Chapter 6

Results of a randomized controlled trial evaluating the effect of a multi-component portion size intervention on portion control behavior and body mass index

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ABSTRACT

Background: Food portion sizes influence energy intake.

Purpose: To determine effectiveness of the “PortionControl@HOME” intervention on body mass index and portion control behavior.

Methods: A randomized controlled trial among 278 overweight and obese participants was conducted. PortionControl@HOME aimed to increase: portion size awareness, portion control behavior, portion control cooking skills and to create a home environment favoring portion control.

Results: Intention to treat multi-level regression analysis indicated statistically significant effects of the intervention on portion control behavior at 3, 6 and 12 month follow-up. The effect on body mass index was significant only at three month follow-up and when outliers (n=3) were excluded (B= -0.45; 95%CI= -0.88 to –0.04). The intervention effect on body mass index was mediated by portion control behavior.

Conclusions: The intervention improves portion control behavior, which in turn influence body mass index. Once the intervention ceased, sustained effects on body mass index were no longer evident. (Current-Controlled-Trials ISRCTN12363482).
INTRODUCTION

Globally, obesity has more than doubled since 1980 and has become a public health crisis. Worldwide, 35% of adults are overweight and 11% are obese [1]. The high prevalence of overweight and obesity is associated with an elevated incidence of co-morbid conditions, such as diabetes mellitus type II [2].

Overweight and obesity develop when energy intake continually exceed energy expenditure. Food portion sizes strongly influence energy intake. Research has shown that when people are offered larger portions their energy intake increases [e.g., 3, 4]. This portion size effect has been demonstrated for a variety of foods, complete daily menus, and even for foods with a perceived unfavorable taste [5, 6]. For example, individuals consumed 30% more energy when offered a large portion (1000g) of macaroni and cheese compared to when they were offered a ‘small’ portion (500g) [4]. The effects of large food portions on energy intake can persist over several days, with no indication of full compensation [7, 8]. Since the 1970’s, portion sizes of foods eaten inside and outside the home have increased considerably, and larger food portions are readily and widely available [9-11]. Given the pervasiveness of large portions in the current food environment and the evidence regarding the influence of portion size on energy intake, food portions are widely accepted as contributing to the global obesity epidemic [12, 13].

A range of environmental interventions have been proposed to reverse the trend towards large portions and the associated higher energy intake [14], many of which have been evaluated for effectiveness [15-22]. For example, a study in worksite cafeterias where small portions of a hot meal were introduced alongside standard (large) portions (~ 2/3 of the weight of the standard portion) showed that approximately 10% of the consumers replaced the regular meal with a small meal [15]. Although this experiment did not determine the effect on actual energy intake, other studies assessing the effect of smaller portions on energy intake have shown mixed effects. While one study demonstrated that a portion size reduction of 25% led to a decrease in energy intake in a laboratory setting [8], limiting portion sizes in a university dining facility did not impact visitor’s energy intake [20]. Interventions regarding portion size labelling have shown limited effects on portion size selection or energy intake [17, 19, 23], although one study found that non-dieters ate significantly less of a snack
food when confronted with dual-column labelling, which contained both single serving and entire package nutritional information [22]. Removing value size pricing also had little effect on the selection of smaller food portions or decreased energy intakes. Nevertheless, it was emphasized that repeated exposure of an absent value size pricing may be required in order to achieve an effect [18, 21].

While environmental strategies to decrease portion sizes seem to be the most commonsense approach to impact population level energy intake, the effects of these strategies on consumption behavior have been mixed. In addition, the feasibility of such environmental interventions needs to be considered in the context of the many parties or organizations (i.e. industry, government) that would be involved, many of whom may have conflicting goals in terms of public health. Therefore it cannot be ignored that tension might exist between effective interventions on consumption behavior and the feasibility in real life settings. Although an ongoing effort to develop effective and feasible environmental portion size interventions is necessary, an alternative solution might be to improve peoples’ ability to control and maintain adequate portion size selection and intake, thereby dealing with environmental stimuli to consume large food portions.

Already, some educational interventions to help people to cope with the availability of large food portions exist. Most educational interventions have focused on decreasing individuals’ experience of portion distortion [24-28], which refers to the phenomenon that people perceive larger portions to be an appropriate amount to eat on a single eating occasion [29]. Most of these educational interventions had positive effects on improving awareness, estimation skills or knowledge about portion sizes, although none of the studies assessed the impact on body mass [24-28].

Although knowledge and awareness about food portions are important prerequisites for behavioral change, these basics are insufficient to achieve changes in actual consumption [30, 31]. Self-regulation of portion sizes selection and intake, and the ability to cope with the supersized food environment are also required [14, 32]. Self-regulation refers to all efforts to steer attention, emotions and behaviors to reach beneficial long-term goals (i.e. weight loss), even when there are short-term temptations (i.e. a nice cookie) or conflicting long-term goals [33]. Therefore, self-regulation strategies to control portion size selection and intake are likely
to be useful for people to obtain. The home food environment is the place where the retail food environment comes together with actual food intake [34] [35] and is an important place that influences portion size regulation [36] and dietary intake [37]. Helping individuals to create a supportive home food environment can be another important target in assisting adequate portion control behavior [37].

