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Theory-based digital intervention to promote weight loss and weight loss maintenance (Choosing Health): protocol for a randomised controlled trial

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ABSTRACT

Introduction Digital behavioural weight loss interventions have the potential to improve public health; however, these interventions are often not adequately tailored to the needs of the participants. This is the protocol for a trial that aims to determine the effectiveness and cost-effectiveness of the *Choosing Health* programme as a means to promote weight loss and weight loss maintenance among overweight/obese adults.

Methods and analysis The proposed study is a two-group randomised controlled trial with a nested interrupted time series (ITS) within-person design. Participants (n=285) will be randomly assigned to either the *Choosing Health* digital intervention or a control group. For intervention participants, ecological momentary assessment will be used to identify behavioural determinants for each individual in order to tailor evidence-based behaviour change techniques and intervention content.

Control group participants will receive non-tailored weight loss advice via e-book and generic emails. The primary outcome is the mean difference in weight loss between groups at 6 months controlled for baseline. Secondary outcomes include blood pressure and percentage of body fat; self-reported measures of physical activity, sitting time, quality of life, cost and theory-derived correlates of weight loss. Secondary outcomes will be measured at baseline, 3, 6 and 12 months. The primary outcome for ITS will be daily weight loss plan adherence. Data will be analysed using regression and time series analyses.

Ethics and dissemination Ethics approval was granted by Faculty of Psychology, SWPS University of Social Sciences and Humanities, Wroclaw, Poland, approval number 03/P/12/2019. The project results will be disseminated through structured strategy implemented in collaboration with the Ministry of Health.

Trial registration details This trial was registered with www.clinicaltrials.gov; registration number NCT04291482.

Strengths and limitations of this study

- This is the first weight loss intervention applying individualised digital tailoring based on individuals' psychological determinants of behaviour measured over time prior to intervention delivery.
- The *Choosing Health* trial will offer insight into factors associated with success in making sustained changes to weight, and secondary outcomes, such as diet and physical activity.
- Between-person and within-person level analyses will provide insight on group differences and personal trajectories of weight change.
- The materials developed for the intervention and the algorithms used to tailor can be applied in future scalable behaviour change interventions.
- The key limitation is that the intervention will not be dynamically tailored in real time but tailored materials will be based on the initial 3 months of ecological momentary assessment.

INTRODUCTION

Worldwide obesity has nearly tripled since 1975, with 39% of the world's adult population classified as overweight and 13% classified as obese.[1] Obesity has a significant impact on individuals' long-term health. It is associated with chronic diseases and health conditions such as type 2 diabetes, hypertension, cardiovascular disease and cancer.[2] Development and implementation of public health interventions targeting clinically significant weight loss has, therefore, been identified as a public health priority. Weight loss over 5% of initial body weight is considered clinically significant as it leads to adaptive health outcomes such as reduced chronic disease risk.[3] However, the long-term effects of existing weight loss interventions are often modest and heterogeneous.[4]

Weight regain following weight loss is common as individuals often struggle to

successfully maintain the new lower weight,[5] after 3 to 5 years the majority of participants in weight loss interventions fully regains or even exceeds their initial weight.[6] Considering current levels of overweight and obesity, there is an urgent need to provide programmes that support individuals in initial weight loss and weight loss maintenance, defined as sustaining significant intentional weight loss accomplished alone or as a result of treatment.[7]

Previous studies assessing predictors of weight loss and weight loss maintenance have employed between-participant designs[8] looking mainly at between-group comparisons of average effects. However, emerging research suggests that long-term individual weight management is dependent on intra-individual changes in psychosocial factors, behaviours and behavioural outcomes[9] and changes in these variables are not sufficiently explored by between-participant designs.[10] Previous studies that gathered daily data on cognitions have typically not accounted for within-person assessment of weight loss predictors (eg, continuously changing levels of motivation and stress) or outcomes (eg, time-based specific improvements in activity, healthy eating). Instead, outcomes have commonly been presented in the form of combined group scores[11 12] providing limited information on individual weight loss trajectories. Psychosocial factors that often influence ongoing weight management (eg, stress, energy level) are often unstable and tend to fluctuate within individuals[13] and they should be explored as they change across time.

Within-person assessments of psychosocial factors underlying health-related behaviours are becoming more frequently used in behavioural science through N-of-1 designs.[14] The main features of N-of-1 designs include the possibility to examine within-person variability in social cognition variables/constructs and outcomes, testing theory predictions within individuals and assessing effects of behaviour change techniques within individuals.[15 16] Applying within-person methods is useful to avoid ecological fallacy, that is, the interpretation of statistical data that occurs when inferences about individuals are based on inferences about the group to which they belong. N-of-1 studies employ ecological momentary assessment (EMA) in order to repeatedly measure changes in psychosocial factors, behaviours and outcomes over time or in response to interventions.[17] To date, only one study has examined within-person variability of effects of predictors on weight loss maintenance over time.[9] However, this study was observational and did not intervene to change salient predictors and assess their effects on relevant outcomes. In order to develop truly personalised interventions tailored to each individual, within-person studies exploring weight loss trajectories are needed.

