A randomized clinical trial of the effectiveness of a Web-based health behaviour change support system and group lifestyle counselling on body weight loss in overweight and obese subjects: 2-year outcomes

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Abstract.
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Background. Weight loss can prevent and treat obesity-related diseases. However, lost weight is usually regained, returning to the initial or even higher levels in the long term. New counselling methods for maintaining lifestyle changes are urgently needed.

Objectives. An information and communication technology-based health behaviour change support system (HBCSS) that utilizes persuasive design and methods of cognitive behavioural therapy (CBT) was developed with the aim of helping individuals to maintain body weight. The purpose of this study was to assess whether CBT-based group counselling combined with HBCSS or HBCSS alone helps to maintain improved lifestyle changes needed for weight loss compared to self-help guidance or usual care.

Methods. A randomized lifestyle intervention for overweight or obese persons (BMI 27–35 kg m⁻² and age 20–60 years), recruited from the population registry in the city of Oulu, Finland, was conducted. This study comprised six randomly assigned study arms: CBT-based group counselling (eight sessions led by a nutritionist), self-help guidance-based group counselling (SHG; two sessions led by a nurse) and control, each with or without HCBSS, for 52 weeks. Subjects visited the study centre for anthropometric measurements, blood sample collection and to complete questionnaires at baseline, 12 and 24 months. The main outcome was weight change from baseline to 12 months and from baseline to 24 months.

Results. Of the 1065 volunteers screened for the study, 532 subjects (51% men) met the inclusion criteria and were enrolled. The retention rate was 80% at 12 months and 70% at 24 months. CBT-based counselling with HBCSS produced the largest weight reduction without any significant weight gain during follow-up. The mean weight change in this arm was 4.1% [95% confidence interval (CI), −5.4 to −2.8, P < 0.001] at 12 months and 3.4% [95% CI, −4.8 to −2.0, P < 0.001] at 24 months. HBCSS even without any group counselling reduced the mean weight by 1.6% [95% CI, −2.9 to −0.3, P = 0.015] at 24 months.

Conclusion. The combination of CBT-based group counselling and HBCSS-based weight management...
is feasible for overweight or obese individuals. Moreover, HBCSS alone could be disseminated to the population at large as an effective means of treating obesity.

Keywords: behaviour change techniques, eating behaviour, intervention, obesity treatment, self-regulation.

Introduction

The prevalence of overweight and obesity in the adult population has grown globally, and currently, two-thirds of adults in developed countries are either overweight or obese [1]. Obesity and metabolic syndrome have a significant impact on healthcare costs. It is estimated that obesity and metabolic syndrome account for between 1% and 3% of total health budgets [2] and this is expected to grow, especially in developing countries.

Weight loss can prevent and treat obesity-related diseases, such as metabolic syndrome. Besides lifestyle factors (nutrition and exercise), the treatment of obesity comprises behavioural therapy, medication and, in severe cases, bariatric surgery [1, 3]. Diet and exercise can reduce weight, but the lost weight is usually regained, returning to the initial level in the long term [4]. Typically, after the first year, 50% of the lost weight has been regained [5]. However, the risk of weight gain is considerably lower if the weight loss is maintained for 2 years [6, 7]. Therefore, the use of person-centred and autonomy-supportive counselling approaches is important to maintain the achieved positive health behaviour changes [8]. In the traditional model of psychotherapy, the therapist is the expert. By contrast, person-centred therapy is a nondirective, empathetic approach that empowers and motivates the client in the therapeutic process. This model is augmented by the autonomy-supportive approach which provides choice, noncontrolling competence feedback and a rationale for tasks. It also avoids controlling behaviours (such as criticisms), controlling statements and tangible rewards for interesting tasks and acknowledges the person’s feelings and perspectives [9].

Weight loss programmes within a cognitive behavioural framework have improved the maintained weight loss in some studies, but results have been inconsistent [10, 11]. Moreover, there is increasing evidence that Web-based interventions targeting lifestyle and eating behaviour can also improve metabolic health. Such interventions are easily accessed, widely achievable, adjustable to different groups of treatment and low in cost. Web-based information systems supporting weight loss and maintenance have thus become an important research area in health behaviour change [12, 13]. These systems may, and indeed should, utilize different types of persuasive features to influence an individual’s health behaviour [14].