Therefore the aim of the present study was to examine the effect of the multi-component educational intervention “PortionControl@HOME” on body mass index and portion control behavior. The hypotheses were that compared to a control group, body mass index would be more favorable at follow-up for the intervention group, and participants in the intervention group would employ portion control strategies more frequently. It was also hypothesized that the impact of the intervention on change in body mass index would be mediated through an increased use in portion control strategies.

METHODS

Participants

The study was conducted according to the ethical standards declared in the Helsinki Declaration of 1975, as revised in 2000, approved by the Medical Ethics Committee of the VU Medical Center, and registered with controlled-trials.com (ISRCTN12363482). From October to December 2011, participants were recruited from six municipalities in the Netherlands in an urbanized area 21 – 45 km from Amsterdam. Dutch adults were eligible to participate if they met the following criteria: 1) body mass index above 25 kg/m², 2) aged between 18-60 years, 3) residing in or within a distance of 15 kilometers of one of the participating six municipalities, 4) were the nutritional gatekeeper of the family (the person of the family who has the biggest food influence, defined by being responsible for doing groceries or making dinner) [38], and 5) only one person per address could participate. Participants were excluded when they reported having or having had one of the following co-morbidities associated with overweight and obesity; 1) diabetes mellitus, 2) cardiovascular diseases, 3) cancer or 4) clinical depression. Moreover, participants that reported to be on a diet, visited a dietician or reported to be or have been in an intensive weight loss treatment within the past six months
were excluded from participation. Finally, females who reported being pregnant or planning to become pregnant were excluded.

Several strategies were used to recruit study participants. First, willing general practitioners (35 of the contacted 73 professionals (47.9%)) and physiotherapists (28 of the contacted 55 professionals, (50.9%)) in the six municipalities distributed an information letter to overweight or obese patients that visited their practice during the recruitment period. This information letter referred potential participants to the study website. Second, flyers and posters referring to the study website were placed in pharmacies (40 locations), public facilities (39 locations) and in the waiting rooms of willing physiotherapists and general practitioners. Finally, participants were recruited through advertisements in local newspapers (in all municipalities) and by messages by local radio stations (in two municipalities). Adults willing to participate had to visit the study website to register themselves for the study and were asked to complete the online application form. All registrations were screened for eligibility by the research team (Figure 1).

**Design**

A two-arm, parallel design, randomized controlled trial (RCT) was conducted between January 2012 and February 2013. After baseline measurements, all participants were randomized at the same time to either the intervention ‘PortionControl@HOME’ group or to a wait-list control group. In each municipality, participants were randomly assigned separately in order to ensure an equal balance in the number of participants per group. Randomization lists were generated with standard statistical computer software (IBM SPSS Statistics 20.0). Based on the randomization list, the researcher (M.P.P) allocated subjects to one of the groups. Due to the nature of the intervention it was not possible to blind participants to their allocated condition.

**Procedures**

Eligible participants completed assessments at baseline (T0, prior to randomization), and at three (T1), six (T2) and 12 (T3) months of follow-up (Figure 1). All procedures followed were in
accordance with ethical standards of the responsible committee on human experimentation and prior to the baseline measurements, written informed consent was obtained. Baseline characteristics (age, sex, educational level, nationality) were assessed by self-report at enrollment via the online application form and during the baseline measurement (T0). Objective measures of body weight and height were collected during home visits by the researchers (E.V. and M.P.P) at baseline (T0) and six month follow-up (T2). Data of body weight were obtained by self-reported data at three month (T1) and twelve month (T3) follow-up. Data on portion control behavior was collected by means of questionnaires at baseline and each follow-up assessment. Intervention adherence among intervention group participants was self-reported at three-month follow up (T1) or objectively measured by the research team when possible. Dieting behavior was assessed by means of one item in the questionnaires at three (T1), six (T2) and twelve month (T3) follow-up. All participants received incentives to prevent drop-out from the study in the form of gifts (i.e. tea-box presents, UEFA Euro cup 2012 gadgets) and a reward coupon (€ 10) for completing the assessments.

**Intervention overview**

The intervention group received the PortionControl@HOME intervention program over three months (between T0 and T1). PortionControl@HOME was developed to stimulate adequate portion control behavior in order to decrease energy intake. The intervention was theory-based and consisted of the following four elements that were developed, pilot tested and reiterated prior to implementation: 1) PortionSize@warenessTool [25]. 2) Portion Control Strategies [32]. 3) Portion control cooking class. 4) Portion control Home-Screener. After completion of the intervention (between T1 (three months follow-up)) and T3 (twelve months follow-up) the intervention group received three online portion control boosters via email repeating the PortionControl@HOME content. The theoretical underpinning and a comprehensive description of the intervention elements are provided in the first two columns of Table 1.
Control condition

The wait-list control group continued with their normal behavior and received the program – without the cooking class - after the 12-month assessments.

Sample size

An *a priori* sample size estimate indicated 284 participants (142 per group) would be sufficient to detect a difference of 1 body mass index -point with a two-sided 5% significance level and a power of 80%, given an anticipated dropout rate of 10%.

Measures

The primary outcome was body mass index assessed at 3, 6 and 12 months. Secondary outcomes included the use of the portion control strategies, intervention adherence and evaluation, and additional dieting behavior.

