

Effectiveness of a web-based real-life weight management program: Study design, methods, and participants' baseline characteristics

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ABSTRACT

Obesity is an important public health concern with limited effective treatment options. Internet-based technologies offer a cost-effective means to treat obesity. However, most of the online programs have been of short duration, have focused on a limited number of treatment modalities, and have not utilized the potential of coaching as part of the intervention. In this paper, we present the design, methods and participants' baseline characteristics in a real-life internet-based weight management program. Healthy Weight Coaching (HWC) is a 12-month web-based intervention for the management of obesity. The program is based on the Acceptance and Commitment Therapy and includes themes important for weight loss, including diet, physical activity, psychological factors, and sleep. In addition to the automated, interactive program, a personal coach is allocated to each participant. The participants are nationally enrolled through referrals from primary care, occupational health, hospitals, and private health care units. Adult individuals with BMI ≥ 25 kg/m² without severe complications are included. On a weekly basis, participants submit their weight logs, training sessions, and lifestyle targets to the internet portal and are scheduled to have online discussions with their coaches 26 times over the course of a year. Questionnaires on lifestyle, diet, physical activity, psychological factors, sleep, and quality of life are completed at baseline, 3, 6, 9, and 12 months, and thereafter yearly until 5 years. Additionally, log data on the use of the service and discussions with the coach are collected. The main outcome is weight change from baseline to 12 months. Recruitment to the HWC is ongoing. Baseline data of the participants recruited between Oct 2016 and Mar 2019 (n = 1189) are provided. This research will bring insight into how internet-based technologies can be implemented in the virtual management of obesity.

Trial registration: The trial is registered at clinicaltrials.gov (Clinical Trials Identifier NCT04019249).

1. Introduction

Obesity is a global challenge associated with extensive health problems from osteoarthritis to cardiovascular diseases and mood-related disorders [1]. Being highly prevalent and multifactorial in nature, obesity is likely one of the most difficult public health concerns. Treating obesity can be effective and, amongst others, has shown its value in the prevention of diabetes [2]. The modern treatment of obesity is based on behavioural changes that modify one's daily lifestyle.

Importantly, the so-called 'third-wave' cognitive-behavioural therapies (CBTs), including the Acceptance and Commitment Therapy (ACT), have emerged in the field of obesity management. These therapies support individuals in improving psychological flexibility, which is the key for motivation in changing health behaviour [3]. The main processes of ACT include clarification of one's values, commitment to act based on these values, being in contact with the present moment (mindfulness), being aware of one's thoughts and feelings without attaching to them, separating oneself from thoughts (defusion), and ac-

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ceptance [4]. The use of ACT has been shown to be efficacious in promoting healthy behavioural patterns in weight loss interventions [5–7].

The traditional modes of delivering behaviour change techniques are costly, as face-to-face treatment requires excessive resources from the health care system. Internet-based technologies have the potential to tackle various health problems in a cost-effective manner [8]. Of interest are internet-based interventions aiming at health behaviour modification; they may be efficient in weight loss, especially when combined with face-to-face treatment [9]. The efficacy is further improved when the intervention includes feedback [10], interaction between participants and health care professionals [10],

[13], and tools for goal-setting and self-monitoring [13]. However, little is known about the utilization and effectiveness of comprehensive online weight loss programs where the third-wave CBT methods are applied with the use of novel internet-based interactive technologies [10]. Moreover, although the treatment of obesity is multidisciplinary, only a few programs have incorporated all of the necessary elements, including diet, physical activity, psychological factors, coping with stress, and sleep. Furthermore, most programs have only short intervention or follow-up periods and do not provide real-time support for the participants [12]. Finally, the programs have rarely been integrated into the real-life treatment of participants.

In this paper, we present the design, methods, and participants' baseline characteristics in an ongoing internet-based weight management program, Healthy Weight Coaching (HWC). We also evaluate factors predicting long-term success of HWC in the treatment of obesity, the cost-effectiveness of the program, and its effects on overall health and quality of life.

