Protocol and Statistical Analysis Plan

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Brief Title:	The Mobile Lifestyle Intervention for Food and Exercise Study
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Study Type:	Interventional
Official Title:	Increasing Social Support for Weight Loss Through the Use of Social Gaming and Points: The Mobile Intervention for Food and Exercise (mLIFE) Study
NCT Number:	NCT05176847
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Protocol Synopsis

Significance and rationale

Overweight and obesity are linked to chronic diseases like type 2 diabetes mellitus (T2DM). Weight loss helps prevent and manage T2DM. Traditional group-based behavioral treatment for weight loss includes self-monitoring, physical activity, weight, and regular group meetings. So- cial support also plays a crucial role in group-based treatment, especially when it combines em- pathy, social support, and healthy competition.

mHealth delivery offers advantages like cost-effectiveness and scalability. It also allows for inte- grating novel approaches to sustain motivation and engagement, such as social gaming to reward behaviors like self-monitoring and social support. Gamifying an mHealth behavioral weight loss intervention holds promise for promoting and sustaining social support, but research on its direct effects is limited. Despite commercial health apps using gamified approaches, no adult weight loss interventions have used gamified rewards or points, and no studies have evaluated the im- pact of reward type on desired outcomes.

Pilot study main results

To explore gamification's role in promoting social support for weight loss, our team developed a mobile app that rewards social support through social gaming. The Social Pounds Off Digitally study, a three-month randomized weight loss intervention, delivered remote content via twice- weekly podcasts· Experimental group participants (n=26) lost more weight (-5.3 kg) than the standard app group (n=25; -2.2 kg; p=0.02). Total points earned predicted % weight loss (p=0.01). This diverse study sample (39% African American) represents one of the more inclu- sive digital weight loss intervention studies

Study aims

The goal of the present study is to examine the mLife intervention in a long-term study and to isolate the use of points to gamify the intervention in order to ensure that use of social gaming leads to improvements in social support and continued weight loss.

Primary aims:

Aim 1: Determine if the mLife app plus points intervention (mLife+points; points for provision and receipt of social support) produces significantly more weight loss at 12 months than the mLife without points (mLife) among 240 adults with overweight or obesity and ≥3 T2DM risk factors.

Hypothesis aim 1: The mLife+points group will lose more weight than the mLife group.

Aim 2: Examine the differences in social support provision and receipt

between groups at 12 months.
Hypothesis aim 2: That the mLife+points group will have greater levels of social support provi-
sion and receipt (both perceived and received) than the mLife.

Secondary Aims

Examine usage patterns over time (e.g., do points sustain engagement and promote weight loss maintenance?), potential mediators (e.g., engagement/self-monitoring) and moderators (demo- graphic factors such as sex, race, age), the usability and acceptability of the interventions and the association of social support provision/ receipt and psychosocial factors (e.g., motivation, enjoy- ment) with weight loss. Create and test predictive models that can be applied to future grant applications.

Overview of Intervention

This is a one-year remote intervention, randomized trial that will be conducted in two cohorts. Participants will be randomized to one of two groups: 1) mLIFE+points (n=120) or 2) mLIFE (n=120). Both groups will receive the same intervention, but in order to isolate the impact of points/social gaming, the mLIFE+points group will receive points for engaging in social support- related behaviors and the mLIFE will not.

All participants will be asked to track all their meals daily via the mLIFE App, use a Fitbit to track their physical activity, and use a Fitbit scale to track their body weight. Also, all partici- pants will receive twice weekly podcasts and daily in-app tip of the day (based on Social Cogni- tive Theory and modeled from the Diabetes Prevention Program). The mLIFE App will also en- courage and facilitate social support among participants. The intervention will last 12 months.

Overview of assessments

Potential participants will be directed to a study website to learn more about the study and com- plete a screening questionnaire. If they qualify, they'll be invited to an orientation session where they'll learn more and sign a consent form. Participants will then complete online surveys mea- suring psychosocial variables and diet, and anthropometric data will be collected. Those who complete all baseline assessments will be randomly assigned to either the mLIFE+points or mLIFE group using a computer program allocation sequence, stratified by sex and baseline BMI (to ensure equal distribution of sex and weight classes among the two groups). All participants will complete assessments at baseline, 6, and 12 months. The study will involve two cohorts, each with 120 participants, staggered by 12 months.

Trial registration

The study was pre-registered on http://ClinicalTrials.gov (NCT05176847) by Dr. Gabrielle Turn- er-McGrievy (PI), Project coordinator (Dr. Carolina Delgado-Diaz) has access to the study dash- board as well.

IRB Review and Approvals

This study was initially approved by the University of South Carolina IRB on April 26th, 2021 (Pro00109784).

Methods and Procedures

Recruitment and Enrollment Plan

Population

The objective is to enroll a total of 240 participants (120 participants in Cohort 1 and 120 partic- ipants in Cohort 2). Recruitment for Cohort 1 commenced in February 2022, while recruitment for Cohort 2 commenced in February 2023.

Inclusion criteria

Assessed through an online screening survey and/or a telephone screening conversation.

- Be between the ages of 18-65 years
- Have a Body Mass Index between 25- 49.9 kg/m2
- Have at least 3 risk factors for type 2 diabetes identified by the NIDDK
- Have an Android or iPhone and up-to-date mobile data plan
- Not being pregnant or planning on becoming pregnant during the study, or breastfeeding
- Not participating in another weight loss program
- Be free of major health or psychiatric diseases, drug or alcohol dependency.

Exclusion Criteria

Assessed through an online screening survey and/or a telephone screening conversation.

- Women that are pregnant, have been pregnant in the last 6 months, anticipate becoming pregnant in the next 24 months, or currently breastfeeding. Women who are pregnant should not be pursuing weight loss and should be under the direct care of a physician. Therefore, women who are pregnant or

who are anticipating they might be pregnant should not partici- pate in this study. If a woman becomes pregnant during the study, she will be advised to con- sult her care provider and will be dropped from the study.

- Someone with an eating disorder (which will be screened with the Eating disorder Screen for Primary care [ESP]).[17] If a participant has an eating disorder, they will be given the NIH brochure with information about eating disorders and contacts for help.
- Currently participating in a weight loss program or taking weight loss medications. Partici- pants can be included in the study if they are trying to lose weight on their own, without any medication.
- Individual recently lost a significant amount of weight (>10lbs in the last 6 months).
- Current use of medications that may significantly impact blood glucose (i.e.metformin, steroids)
- Diagnosed with diabetes
- FOR SECOND COHORT: Currently taking any of long term weight loss medications, in- cluding Bupropion-naltrexone (Contrave); Liraglutide (Saxenda); Orlistat (Xenical, Alli); Phentermine-topiramate (Qsymia); Semaglutide (Wegovy); Setmelanotide (Imcivree).

Recruitment Strategies

Participants were recruited nationwide, primarily via social media (Facebook and Instagram), television interviews, researchmatch.org, promotional materials (i.e., fliers and brochures), in- person targeted community outreach efforts (i.e. neighborhoods, churches, libraries, employers, recreation commissions, and coalitions). The recruitment process for the cohort 1 was launched on February 2022, and on February 2023 for the cohort 2. A waiting list was kept up to date dur- ing the intervention delivery of cohort 1.

All advertising strategies included a brief description of the study with an invitation to inquire for more details. Those inquiring will be directed to the study website: www.mlifestudy.org. All potential participants will be prompted to complete the online eligibility screening administered via RedCap, using the public link of the online survey.

Recruitment and Enrollment report

Recruitment and enrollment (as well as retention) will be reported weekly during the recruitment timeframe using Consolidated Standards of Reporting Trials guidelines. Weekly data will be pulled from the RedCap recruitment projects using the reports feature. The project manager will be responsible for tracking potential

participants who contact the study office via phone or email. This involves reviewing the weekly information registered in the screening report from RedCap. Key metrics to track include the number of contacts, referral sources (e.g., social media, community events), the number of individuals screened online and then by phone, the number of eligible participants, and the number of participants enrolled in the study.

Training Plan

All staff working on participant recruitment and retention, assessment, and/or intervention are required to complete both Good Clinical Practices Training (available at: https://www.sbm.org/ training/good-clinical-practice-for-social-and-behavioral-research-elearning-course), and Social and Behavioral Citi Training (available at: https://about.citiprogram.org/en/course/human-sub- jects-research-2/). Certificates for all personnel are uploaded to OneDrive/mLife Study/IRB/Citi training certificates, and kept up to date.

The project coordinator sets reminders to personnel who are required to complete the refresher and update their certification.
Any staff or students participating in the screening process must be trained by a Project coordina- tor. This training will include observation of phone screenings conducted by experienced staff and being observed by the Project Manager or experienced staff in conducting a phone screening.

All training was conducted online, and recordings were available as part of the personnel training and refreshers. Tutorial videos are listed in the document for each section of the current document.

Guidelines for Interacting with participants

*Maintain a Professional yet Friendly Tone: A*ll online interactions, whether via email, text, or other digital platforms, should be conducted with a positive, approachable, and respectful tone. A friendly and warm manner helps participants feel at ease and ensures their willingness to contin- ue in the study. Even when conveying important or technical information, keep the language simple and clear to avoid confusion.

Timeliness and Responsiveness: Respond to participants' communications promptly, ideally within 24-48 hours. Acknowledge receipt of any participant submissions (e.g., completed sur- veys, questions, or concerns) to confirm their participation. If there will be a delay in responding, inform the participant in advance and apologize for any inconvenience caused.

Assure Participants'Confidentiality: Ensure that participants understand that any personal or sensitive information they share online will be treated with utmost confidentiality. Reassure them that their data will be anonymized for analysis, meaning their names will not be associated with any data used in the study. Clearly communicate that any documents containing personal infor- mation (e.g., consent forms) will be securely stored in accordance with privacy guidelines. Re- mind participants not to share sensitive health information over unsecured platforms (e.g., via text messages). Refrain from communicating with any participant using your personal email or phone line; instead, utilize the University's resources. Do not discuss any participant's medical records or private details with anyone outside the research setting. When conducting a call with a participant, ensure that you are in a private location where the information shared cannot be overheard or recorded by any external individuals.

