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The Effect of Tailored, Daily Smartphone Feedback to Lifestyle Self-Monitoring on Weight Loss at 12 Months: The SMARTER Randomized Clinical Trial

1a-ii) Identify the mode of delivery in the title
Remotely delivered feedback messages. Individuals in SM+FB group received up to three FB messages per day during waking hours tailored to SM data and addressing caloric, fat and added-sugar intake daily and PA every other day. Weekly weight FB was based on whether self-weighing occurred and the amount/weight of change. FB messages addressed one behavior at a time. If the FB message on the smartphone was not opened within one hour of being sent, it disappeared. If the message was opened, the participant could view the prompt icon for the feedback messages and open the app to read the message. Participants used their own smartphones; the other self-monitoring devices (PBF activity tracker and commercially-available smart scale) were provided by the study.

1a-iii) Primary condition or target group in the title
Behavioral intervention. The intervention is grounded in behavioral change theory with an emphasis on Kanfer's self-regulation theory that posits that self-regulation is central to behavior change and includes feedback tailored to the self-monitoring data. At baseline, all participants had a 90-minute 1:1 in-person intervention session with a dietitian on concepts of SBT followed by a demonstration of the Fitbit app to SM diet, a Fitbit activity tracker to monitor PA, and a smart scale for daily self-weighing. Use of the investigator-developed SMARTER app, which was used only for random retrieval of feedback messages from the message library and delivery of message to the participant’s smartphone, was demonstrated to the SM+FB participants so they could view the prompt icon for the feedback messages and open the app to read the message. Participants used their own smartphones; the other self-monitoring devices (PBF activity tracker and commercially-available smart scale) were provided by the study.

1b-i) Key features/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT
*Participants (N=502) were on average 45.0 (SD 14.4) years old with BMI of 33.7 (SD 4.0) kg/m². The sample was 79.5% female (n=399) and 82.5% white participant. This is described in detail in the manuscript.

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
As above, the human involvement was described as 1:1 personal intervention with a dietitian for 90 minutes at baseline.

1b-iii) Open vs. closed, web-based, telehealth, traditional vs. face-to-face assessments in the METHODS section of the ABSTRACT
Smartphone-based intervention.

1b-v) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons
There were no significant between group differences in weight loss; however, results suggest that the use of commercially available digital self-monitoring tools with or without feedback can result in a clinically significant weight loss in over 25% of participants. Future studies need to test additional strategies that will promote greater engagement with digital tools.

2a-ii) Problem and the type of system/solution
*Obesity is associated with several chronic diseases [1, 2]. Obesity prevalence in the United States exceeds 42.4% and disproportionately affects racial and ethnic minority groups.[3, 4]

2a-iii) Primary condition or target group in the title
Behavioral intervention. The intervention is grounded in behavioral change theory with an emphasis on Kanfer's self-regulation theory that posits that self-regulation is central to behavior change and includes feedback tailored to the self-monitoring data. At baseline, all participants had a 90-minute 1:1 in-person intervention session with a dietitian on concepts of SBT followed by a demonstration of the Fitbit app to SM diet, a Fitbit activity tracker to monitor PA, and a smart scale for daily self-weighing. Use of the investigator-developed SMARTER app, which was used only for random retrieval of feedback messages from the message library and delivery of message to the participant’s smartphone, was demonstrated to the SM+FB participants so they could view the prompt icon for the feedback messages and open the app to read the message. Participants used their own smartphones; the other self-monitoring devices (PBF activity tracker and commercially-available smart scale) were provided by the study.

2b-i) Bug fixes, Downtimes, Content Changes
We previously examined the effect of providing feedback to dietary SM and PA; however, the hardware and software used was rudimentary compared to today's technology.[17] Despite those limitations, remotely delivered FB messages enhanced SM adherence and improved weight loss.[31, 38] Those results and significant mobile technology enhancements provided groundwork for the expanded algorithm and FB intervention used in the current trial.