We developed a new type of intervention to combine these two interdisciplinary methods: group counselling based on cognitive behavioural therapy (CBT) was combined with an information and communication technology (ICT) health behaviour change support system (HBCSS) [15]. This approach was based on persuasive system design (PSD) [14] and CBT and delivered by ICT on a weekly basis for 12 months. Our aim was to investigate whether CBT-based group counselling combined with HBCSS or HBCSS alone helps to maintain the improved lifestyle changes needed for weight loss and prevention or treatment of metabolic syndrome. Participants were followed for up to 24 months.

Methods

Trial design

The Prevent Metabolic Syndrome (PrevMetSyn) trial included a population-based randomized sample of overweight or obese participants. All procedures in this intervention trial were performed in accordance with the Declaration of Helsinki (World Medical Association 2013). All study subjects gave written informed consent, and the study was approved by the Ethics Committee of the Hospital District of Northern Ostrobothnia, Oulu, Finland (approval number 29/2012) English version of the study protocol described in Appendix S1. The study was registered with ClinicalTrials.gov (identifier NCT01959763).

Sample size calculation

For the primary outcome of change in weight, we estimated that a standardized effect size of 0.25 (equivalent to 3.0 kg difference assuming a standard deviation of change of 5.0 kg) and 80% power and 5% type I error would require 29 participants with complete data in each arm, giving a total of 252 participants.
As the dropout rate was less than 30%, we estimated that a total of 77 subjects per group, or 56 subjects per group with complete data, would provide 95% power and 5% type I error.

Randomization process

MS Excel was used by an independent researcher to produce a randomization list with random permuted blocks of 24. The randomization process was carried out in two phases. During the first phase, the study subjects were randomly assigned to two different lifestyle face-to-face group counselling arms or a control arm (Fig. 1). Secondly, subjects were randomly divided into users or nonusers of the Web-based HBCSS programme. Therefore, there were six different study arms: (i) CBT-based group counselling (eight sessions; CBT counselling), (ii) CBT counselling with HBCSS, (iii) group counselling (two sessions) and self-help guidance (SHG counselling), (iv) SHG counselling with HBCSS, (v) control arm (usual care, i.e. written information but no intervention) and (vi) HBCSS alone. The study design is illustrated in Fig. 1.

The sample was recruited using information from the Finnish Population Register Centre. Invitation letters were sent to residents aged 20–60 years living in the city of Oulu. The recruitment letters were sent in blocks at five different time-points during a period of 1 year (2013). The intervention started for participants from each block after the screening visit and randomization. Eligibility criteria included (i) BMI of 27–35 kg m\(^{-2}\), (ii) access to the Internet, (iii) no health-related restrictions to losing weight (such as pregnancy) and (iv) no other ongoing treatment of obesity. Exclusion criteria were uncontrolled health factors, such as abnormal laboratory values (thyroid, kidney and liver function tests) or clinically significant illness with contraindication for weight loss or physical activity. Volunteers were invited to a screening visit at the enrolment site of the Oulu University Hospital.

Treatment arms

CBT counselling

The theoretical framework of the CBT counselling with eight sessions was based on a CBT approach integrating the assumptions and strategies of acceptance and commitment therapy [16]. The goals were (i) to obtain and maintain a weight loss of 5%, (ii) to improve eating behaviour (increase in flexible restraint and decrease in uncontrolled and emotional eating) and (iii) to decrease the participants’ risk of diabetes and cardiovascular diseases.

Cognitive behavioural therapy counselling included eight 90-min sessions in groups of eight to nine participants. Seven group counselling sessions were conducted every second week, with the last session after 1 month. Each session was co-led by two qualified or student clinical nutritionists with a basic knowledge of CBT techniques. Each group session comprised a mindfulness exercise, a short psychoeducation session, individual, pair or group exercises, and feedback discussion of a home task (Table S1). Home tasks between group sessions were an integral part of the counselling model, and participants were encouraged to carry out these tasks with care.