Be respectful and Sensitive: Respectful communication is key to maintaining a positive rapport. Always be mindful of the tone and choice of words. Since you are working with participant with overweight or obesity, ensure that all communications avoid comments or language that could be construed as judgmental or insensitive regarding body image, weight, or health. Avoid jokes, sar- casm, or casual remarks related to body image, and ensure all content is supportive and consider- ate. Show respect for their time by being punctual. Log in to all necessary platforms (RedCap, Signup Genius, OneDrive file) for contacting and tracking participants at least 5 minutes before meetings. This ensures you're ready to initiate phone or Zoom calls without delays. If a follow- up is required, connect the participant with the project manager or research assistant. Maintain a professional appearance, demeanor, and speech at all times.

Provide Clear Instructions and Information: When asking participants to complete tasks or sur- veys online, provide clear, concise, and easy-to-follow instructions. Ensure that links, access codes or attachments are easily accessible and functional. Allow participants enough time to re- view instructions and provide information on what is expected from them. If there are any up- coming tasks or deadlines, communicate them well in advance and more than once. All surveys should be programmed to have 2 reminders for completion in Redcap.

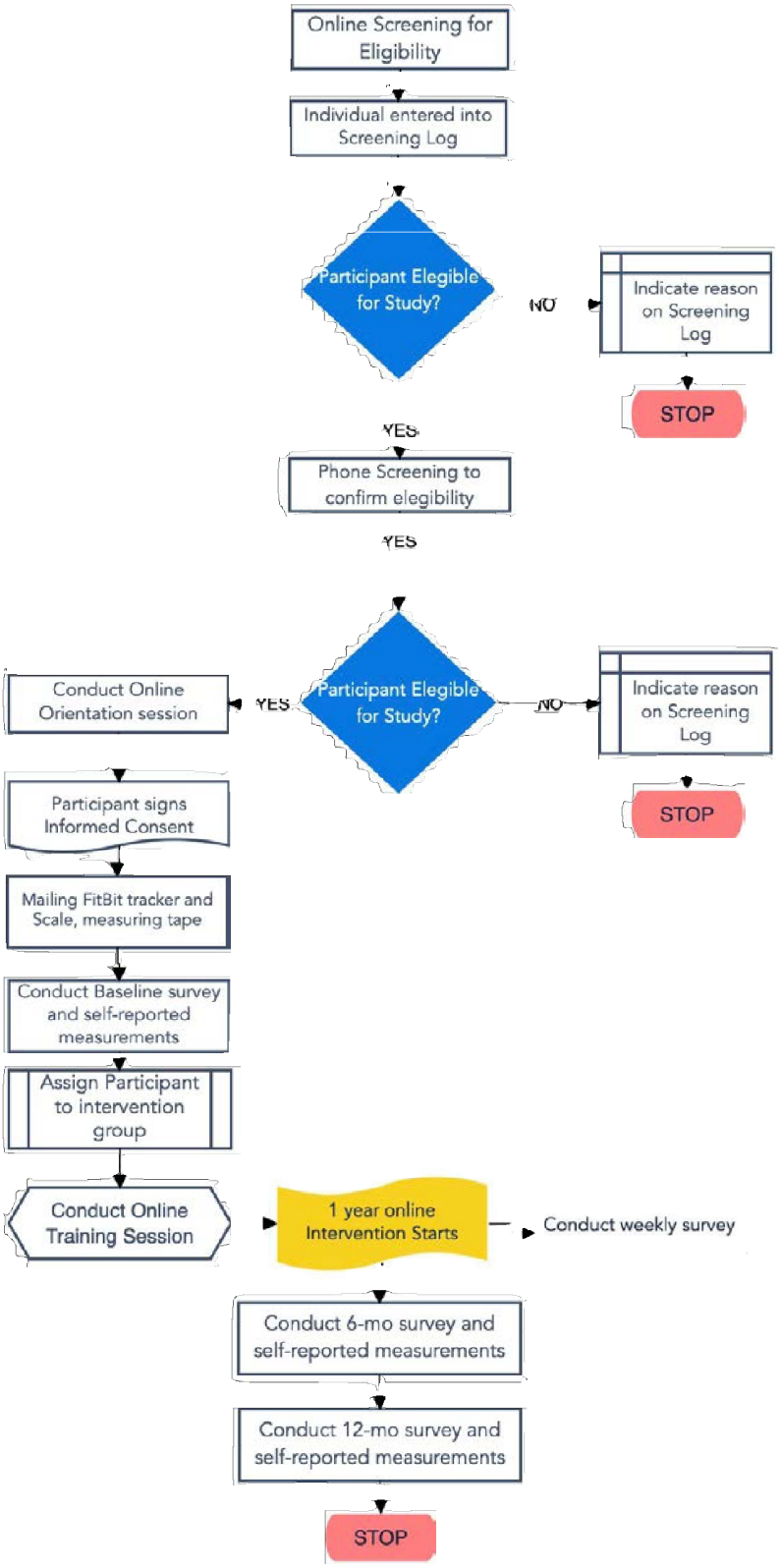
Offer Technical Support: Be proactive in offering assistance for any technical issues that partici- pants may face with online tools or platforms. Provide clear instructions for troubleshooting and offer additional resources, such as the Fitbit user manual and FAQ sites for their devices. Ensure participants know how to

reach out if they encounter problems while participating in the study by clicking in the “help request” feature located in the dropdown menu of their mLife account. Also, advise them to save your email address and the study coordinator’s, Dr. Carolina Delgado: delgadoc@mailbox.sc.edu.

Personalized Communication: Address participants by their preferred names to create a more personalized and friendly experience. When sending bulk messages, ensure that the message is addressed to them directly, and the content is tailored to the specific participant’s status in the study (e.g., reminders, next steps). Refrain from using the BCC feature in your email; use mail merge features in a word processor. Personalized communication enhances rapport and ensures that participants feel valued.

Reassure and Encourage Participation: Regularly express gratitude to participants for their in- volvement in the study, emphasizing how much their participation is appreciated. Encourage open communication by reassuring participants that they can reach out at any time if they have questions or concerns. Ensure that participants feel confident and valued throughout their in- volvement in the study.

Study flow diagram.



Screening Process

Steps to determine eligibility

1. Potential participants are directed to the study's website (www.mlifestudy.org/) to learn more information and complete a screening questionnaire. Phone numbers and e- mail addresses are included on all recruitment material.
2. All screening processes is conducted using RedCap, project "mLife recruitment".
3. The project manager will access the record status dashboard and review one by one of the completed online screening surveys . Once the online screener is reviewed, the "verification form" will determine the eligibility of each individual (eligible, non-eli- gible, or uncertain). The verification form will be marked as complete if eligible or non-eligible and unverified if the eligibility is uncertain.
4. The Project Manager will review each "unverified" verification form and consult with the PI as needed or add a note to gather additional information during the phone screening. Once the decision is made, the Project Manager will mark "complete" the verification form. All verification forms will be reviewed by the project manager and set as "complete". The reasons participants are not eligible to enroll in the study are listed below and should be registered in the verification and enrollment forms.
5. A notification and alert are set in RedCap to automatically send the invitation to sign up for a phone screening to all participants marked as "eligible" or "uncertain" in the "complete" verification forms.
6. The phone screener should be conducted within a week of the online screener comple- tion date. RAs will use the phone screening form to conduct a phone call based on de- termining each person's eligibility. Based on the information gathered from the partic- ipant, at the end of the phone screen, the RA will determine the participant's eligibility and make either one of the following decisions:
   A. If the person is eligible, mark the phone screener as "complete" and invite them to sign up for an orientation meeting.
   B. If the person is ineligible, mark the phone screener as "complete" and inform them of their ineligibility.
   C. If the person's eligibility is uncertain, mark the phone screener as "unverified" and inform them that the decision will be made soon. They will be contacted by the re- search manager.
7. The project manager will access the record status dashboard and review one by one of the completed and unverified phone screeners. Once the phone screener is reviewed, the "enrollment" form will be used to inform of the individual's eligibility. If the per- son is mark as eligible, the participant will immediately receive an email (welcome to the study letter), followed by a text message to confirm the date/time of the orientation meeting. Contrary, if the person is not eligible to participate, they

immediately receive an automatic email informing them of their ineligibility. If the criteria for no inclusion is either diabetes or an eating disorder, additional resources to help are provided.

Orientation Session

We intend to invite at least 155 individuals to the orientation session for a cohort of 120 participants. This assumes a 20% attrition rate between invitation and baseline measurements. All par- ticipants must attend the virtual orientation session to receive study details and sign the consent form. Each session will be conducted via Zoom, lasting 1 hour.

Schedule per cohort

Cohort 1, May 2022 (total of 11 sessions)

May 16, 2022; 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 17, 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 18, 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 19, 10:30 – 11:30 a.m.; 5:30 (makeup sessions)

Cohort 2, May 2023 (total of 11 sessions)

May 8, 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 9, 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 10, 10:30 – 11:30 a.m.; 5:30 - 6:30 p.m.; 7:30 - 8:30 p.m.
May 11, 10:30 – 11:30 a.m.; 5:30 pm(makeup sessions)

Prior to orientation procedures:

1. Longitudinal project for each cohort is set up in RedCap (data collection). The first data col- lection instrument is the contact information form, which public link is shared at the begin- ning of the orientation meeting. This form will be used for attendance to the orientation, and it will determine the participant record ID number. A corresponding ASA-24 login has been assigned to each record.
2. Two emails and then one phone/text message reminder of their scheduled orientation will be sent to all participants. The last email must include the Zoom link and a PDF copy of the study's informed consent for participants to read prior to attending the meeting.
3. A database with the list of the participants scheduled per session will be shared in OneDrive, and will be used for attendance tracking.
4. All orientation materials (presentations, videos, databases, and forms) are stored in One- Drive, see below

Orientation Agenda

1. Begin the Zoom meeting 5 minutes before the scheduled orientation time. Invite participants to join the room. During the opening video and chat***, share the survey link to the contact infor- mation form***
2. Tracking of attendance
3. Intro of the team using a video clip.
4. Dr. Turner McGrievy, the principal investigator, delivers a welcome message. In this message, Dr. McGrievy provides a brief overview of USC, our research, the study's goals, and introduces the concept of randomization and its potential impacts of dropouts.
5. Show a video clip titled "A Day in the Life of the mLife Study" to introduce the study's inter- vention components.
6. Research assistant informs participants that they will be divided into small groups, and a staff member will join each group. During the next 10 minutes, the group will engage in reflection and share their thoughts.
7. Overview of mLife activities, assessments, and the overall timeline. Invite participants to join the breakout rooms for Q&A.
8. Questions and answers session. Questions should be posted in the room's chat, and the staff member in each small group will lead the session. Once all participants' answers are addressed, they are invited to check their email for the link to their informed consent (IC). Participants who decide to participate should sign the form, and a verification window will be accepted before submitting.
9. Explanation of the next steps: baseline assessment and training sessions. Each assessment component (survey, dietary recalls, physical activity, body weight, and anthropometric and blood pressure measurements) has a tutorial video that will be shared with participants as we request each component.
10. Key items and dates. A journey

Informed Consent

Participants receive a pdf copy of the consent form prior to attending an orientation session to learn more about the study. Participants will be given a chance to ask questions at that time and will be asked to sign the consent as described in the orientation procedure. If participants would like more time, they may read it at a later time and, using the electronic format, they will sign it before they enroll in the study. The IRB approved the last version of the IC on 01-18-2022 is used.

