Study Protocol and Statistical Analysis Plan

NCT ID not yet assigned

Document Date: 4/25/25

SOCIAL/BEHAVIORAL/EDUCATIONAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: CommitFit App to Facilitate Health Behavior Change in Clinic Adolescents
IRB Number: 2092610
Version Number: 13
Version Date: 4/25/25
Replacing File ID: 657592
Principal Investigator: Amy Braddock
Funding Source: University of Missouri, School of Medicine, Coulter

I. Research Objectives/Background

Adolescent obesity continues to be a significant public health problem in the United States with 35% of children ages 12-19 years having overweight or obesity in 2012.[1] During the COVID-19 pandemic, child obesity is expected to increase by 2.4%.[2] Because adolescents with obesity are more likely to have obesity as adults,[3] they are at increased risk of developing obesity-related diseases such as heart disease, type 2 diabetes, hypertension, and cancer.[4]

Mobile health (mHealth) apps have shown potential to improve health behaviors and improve short-term Body Mass Index (BMI) in adolescents. Unfortunately, most mHealth apps lack scientific evidence, [6,7] are not grounded in behavior change theory,[8,9] and were not developed by health care experts.[6] Involving health care providers in health behavior change results in better and more sustained weightloss[10,11] and a combination of mHealth an in-person provider counseling is the best means of achieving a healthy weight.[12] Current mHealth apps lack engagement with or tailored advice from the adolescent's health care provider, despite provider willingness to utilize mHealth for child obesity management.[13] Importantly, EHR synced apps can also save providers time and improve patient care by reducing the burden of collecting, analyzing, and documenting data.[14-16]

Building on our expertise in adolescent development and health care patient/provider communication, experience with gamification and user-centered design of electronic decision support, we have developed the "CommitFit" smartphone/tablet app which uses gamification techniques to motivate adolescents to set and achieve their health behavior goals. This current project evaluates the use of CommitFit app through a feasibility and pilot study utilizing interviews, surveys, and analytic software to measure adolescent frequency of use and opinions of the app.

<u>Pilot study</u> – We will recruit 30 adolescents and30 caregivers to beta test CommitFit and use software analytics. We will evaluate changes in health behaviors using surveys, and measured health metrics. Participants will be recruited from a Primary Care Provider

approved clinic list. Body Mass Index and Blood Pressure (BP) from participants recruited will be collected in clinic (on site) 3 times - at the beginning of the study, at the end of 3rd month and at the end of the study. There will be three arms; Control, CommitFit, and CommitFit$. (Each group is described in study design).

SA 3. Pilot study – There will be three groups in the study: 1) Control 2) CommitFit and 3) CommitFit$. 30 adolescents and their caregivers (30, one caregiver per adolescent) will participate in this study. For participants in the CommitFit and CommitFit$ groups, software analytics will be utilized to evaluate how the app was used (frequency of goals set and behaviors logged), duration of use, etc., to evaluate app features and gamification techniques. We will evaluate changes in health behaviors using online/paper surveys, and measure health metrics (height and weight which will be used to calculate Body Mass Index (BMI), and blood pressure) (see study design).

II. Device

CommitFit is a smartphone/tablet app which uses gamification techniques to motivate adolescents to set and achieve their health behavior goals. CommitFit promotes positive health behaviors. It is not a weight loss app and does not log or track weight.

CommitFit is a lifestyle management software app and not a medical device. It does not require an IDE.

III. Recruitment Process

Pilot study:
We will partner with South Providence, to recruit 13-15-year-olds adolescents and their caregivers to use and test the CommitFit app.

We will get the names and email addresses of potential participants from a list of adolescent patients from MU Family Medicine and Child Health clinics to review with the patient's Primary Care Provider (PCP). PCP will remove any patients they do not want contacted to participate in the study. The goal will be to recruit one adolescent along with one of their caregivers to participate in the study. We will contact caregivers of (13-15 old) adolescents through email and mailed letter with information about the study, screening survey, and consent forms. We will obtain consent by having the interested caregiver sign the consent form electronically or signing using Docusign/ Redcap, and/or mailing us back for themself and their adolescent. We will also have adolescent participants read and understand the assent form, and we will answer any questions after explaining the study. We will only enroll adolescent participants after they have read the assent forms and caregivers have signed the consent forms.