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio
SMARTER was a 2-group randomized controlled trial that enrolled 502 adults with random assignment to either 1) SM alone (n=251) or 2) SM+FB (n=251) and examined the efficacy of the approaches.

3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Percentage lean and fat mass were also collected; however, after March 16, 2020 (i.e., COVID-19 pandemic shutdown start) we collected 12-month weight data remotely from the participant's study-validated scale, which assessed only weight and percent fat mass. Staff contacted participants to instruct them to dress in the clothing that was the baseline assessment and report their weight, which was also captured electronically.[25] At 12 months, 189 (37.7%) participants had in-person weights, 205 (40.8%) had remote weights, and 108 (21.5%) were missing weights. Smart scale weights recorded within 2 weeks of 6- or 12-month assessments were used for imputation of missing weights. If no weight was recorded by the smart scale, a 0.01 kg/day weight gain was assumed for the expanded algorithm and FB intervention used in the current trial.

3b-i) CONSORT: Eligibility criteria for participants
Interested individuals who were regular smartphone users completed surveys and a 5-day food diary in which they needed to record at least 200 calories of food intake/day to ensure that they could self-monitor. Once deemed eligible, individuals had an in-person assessment to verify weight and height for body mass index measures. Inclusion criteria were body mass index (BMI) between 27 and 43 kg/m², completion of a 5-day electronic food diary, and ability to engage in moderate PA. Exclusion criteria were needing supervision of diet or PA, pregnancy, serious mental illness (e.g., schizophrenia), alcohol abuse or eating disorder, and current weight treatment.[25]

4a) CONSORT: Eligibility criteria for participants
Interested individuals who were regular smartphone users completed surveys and a 5-day food diary in which they needed to record at least 700 calories of food intake/day to ensure that they could self-monitor. Once deemed eligible, individuals had an in-person assessment to verify weight and height for body mass index measures. Inclusion criteria were body mass index (BMI) between 27 and 43 kg/m², completion of a 5-day electronic food diary, and ability to engage in moderate PA. Exclusion criteria were needing supervision of diet or PA, pregnancy, serious mental illness (e.g., schizophrenia), alcohol abuse or eating disorder, and current weight treatment.[25]
Individuals had to be regular smartphone users to be eligible for the study which means that they carried the phones with them regularly and kept the phone charged. We also did a run-in 5-day self-monitoring of dietary intake using a phone app as part of eligibility criteria screening.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:
Both online and in-person methods were used to recruit individuals. All surveys for screening were conducted online. After initial eligibility was determined, individuals came into the center for the measurement of height and weight to determine body mass index and complete the first 24-hour dietary recall under supervision.

4a-iii) Information giving during recruitment
This paper addresses this briefly as the details are in the previously published methods paper. The intervention consent form was uploaded in the multimedia materials section.

4b) CONSORT: Settings and locations where the data were collected
*We used a combination of online and in-person recruitment/screening procedures. Initial screening of eligibility criteria was conducted online with online consent form to collect these data. For the verification of weight/body mass index (BMI) we conducted in-person assessment.*

4b-i) Report if outcomes were (self-)assessed through online questionnaires
As indicated previously, yes, all surveys were completed online. "We used a combination of online and in-person recruitment/screening procedures. Initial screening of eligibility criteria was conducted online with online consent form to collect these data. For the verification of weight/body mass index (BMI) we conducted in-person assessment."

4b-ii) Report how institutional affiliations are displayed
The University of Pittsburgh letterhead is on the first page of each consent form.

5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered
A previously published methods paper in CCT reports provides more details. The algorithm that drives the app was developed by the investigator (LE Burke) and the app was developed by members of the investigative team at the University of Pittsburgh.

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners
A second methods paper describing the details of the digital component of the study is in progress.

5-ii) Describe the history/development process
"We previously examined the effect of providing feedback to dietary SM and PA; however, the hardware and software used was rudimentary compared to today’s technology."[10] Despite those limitations, remotely delivered FB messages enhanced SM adherence and improved weight loss.[31, 38] Those results and significant mobile technology enhancements provided groundwork for the expanded algorithm and FB intervention used in the current trial, SMARTER.[33]

5-iii) Revisions and updating
As addressed above, a simpler version of the algorithm was developed several years ago and we used industry to send the messages to participants on personal digital assistant (Palm Pilot). We did not have an "app" at that time.