Randomization Procedure

Participants were randomized to a gamified *(mLife+points)* or non-gamified *(mLife)* version of the mLife mobile weight loss intervention where provision of social support was incentivized by providing points for engaging in social support activities (for the mLife+points group) or not re- ceiving points for social support activities (mLife group).

Participants are randomly assigned once 50% of the baseline assessments are completed (either the baseline survey or the three dietary recalls). A computerized blocks system, stratified by race (Black, Other) and sex, is used to ensure equal distribution among groups within each co- hort. Brent Hutto generates a random list of two groups (0s = Standard, 1s = mLife) in blocks of 10 or 4. Separate blocks are created for women and men, as well as white and non-white partici- pants, this results in 15 blocks of 10 for non-white women, 30 blocks of 10 for white women, 3 blocks of 5 for non-white men, and 5 blocks of 4 for white men.

As participants complete 50% of the assessment, a blind staff member uses the demographic data report from RedCap to identify each participant by gender and race add the participant's ID number to the next available spot on the blocks. The group alloca- tion will then be recorded in the RedCap project under the randomization form (randomization event). Participants will not be informed of their group assignment but will be provided with their choice of meeting times and days for the training session. On the day of randomization, par- ticipants will be contacted and asked to select the time and date they plan to attend. The group allocation will be revealed at the first group meeting, after all baseline assessments have been completed. Since the training sessions are scheduled by group, the randomization process must occur before inviting participants to the training meeting.

Participant Status Updates

The project manager is in charge of updating the participant status. The following procedure en- sure efficient and effective updates of participant status, accurately documenting reasons for dropout. The steps described below are completed if a dropout occurs during the intervention timeframe.

Initiating Status Update:
Once a participant informs a team by using any of the retention strategies that they wish or need to drop out, the change of status protocol is activated. The staff member receiving the informa- tion immediately contacts the project manager via email, who is responsible for the following steps.

Communication Process

The project manager reaches out to the participant via email or text message to schedule a phone call. The purpose of the call is to gather information from the participant about the reasons for their dropout, if they wish to share. The manager may also offer resources or alternatives if rele- vant. If the initial contact is incomplete, they will attempt a second and final contact with the par- ticipant via email in two weeks. If no response is received, the manager will consider the partici- pant to have "dropped out" due to personal reasons. If a change of status takes place it is docu- mented.

Report

The project manager reports any changes in the status of participants in the "participants status" form of the RedCap project. The report in the form includes documenting:

- whether the withdrawal of the participant resulted from a decision by the participant or by the investigator (exclusion), and the reasons for the withdrawal, if known.
- whether the withdrawal was from all components of the research study or just the primary interventional component (assessment only).
- Note all communications and documentation in the notes section of the form, make sure it is complete, accurate, and contains all pertinent dates relating to events that resulted in the withdrawal of the participant, especially the date of withdrawal from your research study.

Participant status definitions

Status	Definition	Report
Withdraw	When a participant decides to withdraw from all com- ponents of a research study. The study's Manager must discontinue research activities involving the partici- pant's participation such as: • Interacting or intervening with the participant in order to obtain data about for the research study. • Obtaining tracking data from FitBit, mLife app must be inactivated.	Complete the form immediately. Inactivate mLife account Highlight partici- pant ID in the ASA24 accounts file.

Excluded	When a participant reports a change in their health sta- tus or if an exclusion criterion becomes apparent, the study's manager must discontinue any research activi- ties involving the participant. The participant should be informed of this decision promptly. Examples of exclu- sion criteria that may arise after randomization include pregnancy, the decision to take weight loss medication, or the onset of a major health condition that prevents the participant from complying with the intervention. Participants are made aware of these criteria at the ori- entation and training meetings to prevent any misunder- standings or disruptions during the study.	Complete the form immediately. Inactivate mLife account Highlight partici- pant ID in the ASA24 accounts file.
Assessment only	Sometimes, a participant may wish to withdraw from the primary interventional component of the study but is still willing to participate in other research activities that are outlined in the IRB- approved protocol and in- formed consent document. In such cases, these partici- pants will only be contacted for data collection at the follow- up assessments.	Complete the form immediately. Highlight partici- pant ID in the ASA24 accounts file as "AO". Turn text and no- tifications from the APP off.
Lost to follow- up	Reported at the end of the trial for each of the assess- ments. Participants who were enrolled in the trial but are unavailable during follow-up assessments.	Complete the form after incen- tives distribution. Inactive mLife account (do not remove the link to FitBit)

Completed the study	Reported at the end of the trial: Participants who completed the 12-month assessment with a body weight report. Individuals who participated in the 12-month assessment but did not have an objective report of their body weight were determined as “Assessment Incomplete”.	Complete the form after incen- tives distribution. Inactive mLife account (do not remove the link to FitBit)

Training Session

This online training meeting launches the mLife intervention, equipping participants with skills to access and use the mLife app. Participants learn their group (mLife or mLife+), download the app, and link their Fitbit profile. Within the app, they edit their first name to match their pre- ferred username, keeping their last name and email unchanged. Other participants' usernames display their chosen first name and the initial of their last name. Last names are not displayed for privacy. Sessions are limited to 1.5 hours.

Schedule per cohort

Cohort 1, June 2022

June 28, 10:30 – 12:00M (Control group); 5:30 - 7:00PM (mLife+points group)
June 29, 10:30 – 12:00M (mLife+points group); 5:30 - 7:00PM (Control group)
June 30, 5:30 - 7:00PM (mLife+points group); 7:30 - 9:00PM (Control group) (makeup sessions)

Cohort 2, July 2023

July 5, 10:30 – 12:00M (Control group); 5:30 - 7:00PM (mLife+points group) July 6, 10:30 – 12:00M (mLife+points group); 5:30 - 7:00PM (Control group)
July 7, 10:30 - 12:00M; 5:30 - 7:00PM (mLife+points group); 7:30 - 9:00PM (Control group) (makeup sessions)

Prior to training meeting procedures

1. All of the participant's mLife accounts are created in a bulk upon completion of the randomization process.
2. Signup genius is setup to invite participants for the training meeting. Two signup are required as the training meeting are different per group (social support gamification).
3. Participants are contacted via automatic email sent from RedCap on the day they are randomized and accounts in the mLife application are created. The message includes the notification of the welcome to the study package shipping and the link to SignUp- Genius for the participant to book the training meeting.
4. Approximately 1h prior to each session, an activation link to the mLife account will be sent from the mLife staff site. A database with the list of the participants scheduled per session will be shared in OneDrive (training meeting materials folder). It will be used for preparation and attendance purposes.
5. An attendance form for the training session is included in the longitudinal project in RedCap for each cohort (training event).

Training Meeting Agenda & Notes for Study Personnel

1. Only participants who have completed ALL components of the assessment are confirmed to attend the training meeting.
2. Training meetings are conducted LIVE; the recording of screenshots and in-app tasks are used to conduct and time the meeting.
3. The Principal Investigator opens up the session with a welcome back message and introduces the mLife team.
4. Demo (live + screenshots) of activation of mLife account and link of Fitbit - participants to complete a task in-app (15 min).
5. Q/A in breakout rooms. A staff member will be assigned to each group. At this point, participants will be allowed to share their screen.
6. Demo of intervention components (live + screenshots of mLife app with comments related to the explanations) - include explanations of the graphs for self-monitoring (PA, BW, and Kcals), emphasis on the definitions and importance of each.
7. Demo of diet logging (tutorial video). Participants complete one item/meal log. Reminder set as a text message at 8 p.m. (participants' time zone) (10 min)
8. Demo of tips of the day and podcasts access (live + screenshots). Participants "read" the available tip of the day. The first podcast should be available for them to listen to and mark as listened.
9. Demo of Social support activities (tutorial video). Demo of outreach message. Participants write their first request for support and/or rate a response. They like someone's PA, diet logging, or BW. For the control group, review the checklist. For the +Points group, review the points system and leaderboard, emphasizing its importance in weight loss.
10. Q/A in breakout rooms. A staff member will be assigned to each group. At this point, participants will be allowed to share their screen.
11. Key items and dates. A journey

Notes:

- At the end of the meeting, ALL attendees must have their mLife account active and Fitbit devices synchronized to our site. A staff member will track this procedure via the mLife staff site.
- Tutorial videos for each section of the app with a feedback survey (within the RedCap project / training session event) will be shared with the participants via e-mail immediately after their meeting.
- Three days after the training meeting, a handout with recommendations for physical activity and caloric intake limit will be sent to each participant via email. The cutoff points on baseline body weight for caloric intake limit (handout) are: 1500 kcal/day for participants weighing ≤248 lbs; 1800 kcal/day for participants weighing ≥ 249 lbs.