Intervention tailoring has been incorporated in the design of health behaviour programmes delivered in community and it has been found to be effective in providing personalised support to a wide audience at relatively low cost.[18] Tailored interventions can provide users with individualised feedback based on their demographic profile (eg, age, gender), preferences (eg, keen to learn about changing routines), beliefs (eg, beliefs about consequences of behaviour) and behaviour (eg, adherence to dietary changes). Users of tailored interventions are typically prompted to provide information (eg, using an online questionnaire) and subsequently provided with tailored feedback including information on behaviour change consistent with their responses. In a tailored intervention, feedback is usually based on question responses rather than on whether a particular measure is associated with a key outcome. An alternative approach, involves gathering data over time through EMA, and then providing the participant with tailored information and content that is relevant to the strongest predictors of reported outcomes after accounting for temporal changes in predictor and outcome. The present study will aim to test the effects of an intervention adopting this approach on weight loss maintenance.

Developing interventions to support successful weight loss maintenance also requires an understanding of the challenges individuals face when changing and maintaining behaviour. Interventions focussing on behaviour maintenance from the start of the intervention are more likely to produce long-term effects as intervention participants are less likely to engage in unsustainable behaviour change practices such as extreme dieting or unsustainably high amounts of physical activity.[19] Theoretical explanations for the maintenance of behaviour change have been summarised in a comprehensive systematic review of 100 behaviour theories.[20] This review proposed five main theoretical themes that are relevant to behaviour change maintenance, and are proposed to be distinct from behavioural initiation: maintenance motives, self-regulation, habits, personal resources and contextual influences. These five theoretical themes have also emerged as key themes in a number of qualitative studies summarised in the systematic review and synthesis of research on weight loss maintenance.[21]

The current study

Theory-based and evidence-based behaviour change techniques can support people in losing weight and maintaining it long term.[8 22] However, little research has tested the effectiveness of these techniques using within-person designs that not only examine aggregated between-group effects (eg, intervention vs control comparisons) but also determines personal trajectories of weight loss and tailors the intervention according to the strongest predictors of outcomes. This study will determine the effectiveness and cost-effectiveness of the proposed intervention using an randomised controlled trial (RCT) design (EMA tailored intervention vs control), with a nested interrupted time series (ITS) within-person approach. We hypothesise that participants in the tailored intervention group will lose significantly more weight than participants in the control group at 6 months (post-programme comparison – primary outcome) and at 12 months (maintenance