Randomization:

Adolescents of 13-15 years old- and their caregivers will be randomly assigned to each group (Control, CommitFit and CommitFit$) with a total of 20 adolescents and caregivers per group.

IV. Consent Process

For the Aim 3 portion of the study, we will contact caregivers of (13-15 old) adolescents through email/phone and mailed letter with information about the study, screening survey, and consent forms. We will obtain consent by having the interested caregiver sign the consent form electronically or signing using Docusign/ Redcap, and/or mailing us back for themself and their adolescent or if the caregiver can bring them to clinic, we will do the consent and screening there. We will also have adolescent participants read and understand the assent form, and we will answer any questions after explaining the study. We will only enroll adolescent participants after they have read the assent forms, and caregivers have signed the consent forms.

V. Inclusion/Exclusion Criteria

Inclusion Criteria:
For specific aim 3, adolescents will be 13-15 years old recruited from MU South Providence Family Medicine and Child Health clinics.

For every adolescent interested in participating in the study, one of their caregivers (18 years and above) is also required to participate. Only one caregiver per child will be allowed to participate.

All participants with mild or controlled anxiety and/or depression will be included.

All participants will be required to speak English fluently, read at the 6th grade level or higher, and be proficient with smart phone app use to participate.

Exclusion Criteria: We will screen and exclude adolescents and caregivers diagnosed with severe mental health disorders (other than mild or controlled anxiety and/or depression), intellectual disabilities, or eating disorders via a screening survey. For adolescents, their caregiver will be filling out the screening survey.

VI. Number of Subjects

Pilot study – 30 adolescents and 30 caregivers. For every adolescent interested in participating in the study, one of their caregivers is also required to participate. The study will be limited to one participating adolescent and one of their caregivers.

VII. Study Procedures/Study Design

We will recruit 30 adolescents and 30 caregivers to beta test CommitFit. The study will be limited to one participating adolescent and one of their caregivers. There will be three groups in the study: 1) Control 2) CommitFit and 3) CommitFit$.

All participants will be required to complete a screening survey at the beginning of the study. The eligible participants will be contacted via email/ phone and will give their consent after taking the screening survey, and then they will take the baseline demographic survey for their adolescents and themselves.

Our screening form will include1) list of exclusion and inclusion criteria for participants like English fluency, reading level, severe mental health disorders (other than mild or controlled anxiety and/or depression), intellectual disabilities, or eating disorders.

Our baseline demographic survey form will include 1) demographic information like name, gender, race etc. 2) phone number, mailing address 3) SSN, 4) preferred vendor of eGift card, and 5) email address to send the eGift card, at the beginning of the study after they have signed the consent form. We'll use RedCap to capture all the information as an emailed survey.

After the participants in the CommitFit and CommitFit$ groups download the app, they will be shown how to pick a health behavior (fruits/vegetables, water, decreased sugary beverages, physical activity, sleep) and then set a goal and a time period to work on their goal. They will receive a daily reminder to log their health behaviors. At the end of their goal period, they will be rewarded with points for logging behaviors and successfully achieving their goals. Points will be used to rank the participant on the leaderboard using the username that they registered with. Users will be encouraged not to use or share their real names or any identifying personal information. Users can also use points to unlock gear for their avatar in the gear store. It will take less than 15 minutes to download and learn CommitFit and less than 1 minute each day to log their behavior. Control group participants will receive email handouts with healthy lifestyle tips which they could use if they choose to. They will not use the CommitFit app. All participants will be compensated through eGift cards.

Software analytics will be utilized to evaluate how the app was used (frequency of goals set and behaviors logged), duration of use, etc., to evaluate app features and gamification techniques. We will evaluate changes in health behaviors using online surveys, and measure health metrics (height and weight which will be used to calculate Body Mass Index (BMI), and blood pressure) in the clinic.