Assessments

Participants' assessments will be conducted at baseline, 6, and 12 months of the intervention. The following table and cited references describe the surveys and measurements conducted at each time point:

Instrument	BL	6 mo	12 mo
Demographic, social support and potential mediators/moderators			
Demographic and socioeconomic status			
Demographic variables	X		
Socioeconomic status variables, use of nutrition assistance programs, environ- mental changes	X	X	X
Current medications	X	X	X
Social support provision, receipt and enjoyment			
Number of times a person completes a social support-related activity (SS provi- sion)		X	X
Adapted Multidimensional Scale of Perceived Social Support Scale (MSPSS) – (SS perceived)[1; 2]		X	X
Ratings each participant gives to the social support provided to the after they re- quest support (SS perceived)		X	X
Total number of times other participants provided support to the individual (SS receipt)		X	X
EGameFlow (enjoyment)[3]		X	X
User engagement and user burden			
User Engagement Survey* (adaptation)[4]	X	X	X
User Burden Scale* (adaptation)[5]	X	X	X
Self-efficacy and -regulation and motivation			
Weight Efficacy Life-Style Questionnaire (WEL-Q)[6]	X	X	X
Treatment Self-Regulation Questionnaire (TSRQ)[7]	X	X	X
Potential drivers of weight loss			
NCI's Automated Self-Administered 24-hour Dietary Recall (ASA24®) – 3 unannounced recalls – two weekdays, one weekend day)[8; 9]	X	X	X

Physical Activity (FitBit tracker) – minutes per week of MVPA (min:10h/d, 3 valid days)[10; 11]	X	X	X
Exercise Vital Sign Questionnaire[12; 13; 14]	X	X	X
The Stanford Leisure-Time Activity Categorical Item (L-Cat), short version[15; 16]	X	X	X
Physiological and anthropometric measures			
Height (self-report) / weight (FitBit Aria Scale)[17; 18]	X	X	X
Hip and Waist circumference (self-report).	X	X	X
T2DM (Type 2 Diabetes Mellitus) risk factors (risk score 0 – 10)	X	X	X
Self-monitoring adherence and study compliance/responsiveness			
Monthly survey (self-monitoring)		X	X
Adherence to FitBit devices usage (mLife app – rewards or points)		X	X
Adherence to self-monitoring diet (mLife app - logging ≥2 eating occasions per day)		X	X
Use of intervention components (mLife app - use of all intervention components)		X	X
Factors that may affect compliance: differential dropouts and reasons to discontinue the study		X	X
Factors that may affect compliance: assessment of major life events		X	X

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Participants were informed about the timeframe for each assessment during the orientation session and two weeks before the 6- and 12-month assessments through emails and e-cards. At each assessment point, participants received detailed instructions for each component of the assessment.

The order of the assessment request was in all time points, dietary recalls, survey, physical activi- ty and body weight. Protocols for each component of the assessment are described below.

Dietary recalls

Dietary intake data (24-hour recalls) were collected and analyzed using the Automated SelfAdministered 24-hour (ASA24) Dietary Assessment Tool, version 2020 for cohort 1 and 2022 for cohort 2. Three unannounced dietary recalls were collected at each time-point. Invalid recalls (under 500kcals) were considered and participants were asked to complete another attempt. Total kcals for all valid recalls were averaged. A total of 5 weekdays and 5 weekend days are scheduled are each timepoints, thus enough makeup days are available for the

completion of the assessment.

Steps to request a dietary recall

1. Before the first recall date, the number of recalls completed and remaining per participant has to be determined. Data is exported from ASA24 research site “tracking feature”. If a participant has not enough recalls remaining (8 remaining at 6-mo assessment and 4 remaining at 12- mo assessment), a new account must be assigned by highlighting the participant in the ac- counts Excel database located in OneDrive/mLife/Assessment Materials/Cohort/Dietary re- calls and pasting their identifying information on the last account available.

2. Active participants in each cohort are identified at each assessment time-point (baseline and 12 weeks) by generating the “consort report” from RedCap. Desired participants are enrolled study participants, with a participant status “active” and who haven’t completed the required dietary recalls for that time-point.

3. All databases generated for tracking each recall are securely stored in an Assessment Materials OneDrive folder per cohort. A folder within the Dietary Recalls section is labeled with the date of each recall.

4. On the scheduled day, a recall request is emailed to the participant in the morning using Outlook mail merge, which pulls participant information from the active participants spreadsheet.

5. In the early afternoon of the recall date, a research assistant would examine the completion of the day using the ASA24 Researcher Site. They would then create a list of people to remind to complete the day’s recall on Excel utilizing the earlier created spreadsheet of participants who were contacted that day to complete a recall. The research assistant would then conduct re- minder phone calls using Google Voice. If not able to be reached by phone call, participants are texted. These contacts would be noted in the Reminder Call Excel Spreadsheet. After completing these phone calls, the research assistant would contact the faculty members asso- ciated with the recalls for the assessment time-point and update them on their contacts. The phone call and text message scripts are below.

6. Participants are required to complete the recall before midnight Eastern time zone on the day that the recall was requested in order to be considered completed and valid. In addition, each participant’s recall had a threshold of 500 kcal to be considered valid.

7. The following day, research coordinator imports to RedCap the kcal and date of the recall, and the participants who completed the prior day’s recall data.

Survey

A single survey is requested for completion at each time point. Configure RedCap's Automated Survey Invitations (ASI) feature to automatically send the sur- vey link to the participant's email. The customized email includes the unique survey link, a brief explanation of the survey's purpose, and deadlines for completing the survey at each time point. Set the system to send the initial survey invitation email to the participant immediately after they sign the informed consent form (baseline or on the date of the 6- or 12-month assessment launch). Schedule two reminder emails: the first will be sent **3 days after the initial invitation, and the** second will be sent **7 days later**.

Participants are requested to provide self-reported anthropometric measurements, such as hip and waist circumference and body weight, and physiological measurements, like blood pressure, at each time point. These measurements are reported in the "measurements" section of the survey instrument. Detailed instructions are provided below.

Hip and waist circumference

A tape measure is sent to the participants for hip and waist circumference measurements. The participant will be instructed to measure waist circumference at the iliac crest, and hip circumfer- ence will be measured at the maximum protuberance of the buttocks. Two measurements will be taken and should be within 4mm of one another. If they are not, a third measurement will be re- quested in the survey/

Written tips:

- Stand up straight and breathe out. Use the tape provided for the study.
- Measure the distance around the smallest part of your waist, just above your belly button. This is your waist circumference.
- Then measure the distance around the largest part of your hips - the widest part of your buttocks. This is your hip circumference.
- The accuracy of waist and hip circumference measurements depends on:
    - The tightness of the measuring tape. The tape should be snug around the body, but not pulled so tight that it is constricting.
    - The correct positioning of the tape around the body (horizontal).
- Complete two measures of both waist and hip circumference and report below as indicat- ed. If the difference between the two is greater than 1cm, please repeat the process a 3rd time.
- Report your measurements in centimeters (cm).

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Blood pressure

Participants self-report blood pressure: a recent reading taken at a local pharmacy or at home will be recommended. Measurement should be taken after a five-minute rest period, with a digital blood pressure cuff. A minimum of 2 readings will be taken, and the average of those readings will be reported. If there is a >5 mmHg difference between the first and second readings, addi- tional (one or two) readings will be obtained, and the average of these readings will be used.

The following instructions will be provided to the participants:

Sit quietly for at least 5 minutes before testing.

Don't smoke, drink caffeine or alcohol, or exercise within 30 minutes prior to testing.

Empty your bladder.

Sit up straight in a firm, hard-backed chair that supports your back.

Don't sit or lie on a sofa or bed.

Place feet flat on the floor with legs uncrossed.

Your arm should be supported on a flat surface, such as the chair arm or a table.

The upper arm should be at heart level.

Place the cuff on your upper arm above the bend in your elbow.

See your monitor's instructions for an illustration or ask for a demonstration at your doctor's office.

Don't place the cuff over clothing.

Take at least two readings and record the average result.

Take two readings one minute apart.

Record your readings and upload a picture of the device showing the numbers.

Body-weight

Body weight is determined objectively and self-reported, with units for assessment reported in pounds (lb). The self-reported body weight is one of the first questions in the “health status” sur- vey.

For the objective measure, participants receive instructions on how to use the provided Fitbit Aria Air scale, which syncs data to the Fitbit app. If the scale does not properly sync to their Fit- bit app, participants are asked to take a picture of the scale's display and upload it to the instru- ment for data verification (self-reported, verified).

At the beginning of the trial, the first synchronized body weight reading is recorded as baseline. The body weight at 6 months and 12 months is determined as the last reading at weeks 26 and 52, respectively. The objective measure of body weight data is extracted from Fitbit and is pulled to the mLife site, from where it is exported to a CSV file. The body weight and date are then im- ported to RedCap at the assessment event using the “Body Weight (Fitbit)” instrument. Import- ing the body weight data marks the instrument as “complete,” so it

is not requested again from the participant. However, if no body weight data is reported for a participant at the end of the as- sessment period, they receive a link to either report their body weight directly to the form "Body Weight (Fitbit)" or to manually enter it into their Fitbit profile. In either case, they are prompted to upload a picture of the scale.

Participants follow the instructions below to get their body weight reading. These instructions are included in the RedCap instrument for the participant.

- Use Aria Air while barefoot.
- Make sure your feet are dry before weighing yourself.
- Place Aria Air on a hard, flat surface during use.
- Balance your weight evenly between both feet when you stand on the scale.
- Weigh yourself at the same time each day to see consistent trends. Your weight naturally varies over the course of the day.

Outreach Plan to Address Technical Issues with Participants' Scales

Assessment Preparation:

Before each assessment point, review the weekly data to identify participants whose scales haven't synchronized (no body weight reading in the mLife account) for more than three weeks.

Participant Contact:

Reach out to the identified participants to inquire about any technical problems they may be ex- periencing, particularly with setting up their scales.

Technical Assistance:

Schedule a video call with the participant to provide them with assistance in setting up their scale, if necessary. Share the tips to use Fitbit scales listed below

Tips/Links for Fitbit Assistance

Below, are options to explore regarding your Fitbit device.

