Spark Pilot Study: Weight Loss Intervention for Racial/Ethnic Minorities (#66674)

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1) Have any data been collected for this study already?
No, no data have been collected for this study yet.

2) What's the main question being asked or hypothesis being tested in this study?
Aim 1. To assess the degree to which the target population (i.e., racial/ethnic minority adults with overweight/obesity) is reached by our recruitment efforts for our 3-month remotely-delivered digital intervention for weight loss.

Aim 2. To evaluate feasibility of the two self-monitoring approaches. Other feasibility metrics include retention rate, survey completion rate, dietary recall completion rate, and engagement in other intervention components.
A priori feasibility benchmarks include self-monitoring 75% of days over 3 months, 80% retention at 3 months, 80% survey completion, 80% dietary recall completion, and 80% completion of each of the other intervention components.

Aim 3. To evaluate barriers to and facilitators of intervention engagement and acceptability of procedures via in-depth qualitative interviews.

3) Describe the key dependent variable(s) specifying how they will be measured.
Reach will be assessed by examining the recruitment rate (the proportion of participants who were randomized out of the individuals who completed the online screener and were eligible), as well as evaluating the number of participants recruited from each recruitment strategy.

The primary feasibility outcome is self-monitoring engagement over 3 months. we will examine the percent of days in the intervention that participants self-monitor dietary intake, steps, and body weight.

Retention rate will be assessed by examining the proportion of participants with a recorded weight out of total participants, at 1 and 3 months.

Survey completion rate will be assessed by examining the proportion of participants who completed online surveys at baseline, 1-, and 3-months.

Dietary recall completion rate will be assessed by examining the proportion of participants who completed the dietary measure.

Intervention engagement will also be assessed by examining the percentage of action plans completed, feedback emails read, and lessons reviewed.

4) How many and which conditions will participants be assigned to?
There will be 2 groups. Specifically, the pilot study will randomize participants to a treatment arm with either (1) detailed diet tracking or (2) simplified diet tracking.

All participants will receive a 3-month weight loss intervention. Detailed tracking involves recording all foods/drinks consumed each day in the Fitbit app, while simplified tracking involves recording only highly-caloric items in a checklist via a daily survey sent via email or text messaging.

5) Specify exactly which analyses you will conduct to examine the main question/hypothesis.
For the pilot study, we will use descriptive data to assess reach and other feasibility outcomes, and will compare them to a priori feasibility benchmarks. Specifically, we will assess patterns of self-monitoring engagement over 3 months, by treatment arm, using descriptive statistics (medians and interquartile range if non-normally distributed) and via graphical presentation.

For the qualitative interviews, we will use the framework analysis methodology to code and analyze the qualitative interview data.

6) Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations.
To assess for potential outliers, we will use summary statistics to evaluate the distributions of each variable. We will conduct sensitivity analyses if extreme values are observed.

7) How many observations will be collected or what will determine sample size? No need to justify decision, but be precise about exactly how the number will be determined.
We will recruit up to 40 participants for the pilot study, depending on speed and feasibility of recruitment. This pilot study is not powered for hypothesis

testing.

For the qualitative interviews, we will recruit up to 10 participants -- half with 3-month weight loss of ≥5%, a clinically significant threshold, and half with <5% weight loss. We may choose to recruit fewer per category once we reach thematic saturation, meaning that recruiting additional participants does not provide additional data. This number will also depend on speed and feasibility of recruitment.

8) Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?)
Secondary preliminary efficacy outcomes:
We will assess weight change from baseline to 3 months. We will measure body weight using e-scales (Fitbit Aria Air) that automatically transmit data to the research team. We will also examine changes in caloric intake (measured using the Automated 24-Hour (ASA-24) Dietary Assessment Tool) and physical activity (via self-report measure and the Fitbit activity monitor).

We will examine potential baseline moderators (demographic and psychosocial factors, including race/ethnicity) to determine for whom each self-monitoring strategy works best. We will use the MacArthur approach to assess potential baseline moderators of the intervention effects. To do this, we will conduct hierarchical regression analyses, wherein covariates are entered in step 1, main effects are entered in step 2, and the centered interaction term is entered in step 3. We will probe significant interactions with simple slopes; for continuous moderators, simple slopes will be calculated at the mean and at one standard deviation above and below the mean.

We will use intent-to-treat linear mixed models to examine the main effects of the self-monitoring strategies on each outcome at 1 month and 3 months. Outcomes will be analyzed in a blinded fashion such that treatment allocation is not revealed.

In addition, we will use Spearman rank correlation coefficients (if engagement data are non-normally distributed) to examine the relation between self-monitoring engagement and weight change at 3 months.

Other outcomes: Descriptive statistics will be used to describe baseline characteristics. To determine whether any baseline variables differ by retention status (completers vs. dropout), we will use Pearson chi-square tests for categorical variables, ANOVA for continuous variables, and Fisher exact tests for small cell counts.