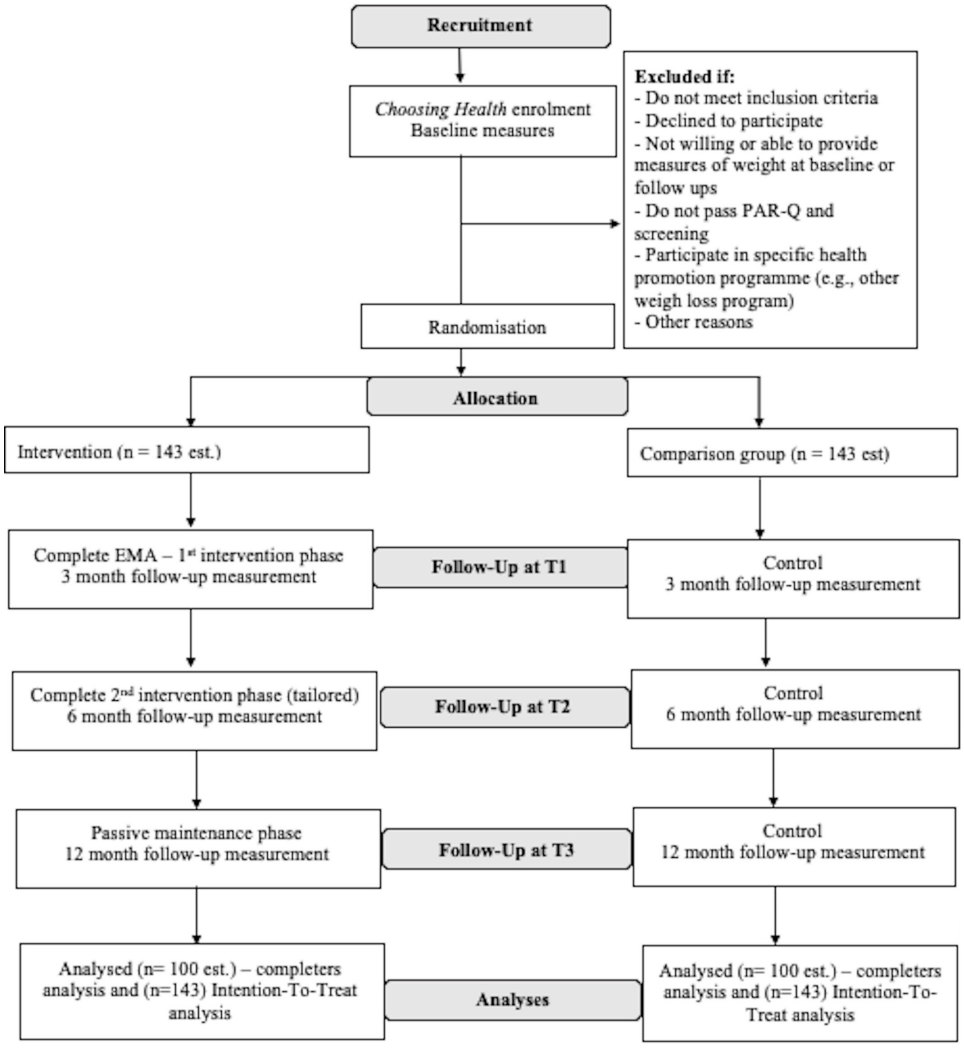

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram. EMA, ecological momentary assessment; est., estimated; PAR-Q, Physical Activity Readiness Questionnaire.

effects assessment – secondary outcome) follow-up when compared with baseline.

METHODS AND ANALYSIS

Study design

This is a two-group RCT to test the effectiveness and cost-effectiveness of the *Choosing Health* intervention with an N-of-1 interrupted time series approach embedded in the intervention arm (figure 1). The RCT is a primary method of assessing intervention effectiveness. The study meets CONSORT (Consolidated Standards of Reporting Trials) criteria for RCTs.[23] The actual study start date was 31st July 2020 and planned study end date is 30th November 2021; however, the study may extend beyond that date.

Participants

Overweight and obese adults aged 18 years or older with a body mass index (BMI) of 25 or higher at the baseline assessment will be eligible to participate. Individuals who report a physical condition or impairment preventing them from being physically active or losing excess body weight will be excluded from the study as well as those who have had a bariatric surgery or are planning to have one within the next 12 months. Prior to study consent, participants will be screened for eligibility using the Physical Activity Readiness Questionnaire (PAR-Q)[24] and have their height and body weight measured to determine their BMI. Individuals who report any contradictions to exercise as indicated by the PAR-Q will be encouraged to consult their doctor to obtain approval to take part in the study; they will be included in the study if they self-certify that they did this, and that will also be the case for breastfeeding women. Individuals who do not have a mobile phone with access to the Internet or who are currently participating in another weight loss programme (eg, regular meetings with personal trainer) or are pregnant will be excluded as well as individuals who are planning to move outside of the study region and are not willing to travel for study measurement sessions. We will also exclude individuals who are on medication that causes weight gain and individuals reporting having a pacemaker as the weighing scale used in the study is not appropriate for use in these individuals.

Table 1 Summary of the intervention steps and content

Intervention group	Control group
Shared components: ► Study recruitment and sign up online, initial contact to confirm eligibility, consent and randomisation to one of two study conditions; ► Each participant attends one-on-one face-to-face visits at baseline, 3-, 6- and 12-month follow-up).	
Basic educational weight loss information in a form of eBook or physical book at the start of the intervention, information provision and other BCTs.	Basic educational weight loss information in a form of eBook or physical book at the start of the intervention, information provision only.
EMA assessment via SMS and feedback report at 3 and 6 months based on the EMA.	No EMA assessment via SMS and no feedback report at 3 and 6 months.
Daily text messages and fortnightly educational factual emails (months 0–3), weekly emails that will fit the predictive domain identified in phase I (months 3–6).	Fortnightly educational factual emails (months 0–6).

EMA, ecological momentary assessment; SMS, short messaging service.

Procedure

Trial participants will be recruited online from relevant groups via email lists, social media (Instagram, Facebook and Twitter), posts on relevant interest pages and through the local press (table 1). Study posters and leaflets advertising the study will be placed in community centres and in other popular locations. The promotional materials will advertise the study as research investigating a digital health tool to lose weight and maintain weight loss. Study advertising materials will direct interested participants to the project website www.wybieramyzdrowie.pl (PL Wybieramy Zdrowie = EN Choosing Health), which will provide study information and will allow participants to access the eligibility questionnaire, read the information sheet and schedule the initial appointment with study facilitator. Participants will attend four face-to-face one-on-one visits with the study facilitator (baseline, and 3-, 6- and 12-month follow-up) at the university premises.