In the CommitFit and CommitFit$ groups, we will have the adolescents take 7 surveys-GAD7, PedQL, Reasons why I think about being healthy, Behavior economics survey, Gamification Survey, CommitFit App Survey, and Commercialization Survey for adolescent subject. Each clinic visit will last from 30 to 60 minutes. Similarly, we will have the caregivers take 4 surveys Gamification Survey, CommitFit App Survey, Behavior economics survey, and Commercialization Survey for caregiver subject. In the control group, adolescents will only take 4 surveys- GAD7, PedQL, Reasons why I think about being healthy, and Behavior economics survey. Caregivers in the control group will take only the Behavioral Economic survey. All participants will take the surveys at the beginning of the study, after end of 3rd month, and at the

end of the 4th month (follow-up visit). All surveys will be available in online and paper format and will take 15 to 30 minutes to complete per participant. Weight, height and blood pressure from all adolescents and their caregivers will also be collected at the clinical site. If your adolescent chooses to stop participating in the study before its completion, you can still remain enrolled in the study, and you will take surveys and clinic visits at the end of 3rd and 4th months. All participants will complete the 5-10 minute paper exit survey at their final 4-month clinic visit.

We will use logic and branching reasoning in Redcap that would allow participants to skip questions. Participants can skip questions that they do not want to answer and can submit without getting an error message if a question is left blank. Questions will include demographics, environmental factors that could influence health behaviors, and technology and mHealth app use. We will be measuring changes in health behaviors (physical activity, water, sugary beverages, fruits/vegetables, and sleep) by analyzing data logged into the app.

There will be three groups (1) Control (2) CommitFit group using the app where the intervention will not include extra monetary incentives and (3) CommitFit$ group using the app which will be pushed with extra monetary incentives. 30 adolescents will be randomly assigned to three groups with each group having 10 adolescents. Their respective caregivers will also join the same groups as their adolescents. Participants will download the app on their iPhone or iPad and if the participant doesn't have either of them, an iPad will be temporarily provided for the time participants are in the study which will be returned to the researchers after the study, we will use a spreadsheet to capture all the information in one place for each participant.

The purpose of this study is to evaluate "CommitFit" a smart phone app to help teens develop and maintain positive health behaviors. We will be measuring changes in health behaviors (physical activity, water, sugary beverages, fruits/vegetables, and sleep) in CommitFit and CommitFit$ groups. The app will only be tracking goal progress and nothing else.

- In the control group (10 adolescents, randomly chosen and their caregivers), we will email handouts with healthy lifestyle tips which participants could use if they choose to. During this time there will be no CommitFit app use by participants. They will also not receive any extra monetary incentives.
- In the CommitFit group, participants (10 adolescents, randomly chosen, and their caregivers) will use regular CommitFit app without extra monetary incentives. Researchers will assist participants to download the CommitFit app. Participants will be asked to use the app for *3 months*, there will be no penalties if they don't use the app for the entire duration or only use it frequently. The adolescents and their caregivers will get an app reminder each day to update their health behavior goals once in morning (8 am) and once in the evening (5pm) on which the participant will spend approximately 1 min in a day.

- In CommitFit$ group, participants (10 adolescents, randomly chosen and their caregivers) will use the CommitFit app just as the CommitFit group for 3 months. In addition to the eGift cards, adolescents will receive 5 cents for every point they earn during the study. There are a maximum of 1050 possible points that can be earned, so the most they can receive is $52.50 in cash at the end of 3rd month of their participation in this CommitFit$ group This will be calculated by tracking the points at the beginning and end of each month for the CommitFit$ group. Only adolescents will receive these extra monetary incentives as this group is set up to simulate adolescent app users receiving incentives from their caregivers for adopting healthy lifestyle behaviors in the real world.
  For all three groups (Control, CommitFit and CommitFit$) – participants – adolescents and their caregivers will come to the clinic and have their height, weight, and blood pressure measured at the beginning of the study, after the third month, and after the fourth month (follow-up visit). These will be conducted in a private exam or conference room by research staff, and for adolescents their caregivers will also be present.

Training: Participants in the CommitFit and CommitFit$ groups will be assisted in downloading the CommitFit app. Researchers will guide them through logging in, show them how to use the app including picking their first goal, setting a behavior level, and setting a time period (1-2 weeks for the first time period), logging their behavior daily, setting notifications, leaderboard, avatar, progress report, gear store, and resources.

Monthly visits: Participating adolescents and caregivers will visit the clinic in person during the 3 visits to provide height, weight, and BPs and fill out online or paper surveys. This will occur at the beginning of the study, after the 3rd month, and after the 4th month (follow-up visit). For all participants, it will take 15 to 30 minutes to complete the surveys. If we obtain any information from the participant, including blood pressure that concerns us, we will work with the clinic nurse provider to develop a treatment plan. For adolescents the cutoff to notify the caregivers will be: 1) For BP, elevated blood pressure (> 130/>=80 mm Hg)[17], 2) For anxiety, a score of >=10 on the GAD-7 represents a reasonable cut point for identifying cases of GAD[18].

