SWAT 211: Effects of a self-directed orientation session on retention in a digital weight loss study

Objective of this SWAT
To determine the impact of a self-directed orientation session on participant retention in a 6-month digital weight loss trial.

Study area: Retention
Sample type: Participants
Estimated funding level needed: Unfunded

Background
Attrition has traditionally been a problem for the delivery of behavioral weight loss and digital health interventions, and for randomised trials of these interventions.[1,2] Because poor attrition can threaten the validity of a trial's results and waste resources, identifying ways to limit attrition and thereby improve the integrity of trials in these contexts is critical.

A strategy that has demonstrated improvements in trial retention of behavioral interventions is the use of orientation sessions before study enrollment.[3] Modeled after the Methods-Motivational Interviewing approach,[4] our purpose for including an orientation session is to assist potential participants in making informed decisions about whether to participate in the Spark digital weight loss study (i.e., the host trial; NCT05249465). This decision-making process takes place before informed consent and enrollment.

Past studies have found that orientation sessions enhanced trial retention; but they relied on pre-post or quasi-experimental designs.[4,5] Now, randomized trials are needed that experimentally manipulate receipt of the orientation session to determine its added impact on trial retention. Further, delivering it via a remote format has potential to enhance scalability.

This embedded study (aka a Study Within A Trial or "SWAT") will rigorously yet efficiently evaluate a novel retention method, a remote orientation session, and provide researchers with the opportunity to replicate these methods in the future. If deemed effective, this orientation strategy could be adopted more broadly as a way to improve retention in digital weight loss trials. After potential participants complete the online eligibility screen for the weight loss trial and are deemed eligible, they will be randomized (1:1) to receive or not receive the orientation session.

Interventions and comparators
Intervention 1: Receipt of an orientation session. This will be self-directed and interactive, lasting 20-30 minutes, comprising tools such as videos, short quizzes, and a creation of a pro/con list, which can be completed on their phones, computers, or tablet devices. The goal is to enhance potential participants' understanding of research procedures, the randomization process, expectations and time commitment, and the importance of retention, while empowering them to choose whether to initiate the next step of the enrollment process.
Intervention 2: No orientation session; after completing the online eligibility screen for the weight loss trial, potential participants are directed to the next step of the enrollment process.

Index Type: Method of Recruitment, Orientation session prior to enrollment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: 6-month retention in the host trial (operationalized as proportion of participants with a recorded 6-month weight uploaded from the smart scale out of total participants)
Secondary: (1) 1- and 3-month retention in the host trial; (2) Weight change at 6 months, assessed via smart scale; (3) Proportion of participants achieving ≥5% weight loss at 6 months from baseline; (4) Engagement in self-monitoring over 6 months, assessed via digital tools (operationalized as average percent of days in the 6-month intervention of self-monitoring dietary intake, steps, and/or body weight, depending on which items assigned to track; (5) Proportion of

eligible participants who enrolled in the weight loss trial; (6) Whether orientation sessions affect characteristics of the sample who enroll in the host trial, compared to those who did not enroll; (7) Perceived value of retention (potential mediator); (8) Knowledge of importance of retention (Intervention arm only); and (9) Completion rates of the orientation session.

Analysis plans
As is common in embedded trials, sample size will be constrained by the number of participants in the host trial (i.e., the Spark weight loss trial). However, a power calculation was run to determine the effect size that could be detected assuming a sample size of 176, 80% power, an alpha of 5% in a two-sided test, and control arm retention of 65% (assuming 35% dropout): we would have 80% power to detect a retention rate of 83% in the intervention arm. To assess differences in trial retention between SWAT intervention and control participants, we will fit a log-Poisson GEE model with robust standard errors and an unstructured working correlation matrix to take into account repeated measures across time.

Possible problems in implementing this SWAT
It is possible that individuals randomized to receive the orientation session do not complete it. We will assess completion rates of the orientation session as well as using an intent-to-treat analyses.

References
1. Moroshko I, Brennan L, O'Brien P. Predictors of dropout in weight loss interventions: a systematic review of the literature. Obesity Reviews 2011;12(11):912-34.
2. Coons MJ, DeMott A, Buscemi J, et al. Technology interventions to curb obesity: a systematic review of the current literature. Current Cardiovascular Risk Reports 2012;6(2):120-34.
3. Goldberg JH, Kiernan M. Innovative techniques to address retention in a behavioral weight-loss trial. Health Education Research 2005;20(4):439-47.
4. Jake-Schoffman DE, Brown SD, Baiocchi M, et al. Methods-Motivational Interviewing Approach for enhanced retention and attendance. American Journal of Preventive Medicine 2021;61(4):606-17.
5. Ritchie ND, Kaufmann PG, Gritz RM, et al. Presessions to the National Diabetes Prevention Program may be a promising strategy to improve attendance and weight loss outcomes. American Journal of Health Promotion 2019;33(2):289-92.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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