5-iv) Quality assurance methods
The rigorous study design and data collection methods as well as the analytic methods are addressed throughout the design and methods paper published in CCT (Burke et al., 2021, Contemporary Clinical Trials 91. doi.org/10.1016/j.cct.2020.105958) and in the current manuscript.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms
The above information is archived at the University of Pittsburgh. A second methods paper describing the details of the digital component of the study is in progress.

5-vi) Digital preservation
The algorithm that drives the app was developed several years ago and we used industry to send the messages to participants on personal digital assistant (Palm Pilot). We did not have an "app" at that time.

5-ix) Ensure that all eligible participants provided informed consent
Individuals in SM+FB group received up to three FB messages per day on their smartphone during waking hours tailored to the most recent SM data and addressing caloric, fat and added-sugar intake daily and PA every other day. Weekly weight FB was based on whether self-weighing occurred and the amount of weight change. FB messages addressed one behavior at a time. If the message was not opened within one hour of being sent, it disappeared; if the message was opened, the participant could save it for future review.

5-x) Clarify the level of human involvement
"Engagement with SM tools was a crucial component of the intervention as the algorithm used the SM data to determine an appropriate FB message. If the participant did not SM, FB messages encouraged SM. After 2 weeks of missing SM data, staff sent an email query about technical issues and encouraged SM. Additional details on the algorithm and FB messages are published elsewhere."

5-xi) Describe use parameters
As above, the feedback messages were programmed to be sent within 3 separate periods of the day: morning, afternoon and evening.

5-xii) Clarify the level of human involvement
There was no human involvement in the delivery of the feedback messages. It was automatically driven by the algorithm.

5-xiii) Describe any co-interventions (incl. training/support)
There were no co-interventions. Everyone in the trial had their own smartphone (their own) and study provided Fitbit and smart scale that they were instructed to use daily. The only difference between the two groups was the provision of feedback messages.

6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Outcomes measures are addressed in the paper: primary outcome, percent weight change from baseline to 12 months. Secondary outcomes measures of days adherent to the dietary self-monitoring and dietary goal and percent of feedback messages sent that were opened.

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed
All online surveys used in this trial are standardized measures that have been used by our investigative for several studies and thus validated in our population.

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/monitored
The intervention dose was preset at 3 feedback messages per day. If there was a variation in the number of messages delivered, it was due to the lack of engagement by the participant in the use of the devices and not self-monitoring, or not opening the messages.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained
A focus group study was conducted with participants after study completion. These data are in the final stage of analysis.

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons
Participants were randomized to the intervention or control arms. The randomization was conducted by permuted block randomization and stratified by gender, body mass index (BMI), and age. The randomization was conducted by a computer-generated software program that was developed and maintained by the study investigators.

7a) CONSORT: How sample size was determined
The sample size for this RCT was determined by the SMART RCT. In SMART, the sample size was determined to be 530 (265 per treatment group) allowing for 0.80 statistical power to detect effect sizes (standardized mean differences, δ) as small as δ=0.301 for the mean percent weight changes at 6 and 12 months between the SM controlled and SM + FB groups when using linear mixed modeling with linear contrasts at a Bonferroni-adjusted significance level of .025 and for at most 20% attrition.

7b) CONSORT: Any applicable, explanation of any interim analyses and stopping guidelines
No interim analyses were conducted during the trial. The sample size was not adjusted for attrition.

7c) CONSORT: Reporting a priori analyses
No additional analyses were conducted during the trial. The sample size was not adjusted for attrition.
After completing the intervention consent, research staff used a randomization software program to determine group assignment that was generated using minimization with stratification by gender (male/female) and race (Black/non-Black) with equal allocation to the two treatment conditions. See Figure 1.

CONSORT Diagram

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

"...staff used a randomization software program to determine group assignment..."