At the baseline visit, eligibility criteria will be confirmed, consent signed, further study information provided and the participant will complete objective and self-reported measures. Feedback on the objective measures will be given (BMI, weight, body fat percentage and blood pressure measures). Participants will then be randomised using an online randomisation tool, randomisation stratified by BMI (25 to 30 and 30+) using block randomisation, eight people per block. We used the block randomisation method to ensure a balance in sample size across groups over time. If the participant is randomly allocated to the intervention group then further EMA instructions will be given. Participants will be scheduled to visit the research site for follow-up data collection at 3, 6 and 12 months.

Intervention – phase I (0 to 3 months)

During the baseline visit, intervention group participants will be shown EMA questions and asked if they fully understand them. They can add their own questions that include their personal predictions regarding factors influencing their weight loss (up to three questions) in order to improve study engagement and compliance; and as it may identify some important and person-specific predictors/determinants. They will be asked to complete EMA daily for 3 months; they will select what time in the evening they prefer to do so (within an 20:00 to 23:00 window). At the end of 3 months, they will attend a study visit to complete the study measures. During this visit the facilitator will provide participants with their report including their EMA data summaries highlighting key predictors of self-reported adherence to their weight loss plan. The facilitator will highlight which behavioural domains the participants could improve. The study includes EMA for two reasons: first, to provide individualised (tailored) intervention feedback using data from the first EMA period and analysed as a single case time series; second, as a method of assessing within-person changes in individuals randomised to the intervention group.

Intervention phase II (3 to 6 months)

Based on the strongest within-person predictors of participants' self-reported weight loss plan, participants will be provided with tailored intervention content. Participants will receive daily text messages and weekly emails that will fit the predictive domain identified in phase I. Participants will be asked to complete further daily EMA measures in phase II, receiving a final personalised report as an incentive. After completing this study phase intervention participants will complete a 6-month follow-up visit that will be followed up with a passive maintenance phase with no EMA and no contact with the intervention participants and final assessment at 12 months post-intervention.

Control group

Control group participants will receive basic educational weight loss information in a form of eBook or physical book at the start of the intervention (online supplemental material 1), fortnightly educational factual emails and they will be asked to meet with the research team at the 3-, 6-, and 12-month follow-up assessment occasions.

Measures for the between group comparisons

The study measures will be taken at four time points, at baseline (Time 0), and at three follow-up occasions at 3 (Time 1), 6 (Time 2) and 12 (Time 3, table 2) months post-intervention. The primary outcome for the

Table 2 Variables assessed during the RCT at different time points

Variable name	Baseline	3 months	6 months	12 months
Demographic variables: age, sex, marital status, ethnicity, education, height (to calculate BMI), work status	X	–	–	–
Objective measures of height, weight, body fat % and BP	X	X	X	X
Food, alcohol consumption and smoking – adapted the Dietary Instrument for Nutrition Education (DINE) (fatty foods, fruit and vegetable and sugary food consumption); alcohol consumption assessed with AUDIT-C and smoking	X	X	X	X
Physical activity (self-reported) and sitting time - International Physical Activity Questionnaire (IPAQ) short version	X	X	X	X
Sleep duration and quality - Pittsburgh Sleep Quality Index	X	X	X	X
Health related quality of life (EQ-5D-5L)	X	X	X	X
Theory-derived psychological constructs: intentions, motivation, self-efficacy, attitudes, action planning and coping planning, goal facilitation and goal conflict, habit strength for physical activity and healthy eating (Self-Report Behavioural Automaticity Index)	X	X	X	X
Economic evaluation: self-reported healthcare utilisation using a validated patient cost questionnaire	X	X	X	X
Characteristics of the intervention, that is, acceptability of EMA phase, the advice provided, intervention delivery and format	–	Only intervention group	Only intervention group	X
Adverse effects	At any time			

BMI, body mass index; BP, blood pressure; RCT, randomised controlled trial.

between-person evaluation of the RCT will be weight objectively measured at 6 months post-enrolment in kilograms with the body composition scale (model: Tanita MC-780 S MA, Japan) to assess between group intervention effects. Demographic variables will be assessed at baseline (Time 0). Secondary outcomes measured at each time point (baseline, 3-, 6- and 12-month) will include self-reported measures of physical activity, sitting time, quality of life and theory-derived correlates of weight loss.[20]

Participants will be asked to self-report a number of key demographic variables: age, sex, marital status, ethnicity, education and work status. Their food consumption will be measured with an adapted version of the Dietary Instrument for Nutrition Education including fatty food, fruit and vegetable and sugary food scores, with higher scores indicating higher consumption, with items tailored to the Polish population.[25] Alcohol consumption will be recorded using the AUDIT-C.[26] Physical activity and sitting time will be assessed using the International Physical Activity Questionnaire (IPAQ) short version,[27] a self-report measure of activity levels. Sleep duration and quality will be measured using the Pittsburgh Sleep Quality Index.[28] Health-related quality of life will be assessed with the widely used health-related quality of life scale, EQ-5D-5 L.[29] All instruments have demonstrated adequate validity and reliability statistics in previous studies.