![Fig. 1 Study design. Subjects (n = 532) were randomly assigned to two different lifestyle face-to-face counselling arms or a control arm. Then, they were randomly divided into users and nonusers of the Web-based health behaviour change support system (HBCSS).](image)
Both cognitive and behavioural strategies were used. Participants were instructed to carefully monitor their meal pattern and weight and to record their weight on a weight loss graph. They were taught to identify and cope with dysfunctional thoughts related to eating, exercise, weight monitoring and weight loss that interfered with their behavioural goals and self-efficacy beliefs. Cognitive and behavioural strategies were introduced to help to identify high-risk situations in which external, internal or social triggers cause eating in an unplanned manner. Problem-solving skills were taught to find ways to break patterns leading to undesirable eating in high-risk situations. Participants were taught the skill of mindful eating and encouraged to practise this at home. Additionally, participants learned how to eat a healthy diet and to make a personal plan for healthy eating and physical activity. One of the eight counselling sessions focused on health information literacy, which has been defined by the Medical Library Association as the ability to ‘recognize a health information need; identify likely information sources and use them to retrieve relevant information; assess the quality of the information and its applicability to a specific situation; and analyse, understand, and use the information to make good health decisions’ [17].

**SHG counselling**

Group counselling with self-help guidance (SHG counselling) was based on a group counselling model [18, 19] that included two 90-min face-to-face sessions. Two registered nurses received education for these counselling sessions. The main framework was constructivist learning theory and the transtheoretical model for change [20]. The main themes of these two group sessions were change of lifestyle, frequency of eating, ‘plate’ model, the amount and quality of food and ‘good life’, as well as weight management with self-help guidance.

**Control arm**

Participants in the control arm of this study received usual care (i.e. personal laboratory results and written information about the factors affecting metabolic syndrome and weight management).

**Web-based HBCSS**

The 52-week Web-based HBCSS was a stand-alone information system designed for the PrevMetSyn study. The PSD model [14] and HBCSS framework [15] provided systematic methods for developing this system. The theoretical basis for the content was the CBT approach [21]. Current scientific and practical knowledge of eating behaviour, diet, physical activity and health information literacy was also applied.

All participants randomly assigned to this study arm received an e-mail with a link to log into the HBCSS with a personal password. Participants were then able to use the system, perform weekly tasks, access information and use the tools of the system, such as self-recording of weight and physical activity. Additionally, participants using HBCSS received weekly reminders to log into the system and notification of new tasks.

The main features of the system included weekly information and the possibility to set goals and follow individuals’ progress within the system by submitting personal entries related to self-monitoring. Weekly information included an article, an exercise and a tip to help with lifestyle changes. The weekly articles provided the user with information related to healthy lifestyle, enhancing motivation through everyday health literature, recognition of and coping with dysfunctional thoughts and emotions related to eating behaviour, weight monitoring, physical activity and self-efficacy beliefs (Table S2). A variety of exercises were provided according to the phase of the intervention to set goals, adopt a healthy lifestyle and flexible eating behaviour, cope with high-risk situations that trigger overeating in an unplanned way and handle relapses. The self-monitoring section was also a major feature of the system. For tracking their progress, users could submit regular entries about their weight loss progress, add notes about their feelings during the intervention and record their eating and exercise in diaries.

All cognitive and behavioural strategies applied in the information content were reinforced with PSD and HBCSS methods such as reduction, tunnelling, tailoring, praise and reminders [14, 21].

**Measures**

To measure the plasma glucose and lipoprotein levels, blood samples were collected at screening and at 12 and 24 months, after a 10-h fast, by a study nurse at the research laboratory of the Oulu University Hospital. Blood pressure, waist circumference, height and weight were also measured. Waist circumference was measured according to the
recommendations of the World Health Organization and the International Diabetes Federation (IDF) with a measuring tape in the horizontal plane midway between the lowest ribs and the iliac crest at the study centre by a nurse trained to measure the waist circumference. Body weight was measured at the study centre using a calibrated scale. Body mass index was calculated by dividing weight by height squared (kg m\(^{-2}\)). None of the weights used in the statistical analyses were self-recorded. However, the study subjects could record their weight in the HBCSS software as part of self-monitoring.

All the procedures are described in detail in the online Supporting information.

Statistical methods

The primary analysis was based on intention-to-treat principles. The primary outcome was absolute percentage weight change from baseline to 12 months and from baseline to 24 months with multiple imputed values where data were missing. A linear mixed-effect model was used to assess the weight change and waist circumference from baseline to 12 months and from baseline to 24 months, adjusting for age and sex. The same model was used for the subjects who completed the study per protocol (completers). Chi-squared test was used to test the differences between study arms in the proportions of patients with low, moderate and high levels of weight change. IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA) was used for the analyses.