Baseline characteristics

Age, sex, nationality, and educational level were assessed by self-report. Education was based on the highest qualification attained and was classified in three groups of educational level: low (“those with less than secondary school or an A-level certificate”), middle (“those with A-levels or Dutch A-level equivalent (VWO) graduation certificate”) and high (“those with polytechnic or university degrees”).
### Table 1. PortionControl@HOME Intervention Elements, theoretical foundation, description and participation rates of elements and assignments.

<table>
<thead>
<tr>
<th>Intervention elements &amp; Theoretical foundation</th>
<th>Element description</th>
<th>Participation rates of intervention elements and assignments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PortionSize@awarenessTool</strong></td>
<td></td>
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</tr>
<tr>
<td>According to the Precaution Adoption Process Model, awareness is the first stage of health behavior change, and increasing awareness is considered a crucial first step in any health behavior change intervention [53]. It has been acknowledged that individuals' awareness of their current behavior and awareness about the recommendations are important prerequisites for behavior change. People who are unaware that they are engaging in unhealthy behaviors (e.g., selecting large portions) or do not have accurate knowledge about the desired behavior are unlikely to address the healthy behavior (e.g., selecting and consuming appropriate servings).</td>
<td>The PortionSize@awarenessTool is an online interactive tool to increase awareness about the relationship between portion size and energy intake, recommended serving sizes and factors that contribute to the selection and intake of large food portions (i.e. value marketing). This element has been described in detail elsewhere, with previous results showing that using the tool resulted in significant improvements in portion size awareness [25].</td>
<td>- Logged-in on the PortionSize@awarenessTool(^a) N = 126 (90.4%)</td>
</tr>
<tr>
<td><strong>Portion Control Strategies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-regulation refers to all efforts to steer attention, emotions and behaviors to reach beneficial long-term goals (i.e. weight loss), even when there are short-term temptations (i.e. a nice cookie) or conflicting long-term goals [33]. In the context of controlling the amount of food consumed, self-regulation refers to efforts to control and maintain adequate selection and intake of the amount of food, thereby resisting or adapting temptations and situations by which one is triggered to overeat [32]. According to the health action process approach several assessments (action planning, coping planning and self-monitoring) can be used to improve actual behavioral change. For example, by action planning, individuals develop a mental representation of a suitable future situation (‘‘when’’ and</td>
<td>Portion control strategies enable people to regulate the portion size they select and eat. An 8-minute video introduction outlined the aim of the strategies and presented several scenarios in which people are vulnerable to select and consume large food portions. An educational book delineated the influences of portion sizes and explored the behavioral strategies in more detail [57]. In order to improve participants’ initial and prolonged use of the portion control strategies, self-regulation assignments, such as action planning, coping planning and</td>
<td>- Watched 8-minute introduction video(^b) N= 9 (10.5%) - Partly N= 63 (73.6%) - Read educational book N= 29 (33.7%) - Partly N = 55 (64%) - Totally - Fulfillment of the assignments: - Action planning assessment N= 39 (46.4%) - In mind - Wrote down on assessment form N = 15 (17.9%)</td>
</tr>
</tbody>
</table>

\(^a\)Please note that due to data protection considerations, the portion size awareness tool was not presented at the end of the study to ensure participant anonymity. Due to data protection considerations, the data on usage rates were not available for the PortionSize@awarenessTool.

\(^b\)Please note that due to data protection considerations, the portion size awareness tool was not presented at the end of the study to ensure participant anonymity. Due to data protection considerations, the data on usage rates were not available for the PortionSize@awarenessTool.
### Intervention elements & Theoretical foundation

<table>
<thead>
<tr>
<th>Element description</th>
<th>Participation rates of intervention elements and assignments</th>
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</table>
| "where") and a behavioral action ("how" e.g., using the portion control strategy), which is expected to be effective to achieve the goal [54]. Coping planning helps individuals to define difficult situations ("when" and "where") how to respond to overcome this barrier (how). An important predictor of weight loss maintenance suggested previously is self-monitoring of the changed behavior or weight loss [56] [59]. Self-monitoring consists of recording eating behavior and dietary intake so that people are aware of their current behaviors [59]. | - Coping planning assessment  
- In mind  
- Wrote down on assessment form |
| self-monitoring were incorporated as these strategies have been found effective in achieving changes in health behaviors [55, 56, 58, 59]. | - Self-monitoring assessment  
- In mind  
- Wrote down on assessment form |
| N= 16 (19.0%)  
N= 20 (23.8%)  
N= 17 (19.8%)  
N= 10 (11.6%)  
N= 28 (20.1%)  
N= 21 (15.1%)  
N= 34 (24.5%)  
N= 56 (40.3%)  
N= 111 (79.9%)  
N= 41 (48.2%)  
N= 64 (75.3%) |

### Portion Control Cooking Class

Energy density is defined as the number of calories in a given weight of food. The higher the energy density, the more calories a meal of a given portion size contains. Lowering the energy density of a meal is an additional solution over and above portion size reduction. In doing so, one might be able to keep the same portion size, but lower the caloric content of the consumed portion [60-62]. Energy density can be reduced by for example adding more water rich ingredients (such as vegetables) or decreasing the fat content [63]. During each class, techniques to lower the energy density of meals were provided, peer discussions were stimulated and skills were trained by preparing meals.