2. Methods

2.1. Health Village

Health Village (Terveyskyla.fi), a national concept coordinated by the Helsinki University Hospital (HUU), is a digital interactive secured portal delivering health-related information and services. The portal has been developed jointly with five university hospital districts and several patient associations in Finland. Health Village provides information and support for citizens, care for patients, and tools for professionals. The service comprises various themed virtual houses. By the end of 2019, more than 32 virtual houses and services were issued, covering more than 80 patient groups. Importantly, being web-based, the platform makes health care services available to all Finns regardless of their place of residence and income level, thus improving treatment equality of citizens. Digital services can be useful when monitoring the management of various chronic diseases. These services complement the traditional treatment pathways.

2.2. HealthyWeightHub.fi

HealthyWeightHub.fi, launched in Oct 2016, was the first somatic virtual house in the Health Village. HealthyWeightHub.fi was developed in collaboration with a number of multiprofessional workgroups in the Abdominal Center of HUU and was based on the current care practice guidelines, recent literature on the treatment of obesity, and specific needs of patients arising from structured interviews. The aims of HealthyWeightHub.fi are to be accessible, affordable, and cost-effective and to provide treatment equality and improved long-term weight maintenance. Moreover, with the use of HealthyWeightHub.fi, we hope to improve adherence, decrease co-morbidities, and improve the quality of life in people with obesity. HealthyWeightHub.fi includes both conservative and surgical treatment arms. In this paper, we describe the elements of the conservative arm.

HealthyWeightHub.fi has a public domain, the digital treatment program available only for those referred to the program (Healthy Weight Coaching, HWC), and the Health Village PRO, a service designed for professionals in the social welfare and health care sectors (Table 1). The public domain includes the ABC of weight management, which is an information package of obesity treatment, long-term weight management, and obesity-related complications. In addition, on the weight management self-help site, a visitor can take part in a 6-week test period, assess their current health status, test new habits, and boost their self-efficacy. Instead of only changing the eating and physical activity habits, the program encourages the participants to tie link the lifestyle changes to psychological well-being.

The one-year treatment program, HWC, consists of automated weekly training sessions with multi-component modules covering eating behaviour, physical activity, sleep, and stress (Fig. 1), as well as individually tailored one-to-one web-based discussions with the personal coach allocated to each participant. The coaches are medical professionals (nurses, nutritionists, physiotherapists, or psychologists). The participants are enrolled in the program through referrals from licensed physicians at health care centres, occupational health units, hospitals, and private health care units. The service is nationally available for all Finnish citizens, and the cost is covered by the patient's municipality of residence.

During the program a number of weight management-related factors, including diet, physical activity, sleep, psychology, coping with stress, and general health, are covered. The program is based on the framework of ACT, the aim of which is to increase mindfulness and

Table 1
HealthyWeightHub.fi service.

Public domain		Digital treatment program	Health Village PRO
	6-week free trial	12-months Healthy Weight Coaching	Professional service
ABC on obesity and weight loss	30 training sessions	Based on referral Virtual coach	Online courses Digital tools Guides
Tests	Physical activity	200 training sessions	
Videos	Nutrition	60 videos and audios	Expert search tool
News	Mindfulness Healthy lifestyle	Health check-up Research	

PRO, professional.

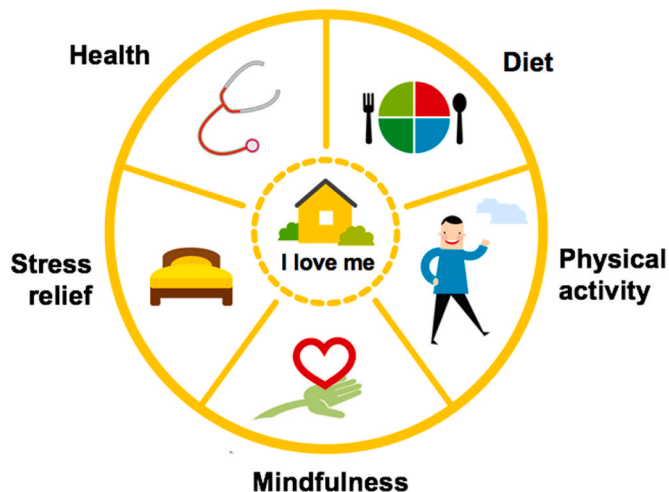


Fig. 1. Elements of healthy weight coaching.

the psychological flexibility needed for a successful lifestyle change [4]. The HWC intervention (Table 2) includes a weekly session with 5–10 different exercises. Amongst the 200 training sessions, around 60 are on video or audio, to widen the range of treatment modalities and to increase motivation.

