Online Platform for Healthy Weight Loss (POEmaS)

February 9th, 2018

STUDY PROTOCOL

Design

This is a three-arm parallel randomized controlled trial which recruited adults (18-60 years) participants classified as overweight or obese (body mass index – BMI >=25 kg/m^2) and who had the intention to lose weight.

Participants and recruitment

Students (current and past) and staff of the Federal University of Minas Gerais (UFMG), Belo Horizonte, in the southern Brazil, were recruited by physical and online advertising (flyers, University website, UFMG mailing list) for one month from the 25th September to 24th October, 2017. They were invited to access the project website www.poemasufmg.com.br, where they can watch a video with details of the project. Interested participants can join the project online and create an account profile after checking for the inclusion and exclusion criteria (Table 1) and signing the informed consent form. Participants excluded from the study can reference colleagues by entering their email.

Table 1- Inclusion and exclusion criteria for recruitment into "POEmaS (Online Platform for healthy weight loss)" Randomized Clinical Trial

Inclusion criteria	Exclusion criteria
Age between 18 and 60 years	Pregnancy
BMI* >=25 kg/m2	Self-report of comorbidities that demand specific dietary or physical activity recommendations- diabetes, heart failure, coronary artery disease, kidney disease, hepatic disease, cancer, phenylketonuria, celiac disease, food allergies, bariatric surgery history
Intention to lose weight by changes in	Participation in any other weight loss

lifestyle habits	program
Internet access	

* BMI: Body mass index

Randomization and allocation

Once informed consent was obtained, participants were randomly allocated to one of the three groups using a stratified randomized block design. Participants were stratified by gender and category of body mass index (25 to <30 or ≥30 kg/m^2) using blocks of variable length (either 3 or 6).

Participants were initially allocated to one of three groups:

(1) Group 1, control group which is submitted to an initial minimal intervention for 24 weeks and subsequently will have access to all the platform functionalities;

(2) Group 2 will follow a standard weight loss program delivered by the website platform for 24 weeks;

(3) Group 3 followed the standard weight loss program enhanced by personalized feedback by a nutritionist based on lifestyle habits reported in the platform for 12 weeks and the standard weight loss program for the following 12 weeks.

Subsequently, subjects received an automatic email with detailed information on the groups they were allocated to. Researchers were blinded to participants´ allocation.

Outcome measures

All outcomes will be assessed at baseline, 12 and 24 weeks afterwards. Weight and BMI change are the primary outcomes of the study and will be self-reported by the participants. Secondary outcomes will be changes in dietary habits, food-related behaviors, physical activity habits, sedentary behaviors, quality of life, health perception, online activity and users´ satisfaction, as detailed in Table 2. Outcome assessors will be blinded to group allocation.

Sample size

Based on a 90% power to detect a significant difference of 4kg weight loss between groups, assuming the SD of weight is 6.0 and using a two-sided significance level of 0.05, and a 40% attrition rate, a sample size of 90 participants was calculated for each group.

Interventions

The interventions will be delivered online for 24 weeks, with new program content distributed to the user weekly for Groups 2 and 3. The content of dietary and physical activity recommendations was based on Brazilian and international evidence-based guidelines. Dietary recommendations focused on particular Brazilian habits. Physical activity recommendations focused on increasing time of leisure exercise and decreasing sitting time.

In group 1, subjects have access to four videos with information on health consequences of excessive weight, dietary and physical activity weight loss recommendations, as well as strategies to behavior change. They also received an e-book with lifestyle habits and behavioral recommendations to lose weight. Access to the study website will be limited for the first 24 weeks and they have been asked not to undertake any other weight-loss program during this time. They will be invited to report their weight, dietary and physical activity habits at 12 and 24 weeks after baseline by email. Afterwards, they will gain access to the standard online platform.