Results

Study population

A total of 1065 persons volunteered for the study and were assessed for eligibility (Fig. 2). Of these volunteers, 580 were invited to a screening visit between 4 February 2013 and 30 March 2016. Eight subjects withdrew immediately after the screening visit, six did not have an e-mail address, two had no Internet access, and three discontinued because of illness. A further 27 individuals were excluded because their BMI was either too high or too low, and two were excluded because of sampling failure. In addition, pregnancy or breastfeeding was the reason for exclusion of one person at the screening stage.

Overall, 532 participants met the study eligibility criteria and were randomly assigned to the six study arms as illustrated in Fig. 2. All study subjects were Caucasian. A total of 108 participants (20.3%) did not return to the study centre for the 1-year visit (Fig. 2), and 49 participants dropped out between the 1-year and 2-year visits. Thus, 375 study subjects completed the study per protocol, and the attrition rate at 24 months was 29.5% (n = 157). No statistically significant differences amongst the dropouts were found between the study arms (Table S3).

Baseline characteristics

The baseline characteristics of participants in the six study arms are shown in Table 1. The mean (SD) age of the study subjects was 46.0 (9.9) years, mean (SD) body weight was 89.5 (11.3) kg, and mean (SD) BMI was 30.5 (2.1) kg m\(^{-2}\). At baseline, 52.3% (n = 278) were obese (BMI > 30 kg m\(^{-2}\)) and 47.7% (n = 254) overweight (BMI 27–30 kg m\(^{-2}\)). Mean (SD) fasting glucose was 5.52 (0.53) mmol L\(^{-1}\), and mean (SD) plasma HDL, LDL and triglyceride levels were 1.47 (0.36), 3.63 (0.95) and 1.49 (1.06) mmol L\(^{-1}\), respectively.

Primary outcome: weight reduction

Amongst all 532 participants included in the analysis (linear mixed-effect model), HBCSS improved weight loss compared with CBT counselling, SHG counselling or control. The combined interventions, that is any type of group counselling or control combined with HBCSS, had a significant incremental effect on weight loss at 12 and 24 months (Fig. 3 and Tables S4–S6).

From baseline to 12 months, the mean reduction in body weight was significantly greater (P < 0.001) in the CBT counselling and HBCSS arm (–4.1%, 95% CI –5.4 to –2.8, P < 0.001) compared with the control arm (–0.5%, 95% CI –1.9 to 0.9, P = 0.500). At 24 months, the difference remained significant: –3.4% (95% CI –4.4 to –2.4, P < 0.001) versus –0.4% (95% CI –1.5 to 0.6, P = 0.380).

Effect of baseline weight on weight reduction

Weight reduction was more marked amongst obese subjects (BMI 30–35 kg m\(^{-2}\)) compared with overweight subjects (BMI 27–30 kg m\(^{-2}\)) in all treatment arms (Fig. 3 and Table S4). Amongst completers receiving both CBT counselling and HBCSS, the mean weight reduction was significantly greater in obese subjects (–4.6%, 95% CI –6.9 to –2.3, P < 0.001) compared with overweight subjects (–2.1%, 95% CI –3.8 to –0.5, P = 0.018).
Success of weight loss

Health behaviour change support system in addition to group counselling (CBT counselling or SHG counselling) considerably enhanced the success of weight reduction recorded at 24 months. Indeed, a success rate of weight loss of ≥10% was increased almost 3-fold in the intervention arms with HBCSS. Weight reduction of ≥10% was recorded in 8.6–11.3% of participants receiving HBCSS (with or without group counselling) and in 3.6–4.7% of those not receiving HBCSS (group counselling or usual care alone).

Weight reduction of ≥5% is considered clinically significant. Study subjects who received both CBT-based group counselling and HBCSS were the most successful in achieving this goal: 32.3% of these subjects reduced weight by at least 5% after 24 months compared with between 14.1% and 18.6% in the other groups (Fig. 4). Thus, the failure rate was only 24.2% in the CBT counselling + HBCSS arm compared with 38.6% to 55.9% in the other arms.

Single methods of lifestyle change

It is noteworthy that HBCSS alone was also associated with weight loss at 12 months (mean decrease 1.3%, 95% CI 2.7 to 0.0, \( P = 0.048 \)) and no weight regain at 24 months both in the overall population and in completers. By contrast, SHG counselling alone or control (no group counselling) had no significant effect on body weight.