Theory-derived psychological constructs will include self-report measures of intentions,[30] self-efficacy, attitudes,[31] action planning and coping planning,[32 33] goal facilitation and goal conflict.[34] Habit strength for physical activity and healthy eating will be measured using the Self-Report Behavioural Automaticity Index.[35] All scales will be translated using back-translation and forward-translation procedures following a standard consensus method.[36] Participants will be encouraged to report any adverse effects they may experience during their participation in the intervention over email or by phone call to the study facilitator when they occur. Characteristics of the intervention including participants' ratings of the acceptability of the advice provided, intervention delivery and format will be measured with items used in previous studies[37 38] in the intervention group only.

Ecological momentary assessment

Psychosocial determinants of weight loss and goal progress will be assessed using EMA using items used to measure these constructs derived from previous studies.[39] Measures taken at each data collection occasion will include motivation, self-regulation, habits, internal factors (perceived stress, energy levels and hunger) and external factors (perceived physical environment and social support, table 3). Participants will also report their subjective assessment of their progress towards a weight loss/weight loss maintenance goal (0 to 100) agreed with the researcher at the initial baseline session, consistent with previous research.[9] On that occasion, participants will be instructed to define a 'perfect day' (equals 100) in terms of weight loss/maintenance, including their physical activity and eating behaviours, and define a 'bad day' with mentoring from the researcher (equals 0). Participants will then be prompted to report their progress reflecting on that agreed goal.

Table 3 Ecologicalmomentary assessment questions asked daily

Item	Theme
How well have you stuck to your weight plan today? (0 – not at all, 100 – completely)	Outcome variable
How motivated were you to focus on your weight today? (0 – not motivated, 100 – very motivated)	Motivation
How many hours of sleep did you get last night? (open-ended question, locked as number)	Resources - sleep
How stressed did you feel today? (0 – not stressed at all, 100 – very stressed)	Resources - stress
How energetic did you feel today? (0 – not energetic, 100 – very energetic)	Resources – energy
How hungry did you feel today? (0 – not hungry at all, 100 – very hungry)	Resources - hunger
How happy did you feel today? (0 – very unhappy, 100 – very happy)	Resources – happiness
How aware were you of your weight plan today? (0 – not at all, 100 – very aware)	Self-regulation – awareness
Have you experienced any significant obstacles to achieving your weight loss today? (0 – none, 100 – a lot)	Self-regulation – obstacles
How much have you relied on your routines in relation to your weight loss plans today? (0 – not at all, 100 – a lot)	Habit – general
How supported by other people in your weight loss did you feel today? (0 – not supported, 100 – very supported)	Environment – social support
How typical was your environment in relation to your weight loss plan today; for example, access to food choices, physical activity opportunities? (0 – as usual, 100 – very different)	Environment / habit
How important has your weight been compared with other things today? (0 – not important, 100 – very important)	Competing goals
Personally relevant question(s) – optional, can be incorporated in the daily assessment, based on self-reported factors that may impact on weight, for example, pain levels, weather, alcohol consumption, any other hypotheses relevant to weight (up to three additional questions)	Other / various
Do you have any comments regarding your day today that may have affected your weight plan? (open-ended question)	N/A

Table shows how assessed variables fit into theoretical themes; however, the distinction is only indicative; all questions adapted from.[9] The order of the questions, apart from the last question will be randomised.

Participants will be asked to complete these EMA survey measures at a pre-specified time each day (phase I – approximately 90 data points; and phase II – approximately 90 data points, 6 months in total; see online supplemental material 1 – simulation study used to define study power). Participants will be informed that the more data points gathered, the more precise and accurate their tailoring will be during the next study phase, as we will be able to understand the most important predictors of their weight loss. To lower participant burden and to enhance participant autonomy, participants will be free to answer EMA less frequently if they consider the requested frequency is too burdensome and they will be able to stop EMA reminders at any time. Weight loss goal progress will be the main outcome measure for the EMA study.

Objective measures

We will gather objective measures of weight, height, body fat percentage and blood pressure. Weight in kilograms and body fat percentage will be measured with a valid and reliable body composition scale (Tanita, MC-780MA S, Japan); with participants wearing light clothing, no shoes, no socks and empty pockets. Height will be measured in centimetres using a free-standing stadiometer (Seca 274, Germany), without shoes. BMI will be calculated as weight in kilograms divided by the square of height in metres (kg/m^2). The participants will be given standard instructions to prepare for the measurements. The measurements will be shared with the participants immediately after they are taken and standard norm ranges will be provided for BMI and for body fat percentage for men and women.

