcome Measures

Indulgence diary

Participants were asked to complete a paper-based indulgence diary for seven days prior to their baseline appointment and seven days prior to the end of the intervention (at eight weeks). Participants were asked to record a detailed description of each indulgence, the time and place they "said no" to it. An indulgence was described/defined as:

"Eating or drinking something that you enjoy but which is usually thought of as "bad" or unhealthy when related to weight control. These indulgences could contribute to weight gain through eating and drinking additional foods."

Participant characteristics

Height was measured to the nearest 0.5 cm and weight to the nearest 0.1 kg. These were used to calculate BMI (kg/m²). Weight change was calculated from baseline to follow-up. Occupation status was classified as student, employed or retired. Participants were also asked about current health conditions and whether they were taking any medication.

Psychological Measures

Food cravings, appetite, and mood and were measured via the Control of Eating Questionnaire which has been validated in previous studies (25, 26). Items of the scales were added together and divided by the number of items to preserve a scale of 0-10. Higher scores were associated with greater appetite, cravings and intensity of mood. The questionnaire has five sub-scales of overall craving control, cravings for sweet foods, and cravings for savoury food, appetite, and mood. In addition to these being measured at baseline and end of intervention, all groups were asked to complete it electronically every four days. Selfregulation was assessed by the short self-regulation questionnaire designed to measure the generalized ability to regulate behaviour so as to achieve desired future outcomes (27). Higher scores indicate greater self-regulation.

Intervention engagement

The number of online questionnaires (control of eating questionnaire) during the intervention period was measured and summarised as a percentage completed for all three groups. For the self-monitoring group and the self-monitoring and feedback group, the number of selfmonitoring diaries completed (and returned) at the end of the intervention was summarised as a percentage of the full number of diaries that could have been completed. The number of text messages sent by the self-monitoring and feedback group was collated.

Procedure

Participants were informed that this was a study examining strategies to help people take control of their eating and reduce indulgences. The study was explained to participants on the telephone and they were prompted to reflect about how many indulgences they consumed and if this would be a suitable study for them. Participants were told there were three groups to which they could be randomised: one focusing on recording hunger and eating control, one on self-monitoring, and one on self-monitoring with feedback. Participants were not told any further details about the intervention groups. Researchers were not blinded to group allocation.

Allocation and randomisation

Participants attended the CPC RPA clinic for their baseline visit and were randomised after giving consent; eligibility assessment and baseline measurements were taken, using opaque sealed envelopes. An independent researcher prepared a simple randomisation list using a software programme.

Interventions

All groups were asked to complete their tasks for eight weeks.

Control group

This group was instructed to make ratings of their hunger, mood, control of eating and food cravings in an electronic record every four days that was sent to them via text message of email.

Self-monitoring group

In addition to making the above ratings, participants were instructed to "say no" to an indulgence seven times per week (goal setting) and describe the indulgence in a booklet provided which they were asked to return at the last research visit. Participants were given tips on how to implement the "say no" intervention at baseline (Table 1).

Self-monitoring and feedback group

In addition to the ratings and the self-monitoring, participants were instructed to send a photograph or detailed description of that to which they had "said no" via text message to the research team. Participants then received feedback about how many kilojoules (kJ) they had saved by "saying no". The text messages were tailored to the individual by selecting the most appropriate text, adding the name of the person and the estimated number of kJ saved by saying no. The research team aimed to respond to participants immediately but during the working week this was within three hours and outside of this time was 15 hours.

Data Analysis

Some participants did not complete seven days of self-monitoring. To allow comparisons and for those with missing data, the number of indulgences and kJ was divided by the number of days for which the diary was kept and then multiplied by seven. As this was a feasibility study data were analysed descriptively with means calculated for the outcome measures and the mean change in indulgences, kilojoules of indulgences, body weight, self-regulation, and control of eating variables are reported.