Components of the metabolic syndrome

Changes in waist circumference were similar to those of body weight, except that both CBT counselling and SHG counselling alone reduced waist
Table 1  Baseline characteristics of the study participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>CBT counselling</th>
<th>CBT counselling + HBCSS</th>
<th>SHG counselling</th>
<th>SHG counselling + HBCSS</th>
<th>Control</th>
<th>Control + HBCSS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>46.4 ± 9.7</td>
<td>44.8 ± 9.6</td>
<td>44.4 ± 10.2</td>
<td>46.4 ± 10.5</td>
<td>46.5 ± 10.2</td>
<td>47.0 ± 9.4</td>
<td>46.0 ± 9.9</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Males</td>
<td>43 (50.6)</td>
<td>44 (50.0)</td>
<td>45 (51.7)</td>
<td>47 (51.1)</td>
<td>43 (48.3)</td>
<td>48 (52.7)</td>
<td>271 (50.9)</td>
</tr>
<tr>
<td>Females</td>
<td>42 (49.4)</td>
<td>44 (50.0)</td>
<td>42 (48.3)</td>
<td>45 (48.9)</td>
<td>46 (51.7)</td>
<td>43 (47.3)</td>
<td>262 (49.3)</td>
</tr>
<tr>
<td>Antihypertensives, n (%)</td>
<td>17 (20.0)</td>
<td>14 (15.9)</td>
<td>23 (26.4)</td>
<td>23 (25.0)</td>
<td>23 (25.8)</td>
<td>20 (22.0)</td>
<td>120 (22.6)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>3 (3.5)</td>
<td>2 (2.3)</td>
<td>2 (2.3)</td>
<td>1 (1.1)</td>
<td>2 (2.3)</td>
<td>3 (3.3)</td>
<td>13 (2.4)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>90.0 ± 12.1</td>
<td>89.5 ± 10.1</td>
<td>90.5 ± 11.6</td>
<td>89.7 ± 11.7</td>
<td>88.6 ± 11.1</td>
<td>88.7 ± 10.9</td>
<td>89.5 ± 11.3</td>
</tr>
<tr>
<td>BMI (kg m^{-2})</td>
<td>30.5 ± 1.9</td>
<td>30.3 ± 2.1</td>
<td>30.7 ± 2.2</td>
<td>30.4 ± 2.1</td>
<td>30.5 ± 2.3</td>
<td>30.3 ± 2.0</td>
<td>30.5 ± 2.1</td>
</tr>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic (mmHg)</td>
<td>134.0 ± 17.1</td>
<td>127.0 ± 14.3</td>
<td>125.8 ± 16.2</td>
<td>133.1 ± 17.6</td>
<td>132.2 ± 16.0</td>
<td>129.9 ± 14.6</td>
<td>130.3 ± 16.2</td>
</tr>
<tr>
<td>Diastolic (mmHg)</td>
<td>85.5 ± 10.5</td>
<td>81.6 ± 9.4</td>
<td>79.9 ± 9.2</td>
<td>83.5 ± 10.8</td>
<td>82.9 ± 11.1</td>
<td>82.2 ± 9.9</td>
<td>82.6 ± 10.2</td>
</tr>
<tr>
<td>Glucose (mmol L^{-1})</td>
<td>5.5 ± 0.5</td>
<td>5.5 ± 0.5</td>
<td>5.5 ± 0.5</td>
<td>5.6 ± 0.8</td>
<td>5.6 ± 0.5</td>
<td>5.5 ± 0.5</td>
<td>5.5 ± 0.5</td>
</tr>
<tr>
<td>HDL-chol (mmol L^{-1})</td>
<td>1.4 ± 0.3</td>
<td>1.4 ± 0.4</td>
<td>1.4 ± 0.3</td>
<td>1.5 ± 0.4</td>
<td>1.5 ± 0.3</td>
<td>1.5 ± 0.4</td>
<td>1.5 ± 0.4</td>
</tr>
<tr>
<td>LDL-chol (mmol L^{-1})</td>
<td>3.6 ± 0.9</td>
<td>3.6 ± 1.0</td>
<td>3.6 ± 0.9</td>
<td>3.8 ± 1.0</td>
<td>3.6 ± 1.0</td>
<td>3.5 ± 1.0</td>
<td>3.6 ± 1.0</td>
</tr>
<tr>
<td>Triglycerides (mmol L^{-1})</td>
<td>1.5 ± 0.9</td>
<td>1.5 ± 1.0</td>
<td>1.6 ± 1.6</td>
<td>1.3 ± 0.5</td>
<td>1.5 ± 0.6</td>
<td>1.7 ± 1.4</td>
<td>1.5 ± 1.1</td>
</tr>
</tbody>
</table>