The Health Village PRO domain supplements social welfare and health care professionals by offering them online training courses and practical guides on how to initiate the treatment of obesity and help the patients with lifestyle change.

2.3. Study design

Data collected during the ongoing HWC intervention are used to evaluate the effects of the program. Data on weight, diet, physical activity, and mood are collected online over the 12-month program. The participants are asked to provide their weight data at least weekly during the training sessions. In addition, participants complete questionnaires on lifestyle, diet, physical activity, psychological factors, sleep, and quality of life at baseline, 3, 6, 9, and 12 months, and yearly thereafter until 5 years. Data on age, sex, and municipality are derived from a national register since the registered participants log into the program using a secured national electronic personal identification system. The study protocol was approved by the Ethics Committee of the Helsinki and Uusimaa Hospital District (HUS DNo 327/13/03/00/2015, GDPR update HUS/587/2019). The study was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki. Informed consent was obtained from all individuals included in the study. The database for the current study was created on 12 March 2019, and it included data from all program participants since the initiation of the HWC in October 2016.

2.4. Study population

To be included in the HWC, age ≥18 years, Body Mass Index (BMI) ≥25 kg/m², access to a computer or a smartphone with an internet connection, and willingness to participate in the digital treatment program are required. Referrals for individuals with diagnosed severe illness requiring assessment from the specialty care obesity centre and those currently pregnant are not accepted to the HWC. The number of participants enrolled in the program between October 2016 and March 2019 was 1688; of these participants, 1453 (83%) consented to their data being used in the study. Following a two-week test period, 1189 of the consenting participants were continuously active in the

Table 2
Content of the Healthy Weight Coaching intervention.

Content of the coaching program	Key points
Values	Recognition and practices What are the most important values for me? Am I living according to my values? How do I live my life according my values?
Mind	Recognition and practices (e.g. observing thoughts, accepting feelings)
Mindfulness	Recognition and practices (e.g. contact with the present moment and acting mindfully, exercising mindful eating)
Mental well-being	Information and practices on mental well-being
Weight management	Information and practices on weight management (e.g. appetite control, managing eating frequency, portion size, buying food, making healthy food, diet planning)
Healthy diet	Practices involved in eating behaviour and a healthy diet (e.g. plate model, vegetables and fruits, fibre, protein, drinks, sweets)
Exercise	Information and practices about health-related physical activity
Stress	Information and practices about stress and life management
Sleep	Information and practices on sleep hygiene, environment, relaxation

program, thus forming the baseline population of the current study. The power calculations reveal that a sample size of 21 is required to receive a similar weight loss as in Ref. [9] (mean of 4.1%, SD 6.1), with a power of 80% and a level of significance of 5% (two sided).

2.5. Measurements

The primary outcome is the percentage of weight change from baseline to 12 months. The effectiveness of the intervention will be assessed by focusing on the amount of weight loss, inter-individual variability in the weight loss response, as well as possible variables contributing to weight loss success. Comparison will be made by comparing the change to the baseline. The results will also be compared to those obtained in the treatment arm in intervention studies with parallel groups. The secondary outcomes are categorical weight loss, sleep, health-related quality of life, psychological flexibility, eating behaviour, cost-effectiveness and use of health services. A list of all variables collected in the study is shown in Table 3.

2.5.1. Anthropometric measurements

Upon entering the program, the participants report their weight, height, and waist circumference on the internet-based questionnaires. Based on the self-reported weight and height, we calculated the BMI as weight in kilograms divided by height in metres squared (kg/m²). During the intervention participants may daily record their weight data into the program, but are asked to do so at least once a week as part of the self-monitoring of weight. Waist circumference is self-measured and reported every three months.

2.5.2. Psychological flexibility

Psychological flexibility is assessed using the Acceptance and Action Questionnaire for Weight [14] (AAQW). The AAQW is a 22-item, Likert-type scale that measures acceptance of weight-related thoughts and feelings with valued actions.