FoodWorks (Xyris Software, 2017) was used to analyse the indulgence diary data and was entered by one author and then checked by a second. Any discrepancies were discussed with a third author. Standard serving sizes were used if participants did not specify these and were based on the Australian guidelines: www.eatforhealth.gov.au. On several occasions people reported having multiple servings e.g. cheese and crackers. These were defined as one indulgence as they were eaten at the same time. However, if a person reported having cheese and crackers in the morning, and then again in the evening these were counted as two indulgences. Each beverage was counted as one-indulgence and standard measures were used.

Results

Feasibility

Participants were recruited between September and October 2016, i.e. within two months, and follow-up took place from October until December 2016. In total 68 participants were assessed for eligibility (see Figure 1). Twenty-three people were excluded (see Figure 1) and 45 participants were randomised with a recruitment rate of 66%. The overall follow-up rate was 80% (n=36).

In all groups participants completed the control of eating questionnaire every four days electronically. There were seven entries without an ID number or with an ID number entered incorrectly. The completion rate was high but responses did vary between no response and 14 responses. Overall, participants completed the questionnaire on 7.5 (SD 4.4) occasions i.e. 63% of the time.

Not all participants recorded seven days of indulgences at baseline: 84.4% did so but 9% completed 6 days, 4.4% 5 days and 2.2% (n=1) completed four days. Overall, there were few difficulties analysing the indulgence diaries. The exception was if the person had a second portion, as there were not enough details given to estimate kJ as they had simply written, for

example, "too much". At follow-up 32 participants provided indulgence diaries (71% of total sample and 89% of those who attended follow-up) for seven days. There were missing diaries for participants who attended follow-up and this was due to them forgetting the diary and then not posting the diary to the research team.

Only 14 participants out of 30 (the two intervention groups) returned their self-monitoring diaries and, of these, 10 wrote down the indulgences to which they had "said no" and four wrote down the number of indulgences they had eaten. In total the self-monitoring and feedback group sent 87 text messages. Ten out of 15 participants sent at least one text message and the range was between one and 23. Some participants "said no" to more than one indulgence in a text message, thus the number of indulgences to which they had "said no" was greater than the number of text messages. Both intervention groups reduced the number of indulgences they had eaten by at least seven at follow-up.

The reasons given for not attending follow-up do not appear to be related to the "Say No" intervention (Figure 1). Participants who did not return to follow-up had similar characteristics to those who completed follow-up.

Change in indulgences and effect sizes for future trials

Participants in the three treatment arms were similar on all baseline characteristics (Table 2). At baseline participants were, on average, having 27 (SD 12.5) indulgences per week, equivalent to approximately 3.9 (SD 1.8) indulgences per day (Table 3). This was an additional 22047 (SD 11614) kJ of energy intake per week at baseline. At follow-up there was a decrease in indulgences to 19.6 (11.3) per week. There was a trend for greater reductions in indulgences in the intervention groups compared to the control group.

Participants who returned their diaries that described what they "said no" to were "saying no" to eight indulgences per week and this decreased slightly by week six. Figure 2 details the foods to which participants had "said no". The most frequently reported foods or beverages participants "said no" to were sweet foods/bakery items, alcohol and chocolate.

For the differences found here in indulgences between groups i.e. a mean difference reduction of 4.9 indulgences between the control group and the self-monitoring group, a sample size of 190 participants would be required based on the standard deviations within this study to test the effectiveness of the intervention. With a loss to follow-up of 20%, 228 participants would need to be recruited.

Weight Change

Participants lost 0.6 kg (SD 1.8) during the eight-week intervention, with no differences by group (Table 3).

Self-regulation

The average score for self-regulation was 99.6 (SD 9.2); equivalent to the second upper quartile of total scores suggesting most people had good perceived self-regulation. All groups had improved self-regulation scores at follow-up but no pattern by group was observed (Table 3).

Control of eating

At baseline the self-monitoring group had greater overall difficulties with food cravings and control of eating than the control group and both the intervention groups had greater cravings for sweet foods (Table 3). Scores improved for cravings/control of eating in all groups. There appeared to be a trend of greater improvements in the self-monitoring group compared to the other groups.