- Fitbit Support Line: call 24 hours a day (877) 623-4997
- Fitbit Live Chat: 24 hours a day.
  Fitbit.com > scroll all the way down, click "Product Help" > click "GET SUP- PORT" under "Let's Talk"
- Fitbit Community: Search for info/questions among other Fitbit users
  Fitbit.com > scroll all the way down, click "Community" > search anything in the search bar regarding your device, also feel free to explore the page for guidance
- Twitter: @FITBITSUPPORT
  Give this account a follow on twitter and direct message the account with any questions you may have
- Trouble with Bluetooth pairing?
  There is a small black circle button on the back of your scale. Press and hold that

button for one minute until the screen flashes “otA” then your scale has been re-set. Once your scale is reset, try and repair your device to your app.
Some participants have also found that restarting their phones help debug any Bluetooth troubles.

- Need to change the weight units to lb?
  Tap the small black circle button on the back of your scale to switch your weight unit.

Escalation to Fitbit Customer Service:

If the research team is unable to resolve the issue during the video call, contact Fitbit customer service on behalf of the participant. Follow up with Fitbit to ensure that the problem is resolved promptly. Document the case number in the tracking database.

Device Replacement:

If Fitbit fails to offer a solution, arrange for a replacement device to be sent to the participant. Follow the procedure for Distributing mLIFE Study Kits. Each step of the process is tracked and documented in a database created for each assessment time point per cohort, located in OneDrive/mLife/Retention/Cx_202x.

Physical activity

A FitBit Versa 2 tracker will be used to objectively assess and monitor minutes per week of mod- erate to vigorous-intensity physical activity (MVPA). During the orientation, the participants are instructed to wear the tracker at least 10 h daily, during asleep and awake time. Fitbit uses a pro- prietary algorithm to determine activity levels, which are defined as vigorous, moderate, light, or sedentary and activity intensity—active zone minutes (time spent in the fat burn, cardio, or peak heart-rate zones), the number of steps per day, and resting heart rate will be pulled from the Fit- Bit public API to the mLife App. For data analysis, participants’ data is considered valid if they had a wear time of ≥600 minutes per day.

The average of three valid days within a week during the assessment period is imported to Red- Cap at the assessment event using the “Physical Activity (Fitbit)” instrument. Baseline data was reported for Week 0, and 6-month and 12-month assessments were reported for Weeks 26 and 52, respectively. When data for the week of intervention is unavailable, data from two weeks before or the week after the time point cutoff is considered for assessment.

Additionally, self-reported physical activity was assessed using the Exercise Vital Sign Questionnaire and the Stanford Leisure-Time Activity Categorical Item (L-Cat), both of which were included as questions within the “health status questionnaire of the survey.

Procedure for Distributing mLIFE Study Kits

The mLIFE Study kits, which include a **Fitbit Versa2**, **Fitbit Aria Air Scale**, and **non-elastic measuring tape**, are distributed to participants who have completed at least the initial survey or **three dietary recalls**. These devices are critical for tracking physical activity, weight,

and conduct the hip and waist circumference measures at each time point.

All devices are bought in bulk and kitting services are hired to receive the orders of the Fitbit devices and tapes and to create and label each kit box. USC Post office provides the shipping services to the participants. Once the shipped to a participant, an email containing the **tracking number** is sent to the participant. A designated study assistant monitors the tracking progress to ensure timely delivery. Upon receipt of the kit, a courtesy **phone call** is scheduled to confirm successful delivery and to ensure the participant understands the setup and usage instructions for the devices. If required, a video call is scheduled to assist with the device setup.

The kits includes a welcome letter which provides step-by-step guidance on creating a **Fitbit account**, syncing devices, and verifying the account. Participants are instructed to sync their devices at least once every 5 days and upload a picture of the scale's display for data verification. Additionally, a training session is scheduled to guide participants through linking their Fitbit account to the mLIFE app, ensuring smooth device usage and data synchronization. All kit distribution is tracked in the study's OneDrive/Retention/Cx_202_.

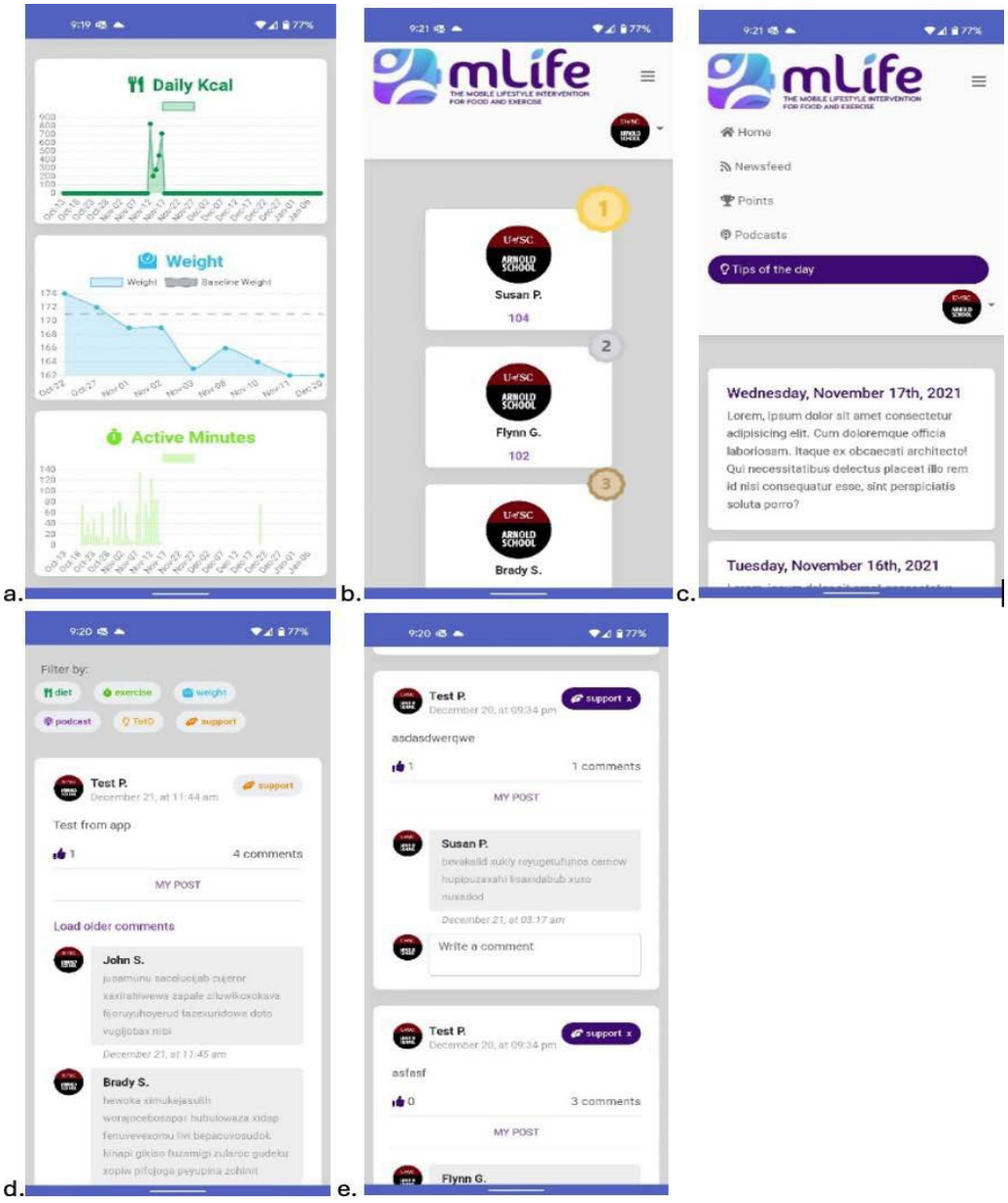
During the courtesy call, the RA reminds the participants of the following:

1. Create a FitBit profile on the website (no app). When linking the profile to the mLife app, permission to access FitBit physical activity data will be asked.
2. Wear Versa 2 on your non-dominant wrist. When not exercising, wear it a finger's width above your wrist bone. During workouts, wear it higher for a better fit. Frequent bending of the wrist during exercises like bike riding or weight lifting could interfere with the heart-rate signal if the watch is lower.
3. Wear the Fitbit device on top of your wrist, ensuring the back is in contact with your skin.
4. Follow the manufacturer's instructions for cleaning and caring for the device.

Study Intervention

The intervention design promoted weight loss and weight-loss maintenance by focusing on diet and PA behaviors and facilitating social support, grounded in theoretical perspectives such as supportive action, appraisal, and relationships, as well social support provision and receipt. The mLife intervention consisted of 5 main components: daily tracking of 1) diet, 2) PA, and 3) body weight; 4) podcasts and tips of the day; and 5) gamification of social support activities. As mentioned above, participants were provided a Fitbit watch and scale for PA and body weight tracking, with all intervention components implemented remotely through the mLife app (cohort 2 tracked diet outside of the app). Both groups will be instructed to follow the same

dietary (re- duced energy diet) and PA recommendations (progressed up to a goal of 150 minutes of moder- ate or 75 minutes of vigorous activity/week). These recommendations will be provided via hand- out at the orientation and reinforced in the podcasts. The figure below displays images of the mLife app components.



mLife intervention components delivered via the mLife app:
a. diet, physical activity (PA), and weight tracking; b. leaderboard and points tracker; c. tips of the day; d. newsfeed; e. social support requests

App Development and Use

A progressive web application, incorporating improved features from the pilot Social POD app, delivered the mLife weight loss program. It integrated the NutritionIX Database via API for diet logging. For cohort 2, Participants used FitBit devices to track activity and weight, and the API displayed Fitbit data.

Based on Cohort 1 feedback, two adjustments were made for Cohort 2. Participants were initially limited to one response to peer support requests, but this hindered social interactions, so unlimit- ed responses were allowed. The in-app graph displayed only "active minutes" per day, but the FitBit app emphasized "active zone minutes," so the mLife app adjusted to display both.

Cohort 2 also made an adjustment based on Cohort 1 feedback. Participants expressed dissatis- faction with the in-app diet tracking feature's lack of recipe building and barcode scanning. So, Cohort 2 logged their diet in the Fitbit app, and the data was synchronized to the mLife app.