The results are presented as means ± SD, unless otherwise stated. CBT, cognitive behavioural therapy; HBCSS, health behaviour change support system; SHG, self-help guidance; HDL-chol, high-density lipoprotein cholesterol; LDL-chol, low-density lipoprotein cholesterol. The reference values are as follows: plasma glucose, 4.2–6.0 mmol L^{-1}; HDL cholesterol: women, >1.2 mmol L^{-1}, men, >1.0 mmol L^{-1}; LDL cholesterol, <3 mmol L^{-1}; triglycerides, <1.7 mmol L^{-1}.
circumference at 24 months. Systolic blood pressure was reduced at 24 months in all study arms except the SHG counselling arm (Table S7). Only CBT counselling resulted in a statistically significant lower blood glucose with as well as a trend towards a change in HDL cholesterol. At the same time, there was no statistically significant change in LDL cholesterol (data not shown), although the decreasing trend was similar in most arms. There was a decreasing trend in triglyceride level during 24 months of study, but a statistically significant change was only observed with HBCSS alone (see Table S7).

Discussion
In this randomized long-term lifestyle change trial, an Internet-based HBCSS was effective in
improving weight loss and reduction in waist circumference for up to 2 years. Interventions using the HBCSS had significantly higher success rates regardless of the type of group counselling (CBT or SHG), compared to counselling alone. In addition, the success rate was also high in participants in the control group who received HBCSS (but no face-to-face counselling).

In the intervention group receiving CBT-based group counselling together with HBCSS, about 33% achieved weight loss of 5% or more at 24 months compared with 14–16% in the intervention arms without HBCSS (Fig. 4). A similar difference was observed in the number of participants achieving weight loss of 10% or more between these intervention arms. Furthermore, only 24% of the participants in the intervention group receiving CBT-based group counselling together with HBCSS gained weight by 24 months, compared with 39–56% in the intervention arms without HBCSS.

Moreover, HBCSS alone was effective in reducing body weight and waist circumference (Table S7) for up to 2 years. This finding shows that the HBCSS is also useful as a stand-alone counselling method. It is important in clinical practice as face-to-face counselling cannot be provided for all obese or overweight subjects due to the increasing prevalence of obesity and limited healthcare resources even in affluent countries.

It was shown that the CBT counselling model was less effective without additional HBCSS, with significant weight regain by 2 years [8]. This is consistent with the findings from some short-term studies [22]. In a previous study, Web-based counselling (daily reminders and weekly tasks) with telephone contact improved weight loss at 12 weeks compared with general weight loss counselling [23] and an Internet-delivered programme improved weight loss in subjects who were otherwise not expected to lose weight [24]. However, results from previous weight loss or lifestyle change intervention trials often lack a control group [10, 25, 26]. Our study included one arm without face-to-face counselling as a control group, receiving only written material at the screening visit. In the first model (CBT counselling), participants received eight group sessions with CBT-based methods led by two clinical nutritionists. The aim was to change health behaviour, especially eating behaviour. Previously, a meta-analysis had shown that CBT when combined with a diet or exercise intervention increases weight loss compared with diet or exercise alone [27]. In the second model (SHG counselling), the aim of the two group sessions led by a nurse was to improve self-efficacy. The HBCSS programme was based on PSD but also included person-centred features, such as goal-setting, mindfulness practices and self-monitoring of eating behaviour, elements that have previously been shown to be effective in achieving weight loss and maintaining stable weight [8, 28]. Further analyses are needed to reveal the most important features that contribute to long-term weight change.