Resting systolic and diastolic blood pressure will be measured with a validated digital blood pressure monitor (Omron HBP-1100 Professional Blood Pressure Monitor, Japan) after at least 5 min sitting still. For the measurement, participants will be instructed to keep feet flat on the floor, arms free of clothing or wearing loose/thin clothing and have the monitor cuff fitted at the level of heart on their non-dominant and instructed to be still with minimal movement. If measured systolic blood pressure exceeds 140 mm Hg and/or measured diastolic blood pressure exceeds 90 mm Hg, up to two further measures will be taken and recorded. If the blood pressure is measured more than once the mean value of the measures will be taken as the final recorded blood pressure. In line with duty of care, participants will be given a letter explaining the circumstances in which they had their blood pressure measured and recorded and will be told to consult their physician in the event of an elevated blood pressure measurement.

Sample size

Projected sample size was calculated based on a statistical power analysis using the G*Power software. In order to detect a medium-to-large effect size for weight between the intervention and control groups (4 kg of weight loss difference with a SD of 10 kg at 6 months and a mean

comparison condition body weight at 6 months follow-up of 85 kg), we estimate that a total of 100 participants per group would be required to achieve 80% power with alpha set at 0.05. Based on an estimated average drop out of 30% from online tailored interventions,[40] a sample size of 285 participants is required to ensure 80% power.

To estimate statistical power for the within participant components (ie, the required number of observations per participant), we conducted a simulation study (online supplemental material 2). As effect sizes and autocorrelation will likely differ between participants, as found in previous work,[9] we describe the power for a range of parameters. We also consider a reduced type II error rate (false negative) with a corresponding increased type I error rate (false positive) preferable for the identification of potential predictors and so include power scenarios where alpha is set at 0.1. Results showed that 60 observations per participant in each study phase (phase I and phase II) would provide the following power for the two within participant study components: (1) for the identification of predictors of weight loss behaviour in phase I only, 60 observations will provide 80% power for an 0.5 effect size (*d*) with an autocorrelation of 0.5 and alpha at 0.10; alternatively, 50 observations would suffice to provide 80% power for an 0.5 effect size with an autocorrelation of 0.1 and alpha at 0.05; (2) for the interrupted time series component, 60 observations per phase would provide 77% power for an 0.8 effect size with an autocorrelation of 0.2 and alpha at 0.05.

Data analysis

In order to test the effectiveness of the *Choosing Health* programme for the primary between-person analysis, multiple regression will be used with BMI and any additional baseline confounders (determined a priori as part of the statistical analysis plan and for variables with clear between-arm imbalances), as fixed covariates. This approach will be used for the secondary measures collected at 3, 6 and 12 months. A further secondary analysis will use multilevel modelling with a 2 (condition: control and intervention) x 4 (time: baseline, 3-, 6- and 12-month follow-up) mixed-model design, with condition as a between-participants effect and time as a within-participants effect. Models will be conducted to compare change between conditions of the primary outcome (weight) and secondary outcomes (eg, physical activity, theory-derived psychological constructs). Data will be treated using a full intention-to-treat assumption with complete-case analysis reported for comparison. To test our hypotheses that there are different associations of predictor variables with outcome within-individuals, we will use within-person time series analytical methods[41] employing generalised additive mixed models.[42] This approach will be used for both the predictors analysis (phase I only) and to compare the two phases in the interrupted time series component.

Qualitative data from the interviews and user engagement workshops (that were part of intervention development process, n=40) will be transcribed verbatim and analysed to explore effectiveness and implementation aspects of the intervention. Qualitative data from open-ended responses to EMA surveys, from the interviews and user engagement workshops will be analysed using the Framework Method[43] and employing theoretical themes[20] as a starting framework. A combination of inductive and deductive methods will be used following the six-step thematic analytical approach[44] including familiarisation with the data, generating the initial codes, combining codes into overarching themes, looking at how the themes support the data and the overarching theoretical perspective, defining the themes and writing the report and conducting member checking.[44] One independent researcher will code the data using QSR NVivo and another one will independently code 20% of data to check for coding consistency; other research team members will contribute to data interpretation and analysis.

Intervention development

Intervention content was informed by (1) other publicly-available online national weight loss materials (eg, LiveWell, UK; LiveLighter, Australia; National Diabetes Prevention Program, USA; the Food and Nutrition Guide, Canada); and (2) other available intervention materials from successful weight loss interventions.[45 46] We mapped the materials available to fit with the relevant theoretical domains[20] and divided the content into separate packages (addressing maintained motivation, self-regulation, resources, environmental and habitual influences) and theoretical subcategories (eg, resources: sleep, energy level, happiness). Content of the intervention is based on behaviour change theories[20] and includes state-of-the-art behaviour change techniques.[47 48] The main content includes guidelines for healthy eating, physical activity and weight loss, techniques for self-monitoring of weight and physical activity, encouragement to form action plans and coping plans, suggestions for how to best form healthy habits, how to use social support and how to restructure the environment in order to aid weight management. Tailored intervention content is relevant to the predictive domains indicated through EMA (table 4).