Discussion

This study aimed to examine the feasibility of two brief interventions to reduce the number of indulgences a person consumes. All bar one of the feasibility progression criteria were achieved. The study had a high conversion rate of screening to recruitment of 66% and participants were successfully recruited within two months. Retention rates were 80%, suggesting that it is feasible for participants to take part in the study and to provide follow-up data. Participants completed the indulgence diaries at baseline but there were some with missing days and in future studies participants could be prompted at appointments or by text message to remember what they ate and record it.

The intervention groups were asked to self-monitor what they "said no" to in a diary on a weekly basis (as part of the intervention) and just less than 50% returned these diaries. This was the only feasibility progression criterion not achieved. The on-line questionnaires (control of eating measures) had a 63% response rate and participants were asked to complete these on a greater number of occasions (every four days) that could be argued were more burdensome. This latter method could be used in future studies or we could send reminder text messages or emails for participants to complete their diaries.

The self-monitoring and feedback group sent eighty-seven text messages. Some participants noted difficulties with taking and sending photographs. For example, some reported since they had not physically seen the indulgence they could not take a photograph, even though they had thought about consuming the food or beverage and had "said no". Therefore in developing the intervention further we could explore the use of an app, which contained foods and beverages and they could select automatically such as integration with my fitness pal or other applicable application.

The initial intervention results appear promising. By introducing a strategy that involved "saying no" to an indulgence (defined by the person) the intervention groups changed their behaviour and reduced their indulgences by 14 and nine indulgences per week, whereas the control group reduced their indulgences by only four, with an average indulgence being approximately 800 kJ. There was no evidence that feedback (accountability) improved the "Say No" intervention. The follow-up measurements took place for the majority of participants at the start of the Christmas holiday period in Australia. It is likely there were more opportunities for consumption of indulgences and therefore reducing the number of indulgences at this time might have been harder than at other times as there were more opportunities to eat. Previous evidence has shown that on average people gain 0.4-0.7 kg during the holiday period from November to January, which suggests an increase in energy intake therefore intervention at this time is warranted (28).

Overall, general self-regulation was high at baseline and there were small further improvements. In developing this intervention there was a concern that "saying no" might increase food cravings, as people would stop themselves from having an indulgence and then possibly become fixated upon it. Equally the intervention is about control of food and beverage intake thus we might expect control of eating to increase. The results showed that cravings decreased and overall control of eating improved in all groups, both positive outcomes.

Previous studies have found that people snack around 14 times per week (11, 13, 17). We found at baseline people indulged on average 27 times per week, nearly double the amount previously reported. This is likely to reflect how we defined an indulgence compared with a snack. People could still have indulgences as part of meals and these would not be considered a snack, as a snack is normally defined as something eaten between meals, hence why differences may be found. Additionally, snacking on healthy foods can be beneficial for some

people as a strategy to help with hunger and achieve recommended nutrient consumption(29, 30).

We hypothesised that if participants "said no" seven times per week they would reduce their intake by around 10,000 kJ per week. The self-monitoring group, on average, achieved this and reduced indulgences by 14. The reduction in indulgences was higher than we hypothesised and this may be partly explained by the indulgences consumed in this study being of less energy and consisting of 830 kJ on average compared to 1368-1690 kJ reported in previous studies (11, 13, 17). However, a substantive amount of energy was consumed through indulgences and the most common indulgences were sweet foods/bakery items, alcohol and chocolate.

Hill and colleagues have suggested that a 420 kJ reduction in intake per day could prevent weight gain in most of the population (31). Here we showed that participants reduced the number of indulgences they ate and in the intervention groups this was a change of 1090 kJ per day. Weight change here was small, ranging from -0.3 kg to -0.9 kg in the intervention groups over eight weeks. However, using Hill and colleagues' calculation for preventing weight gain a reduction of approximately five indulgences per week compared to the control group could be clinically significant which may help prevent the population gaining further weight. On the basis of the variance observed here the value of a full effectiveness trial is questionable. However standard deviations in small feasibility trials should not be relied on to indicate future sample sizes (32). Most of the other feasibility assessments were positive and there are aspects of the intervention that can be refined including the feedback mechanism (text messages), improvement of diary completion and methods to follow-up participants.