A three bi-weekly cooking classes (3 hours each) that were led by dietician and health professionals (M.P. and E.V.) were offered. The portion control cooking classes provided demonstrations of 1) appropriate servings of common foods consumed and 2) preparation of meals lower in energy density During each class, techniques to lower the energy density of meals were provided, peer discussions were stimulated and skills were trained by preparing meals.

### Portion Control Home Screener

The modern food environment has been related to an increase in people’s energy intake and has therefore been associated with the raise in overweight and obesity prevalence [64]. An important setting that influences eating behavior and dietary intake is the home food environment [37]. The home food environment affects the intake of food and the portion size of meals consumed. The ‘Home Screener’ is a screening-and-feedback instrument developed to assist individuals to shape a home food environment that supports adequate portion control behavior. The Home-Screener use:

- Filled-out home screener (yes)  
- Read advice presented (yes)  
- Home-Screener use b  
N= 41 (48.2%)  
N= 64 (75.3%)
environment is the place where the retail food environment comes together with actual food intake [35]. In the Netherlands, approximately 81% of all meals consumed at home [65]. Moreover, the home food environment is fundamental in the development of food preferences and consumption habits [66, 67]. According to the ANGELO-framework (ANalysis Grid for Environments Linked to Obesity) the physical home food environment which refers to what is present in the home [34].

Screener was developed by the research team and was pilot tested among more than 90 households (unpublished work). Based on this pilot test, items that could not be assessed reliably were deleted and the Home-Screener was developed for its final form as used in this study. The Home-Screener identify aspects of the physical home food environment that influence the amount of food consumed [36, 68-72]. It includes 20 questions on the amount of food available, the visibility and accessibility of foods, contextual food cues and the size of crockery and cutlery. As the Home-Screener was developed to eliminate surplus energy intake, the instrument targeted energy dense foods and beverages (e.g., snacks, sweets, sugar sweetened beverages). Participants could screen their home food environment indicate the supportiveness of the physical home food environment of adequate portion control behavior. Based on their screening, users were provided with feedback (i.e. which home environmental changes could be effective) and written assignments (i.e., writing down plans on what to change) to improve their home food environment in such a way that it stimulated adequate portion size selection and intake.
## Intervention elements & Theoretical foundation

<table>
<thead>
<tr>
<th>Element description</th>
<th>Participation rates of intervention elements and assignments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Portion Control Boosters</strong></td>
<td></td>
</tr>
<tr>
<td>The portion control boosters were based on the theoretical approaches and frameworks of the four elements of the PortionControl@HOME intervention.</td>
<td>No measures determined</td>
</tr>
<tr>
<td>At the beginning of the summer (June 2012), the late summer (September 2012) and prior to the Christmas-holidays (December 2012) portion control Boosters were provided by email. Booster 1 contained information about reference serving sizes, extra tips to control portion size selection specified at typical summer events (e.g., during holidays) and provided some low-energy dense recipes for typical barbecue dishes. Booster 2 repeated all portion control strategies provided during the intervention period. Moreover, individuals were stimulated to monitor their current use of the strategies and to formulate new coping plans to stay on track. Booster 3 repeated the portion control strategies and home-environmental tips aimed at typical Christmas holiday temptations and appropriate servings of typical Christmas meals were presented. Participants were also encouraged to visit the PortionSize@warenessTool again.</td>
<td></td>
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</table>
Body mass index

At baseline (T0), weight was measured using two different scales; a professional one (the Marsden MPMS-250 digital scale, Oxfordshire, United Kingdom) and the participant’s scale, in light clothes and with shoes removed. Measurements were highly correlated (regression coefficient= 0.99; intercept= -0.10), indicating that both scales yield largely similar results. At T2 the weight was also objectively measured using the professional scale, during a home visit from the researchers. At T1 and T3 participants were asked again to weigh themselves. Height was measured at baseline to the nearest mm with a stadiometer (Seca 214, Hamburg, Germany). Body mass index was calculated as weight (kg)/height (m)^2.

Portion Control Behavior

Self-administered portion control behavior was measured using a 32-item questionnaire that assessed the strategies incorporated in the PortionControl@HOME intervention program. Participants indicated their use of the strategies on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). A mean score of the 32 items was computed to reflect general use of portion control strategies (T0 Cronbach’s α = 0.78). This questionnaire has been used before and is described in more detail elsewhere [32].

Dieting behavior

To account for any possible confounding effects on weight change and to rule out alternative explanations for weight loss, dieting behavior was assessed by one item (e.g., “Did you follow a popular diet or followed a weight loss treatment during the past three months period?”) followed by seven response options ranging from “never”- “yes, over the past three months”. Answers were categorized by “never” “shorter than one month” and “1 month or more” and percentages for each group were calculated.
Intervention adherence

Intervention group participants self-reported their use of the educational book (“Did you read the educational book”? ‘Yes, completely’/’Yes, partly’/’No, not at all’). The use of the Home-Screener was determined by two questions: (a) “Did you complete the screening as proposed by the Home-Screener” ‘Yes, completely’/’Yes, partly’/’No’ and b) “Did you read the advices regarding your home food environment provided by the Home-Screener”? ‘Yes, all advice’/’yes, some advice’/’No, not any advice’) at three month follow-up (T1). Fidelity of the cooking class and website was assessed by recording attendance with cooking classes (ranging from zero to 3 classes) or using the PortionSize@awarenessTool (logged-in on the website: yes/no). Also the fidelity of the action planning, coping planning and self-monitoring exercises/assignments were determined by items asking the participants if they fulfilled the assignment ‘yes, in mind’/’yes, wrote down on the assessment form’/’no, not at all’.