2.5.3. Quality of life

The RAND-36 questionnaire [15] is used as an indicator of the health-related quality of life. It contains eight health concepts: physical functioning, role limitations caused by physical health problems,

Table 3
Variables collected in the study.

Socio-demographic status
Age, sex, marital status
Education, current work status
Anthropometric measurements
Weight, height, waist
Health
Subjective health, quality of life
Diseases
Medication
Pain
Use of health services
Weight and weight loss history
Weight history
Weight development
Psychological variables
Motivation
Psychological flexibility
Body image
Loneliness
Lifestyle
Eating behaviour
Physical activity
Sleep
Smoking
Alcohol consumption

role limitations caused by emotional problems, energy, emotional well-being, social functioning, pain, and general health perceptions.

2.5.4. Eating behaviour

Eating behaviour is assessed by the Three Factor Eating Questionnaire (TFEQ). The TFEQ is a validated measure of the three eating-related constructs: dietary restraint, disinhibition, and susceptibility to hunger [16]. Dietary restraint refers to the tendency to consciously restrict food intake as a means of controlling weight, disinhibition refers to a tendency to overeat in response to negative emotional states or the presence of highly palatable foods, and the hunger subscale assesses susceptibility to feelings of hunger.

2.5.5. Food and nutrient intake

We first piloted an electronic food-diary and after 2019, used a of the mobile phone application MealLogger [17] to guide the patient's food habits and allowed participants to take a time stamped photograph of their meal, include a detailed description of the meal content, and identify which meal they were eating (i.e., breakfast, lunch, dinner, beverage, or snack). Every three months throughout the study, the participants also complete and self-assess the three-day food diaries.

2.5.6. Sleep

The sleep questionnaire was modified based on the Basic Nordic Sleep Questionnaire [18] and a questionnaire used in the National FINRISK Study [19]. In the questionnaire, participants report their sleep duration, sleep chronotype, tiredness, sleep apnea, and use of sleep medication.

2.5.7. Other lifestyle-related measures

Questionnaires on physical activity, use of alcohol, use of tobacco products, and use of health services were modified from the questionnaires used in the National FINRISK Study [19]. This allows us to compare the results with those in the general Finnish population.

Questionnaire data are based on self-reported information collected through electronic forms. The study included a wide range of psychological, physiological, health, and lifestyle measurements.

2.6. Statistical analyses

Basic characteristics are reported as frequencies (%) for categorical data and mean ± standard deviation (range) for continuous data. The statistical elements for predicting the long-term success factors as well as overall health and quality of life will begin with the creation of classes through a hierarchical system prediction model. Comparisons between different classes will be tested using the Mann-Whitney method test (two groups) or one-way analysis of variance test (more than two groups) for continuous variables and chi-squared test for categorical variables. The cost-effectiveness of the program will evaluate the cost-benefit by measuring the potential in terms of capacity released. The analysis will include direct costs: salaries of coaches, and the cost of ICT development and maintenance compared to outpatient treatment, the patient's fees and travel expenses.

3. Results

Of the 1189 participants, 81% (n = 963) were women. Baseline characteristics are shown in Table 4. The participants had a mean age of 48.6 years and a mean BMI of 40.6 kg/m².

Table 4

Baseline characteristics of participants. Values are means ± standard deviation (range).

Baseline characteristic	Total (N = 1189) Mean S.D (range)	Women (N = 963) Mean S.D (range)	Men (N = 226) Mean S.D (range)
Age [years]	48.6 ± 11.4 (19–78)	48.4 ± 11.2 (19–78)	49.6 ± 12.1 (22–73)
Waist [cm]	120.6 ± 15.3 (83–180)	118.1 ± 14.0 (147–184)	133.8 ± 15.0 (95–176)
Height [cm]	168.7 ± 8.4 (147–198)	166.0 ± 6.1 (147–184)	180.3 ± 7.1 (158–198)
Weight [kg]	115.8 ± 23.8 (60.2–284.0)	111.3 ± 20.4 (60.2–193.0)	135.2 ± 27.5 (83.0–284.0)
BMI [kg/m ²]	40.6 ± 7.1 (26.3–79)	40.4 ± 7.0 (26.3–72.5)	41.5 ± 7.8 (27.2–78.7)

4. Discussion

This article introduces a research protocol for a real-life intervention for patients with obesity who are in the web-based weight management program, the HWC, within the HealthyWeightHub.fi which is both an information and a self-help site and, through the HWC, a true digital treatment portal. The need for a low-cost and easily accessible treatment mode for obesity was rationalized by the limited resources and the low availability of face-to-face treatment for obesity country-wide. The HWC was created to provide people with obesity the best possible care regardless of financial status or place of residence and to complement the health care units with an affordable, standardized, and long-term treatment option.