Strengths and Limitations

This was a novel intervention for which we tested its feasibility. Recruitment was straightforward, which suggests the topic is of interest and importance to people. This type of intervention could be implemented in practice by health teams or as a public health message. The study had an 80% follow-up rate and participants engaged in the study as determined by completing the questionnaires, sending text messages and the reductions in the indulgences they consumed.

However, assessing diet is difficult and defining an indulgence was problematic. For this study, participants were asked to define what an indulgence was for them and they might have changed their mind during the study, although anecdotally there was no evidence of this. We did consider using the term discretionary foods. However an individual might not identify discretionary foods as indulgences as these might be part of their normal diet. The alternative is to record everything that a person consumes. This is time consuming and a person may not record everything that they eat (28, 33). In addition, being an open study, there could have been demand characteristics in play, as all participants knew the outcomes that were expected. The observed differences in behavioural outcomes between intervention and control arms therefore need further examination in a controlled trial.

Conclusions

This intervention was feasible and acceptable to participants. The measures used were appropriate and progression could be undertaken after some refinements to a full trial design. The trial identified some methodological challenges that should be addressed for an effectiveness trial. These are, as examples, improvements in indulgence diary completion, the use of self-monitoring diaries throughout the intervention, and the feedback mechanism (i.e. text messages). It is valuable to explore interventions that help people to moderate their indulgent or discretionary eating episodes. The environment facilitates discretionary eating and though this could be altered any such broad changes are slow in happening. Therefore strategies that people can incorporate into their lives that help in the self-determination of food choices and consumption are urgently needed. The present intervention may describe one of these but will need further development.

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 Table 1: Behavioural change techniques used in the intervention based on CAL-ORE taxonomy(34)

Behavioural technique	Definition				
Control Group					
Use fellow up prompts	Participants were instructed to complete the control				
Use follow-up prohipts	of eating questionnaire every four days.				
Self-monitoring Group					
Goal setting	Participants were instructed to "Say No" seven times across a week.				
Prompt self-monitoring of behavioural	Participants were instructed to record the numbers of				
outcome	times they "said no" in the diary provided.				
Provide information on the consequences of behaviour in general	Participants were given the following information: 'We live in an environment that promotes opportunities to eat and drink when we are not always hungry. As we live in an environment where there are many opportunities to eat and drink sometimes we need to "say no" to indulgent foods and drinks to control our weight.				
Provide information on where and when to perform the behaviour	Participants were given the following instructions: "We are asking you to "say no" seven times across the week. You can decide which indulgences you would like to "say no" to as we don't want to be prescriptive because everyone's eating behaviours are different. We also don't want you to "say no" to everything as that would be very hard to continue with in the longer term. It also means that you can still have indulgences but control how many indulgences you have."				
Use follow-up prompts	Participants were instructed to complete the control of eating questionnaire every four days.				
Self-monitoring and Feedback Group					
The same techniques as group two were used and the additional techniques of:					
Feedback on behaviour	Participants were asked to send a photograph or message to the research team of what they "said no" to. The research team then provided tailored feedback messages.				