Intervention format and mode of delivery

The intervention consists of information materials provided at baseline in the form of an eBook or a physical book depending on participants' preferences. The book includes the rationale for the intervention, basic information on healthy eating and behaviour change and tables allowing self-monitoring of weight, physical activity and eating (ie, a brief food diary). The book is non-tailored and includes weekly tasks for the participants to complete during 26 weeks (initial 6 months) to support their weight loss and maintenance (online supplemental material 2). Consistent with guidelines on user engagement in intervention development,[49] the book was co-designed with potential users who were asked about their perceptions of

Table 4 Behaviour change techniques that will be employed to help participants address their personal strongest predictors of weight loss outcomes; theme based on theory and previous studies

Theme most predictive of the outcome	Behaviour change techniques to be used (examples)
Motivation	Techniques supporting motivation, for example, retrieval of past success, role models; coping models
Resources - sleep	Information provision; techniques to improve sleep; problem solving; action planning, coping planning and relapse prevention
Resources - stress	Information provision; techniques to lower stress levels, problem solving; action planning, coping planning and relapse prevention
Resources – energy level	Information provision; techniques to improve energy levels, for example, physical activity, problem solving
Resources - hunger	Information provision; techniques to deal with hunger; problem solving; action planning, coping planning and relapse prevention
Environment – social support	Searching for and enhancing social support; problem solving; action planning and coping planning
Resources – happiness	Information provision; techniques to improve mood; action planning and coping planning
Self-regulation – awareness	Techniques enhancing awareness of weight plan, for example, reminders
Self-regulation – obstacles	Coping planning, relapse prevention, problem solving
Habit – general	Habit formation techniques, identifying relevant cues
Habit - environment	Environmental restructuring, incentives and disincentives system
Competing goals	Dealing with multiple goals, goal prioritising, goal setting, goal contrasting, for example, based on goal importance
Other (chosen by the participant)	Various techniques, depending on the predictor selected, personally tailored to the participants by the intervention facilitator

content usefulness, applicability and any further feedback on the content and design. The book was adapted in line with users' suggestions, for example, bigger fonts, less text, more space for notes, more autonomy supportive phrasing, for example, emphasising that the users understands best their habits and how to change them.

The intervention group will also receive a series of daily text messages and weekly email messages supporting their weight loss and promoting weight loss maintenance. In phase I (month 0 to 3), the messages and emails will be generic and factual; in the phase II of the intervention, participants will receive text messages and emails tailored to the strongest predictors of outcomes identified in phase I. For the intervention group, after phase I participants EMA data will be analysed and when they attend the 3-month assessment, they will receive a report summarising their own data collected so far and indicating the strongest predictor of adherence to a weight loss plan for them (eg, changing motivation, energy levels). The assessment session will be facilitated by the trained researcher who will provide an explanation for time-based predictors of outcomes and will explain that further message tailoring will be based on these specific predictors. The emails and text messages for phase II will be set up to fit predictive domains for each participant. We have created a database of daily text messages and weekly emails for each domain (www.osf.io/sf264/) and we tested them with the users.

Participant and public involvement

We involved public representatives at an early stage of the intervention development through a series of five user engagement workshops, which included a total of 40 people. We described the programme, aims and how we are aiming to deliver the proposed intervention. The workshop participants were presented with proposed study materials and their priorities, experience and preferences were discussed in an open discussion. The workshops topics built on each other and we refined the research based on feedback, for example, we developed additional general weight loss materials that will be provided to intervention and control groups. As EMA studies can be burdensome, we also discussed participants' views on the feasibility of the proposed assessments and the proposed EMA questions. As most scales used in the study do not have Polish translation, we also discussed with the workshop participants any items that were challenging to translate. We gathered suggestions for how best to recruit participants and design study procedures. We also presented our study dissemination plans and gathered additional suggestions for how best to undertake dissemination.

The content of the intervention, including emails, text messages and eBook were also thoroughly tested with the users through the user engagement workshops (detailed results will be described elsewhere). Workshop participants were asked to give feedback on content, user-friendliness, accessibility and clarity of the information and other aspects of the proposed programme. The messages were revised after the workshops to include participant feedback. The messages were also validated by a group of 10 health psychologists who were asked to assign specific messages to pre-defined domains and rate

their quality and content. The aim of this exercise was to assess the content and check if the messages clearly fit with the theoretical domains.