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

The trial statistician developed the random allocation sequence using a randomization software. "The trained research ran the program to determine the treatment assignment. Using minimization with stratification by gender (male/female) and race (Black/non-Black) with equal allocation to the two treatment conditions."

11a) CONSORT: Blinding - if done, who was blinded and to whom

"...participants knew the difference between the two interventions..."

11a-i) Specify who was blinded, and who wasn’t

"Key staff who conducted the assessments were not blinded to the treatment assignment, whereas all other personnel and investigators, including the statisticians, were blinded to assignment. Since participants were informed of both treatment conditions they could not be blinded..."

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator"

It is not addressed in the paper but via the informed consent process, participants knew the difference between the two interventions.

11b) CONSORT: If relevant, description of the similarity of interventions

It is not addressed in the paper but via the informed consent process, participants knew the difference between the two interventions.

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes

Continuous variables were summarized as mean ± SD, and descriptive statistics for categorical variables were reported as counts (%). Appropriate group comparative analyses were performed on participant descriptors and outcome variables at baseline by randomized treatment assignment.[39] The effect of treatment assignment on percent weight change over 12 months was examined using linear mixed modeling following intention-to-treat. Models included random intercept and unstructured variance-covariance matrix for the repeated assessments, supported by Akaike’s Information and Bayesian Information Criteria. The base model included fixed effects for time (baseline vs. 6 months and 12 months), group (SM+FB vs. SM alone), time (baseline vs. 6 months and 12 months), and group by time interaction.

The effect of the percentage of FB messages opened on percent weight change from baseline to 12 months for the SM+FB group was analyzed using univariable linear regression. Additionally, the associations of monthly percentage days adherent to the calorie goal with treatment assignment and the percentage of FB messages opened were analyzed using separate linear mixed models with random intercept and slope for the total sample and for the SM-FB group, respectively. We conducted sensitivity analyses on the treatment effects on monthly percentages of days adherent to the calorie goal over 12 months in the total sample and on the percentages of days adherent to the calorie goal in the SM+FB group for the varying monthly percentage of days with sufficient dietary SM data (data not shown). Here we report the results for the varying 30 days with sufficient dietary SM data. Model assessment (i.e., residual analyses with influence diagnostics) was performed for each fitted model; sensitivity analyses were conducted for outlying/influential observations, and to explore the effect of the COVID-19 pandemic on the efficacy of treatment assignment on percent weight change (data not shown). All analyses were performed using R version 9.4.3 (R Core Team, R Core Team, Vienna, Austria).

12a-ii) Imputation techniques to deal with attrition / missing values

Missing weight values were imputed using self-monitoring data from the Wi-Fi scale being used for weight self-monitoring at home. If the weight self-monitoring data were more than ±14 days from the projected 6-month data, 0.30 kg/month or 0.01 kg/day weight gain was assumed from the last available self-weighing value (Wadden et al, Arch Int Med 2001).

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses

All analyses conducted described above.

RESULTS

13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

All of this information is in the detail CONSORT figure, Figure 1 in the paper.

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons

The randomized sample was 502. At 12 months, overall retention was 78.5%. Retention was similar by treatment condition, SM+FB (80.5%) and SM (76.5%) (X2 = 1.18, P = .277).

13b-i) Attrition diagram

At 12 months, overall retention was 78.5%. Retention was similar by treatment condition, SM+FB (80.5%) and SM (76.5%) (X2 = 1.18, P = .277). See CONSORT figure for full details.

14a) CONSORT: Dates defining the periods of recruitment and follow-up

Recruitment, conducted in the greater community surrounding Pittsburgh, PA, commenced in August 2018 and ended in March 2020. The intervention trial was completed in April 2021.

14a-i) Indicate if critical "secular events" fell into the study period

On March 16, 2020, the university shutdown all in-person encounters with study participants. Therefore, we abruptly ended recruitment, screening and enrollment procedures after March 16, 2020 (i.e., COVID-19 pandemic shutdown start). We collected 12-month weight data remotely from the participant’s study-provided scale, which assessed only weight and percent fat mass. Staff contacted participants to instruct them to dress in clothing like the baseline assessment and report their weight, which was also captured electronically.[25]

14b) CONSORT: Why the trial ended or was stopped (early)

No, the trial was not ended early.