Group 2 has access to the study website program for 24 weeks. The platform used in this study was adapted from a commercial product (Cybergia® Inc.), which runs various Internet-based health programs in Brazil (www.cybergia.com). The platform is cloud-based progressive, web-app developed and can be accessed in desktop and smartphone environments. It has three areas: 1) Main area, presenting weekly updated tasks such as content (video, articles), suggested dietary and physical activities and questionnaires; 2) Self-monitoring area, containing a food diary, functionalities for activity self-report and charts; 3) Social area, containing a private social network where users can share and react to photos and posts. Connecting these areas, the platform presents gamification mechanics, such as weekly points (connected to completing tasks and interacting with other participants) and social challenges, which invite users to complete one-time

specific tasks and share their accomplishments. Interaction with the project's team was restricted to public posts and selected comments on the social network.

Group 3 has access to this online program plus weekly individual chat in the platform with a dietitian. At these times, they have the opportunity to discuss and manage individual issues.

Quality Control

Several procedures will be employed to optimize the quality of the study and maximize internal validity and reliability of the program delivery and outcome assessments. Assessors of the main outcome measures are blinded to the participants' group allocation. Assessment protocols and orientations to participants were standardized in written documents. Validation of self-reported weight and height will be performed by correlation to measurements for a random sample of 10% of the study population. Personnel will be trained on anthropometry procedures prior to the assessment. Regular team meetings between the clinical and information technology teams, in order to align strategies, are planned.

Measurements and instruments

Demographic Data

Data on gender, education, civil status and place of work will be collected at baseline. Questionnaires to obtain current medical conditions and medications will be completed at baseline and 24 weeks.

Anthropometry

Weight and height will be self-reported by the participants and BMI will be calculated by the formula weight in kg/ (height*height) in m^2. For the random 10% sample selected for additional measurements, weight will measured in light clothing, without shoes on a Welmy ® analogic scale with stadiometer. For this sample, waist circumference will be measured at the mid-level between the last rib and the iliac crest using an inelastic tape and body composition will be measured by electrical bioimpedance using Sanny ® Bioimpedance.

Dietary intake and food-related behavior

For groups 2 and 3, calculation of the total daily caloric intake and dietary nutrients will be performed by an automatic dietary calculator which was based on food nutrition composition tables for the Brazilian population (http://www.unicamp.br/nepa/taco/).

Questions about the total number of daily serves of fruit and vegetables, and whole carbohydrates sources, as well as weekly serves of sweetened beverages and snack foods will be applied. Moreover, food-related behaviors, including number of days taking breakfast, number of daily meals, frequency of take-away food consumption and eating while watching television will be assessed by questionnaires.

Eating behavior

The random sample selected to anthropometry will have cognitive and behavioral components of eating assessed across three scales of cognitive restraint, uncontrolled eating and emotional eating by the Brazilian version of the Three Factor Eating Questionnaire-R21, (TFEQ-R21).

Physical activity and sedentary behavior

- The short-form of the International Physical Activity Questionnaire (IPAQ) will be used to estimate total MET-minutes/week and to classify participants into either high, medium or low physical activity categories according to the IPAQ Scoring Protocol [18].
- The daily screen-time (i.e., in front of TV, computers, video games, smartphones) and the daily sitting time will be used to assess sedentary behavior.
- Pedometers: the number of steps will be measured by XXX pedometer in the sample randomly selected to anthropometry.

Health perception

The Brazilian version of the *12-item Short-Form Health Survey – Version 2*, (QualityMetric Incorporated, Lincoln, RI, USA) which is a self-reported measure of health-related quality of life (HRQoL) designed to investigate multidimensional aspects

of physical and mental health for the general population and those with chronic diseases, will be applied to all participants.

Self-rated health will be assessed by one question derived from the Short-Form-36(SF-36)- "In general, you say your health is…" with "excellent", "very good", "good", "regular" or "bad" as alternative answers.

Body image perception and satisfaction will be assessed by a scale in which the participant can choose his current and ideal silhouette from 15 options, according to gender.

Online activity and satisfaction with the weight loss program

Self-monitoring entries, posts and comments in forums and chats will be collected and stored in the platform database and exported as CSV files. For Group 3, we also analyzed the number of interactions with the nutrition specialist. To assess users´ satisfaction with the weight loss program and with the web-based platform we will develop and apply a specific questionnaire.