Participants and staff member accessed the mLife application from the study's website, under the login menu: https://mlifestudy.org/study/guest/login Participants access their account using the Email provided during the orientation, contact information form in RedCap project.

IT team assist with any account issues or data display concerns through the help request RedCap project, as detailed under retention strategies.

Intervention components procedures

Both groups will receive the same intervention, but to isolate the impact of points/social gaming, the mLIFE+points group will receive points for engaging in social support-related behaviors, and the mLIFE will not. The intervention components and points system is displayed below.

Intervention Components	Points
Podcasts (within the app):	
Nutrition and exercise information	N/A*
Audio diary	N/A
Goal setting	N/A
mLIFE app:	
Self-regulation features	
Diet, PA**, and weight tracking app components	N/A
App notifications at specific times to remind participants to self-monitor	N/A

Newsfeed of activity listing when someone self-monitored diet, PA, and weight; downloaded a podcast or read a tip of the day; or requested social support on a topic.	N/A
Leaderboard and Points tracker	N/A
Social support features	
Thumbs Up that someone tracked their diet for the day (posted to newsfeed)	1
Thumbs Up a notification that someone logged 30 min of PA for the day (posted to newsfeed)	1
Thumbs Up a notification that someone logged their weight for the day (posted to newsfeed)	1
Thumbs Up a notification that someone listened to a podcast or read a tip of the day (posted to newsfeed)	1
Sending someone an encouraging message when they have not logged on (choice of 3 pre-populated messages or ability write their own message)	1
Sending out a request for help on a specific topic related to diet or PA	1
Responding to a request for help	1
Thanking someone for a thumbs up or response to a request for help (participants will also rate how supported they felt for each response they receive)	1
Total max points possible per day:	8

Within the study's app, the participants can monitor their physical activity data from the FitBit tracker, log their food and engage in social support activities. FitBit app is used for body weight saving and in cohort 2 only, Fitbit nutrition feature is used for diet logging. The procedures for the 5 components are described below

Diet tracking.

Both groups were instructed to follow the same dietary (reduced energy diet) recommendations, which were provided via e-handout at the beginning of the study and reinforced in the podcasts. Participants were asked to enter all food and drink items consumed daily into the mLife app and were instructed to select the best match listed within the dietary database. Recently consumed foods were programmed to be 'remembered' within each participant's search history for ease of use. Participants were able to view their individual diet log and daily total kilocalorie intake within the mLife app.

Physical activity tracking

Participants wore wrist-worn Fitbit Versa2 to self-monitor their physical activity (PA). The Fitbit synced PA data (steps, sedentary, lightly active, fairly active, and very active categories) to the

mLife app for self-monitoring. Heart rate data (number of minutes in heart rate zones) was also displayed in the mLife app. Participants wore the Fitbit daily and didn't modify the default heart rate zone.

PA data was displayed in the mLife app in two ways: total minutes of moderate to vigorous PA and total number of 'active zone' minutes. Fitbit used the term 'active minutes' to denote minutes spent performing MVPA (>10 consecutive minutes) calculated by METs. Activities at or above about 3 METs count towards active minutes. 'Active zone minutes' denote time spent in light to near maximal heart-rate zones (fat burn to peak). Participants earned 2 active zone minutes for each minute spent in the vigorous and near maximal heart rate zone (cardio and peak zones).

Body weight tracking.

Participants received an Aria Air Fitbit scale and were asked to weigh themselves daily for regular feedback. Fitbit scales synced to the mLife app via Bluetooth and the Fitbit app, allowing par- ticipants to view weight graphs and track changes over time.

Remote content delivery via podcasts and tips of the day.

Remote intervention content was delivered through podcasts and tips of the day. Designed using the Diabetes Prevention Program and Social Cognitive Theory. New podcasts are released every Monday and Thursday morning for the first 6 months, then once weekly for the second half of the intervention. Podcasts were 10-15 minutes long and tracked in the mLife app. On podcast release days, participants received a notification for a tip of the day.

Podcasts for the first 6 months structure:

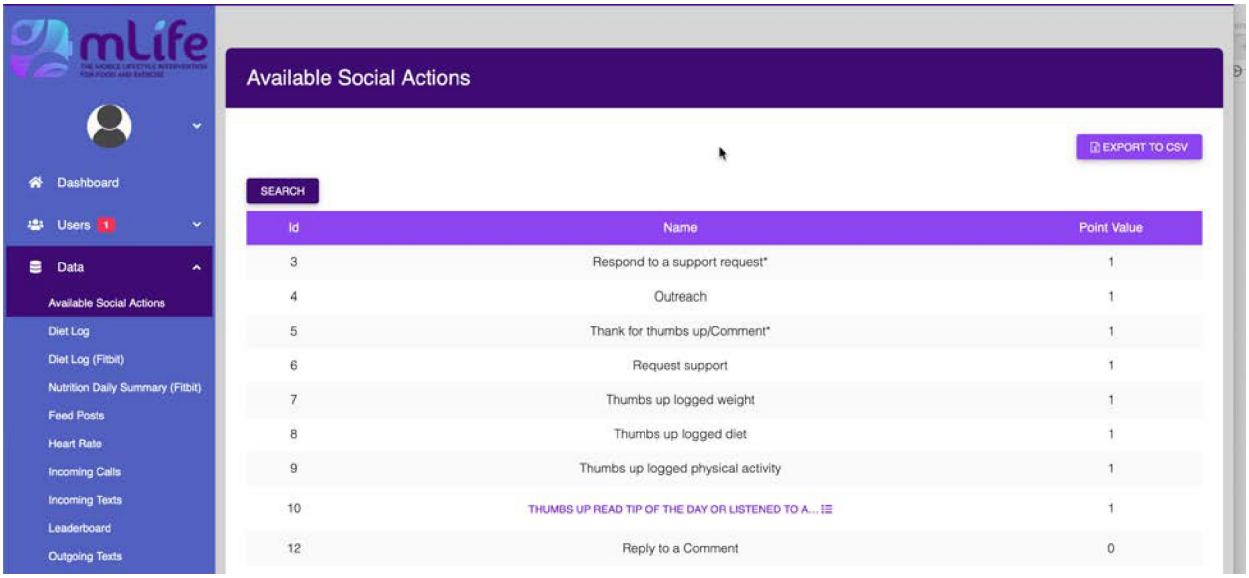
1. introduction
2. audio diary of person discussing their weight loss efforts
3. nutrition/exercise information
4. continuing soap opera
5. a goal-setting activity.

Podcasts for months 7-12 structure:

1. introduction
2. nutrition/exercise information
3. scripted audio interviews or audio diary of person discussing their weight loss experiences
4. a goal-setting activity.

Social support activities and gamification

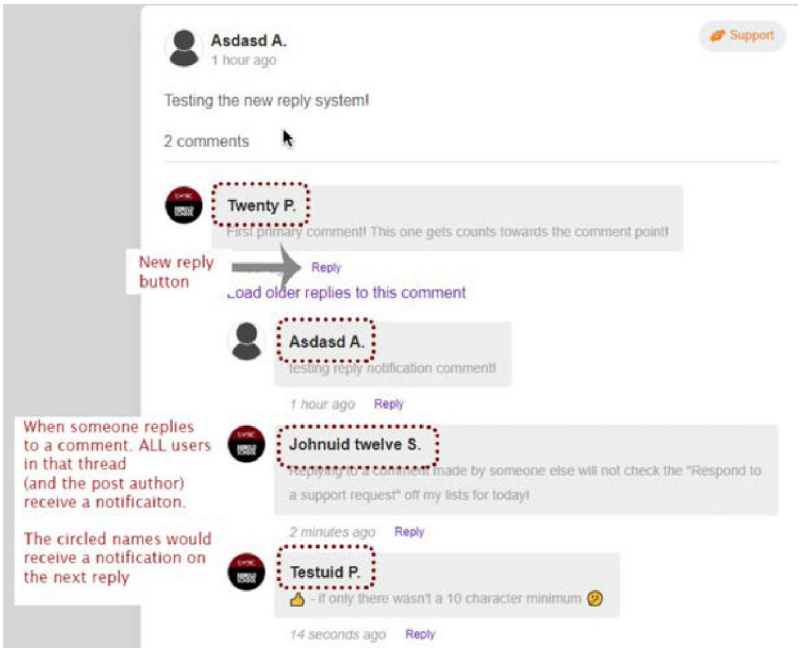
The mLife app offered eight social support activities to engage users and test gamification. It au- tomatically posted newsfeed when users logged meals, exercised, tracked weight, or listened to podcasts. Users could “like” posts and request support from peers by commenting or asking questions. Peers could comment and respond to support requests, and users received notifications when peers offered support.Refer to the graph below that shows the gamified social actions with- in the application id and point value for the leaderboard.



Participants are also prompted to send supportive messages to inactive peers. When inactive for more than 24 hours, an outreach request is posted in the newsfeed: “(username) hasn’t been active for more than a day. Please send them an encouraging message to return.” Participants can choose a pre-written message or create a custom message and send it via text. Pre-written messages are created using Social Cognitive Theory to target social support, self-efficacy, and out- come expectations regarding self-monitoring behavior. Once an outreach message is sent, the request is closed.

Participants earn up to 8 points per day for social support interactions. They can provide support as many times as desired, with a maximum of 1 point per activity. The mLife+Points group views the 8 activities, their daily points, and an overall leaderboard that resets monthly to boost motivation. The mLife group is unable to see the points earned; they have daily checklists. However, the mLife app calculates points for objective comparison between groups.

Posting a “request for support” comment or question in the app’s newsfeed allows mLife peers to comment and respond. Initially, participants could only post one response to peer requests to control moderation, but this limited social interactions, so unlimited responses were allowed at the 8 weeks data inspection. See the comment replies example graph below.



All participants' social interactions are posted in the newsfeed.