Follow-up visit: At the end of the fourth month, adolescents and their caregivers-will once again visit the clinic in person to get their height, weight, Blood Pressure measured, and fill out electronic or paper surveys.

VIII. Potential Risks

There are minimal risks expected for participants in this study. We will do everything we can to help participants feel comfortable when completing the surveys, and height, weight, and blood pressure checks. However, any participant can skip any questions or not participate in any part of the study. If any participant feels uncomfortable at any time, we will encourage them to notify the research staff and we will inform the caregivers and debrief them and their adolescent

immediately. If we obtain any information from participants, including elevated blood pressures that concerns us, we will work with the patient's PCP and notify the participant immediately. We have programmed CommitFit to set limits on health behavior goals to prevent extreme or unhealthy goal setting and behaviors. The CommitFit App will not collect any personal or sensitive information from any participant. CommitFit promotes positive health behaviors. It is not a weight loss app and will not ask any participant to log or track their weight.

We will be collecting information about all participants from surveys. We will check health metrics (blood pressure, height, weight). We are collecting this information to determine if using the CommitFit app has any influence on the user's health. All of this information will be kept private to researchers in the study, but there is always a small risk of loss of privacy if there is an accidental disclosure of participants' information, including logged health behaviors and information provided in the surveys. We will reduce this risk by removing participants' names and any other identifying information from their results and taking the steps below to protect their privacy.

We will be asking the adolescent about their anxiety and the adolescent's answers may be reported to the caregiver and their PCP if needed. Also, if we obtain any information from the participant, including elevated blood pressure that concerns us, we will work with the PCP and notify the participant/caregiver immediately. The cut off to notify the PCP and participant/caregiver will be 1) For BP, elevated blood pressure (> 130/>=80 mm Hg), 2) For anxiety, a score of >=10 on the GAD-7 represents a reasonable cut point for identifying cases of GAD.

There is also a small potential risk of harm from accidental breach of personal and health information and data. We will remove identifying information from all data before analyzing, sharing, or publishing any results. We will keep participants' data and participation status confidential and secured on a password protected laptop and server. We will assign a code to each participant and keep the code key in a locked office drawer. We will also keep back-up files on an USB drive in a locked office drawer. We will report any unanticipated problems or deviations to the IRB within 5 days.

IX. Anticipated Benefits

There will be no direct benefits to the individual participant, but they may benefit indirectly from the health behavior education and behaviors promoted through app use. Society will benefit directly and indirectly through new innovative technology that will, if deemed effective, improve health behaviors of adolescents, and their caregivers.

X. Compensation

We will offer each adolescent and caregiver $50 eGift cards at the time of enrollment, $50 at the 3 months visit, and $50 at completion of the study only (4-month visit) for a total of $150 e-gift cards for each adolescent and caregiver. Caregivers will receive payment via gift card codes

emailed to them for their and their adolescents' participation. Potential vendors are Walmart, Amazon, and Target.10 participating adolescents in the CommitFit$ group will also receive 5 cents per point up to $52.50 in extra monetary incentive in cash at the 3-month visit.

XII. COST

All cost will be covered by the research study.
For participants who will receive an iPad for the study, they will be required to return the functioning iPad to receive their last $50 eGift card. However, if you have borrowed an iPad for this study and you lose or break it than the third payment of $50 will be withheld to offset the expense of it.

XIII. Data Safety Monitoring Plan

The Principal Investigator (Dr. Braddock) and research team will be responsible for monitoring the safety of this trail, executing the Data and Safety Monitoring plan, and complying with the reporting requirements. The Data and Safety Monitoring report will include participants' socio-demographic characteristics, expected-versus-actual recruitment rates, any quality assurance, and any actions or changes regarding the protocol. All personnel involved with this study will complete appropriate IRB training. We will maintain certification of this training.

We will use the Research Electronic Data Capture (REDCap) online database management system that the University of Missouri provides. In this secure network, we will store all study data, data collection instruments, monitor enrollment, and manage secure storage. If a participant's privacy is breached or there is an unexpected adverse outcome, these events will be reported to the IRB within five days, once we are made aware of the event.