15) CONSORT: A table showing baseline demographic and clinical characteristics for each group

The CONSORT figure shows the number of eligible and ineligible individuals and the reason for exclusion.

15-i) Report demographics associated with digital divide issues

We did not find differences in primary outcomes by these groups at this point. We are in the early phase of examining in detail the engagement of participants in all components of the study protocol, which may shed light on the digital divide effect if there was any in our study.

16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16b) Report multiple "denominators" and provide definitions

At baseline, 500 participants had complete body fat data. At 6 months, 338 participants had body fat data, and at 12 months, 186 participants had data.

At baseline, all participants (n=502) had complete waist circumference data. At 6 months, 69 males had waist circumference data, and at 12 months, 37 males had data.

At baseline, all participants (N=502) had complete blood pressure data. At 6 months, 348 participants had blood pressure data, and at 12 months, 189 participants had data.

At baseline, all female participants (n=399) had complete waist circumference data. At 6 months, 271 females had waist circumference data, and at 12 months, 149 females had data.

16-ii) Primary analysis should be intent-to-treat

"The effect of treatment assignment on percent weight change over 12 months was examined using linear mixed modeling following intention-to-treat."

17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

"...The effect of the percentage of FB messages opened on percent weight change from baseline to 12 months for the SM+FB group was analyzed using univariable linear regression..."

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

"...The process variable of adherence to self-monitoring was examined briefly as this is the focus of another major paper...."

17a-ii) Imputation techniques to deal with attrition / missing values

The trial statistician developed the random allocation sequence using a randomization software. "The trained research ran the program to determine the treatment assignment. Using minimization with stratification by gender (male/female) and race (Black/non-Black) with equal allocation to the two treatment conditions."

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended

We do not report binary outcomes.

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Analyses were conducted in the intervention group of the effect of opening the feedback messages. "...In the SM+FB arm, median [inter-quartile range] percentage of FB messages received from baseline to 12 months was 42.19% [45.30] and ranged from 1.28% to 93.70%.

18-i) Subgroup analysis of comparing only users

Analyses were not conducted examining only users.
No unintended effects were observed or reported.

This paper focuses on the primary outcome of the RCT: percent weight change and effects of intervention (opening feedback messages) on the outcome. These other topics (qualitative interviews) are not the focus of this paper.

DISCUSSION

"Limitations include recruitment of fewer males and minorities than targeted, which limits generalizability. The COVID-19 shutdown ended all in-person interactions including assessments which may have affected engagement."

Generalizability to other populations

"...recruitment of fewer males and minorities than targeted, which limits generalizability"

"It is possible that the inclusion of standard behavioral treatment with in-person contact and group sessions or individual coaching would have had a significant impact on adherence to SM and engagement with the devices. Studies that have included in-person coaching have reported larger weight losses. However, these studies do not address the key issues addressing the high rates of obesity prevalence and the limited access to weight loss programs, and also the issue we addressed of reducing burden and cost while increasing scalability."

"...it is difficult to ascertain how much of the human interventionist component can be replaced to make weight loss treatments scalable to a broader reach and lower operational costs. This critical gap in the evidence needs to be addressed in future studies so we can broaden our reach to the millions who need weight loss treatment, particularly those who do not have access to existing clinical and commercial weight loss programs."

Other information

The study is registered with Clinicaltrials.gov (NCT03367936).

The full IRB approved protocol was uploaded to the Multimedia Materials section. A detailed methods paper was published in Burke et al., CCT, 2020.

The study was approved by the Institutional Review Board at the University of Pittsburgh and registered on ClinicalTrials.gov (NCT03367936). Research staff informed all participants of screening procedures prior to obtaining consent and performed in-person informed consent for the intervention study.

No authors/investigative team members have any conflicts to disclose.