Participant Retention

Our retention and adherence strategies will target the following main areas:

Intervention

1. mLife incorporated several in-app features to support participant activity monitoring and app usage. Inactive participants, defined as those who haven't logged in for three consecutive days or more, are displayed on the Management Page dashboard. On the third day of each mLife week intervention, designated research assistants contact inactive participants via phone call or email. This outreach process underwent several reviews and modifications to enhance retention efforts and ensure accurate intervention progress reporting to participants.
2. During the intervention, participants were able to submit a form within the mLife app to request technical assistance from the mLife staff. This form was collected and tracked via Red- Cap. An RA is assigned to derive each request to a staff member to provide assistance to the participants.
3. The research team stays in contact with participants by sending birthday and holiday cards during the study. Mid-way through the study, participants were mailed a postcard reminding them of the importance of engaging in the mLife app.
4. Monthly surveys were administered to collect participant feedback regarding changes in medication, health status, life events, and satisfaction with the mLife app and intervention components. The distribution, tracking and data report is conducted via the RedCap projects.
5. Monthly e-newsletters are sent to all enrolled and active participants. To retain and motivate members of the mLife+Points group, the top three individuals on the leaderboard for the

month are included in these newsletters. The newsletter is sent to each participant via email as confirmation of completing the monthly survey. For those participants who did not respond to the survey, an email is sent via email.

Assessment

Participants are provided with a $50 Amazon gift card incentive for completion of all assessment measures at 6 months and again at 12 months. The breakdown of the incentive was based on the completion of each component of the assessment as follows: survey and measurements $10, body weight $15, dietary recalls $15, and 3 valid days of physical activity assessment $10. The incentives are sent directly from Amazon to the participant's email. The project Manager uses the Assessment Tracking Report from the RedCap project to determine completion of each component.

Adherence

We use the intervention monitoring RedCap project to track adherence to each of the intervention components. Dietary intake will be assessed using 24-hour recall data at 0, 6, and 12 months. In addition, we will use the data obtained from objectively self-monitored participant diet data. This approach assesses the degree to how each participant has met a priori energy limits and distribu- tion adherence criteria. Overall adherence to intervention delivery will also be assessed by collected data in the mLife application. Process data will be collected before, during, and after the intervention.

Study Compliance

In an effort to maximize adherence to the protocol and minimize noncompliance, training on the study protocol, weekly review of the aggregated data, and routine communication with the team has been put in place to help minimizing protocol deviations. However, the Project Manager oversees all recruitment, randomization and assessment procedures, keep IRB approval up to date, and confirm each participant is using the provided devices properly and syncs with the corresponding app based on group allocation.

The project manager monitors each of the aspects and maintains a log of all protocol deviations (OneDrive > mLife study > Administrative > Protocol Deviations Log. All deviations should then be reported to the DSMO.

Protocol deviations include, but are not limited to the following:

- Randomization of an ineligible participant
- Failure to obtain Informed Consent
- Failure to keep IRB approval up to date
- Wrong app version downloaded by a participant
- Outcome measurement not performed

Data Collection, Storage and Management

For the mLife study, Dr. Carolina Delgado-Diaz served as Data manager by completing the following tasks before, during and after the completion of the trial.

Data manager duties:

- **Data Collection and Entry:** Ensure accurate and timely data collection and entry from all trial sites, maintaining data integrity and quality.
- **Database Design and Maintenance:** Develop and maintain the clinical trial database, ensuring it is user-friendly and meets all project requirements.
- **Data Cleaning and Validation:** Conduct regular data cleaning and validation processes to identify and resolve discrepancies, ensuring data consistency and reliability.
- **Data Security and Confidentiality:** Implement and enforce data security and confidentiality protocols to protect sensitive information in compliance with regulatory standards.
- **Monitoring and Reporting:** Monitor data collection activities, generating regular reports and summaries for the research team and regulatory parties.
- **Training and Support:** Provide training and support to clinical trial staff on data management systems and protocols.
- **Regulatory Compliance:** Ensure all data management activities comply with relevant regulatory and ethical guidelines, such as the IRB and GCP.
- **Liaison with IT and Researchers:** Work closely with IT professionals for system enhancements and PI and co-investigators for data preparation and analysis.

All data related to the mLife study, including but not limited to surveys, attendance to online meetings, informed consent forms, surveys, physical activity, diet and body weight data, adherence to intervention and release of newsletters is captured using the following systems:

- **OneDrive**: This cloud storage system is used for maintaining a copy of the mLife study data. Once data is collected in any other platform, it is transferred and stored in the corresponding folder. This serves as a backup storage solution and allows easy access to data for authorized staff members.
- **ASA24**: ASA24 is used for capturing self-reported dietary data. All diet-related data will be stored in this tool, and a backup is kept in the mLife OneDrive.
- **mLife Server (Hosted in the ASPH)**: This is the primary server where all study intervention-related data is initially captured and stored.
- **RedCap**: This is a secure, web-based data collection tool specifically used for distribution of orientation materials, capture of informed consent, distribution and collection of assessment surveys, and tracking mLife study data. This is the primary platform for all implementation of the study's procedures.

The institutional cloud storage service, is used as repository for the mLife study. Undergraduate research assistants (RAs) are granted access to specific folders based on their tasks by the project manager. The project manager, the principal investigator (PI), the research assistant (staff mem- ber), and graduate assistants have full access to the main folder. All information related to the mLife study, including drafts and working documents, must be stored and accessed using the University credentials.

Plan for Data Quality Control Procedures

The PI and the project manager will review all data collection forms and surveys on an ongoing basis for data completeness and accuracy as well as protocol compliance. Any ambiguity in the response to a question will be brought to the attention of the Project Manager for clarification. If the Project Manager is unsure how to resolve the issue, the matter will be brought to the attention of the Principal Investigator. The Project Manager will maintain a log so that future occurrences of problems will be handled in the same manner. Further, these issues will be discussed during project meetings to ensure that data resolution is handled consistently.

The data entry system (RedCap) requires a login identification and password in order to gain access to the data. Where appropriate, validation and range rules are applied to the actual entry field. Data found to be inconsistent after the verification has been run will be compared to original questionnaires and recorded values to resolve any discrepancies.

Data Safety Monitoring Responsibilities

The entire team for this project will meet at least monthly in the first year in order to coordinate planning of the study and oversee recruitment efforts. Staff, graduate assistants, and the PI will meet weekly. In addition, weekly individual meetings with the PI and project coordinator will occur to ensure recruitment efforts are yielding our target goals and weekly meetings with the PI and the nutrition interventionist will occur in order to ensure intervention content is being devel- oped/ collected in a timely manner. The project coordinator will oversee the monthly reports to the DSMB that detail recruitment efforts and enrollment demographics. Sub-committees for each aim will also be formed. All sub-committees will be led by PI Turner-McGrievy. Sub-committees for Aim 1 will include Drs. Wilcox and Valafar; Aim 2 will include Drs. Monroe and Valafar.

Progress reports, including participant recruitment, retention/attrition, and adverse events (AEs), will be provided to the DSMB semi-annually. An Annual Report will be compiled and will include a list and summary of AEs, whether AE rates are consistent with pre-study assumptions, reason for

dropouts from the study, whether all participants met entry criteria, whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study, and conditions whereby the study might be terminated prematurely.
The Annual Report will be sent to the DSMB and will be forwarded to the USC IRB and NIH. The USC IRB will review progress of this study on an annual basis. The PI will also send copies of signed recommendations and comments from the DSMB to the NIH Program Officer within 1 month of each monitoring review.

Statistical Design and Power

I. The below statistical plan justifies the proposed sample size based on appropriate study assumptions, as well as our plans for evaluation of the primary outcomes by race/ethnicity and sex, including all relevant data that assess whether the trial includes adequate numbers for valid analyses of subgroups. Below we also justify the adequacy of power to analyze subgroups of participants:

Aims 1 and 2

We are powering our study to detect differences in weight loss at one year between those randomized to mLife+points and mLife groups (Aim 1) and differences in social support provision and receipt at one year between groups (Aim 2). For Aim 1 power, we used an F-test on the interaction between time (two levels) and treatment arm (two levels) in a two-way ANOVA with repeated measurements. We assumed **conservatively** a small effect size (Cohen's $d = 0.1$). Moreover, we used our NETworks pilot work, which collected weight loss outcomes at one year,[1] to determine the intra-cluster correlation (ICC) which is the correlation of weight between times within individuals. The pilot study estimate of the ICC was 0.9 but 2e judged that this estimate may be too optimistic and lead to an inadequately low sample size (see Table 5). Therefore, we used a more **conservative** ICC = 0.7. In summary, we calculated that to achieve 95% power (alpha = 0.05) for Aim 1 assuming a small effect size (Cohen's d = 0.1) and ICC equal to 0.7, we need a sample size equal to 200. Further, we assumed an attrition rate of 15-20% and increased the sample size to 240. Thus, we aim to recruit a total of 240 participants (~120 per cohort), with the initial randomization assigning 120 to mLife+points and 120 to mLife. This sample size will also give us abundant power for the study in Aim 2. Based on our Social POD pilot work, we are powering Aim 2 from both differences in overall app usage (Social POD 50.7 ± 25.0 days and standard 34.4 ± 25.8 days out of a possible 84 days)[2] and points earned (representing social support provision). Social POD pilot participants earned a mean of 202±105 points/participant.[3] We are assuming a difference of 50 points between groups with a SD of 105. Therefore, with the sample size chosen for Aim 1, our

power for Aim 2 will be 99% for app usage and 95% for points earned.
The sample size for our study has been chosen to ensure sufficient statistical power to detect differences in weight loss at one year after baseline between those randomized to mLife+points and mLife groups (Aim 1) and differences in social support provision and receipt and at one year between groups (Aim 2).

Sample size according to F-test

Because our main outcomes will be measured at 12 months, we are using pilot work that collected weight loss outcomes at one year. Based on our pilot data (NETworks trial as this provides 12-month outcomes for weight), as well as several other one-year mHealth intervention studies,[4-7] we calculated the sample size necessary to achieve 95% power (alpha = 0.05) for Aim 1 assuming a small effect size (Cohen's d = 0.1) and an intra-cluster correlation (ICC) equal to 0.7. The sample size estimate was 200. For this calculation, we used an F-test on the interaction between time (two levels) and treatment arm (two levels) in a two-way ANOVA with repeated measurements (RM-ANOVA). We used a more conservative value of the ICC as compared to the actual estimate from the NETworks trial data (ICC = 0.9), as the latter would have resulted in a much smaller sample size (for a larger ICC, the residual sum of squares decreases, therefore precision increases and sample size decreases. The opposite is true when the test is strictly between subjects). Further, we assumed an attrition rate between 15 and 20%, and increased the sample size to 240. Thus, we aim to recruit a total of 240 participants (~120 per cohort), with the initial randomization assigning 120 to SocialPOD+points and 120 to SocialPOD-points.
Based on pilot study for overall app usage (Social POD 50.7 ± 25.0 days and standard 34.4 ± 25.8 days out of a possible 84 days)[2] and points earned (mean of 202±105 points/participant with estimated 50 point difference between groups),[3] our power for Aim 2 will be 99% for app usage and 95% for points earned based on our sample size from Aim 1.