Statistical analyses

Statistical analyses were conducted using standard statistical computer software (IBM SPSS Statistics 20.0). All statistical tests were two-tailed and a 5% significance level maintained throughout the analyses.

Descriptive statistics were used to characterize the intervention and control group at baseline. Moreover, descriptive statistics were used to identify dieting behavior of all participants and the overall intervention adherence of the intervention group participants.

A multi-level regression analysis on the principle of intention-to-treat (ITT) was conducted, using the data collected from all randomized participants. First, crude analyses including adjustment for baseline values of the outcomes were conducted. Second, based on previous studies indicating associations between portion control behavior and socio-demographic characteristics we adjusted for age, sex and educational level additionally [32]. In a third model, dieting behavior was also entered as a covariate in the adjusted analysis of the primary outcome. All models included time and an interaction term between time and the intervention variable in order to assess time specific intervention effects. Analysis including and excluding the outliers (body mass index change >3x SD above or below mean body mass
index change between T0 and T2 (objectively measured data) were performed to whether the intervention effect was robust against these outliers in the data. Similar analyses were conducted for portion control behavior.

A mediation analysis was conducted to determine whether portion control behavior mediated the potential intervention effect on body mass index [39]. To achieve this, the association between ‘group’ and ‘portion control behavior’ was first assessed. Second, the association between ‘portion control behavior’ and ‘body mass index’ was ascertained. Third, the association between ‘group’ and ‘body mass index’ was examined. Finally, the association between ‘group’ and ‘body mass index’ adjusted for the variable ‘portion control behavior’ was established. A Sobel test [40] was conducted to determine if potential mediation was statistically significant.

RESULTS

Response

Figure 1 shows a flow chart of the number of screened potential participants, recruitment and follow-up. A total of 617 individuals completed the online registration, of which 289 fulfilled the inclusion criteria. Reporting ‘suffer from or having a history with one of the co-morbidities associated with overweight and obesity’ was the most important reason why participants were excluded from participation. When contacted by the research team, 11 participants were ineligible prior to randomization (e.g., pregnant, refuse to participate, failed to contact). Therefore, a total number of 278 participants were randomized into the intervention or control group. At three month (T1) follow-up, 85 (61.2%) and 111 (79.9%) participants in the intervention and control condition, respectively, returned the questionnaires with weight related measures. Reasons for missing data included questionnaires not being completed and returned, or participants requesting drop-out. At six-month follow-up (T2), a larger sample of individuals completed the measurements compared to three-month follow-up T1, probably due to the fact that they were visited at home by the researchers. During this measurement, a total of 105 (75.5%) individuals in the intervention group and 118 (84.9%) individuals in the control group participated. At 12-month follow up (T3), 89 (64.0%) and 102 (73.4%)
participants completed the weight related measures themselves. Logistic regression analysis determining drop-out (yes/no) including the variables age, sex, educational level and group-allocation indicated that allocation to the intervention group was significantly associated with higher drop-out rates during the study (Odds ratio (OR) = 2.2, P= 0.013).

Baseline characteristics

A total of 278 participants completed the baseline measurements. Participants were on average 45.7 (SD = 9.2) years old, the majority were female (84.5%) and obese (65.1%). Almost all participants (96.8%) had a Dutch nationality (other 3.2% e.g., Surinam, French, German) and 42.7% had a high educational level (Table 2).

Table 2. Baseline characteristics of the participants allocated to the intervention and control condition

<table>
<thead>
<tr>
<th>Group characteristics</th>
<th>All</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=</td>
<td>278</td>
<td>139</td>
<td>139</td>
</tr>
<tr>
<td>Age</td>
<td>45.65 (9.20)</td>
<td>45.87 (9.22)</td>
<td>45.42 (9.21)</td>
</tr>
<tr>
<td>Sex</td>
<td>84.5 (235)</td>
<td>84.9 (118)</td>
<td>84.2% (117)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% low</td>
<td>20.9</td>
<td>24.8</td>
<td>17.2</td>
</tr>
<tr>
<td>% medium</td>
<td>36.4</td>
<td>32.0</td>
<td>40.6</td>
</tr>
<tr>
<td>% high</td>
<td>42.7</td>
<td>42.2</td>
<td>43.2</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>94.11 (15.8)</td>
<td>94.95 (15.37)</td>
<td>93.27 (16.20)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>32.4 (4.8)</td>
<td>32.86 (4.95)</td>
<td>32.00 (4.57)</td>
</tr>
<tr>
<td>BMI 25≤30</td>
<td>34.9 (97)</td>
<td>31.7 (44)</td>
<td>38.1% (53)</td>
</tr>
<tr>
<td>BMI &gt;30</td>
<td>65.1 (181)</td>
<td>68.3 (95)</td>
<td>61.9% (86)</td>
</tr>
</tbody>
</table>
Figure 1. Flow of recruitment, randomization and follow-up of the study participants
**Dieting behavior**

Participants in both the intervention and the control group reported to be on a diet during the follow-up measurements. Participants in the intervention and the control condition were on a diet for more than one month in the following proportions: T1: 7.0% vs. 15.9%; T2: 8.5% vs. 15.5% and at T3: 5.0% vs. 7.5%. At three-month follow-up significantly more participants in the control group were on a popular diet for a longer period (> 1 month) than participants in the intervention condition ($X^2 = 5.97, df = 2, P = 0.05$).