	Total n=45	Control group n=15	Self-monitoring n=15	Self- monitoring and feedback n=15
Age mean (SD)	53.7 (11.7)	56.7 (10.9)	55.1 (9.7)	49.5 (13.5)
Male n (%)	12 (26.7)	4 (26.7)	5 (33.3)	3 (20.0)
Baseline BMI mean (SD)	32.3 (4.1)	32.4 (4.1)	32.3 (4.9)	32.1 (3.3)
White participants n (%)	38 (84.4)	14 (93.3)	11 (73.3)	13 (86.7)
Health conditions n (%)				
Type 1 diabetes	1 (2.2)	1 (6.7)	0	0
Type 2 diabetes	3 (6.7)	0	3 (20.0)	0
Insulin Resistance (self-	1 (2.2)	1 (6.7)	0	0
reported)	5 (11.1)	3 (20.0)	1 (6.7)	1 (6.7)
Hypertension	3 (6.7)	0	1 (6.7)	2 (13.3)
Asthma	1 (2.2)	0	1 (6.7)	0
Osteoarthritis	20 (44.4)	7 (46.7)	5 (33.3)	8 (53.3)
None	2 (4.4)	1 (6.7)	0	1 (6.7)
Other	9 (20.0)	2 (13.3)	4 (26.7)	3 (20.0)
Multiple conditions				
Taking medication n (%)	26 (57.8)	10 (66.7)	8 (53.3)	8 (53.3)
Occupation n (%)				
Employed	33 (73.3)	9 (60.0)	12 (80.0)	12 (80.0)
Retired	10 (22.2)	5 (33.3)	3 (20.0)	2 (13.3)
Student	1 (2.2)	0 (0)	0 (0)	1 (6.7)
Missing	1 (2.2)	1 (6.7)	0 (0)	0 (0)

Table 2: Baseline characteristics of participants

Table 3: Outcomes at baseline and follow-up

Mean (SD)	Control n=15	Self- monitoring n=15	Self-monitoring and feedback n=15
Baseline number of indulgences per week	26.5 (11.9)	24.2 (10.7)	30.6 (14.5)
Mean difference in the number of indulgences per week	-4.1 (10.0)	-13.8 (16.8)	-9.0 (11.7)
	n=13	n=9	n=10
Imputed data* Mean difference in the number of			
indulgences per week.	-3.5 (9.4)	-8.3 (14.5)	-6.0 (10.4)
Baseline kJ of indulgences across a week	22651	19003	24487
	(12542)	(7885)	(13702)
Change in kJ per week	-3650 (13277)	-10205 (10320)	-5022 (7290)
	n=13	n=9	n=10
Baseline kJ per indulgence	842 (256)	824 (181)	846 (317)
Week eight kJ per indulgence	869 (270)	1005 (712)	789 (362)
Baseline Weight	88.2 (12.6)	92.2 (21.3)	90.6 (9.1)
	n=15	n=15	n=15
Weight change	-0.5 (1.6) n=13	-0.3 (2.6) n=10	-0.9 (1.2) n=13
Bacolino Solf regulation	107 8 (15 8)	106 6 (16 8)	100.7(10.3)
Dasenne Sen-regulation	n-15	n = 15	n-15
Solf regulation change	11-13	II = 13	1 = 13
Sen-regulation change	2.3(0.4)	5.0(15.2) n-9	n-12
Craving/Control Overall	m=12	n=9	II-12
Baseline	5.6 (2.5)	6.6 (2.0)	6.3 (2.4)
Change	-1.0(1.9) n=12	-1.7(2.4) n=8	-1.4(3.0) n=8
Cravings for sweet foods	110 (117) 11 12		
Baseline	4.0 (2.4)	5.2 (2.5)	5.2 (2.1)
Change	-1.3 (1.5) n=12	-1.4 (1.4) n=9	-1.8 (2.8) n=9
Cravings for savoury foods			
Baseline	5.8 (2.5)	5.3 (1.7)	5.6 (2.0)
Change	-1.6 (1.4) n=12	-1.7 (2.8) n=9	-1.9 (2.4) n=12
Specific craving items			
Food craving frequency			
Baseline	5.8 (2.8)	6.7 (2.3)	7.7 (2.4)
Change	-1.3 (2.3)	-2.3 (2.3)	-0.8 (4.0)
Food craving strength			
Baseline	5.5 (3.3)	6.7 (2.0)	6.9 (2.6)
Change	-0.9 (2.2)	-1.6 (3.0)	-1.3 (3.4)
Difficulty in resisting food cravings			
Baseline	5.3 (2.9)	6.6 (2.4)	6.0 (3.4)
Change	-0.5 (3.1)	-1.6 (3.0)	-1.4 (4.6)

*Missing data was imputed with baseline observed carried forwards i.e. no change.