In general, the results measuring impacts of various web-based weight loss programs compared with traditional programs have been conflicting. A systematic review of 20 systematic reviews [11] concluded that the effect sizes of the included studies were small, and thus, the clinical relevance of the methods is unclear. Similarly, Kodama et al. [20] noted significant heterogeneity regarding duration, setting, participants, and programs used. According to Kodama et al. the effect of web-based weight loss programs was reduced with longer duration of the program, being the greatest within the first six months and insignificant after 12 months. However, in a systematic review including 127 articles and 84 separate studies, Hutchesson et al. [21] noted that while the web-based interventions are more effective in the short term, this also applies to the traditional weight loss programs. It is unclear which features in a program predict the outcome. Weinstein et al. [22] observed that while weight management via a web-based intervention might be as effective as a face-to-face intervention, it might be less appealing to the patients. On the other hand, 24/7 accessibility to the web-based programs, the ability to communicate more anonymously, and the feeling of self-control may result in a more engaging and empowering mode of treatment than experienced in the traditional, less frequent face-to-face treatment modes [10].

The modern treatment of obesity takes a holistic approach, and in the HWC program, the ACT, coping with stress, and significance of well-being are central in supplementing the traditional forms of treatment, which are based on only eating behaviour and physical activity. In the philosophy of the HWC, empowerment and coaching instead of advising or instructing, are considered the keys to success. Thus, the ACT, a so-called 'new wave' of cognitive behavioural therapy, supports flexible decision-making in everyday life that, in contrast to rigid rules, has a long-lasting effect [11]. Inner motivation is an important factor when changing one's lifestyle. Thus, we decided to apply the ACT framework, which is based on strengthening one's inner motivation through, for example, psychological flexibility [23]. The HWC uses the six key technical components that have been shown to significantly decrease weight in guided internet-delivered weight loss programs: self-monitoring, professional feedback and communication, goal-setting, group support, use of a structured program, and use of

an individually tailored program (in HWC through personal coaching) [24]. In general, tailored programs incorporated into these tools have lower attrition rates than generic programs. Subjects have also described tailored programs as more interesting [22].

This study has a number of strengths and limitations. Among the strengths is the use of a large prospective dataset collected in a real-life weight management program. Study programs are rarely integrated into real-life treatment of the patients. A pragmatic trial within a clinical practice will improve both the generalizability of the trial results and the recruitment rates, and thus, the feasibility of the trial [25]. The result may advance understanding of how to design a holistic web-based weight loss program. It may also enable identification of patients who will benefit the most from digitalized treatment modes. Our calculation of the cost-effectiveness is an additional strength.

Limitations include the self-reported questionnaires and self-measured weight. The lack of a control group is explained by the real-life study design. Despite these limitations, the study will be amongst the first ones in a clinical care setting to use an internet-based holistic weight loss program encompassing a wide spectrum of behaviour and lifestyle approaches and a personal coach.

In conclusion, the HWC is a multi-component program designed to help adult patients with overweight or obesity make long-term behavioural changes in order to promote weight loss and to improve participants' health and quality of life. This study will bring insights into how new technologies can be directly implemented in virtual health care systems to improve treatment of obesity and patient care.

Authors contributions

LS and KHP devised the concept of the study and its design. LS and KHP conducted the trial, and RK supervised its progression. LS drafted the manuscript. All authors contributed to revising the paper and approved the final manuscript. KHP is the principal investigator and the guarantor of the study.

CRedit authorship contribution statement

A.J. Ahola: Writing - review & editing. **S. Kupila:** Writing - review & editing. **R. Korpela:** Supervision, Writing - review & editing.

Declaration of competing interest

The authors declare no conflicts of interests.
Alcohol consumption.

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