**Body mass index**

Overall, mean body mass index decreased in both groups between baseline and T1 (intervention 2 points and control 1 point, Table 3) but increased again between T1 and T3, although mean body mass index remained below the baseline values. Mixed model analysis showed that at three months the estimated difference between the intervention group and the control group in the fully adjusted model (corrected for demographic variables and dieting behavior) was $-0.42$ (95% CI: $-0.91$ to $0.07$, Table 4). This difference was more pronounced and statistically significant when outliers (n=3) were excluded from the analyses ($B = -0.45$; 95% CI: $-0.88$ to $-0.04$). Differences between both groups were smaller at 6 months follow-up ($B= -0.13$; 95% CI: $-0.63$ to $0.37$) and absent at 12 months follow-up ($B= -0.03$; 95% CI: $-0.53$ to $0.47$) (Table 4).

**Portion Control Behavior**

Table 3 shows that mean portion control behavior for the intervention group at T1 increased by 0.49 points (on a five-point Likert scale) and that this stabilized over the follow-up period. At follow-up, the estimated differences between the intervention and the control group were $0.33$ (95% CI: $0.23$ to $0.43$), $0.30$ (95% CI: $0.19$ to $0.40$) and $0.35$ (95% CI: $0.24$ to $0.45$) at 3, 6 and 12 months, respectively. These differences were less evident when outliers were excluded from the analyses, although differences between groups remained statistically significant (Table 4).
Table 3. Descriptive statistics Body Mass Index and Portion Control Behavior of the complete cases in the intervention group and control group at baseline (T0) and three (T1), six (T2) and 12 (T3) month follow-up

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>T0</th>
<th>n</th>
<th>T1</th>
<th>n</th>
<th>T2</th>
<th>n</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body Mass Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention group</td>
<td>139</td>
<td>32.86 (4.95)</td>
<td>85</td>
<td>30.88 (4.73)</td>
<td>105</td>
<td>32.15 (5.07)</td>
<td>89</td>
<td>31.45 (4.96)</td>
</tr>
<tr>
<td>Control group</td>
<td>139</td>
<td>32.00 (4.57)</td>
<td>111</td>
<td>30.95 (4.69)</td>
<td>118</td>
<td>31.40 (4.75)</td>
<td>102</td>
<td>30.84 (4.73)</td>
</tr>
<tr>
<td><strong>Portion Control Behavior</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention group</td>
<td>127</td>
<td>3.24 (0.46)</td>
<td>86</td>
<td>3.73 (0.48)</td>
<td>83</td>
<td>3.68 (0.50)</td>
<td>91</td>
<td>3.77 (0.48)</td>
</tr>
<tr>
<td>Control group</td>
<td>126</td>
<td>3.21 (0.49)</td>
<td>113</td>
<td>3.36 (0.50)</td>
<td>104</td>
<td>3.40 (0.51)</td>
<td>109</td>
<td>3.42 (0.42)</td>
</tr>
</tbody>
</table>

\(^a\) T0 and T2 represent the objectively measured Body Mass Index and T1 and T3 represent the subjectively measured Body Mass Index

\(^b\) Portion Control Behavior measured on a five-point Likert Scale
### Table 4. Time specific intervention effects on Body Mass Index and Portion Control Behavior at 3, 6 and 12 month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Body Mass Index (kg/(m^2))</th>
<th>Portion Control Behavior</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Body Mass Index</td>
<td>Body Mass index</td>
<td>Portion Control Behavior</td>
<td>Portion Control Behavior</td>
</tr>
<tr>
<td></td>
<td>Without outliers^D</td>
<td>Without outliers^D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimates of fixed effects between Groups (95% CI)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3 month follow-up (T1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crude model^A</td>
<td>-0.29 (-0.77 0.20)</td>
<td>-0.37 (-0.79 0.04)</td>
<td>0.32 (0.22 0.42)</td>
<td>0.31 (0.22 0.41)</td>
</tr>
<tr>
<td>Adjusted model 1^B</td>
<td>-0.32 (-0.83 0.18)</td>
<td>-0.40 (-0.83 0.03)</td>
<td>0.31 (0.21 0.42)</td>
<td>0.31 (0.21 0.40)</td>
</tr>
<tr>
<td>Adjusted model 2^C</td>
<td>-0.42 (-0.91 0.07)</td>
<td>-0.45 (-0.88 -0.04)*</td>
<td>0.33 (0.23 0.43)</td>
<td>0.32 (0.22 0.42)</td>
</tr>
<tr>
<td>6 month follow-up (T2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crude model^A</td>
<td>0.035 (-0.44 0.51)</td>
<td>-0.12 (-0.52 0.29)</td>
<td>0.29 (0.19 0.40)</td>
<td>0.26 (0.16 0.36)</td>
</tr>
<tr>
<td>Adjusted model 1^B</td>
<td>0.002 (-0.49 0.49)</td>
<td>-0.14 (0.56 0.28)</td>
<td>0.29 (0.18 0.39)</td>
<td>0.26 (0.16 0.36)</td>
</tr>
<tr>
<td>Adjusted model 2^C</td>
<td>-0.13 (-0.63 0.37)</td>
<td>-0.23 (0.66 0.19)</td>
<td>0.30 (0.19 0.40)</td>
<td>0.27 (0.17 0.36)</td>
</tr>
<tr>
<td>12 month follow-up (T3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crude model^A</td>
<td>0.04 (-0.46 0.53)</td>
<td>-0.16 (-0.58 0.26)</td>
<td>0.35 (0.25 0.45)</td>
<td>0.32 (0.23 0.42)</td>
</tr>
<tr>
<td>Adjusted model 1^B</td>
<td>-0.01 (-0.51 0.49)</td>
<td>-0.20 (-0.63 0.23)</td>
<td>0.34 (0.24 0.44)</td>
<td>0.32 (0.22 0.41)</td>
</tr>
<tr>
<td>Adjusted model 2^C</td>
<td>-0.03 (-0.53 0.47)</td>
<td>-0.19 (-0.62 0.24)</td>
<td>0.35 (0.24 0.45)</td>
<td>0.32 (0.22 0.42)</td>
</tr>
</tbody>
</table>