Our aim was to develop effective but low-cost methods that could be used for lifestyle change counselling in public healthcare services. Access to nutritionists is limited, especially in smaller healthcare units. Therefore, short-term education of nurses who participate in lifestyle change counselling might be a practical solution. An HBCSS delivered via the Internet could increase the accessibility of counselling for all citizens, especially when offered free of charge. However, an HBCSS in

![Fig. 4 Weight loss success at 24 months according to the counselling method and the health behaviour change support system (HBCSS) amongst completers (70% of subjects completed per protocol, 24-month follow-up). Green bar represents weight loss of ≥10%, blue bar represents weight loss of 5–9.99%, white bar represents weight loss of 0–4.99%, and red bar represents weight gain. In the intervention arm receiving cognitive behavioural therapy (CBT) and HBCSS, 75.8% of subjects succeeded in losing weight and only 24.2% gained weight. In the control arm, 44.1% lost weight, whilst 55.9% gained weight (P < 0.001 compared with CBT and HBCSS).]
addition to patients’ motivation through self-help guidance delivered by nurses resulted in a smaller weight reduction than the combination of HBCSS with CBT-based counselling by nutritionists. Even so, counselling may be delivered to a larger segment of the population and thus may be more beneficial for public health. We hypothesized a priori that even short-term face-to-face counselling (two sessions) would enhance the effect of the HBCSS and reduce the dropout rate. Unfortunately, two group sessions focusing on motivation did not produce any additional weight reduction compared with stand-alone HBCSS.

The weight reduction seen here was smaller than in some recent trials [29]. Although highly intensive counselling [16, 30] is more efficient, it is not feasible in common practice due to a lack of resources. Therefore, the finding that weight loss was maintained after the HBCSS is encouraging in terms of developing weight loss counselling/management in routine practice. Our study population was less obese than in most previous weight loss studies, in which the mean BMI was >35 or >40 kg m$^{-2}$. Half of our study subjects were overweight (BMI 27–30 kg m$^{-2}$), whilst the others had class 1 obesity (BMI 30–35 kg m$^{-2}$). In the present study, mean body weight was 89.5 kg and mean BMI was 30.5 kg m$^{-2}$. An effect of baseline body weight on weight reduction was also observed in our study: weight reduction was increased 2-fold in obese subjects compared with overweight subjects (Fig. 3 and Table S4).

Even a small reduction in weight is important for health, as demonstrated in previous diabetes prevention studies [31, 32]. Weight reduction is associated with a decrease in waist circumference, which is a major risk factor for and the main criterion in the IDF definition of metabolic syndrome. The HCBSS used in this study was also effective in decreasing waist circumference. This finding is in accordance with a recent meta-analysis showing that Internet-based interventions improve the decrease in waist circumference compared with minimal or no support [30]. The other components of metabolic syndrome were slightly improved by the HBCSS, although the changes did not reach statistical significance.

Software-based information systems and especially smartphone apps suffer from a decrease in participation rate with time [33, 34]. This was not the case in the present trial as shown by the fact that the dropout rate was lowest amongst participants who received the HBCSS alone. Our system sent a mobile text message reminder every Monday, and if the recipient did not use the HBCSS, a reminder was sent automatically 2 days later.

Some limitations of the study should be noted. First, blinding was not possible. Secondly, the reasons for discontinuing are not known for all noncompleters. In addition, more weight could have been lost if highly intensive counselling had been used. However, the aim of this trial was to use counselling methods that could be implemented in routine practice or for the general population.

Conclusions

An HBCSS with PSD features and CBT-based methods had a major impact on weight loss as well as on waist circumference, the main criterion that defines the metabolic syndrome. It also improved other components of metabolic syndrome, even though the changes were small. In conclusion, this randomized trial showed that an HBCSS based on PSD and CBT methods can facilitate weight loss, and weight loss maintenance, when delivered in combination with group counselling (mainly CBT-based) and also, to some extent, without face-to-face counselling. The latter may prove to be important in implementing new cost-effective means to prevent obesity and the development of cardiovascular disease risk factors.

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Conflict of interest statement

There were no conflict of interests to declare.

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**Supporting Information**

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Table S1.** Description of CBT-based group counselling model.

**Table S2.** Internet-based health behaviour change support system counselling: themes of weekly articles and exercises.

**Table S3.** Characteristics of completers and drop-outs.

**Table S4.** Change in body weight (kg) after 12 and 24 months of follow-up.

**Table S5.** Change in body weight (kg) after 12 and 24 months of follow-up.

**Table S6.** Body weight change of study completers ($n = 375$).

**Table S7.** Changes in the components of metabolic syndrome (95% CI) after 24 months.

**Appendix S1.** Prevention of metabolic syndrome by lifestyle counseling – development of new counseling methods applicable to basic healthcare.