We plan to use a random-effects (RE) model which is mathematically equivalent to repeated-measures-ANOVA.[8] However, in the presence of loss to follow-up, RE models can handle responses that are missing at random. RE models can be adjusted for additional covariates if needed (though the randomization procedure should make this unnecessary). RE models provide additional information about the variance of the random effects which is valuable for understanding heterogeneity of responses and assessing the intra-cluster correlation (ICC).

Analysis Plan

I. Below details how the outcomes will address the hypotheses being tested:

We have two main hypotheses in this study. We are examining our outcomes among 240 adults with overweight or obesity and ≥3 T2DM risk factors.[9]

Hypothesis 1: That the SocialPOD+points group will lose significantly more weight than the SocialPOD-points group.

Hypothesis 2: That the SocialPOD+points group will have greater objectively measured levels of social support provision and receipt than the SocialPOD- group

In order to ensure that each of these hypotheses can be addressed we must measure the following outcomes:

Objective body weight assessments

Objective assessment of social support provision and receipt via the app

Type 2 diabetes risk factors (assessed at baseline, 6 months, and 12 months): body weight, body circumference measures, and blood pressure

Demographic data (race/ethnic group and sex)

These outcomes will help us examine how weight loss and social support provision and receipt may differ between groups.

III. Below describes our plans for interim and final analyses and methods for handling missing data:

Aims 1 and 2

Data from all study measures will undergo initial data cleaning to identify potential outliers, determine distributions of variables, assess normality, and enumerate loss to follow-up and other missing data. Descriptive statistics at baseline will be compared between treatment groups to evaluate the success of randomization. ***Analyzing changes in weight between groups at year one (Primary Aims 1)***: For Aim 1, the two levels of the treatment effect will be assignment to SocialPOD+points vs. SocialPOD-points, and the entire study sample will be included. Primary Aim 1will be addressed using a repeated-measures mixed model with maximum likelihood estimation as provided by PROC MIXED in the SAS® system. Under the assumption that missing data are missing at random, mixed models provide unbiased estimates. These will be adjusted using robust computation of standard errors if non-normality is detected. These models will be estimated applying an intent-to-treat principle. Models for each primary aim are of the same form, with the difference of the groups being compared. Models will examine weight at baseline and at 12 months with a two-level time effect, two-level treatment effect, and two-way interaction between time and treatment. The repeated-measures model will contain time, treatment, time-by-treatment interactions, and any covariates associated with weight loss. Models will be adjusted for changes in PA (via

accelerometers). If the time-by-treatment interaction in a model is significant at the 0.05 level, this will be interpreted as a significant weight-loss effect for one treatment relative to the other.

Analyzing differences in social support provision and receipt between groups (Aim 2): For Aim 2, the model will regress support provided (total points earned) and social support received (mean of ratings of support provided to the individual over the 12 months) on treatment group, adjusted for the same covariates used in Aim 1.

IV. Below details various types of bias and how our study aims to avoid them.

Type of Bias	How to Avoid
Pre-trial bias	
Flawed study design	We have a clearly defined risk and outcome and are using objective or validated methods. Standard operating procedures will be developed for data collection and assessors will be blinded to random assignment.
Selection bias	We will select participants using rigorous criteria to avoid confounding results. Participants will originate from the same general population. Because this is a well-designed, prospective stud, selection bias should be avoided as outcome is unknown at time of enrollment.
Channeling bias	We will assign participants to study cohorts using rigorous criteria, stratifying by sex and race.
Bias during trial	
Interventionist bias	All study personnel interactions with participants will be standardized. As part of our treatment fidelity process, interactions with participants (e-mails, phone calls, etc.) will be regularly assessed and monitored to assure equal treatment among groups.
Recall bias	We will use objective data sources whenever possible. While surveys and the dietary recalls will rely on memory, these measures are currently the gold-standard way to assess these outcomes.
Transfer bias	We will carefully design plan for lost-to-follow-up participants prior to the start of the study. This will include number of contacts required after a participant does not attend classes or assessment visits.

Outcome Misclassification	We are using objective validated measures to assess all primary outcomes.
Bias after trial	
Citation bias	Our trial will be registered with clinicaltrials.gov prior to study recruitment for cohort 1. We will heck registries for similar unpublished or in-progress trials prior to publication.
Confounding	Known confounders will be controlled during data analysis (such as medications). Unknown confounders will be controlled with randomization.

* Adapted from Pannucci CJ, Wilkins EG. *Plast Reconstr Surg*. 2010 Aug; 126(2): 619–625.

V. Consideration of relevant biological variables

Of primary interest in the present study will be examining differences in outcomes by sex and age. Previous research has demonstrated that men lose more weight than women in behavioral weight loss interventions, but there is no indication that different weight loss strategies should be used.[10] There is evidence that men may interact with technology, including health-related mobile technology, differently than women. For example, a study examining gender differences in usage of a physical activity app found that enjoyment and goal-setting were more important for women than men but that men more often shared their results and used the live tracking function in the app.[11] Other research has found that men feel that mobile phone usage is more appropriate across a variety of social situations than women.[12] In addition, those under 50 (and particularly those under 30) tend to have higher rates of smartphone ownership than those over 50.[13] Based on these findings, we aim to conduct sub-analyses examining the impact of sex and age on social support provision and receipt and weight loss. We have been successful recruiting both men and AA participants in our previous studies and being situated in South Carolina and housing this work within the Prevention Research Center (where the current main research project is among AA churches in SC) will ensure we can consider both of these relevant biological variables. Our models will also control for other factors that could impact outcomes, including age, BMI, SES, baseline lab values, and medication use.

A. Below details out approach to data management and validation, including our data management system, methods of data entry and cleaning, and event tracking and logistics

Ms. Mary Wilson, Project Manager, and Dr. Brie Turner-McGrievy, study PI, will develop and maintain the computerized data management system for this study. Use of the data management system will be restricted to only those persons having access authority.

Participant surveys

Participants will complete all surveys electronically using a secured online platform. Electronic data will be imported into the study's database. Any paper documents, like attendance sheets, will be entered in the tracking database and stored in a locked filing cabinet. This study will use the IRB-approved OneDrive for storage of online files.

Local Tracking Application

An online tracking database will be used to track study participants. This local application will allow the study personnel to input demographic, contact information, form & visit tracking, and other data about individual participants. Access to the local application will be restricted by use of individual username and passwords.

The tracking database will have three primary forms:

Screening Forms – This form is used to track attempts to reach participants who completed an online screening form.

Measurement Tracking – This form tracks all measurement activities, including scheduled and actual dates of all measurement visits; location of measurement visits; return of accelerometers; distribution of incentives; completion of the three ASA24 dietary recalls; and participant status and status changes.

Intervention Tracking – This form has subforms that are used to record randomization assignment; participant-level tracking for the intervention groups.

Below is a screenshot of the tracking application we are currently using in our NIH R01 study:

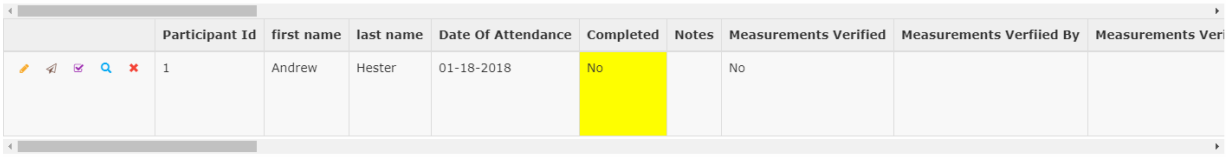
B. Methods for monitoring the quality and consistency of the intervention and data collection

The intervention quality and consistency will be monitored with our treatment fidelity plan (see our Process Evaluation Plan in the Recruitment and Retention section of this grant). For the quality and consistency of data collection, our plan includes the following:

Trained assessors who are blinded to study assignment: All assessors will go through rigorous training in order to know how to accurately assess height, weight, blood pressure, and other physiological outcomes.

Training participants on survey data: All participants will be trained on how to complete questionnaires and dietary recalls to ensure accurate data. Participants will complete the baseline questionnaire and the first dietary recall in person in order to ensure participants can have questions answered about the process. Missing answers on the electronic surveys will be highlighted for participants to complete.

Electronic entry of survey and dietary data: All participants will enter the data for surveys and recalls directly themselves to avoid data entry issues common with paper surveys.
All data entered or imported into the database will be double checked: Once data has been double verified in the database, there is a purple check box that personnel will select to indicate the verification has occurred:



	Participant Id	first name	last name	Date Of Attendance	Completed	Notes	Measurements Verified	Measurements Verfiied By	Measurements Ver
	1	Andrew	Hester	01-18-2018	No		No		

C. Policies and methods for ensuring blinding of study results
While participants and interventionists cannot be blinded to study assignment, all assessors (lab and measurement personnel) will be blinded to assignment. In addition, the study statistician will be blinded to participant identification during the randomization process and will also be blinded to group assignment (random numbers will be used to delineate which of the 2 groups a participant has been randomized to) for statistical analysis.

D. Data confidentiality and subject privacy
The database will be stored on a University managed data server with daily backups to tape drives. Staff will not keep copies of databases on thumb drives of portable external drives (unless they remain at USC and are locked). Survey data will remain in locked filing cabinets in the project manager's office. Other than the database, no other documents will contain identifiable information. All surveys and lab assessments will only use participant ID number

E. Data Reports generated by the project will be:
De-identified Data Safety reports for the PI (monthly) and the Data Safety and Monitoring Board (quarterly)
Publications authored by project team members based on research performed in this project
Data from experiments

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