^A adjusted for baseline Body Mass Index / ^B adjusted for baseline Body Mass Index, age, sex and educational level / ^C adjusted for baseline Body Mass Index, corrected for age, sex and educational level + dieting behavior in the period prior to the measurement / ^D Outliers are defined as 3x larger or smaller than the Standard Deviation of the mean difference between T0 and T2: Body Mass Index (±5.52 Body Mass Index points) = 3 outliers; 1) -5.52 Body Mass Index points, 2) -12.73 Body Mass Index points, 3) -10.56 Body Mass Index points). Portion Control Behavior (±1.20 points) = 4 outliers.
Mediation Analysis

Because the mixed model analyses only indicated an effect of the intervention on body mass index change at three-month follow-up, a mediation analysis was only conducted for this time (baseline to 3-month follow-up). Results showed a statistically significant positive association between group-allocation (intervention) and portion control behavior ($b = 0.34, p < .01$), as well as a negative association between portion control behavior and body mass index ($b = -0.83 p < .01$). The intervention was also statistically significantly associated with a decrease in body mass index ($b = -0.45 p < .05$). In the final step, when portion control behavior was added as covariate, the effect of the intervention was attenuated ($b = -0.20 p = 0.35$), indicating the intervention effect was mediated by portion control behavior. The Sobel test indicated that portion control behavior significantly mediated the intervention effect on body mass index ($p < .001$, Figure 2).

![Diagram showing mediation analysis]

* = $p < .05$; ** = $p < .01$; ns = non-significant

Change T1-T0 = differences between three month follow up and baseline measurements for Portion Control Behavior or Body Mass Index

Group = Intervention compared to the control condition.

1),2),3) = Regression coefficient between the variables.

4) = regression coefficient between variables after correction for Portion Control Behavior change T1-T0.

Figure 2. Mediation analysis of group-condition, Portion Control Behavior and Body Mass Index at three month follow-up
Intervention adherence and evaluation

Of all 139 intervention group participants, 126 (90.4%) logged on to the website aimed at portion size awareness and 56 (40.3%) attended all three cooking class meetings. A total of 34 (24.5%) and 21 (15.1%) participants attended two or one cooking class, respectively. Twenty-eight participants (20.1%) did not attend any cooking class. Ten participants (7.2%) did not attend one of the cooking classes and did not visit the website. Of the 86 intervention participants that completed the follow-up questionnaires at T1, 55 (64.0%) and 29 (33.7%) reported that they had read the educational book completely or partly, respectively. Moreover, 48.2% reported to have filled-out the Home-Screener completely whereas 75.3% of the participants reported to have read all advice presented in the Home-Screener. The fidelity of the assignments (both in mind or writing down on the assessment form) regarding action planning (64.3%) was moderately higher than the assignments regarding coping planning (42.8%) and self-monitoring (31.4%, Table 2).

DISCUSSION

The PortionControl@HOME study aimed to examine the effects of a multi-component educational intervention aimed at portion size on portion control behavior and weight change in overweight and obese participants. In partial support of the hypothesis, the intervention group reported a greater weight loss compared to the control group after completing the intervention (T1), although this difference (-0.45 body mass index points) was only statistically significant when three outliers were removed from the analysis. The effect of the intervention was not sustained at six and 12 months follow-up. Compared to the control group, the intervention group reported a significantly higher increase in self-reported portion control behavior. Further analysis indicated that the effect of the intervention on weight loss at three-months was mediated by portion control behavior. Collectively these results suggest that the PortionControl@HOME intervention can be useful to improve portion control behavior and initial weight loss; however additional efforts and more intensive behavioral supports are needed to strengthen and prolong the intervention effect. These findings are consistent with previous notions of positive effects on weight loss during or directly after
interventions (initial change) but the disappearance of the effects once the intervention was terminated (failure of maintenance) [41].