Economic evaluation

This study will include an evaluation of the cost-effectiveness of the *Choosing Health* programme at 6 and 12 months post-intervention, short-term within-person trial and a projected estimate after 5 years, long-term modelling, with respect to the primary outcomes of the trial and quality of life. Data on resource utilisation will be collected using self-report questionnaires including utilisation of healthcare services, and medication use. All measures will be taken at baseline and at each follow-up point. Given the presumably low feasibility of obtaining health administrative data in the study time frame, we intend to collect self-reported healthcare utilisation using a validated patient cost questionnaire.[50] While we acknowledge the potential for recall bias, there is evidence to suggest that this is a valid method for collecting healthcare resource utilisation for use in economic evaluation when administrative data is not easily accessible.[51] Costing information will be applied based on established costing methodologies drawing on primary research and national costing activity.[52] We will develop an economic model to estimate cost-effectiveness of the *Choosing Health* programme. Costs will include direct costs associated with the programme, including set up costs and cost of trained facilitators' time. In terms of outcome measurement, we will include short-term outcomes that will enable us to look at the weight reduction and cost per quality-adjusted life years (QALYs). The QALY is the most widely used approach for estimating quality of life benefits in economic evaluations. Quality of life scores will be measured using the EQ-5D-5L questionnaire.[53] The scores obtained from the questionnaire will be used to formulate the cost per QALY. Sensitivity analysis will be undertaken to test the robustness of the results.

Process evaluation

A process evaluation will be embedded in the RCT to provide insight into whether the *Choosing Health* programme is delivered as intended, and why it did or did not produce the intended outcomes.[54] We will investigate the processes that are necessary for implementation of the *Choosing Health* programme, the way in which the programme operates on outcomes and on any unintended outcomes and participants' and facilitators' experiences of the programme. At both post-programme measurements, the intervention group will be asked to complete self-report questions focussing on: experiences with the programme; which elements of the programme they found most useful; and the perceived impact of the programme on their lives. The intervention will be evaluated following the guidance on process evaluation for complex interventions[54] assessing intervention uptake, feasibility, usability and effectiveness. We will also conduct data-prompted interviews[55] with purposefully selected participants (n=20) to explore their experiences of trial participation, incorporating researchers reflexive journal notes.[56]

Data management

Hard copies of data documents will be securely stored in locked cabinets in the university and will contain participant IDs but no identifying information. A document linking participant IDs with participants' identifying information will be stored on a password-protected computer file on the host university's computer server. The project data will be stored securely for 10 years, in line with the data management policy at the university; only members of the research team will be able to access the paper data. A fully anonymised data set, statistical code and all study materials will be made publicly available on the Open Science Framework.

ETHICS AND DISSEMINATION

Ethical approval for the study was granted by Faculty of Psychology, SWPS University of Social Sciences and Humanities, Ethics Committee, Wroclaw, Poland, approval number 03/P/12/2019. All participants will be required to give study consent in order to participate. From the start of the project, we will work closely with health promotion communities in Poland, including the Ministry of Health and key stakeholders—policy and practice representatives as well as the general public. We will involve the stakeholders at various stages of the intervention design and we will seek their opinion and advice throughout the project.

We will also ensure that study findings are widely disseminated. The key features and findings of the project will be disseminated among the health promotion community in a final dissemination and translation event. The event will focus on disseminating findings of the trial to the public, academics, current and future stakeholders and health promotion and policy practitioners. We will invite several programme participants and national health promotion website users to share their experience and perspectives on the programme. Representatives from digital media agencies and social marketing companies will be also invited to join in discussions about the sustainability of the project and translation of the project interface into other health promotion behaviours; for example, smoking cessation and medication adherence. Research findings will be presented to highlight health implications for the users and further routes for programme deployment. We will run a workshop as part of this dissemination event (including those from the local Ministry of Health) to upskill health promotion practitioners in behaviour change techniques, and weight loss promotion practices.

Understanding weight loss practices and developing programmes that can effectively support weight loss and weight loss maintenance is timely and needed. We aim to develop a digital health platform which with time can become a self-sustainable tool for weight loss management.

The *Choosing Health* study is set to provide information on the most effective methods for the tailoring of intervention content to maximise treatment effectiveness. In future research the online platform is also expected to be a useful tool for gathering ongoing data on weight loss practices in Poland, similar to the ongoing National Weight Loss Registry (www.nwcr.ws) which gathers data on weight loss maintenance practices in the USA.[57]

It was agreed that after trial completion, the health promotion content from this trial will be also included on the Ministry of Health national health promotion website www.pacjent.gov.pl. This is a government-funded website where all Polish citizens can create a profile and access their medical data, including medical history, medication prescriptions and medical appointments. This website is relatively new, and our research team was tasked to provide the materials for the *Live Healthily* section of this website. If proved effective, the content of the intervention from the present study will be available to everyone who will register and open the account on www.pacjent.gov.pl; where the users will be able to freely navigate through the content they consider relevant and provide feedback on its content. This partnership has already been established.

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