Several explanations for the temporary intervention effect are proposed. First, the results indicated that a minority of the individuals completed the coping planning and self-monitoring assignments (with 42.8% and 31.4% respectively), although these strategies have been proposed as important in behavioral change [42, 43]. Moreover, while the intervention was based on behavior change theories (e.g., the health action process approach), additional behavioral change theories (i.e., dual process theory) may be needed to strengthen the intervention effects. Second, the duration of the intervention (3 months) may have been of insufficient duration to achieve adequate and prolonged weight loss among the present study population. Also the inclusion of the booster sessions had no added value, which is consistent with previous studies [44, 45]. It can also be suggested that the current intervention is more suitable for weight gain prevention. For example, the intervention could target weight maintenance among individuals with a body mass index slightly below 25. The aim of the intervention would then be to prevent overweight. However, it can be questioned if this group with a healthy body weight is motivated to participate in such a comprehensive intervention program and future studies are needed to confirm this assumption. A third explanation for the temporary effect on BMI change might be the absence of the incorporation of relapse prevention strategies in the program. A future portion control program should also focus on relapse prevention, in order to prevent individuals from falling back in their old dietary pattern [41]. Practical portion control relapse prevention strategies that could be added to a prolonged program are; 1) The identification of personal high-risk situations for failures and lapses; 2) The practicing of coping with real-life high-risk situations; 3) The identification and use of problem-solving techniques; or 4) The planning for a long-term portion control life style to maintain or lose weight. It is important that participants develop the mastery of such strategies that accompany the difficulties they experience to maintain their portion control behavior [46, 47].

Another direction to achieve sustainable results is to combine the educational intervention with environmental efforts aiming to create a more “portion-friendly” choice environment. The importance of combining both public health actions was demonstrated in recent
research, which revealed that using self-regulation strategies weakened the effect of the food-rich environment but did not eliminate the impact of this unfavorable food environment [48]. Environmental efforts that could support portion control behavior might encourage portion sizes to align with nutritional guidelines, or could encourage reference food portions to become the default option. Although it was emphasized in the introduction that both feasible and effective environmental efforts might be difficult to achieve, ongoing research into the feasibility of such strategies and the combined effects of educational and environmental interventions is needed.

It is important to highlight that many people were interested in the intervention. A total of 620 individuals signed up for participation in the study. This suggested that overweight and obese participants are motivated to participate in behavior change interventions. A previous study among obese individuals supported this finding and showed that obese adults preferred non-commercial interventions to improve lifestyle above programs that were focused on weight-loss only [49]. Moreover, our study suggested that offering the PortionControl@HOME intervention may reduce the interest in popular or “quick fix” diets, which was illustrated by the finding that less intervention group participants engaged in such diets during the intervention period.

Intervention group participants’ initial use of the program-elements was high and the use of each intervention-element (website, book, cooking-class, and home-screener) ranged between 48.8%-98.8%. However, the fulfillment of the individual assignments as recommended by the program was much lower. Unfortunately, the loss to follow-up in the intervention group was significantly higher than in the wait-list control condition. This was probably due to the fact that the intervention group participants already completed the PortionControl@HOME program and no incentives to complete the measures were left after the intervention period. Moreover, the actual drop-out (31.3%) was higher than expected when designing the trial (10%).

Some strengths and limitations need to be discussed. Strengths include the multi-component intervention, the pilot-testing of the elements before implementation and the use of a randomized controlled trial with intention to treat analysis. Limitations of the study included the amount of missing data and the partly subjectively measured body mass index [50,51].
Self-reported body mass index has been associated with underreporting of actual weight, which in turn may be associated with an overestimation of weight loss in this study [51]. However, it was assumed that both the control and intervention group would underreport their weight to the same extent. In addition, self-reported weight and objectively measured weight was highly correlated at T0. Therefore, self-reported body mass index was regarded a valid alternative to measured body mass index.

Randomized controlled trials (RCTs), are considered to be the gold standard for determining the efficacy of interventions and we mention it as one of the strengths of our study. However, recently it has been questioned whether a standard RCT design is the most appropriate for assessing weight-loss interventions (or other lifestyle or policy programs) that are compared to usual care [52]. This is because control group participants may be motivated to change behavior throughout the study period, and thus does not truly reflect a ‘usual care comparison’. Moreover, behavioral weight-loss intervention trials cannot be blinded or compared to a placebo control condition, which means participants in the control group are aware of their allocated condition. Considering the fact that the use of the portion control strategies were ascertained almost literally in the questionnaires (i.e. the portion control strategy “when preparing a meal, don’t snack on the ingredients” corresponded to the item in the questionnaire: “When preparing a meal, I snack on the ingredients”) the control group could have been contaminated with the portion control strategies as provided by the intervention program. When designing future studies to evaluate weight loss interventions, new designs (for example cohort randomized controlled trials) should be considered.

CONCLUSION

The results of this study suggest that the intervention improved portion control behavior. Furthermore, the intervention-effect, mediated by portion control behavior, may have favorable effects on weight at three months follow-up immediately after the intervention but not at six or twelve months. Therefore, additional efforts or prolonged programs are needed to maintain the effectiveness. Future research should identify effective supplemental intervention strategies and should examine the effect of portion control programs in combination with efforts that create a more “portion-friendly” choice environment.
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