XIV. Data Management and Sharing Plan

Element 1 Policy for Data Management and Sharing (DMS Policy): We are committed to transparency, collaboration, strengthening analyses through combined datasets, and enhancing the value of research and public knowledge. We support the public dissemination and sharing of our research results. Furthermore, we recognize that the proposed project may result in novel ideas for new methods and data that could benefit the public health community and result in new frontiers of discovery, while being mindful that the confidentiality and privacy of participants in research must be protected at all times.

A. Types and amount of scientific data expected to be generated in the project: The proposed research will include data from approximately 30 dyads (60 total participants, adolescents and caregivers). The final dataset will include survey data, analytic data generated from the mHealth CommitFit app software, anthropometrics (height, weight, blood pressure, waist circumference), lab values (adults only). To protect the identities of participants, all data will be deidentified before final storage and sharing.

B. Scientific data that will be preserved and shared, and the rationale for doing so: All quantitative data will be collected via REDCap and stored via the HIPAA protected REDCap server.

Element 2: Standards: We will adhere to NIH, HIPAA, and IRB standards for data management and sharing. In the absence of formal standards for the management, use, and sharing of research data or other materials, best practices will be used. Information about research processes, including data analysis, will be maintained using formalized, documented procedures. This information will be accessible to all members of the research team and will be shared alongside the final dataset.

Element 3: Data Preservation, Access, and Associated Timelines: Timelines for distribution of data will vary depending on any required restrictions in accordance with federal and/or institutional policies and guidelines. We expect the data will be disseminated through publications, presentations at scientific symposiums, and seminars within a year of project completion.

A. Repository where scientific data and metadata will be archived: We will include publications resulting from the study/grant and dataset used for the analysis, during and after the grant period, in an archived repository. A long-term data sharing and preservation plan will be used to store and make publicly accessible, the deidentified data beyond the life of the project. Completed data will be deposited into the Data Repository for the University of Missouri (MOspace Institutional Repository). MOspace Institutional Repository is the digital institutional repository for the University of Missouri System and is a joint initiative of the University Libraries, the Office of the Library Systems, and the Division of Information Technology. It is a free service for MU students and faculty and provides permanent storage and dissemination for deidentified research data.

B. How scientific data will be findable and identifiable: MOspace items will include appropriate metadata and are identifiable through a permanent URL. Items will be findable via the MOspace web site at https://mospace.umsystem.edu, and searchable via Google and other search engines. Data will be disseminated in open formats to the greatest extent possible and will be accompanied by robust documentation and metadata to maximize reusability.

C. When and how long the scientific data will be made available: Data and corresponding documentation will first be made available after publication of primary outcomes, in accordance with journal policies. Materials deposited in MOspace will be made available permanently and for future research needs.

Element 4: Access, Distribution, or Reuse Considerations:

A. Factors affecting subsequent access, distribution, or reuse of scientific data: Only IRB-approved project staff, researchers, or other IRB-approved entities will have access to identifiable data. We will enforce strict protocols for protection from unauthorized access to physical and electronic data. We will specifically include appropriate language in our informed

consent documents to request broad sharing of deidentified participant data through MOspace and upon request from researchers.

B. Control of access to scientific data: All data will be shared within IRB and HIPAA-approved parameters. The PI will monitor and restrict access of identified data to IRB-approved staff. All significant contributors to the data will be credited. Deidentified data submitted to MOspace and upon request, will be publicly accessible.

Data that are unable to be sufficiently deidentified will not be made available for sharing, to protect the identity of the participant. Although the final dataset will have identifiers removed prior to release for sharing, because of the small sample size, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Data that cannot be sufficiently deidentified will not be shared.

Element 5: Oversight of Data Management and Sharing: Study Principal Investigator, Dr. Braddock, will be responsible, before, during, and after the study, for data collection, management, storage, and sharing. She will maintain the Data Management and Sharing Plan with updates when necessary. At the conclusion of the study, Dr. Braddock will deposit all deidentified data and corresponding documentation into MOspace and destroy any identified data not required for additional analysis or publications and in compliance with IRB protocols

XV. Statistical Analysis Plan

Descriptive statistics were used to examine baseline demographics and to examine study outcomes over time between study arms. Chi-square analysis was used to compare group differences for categorical outcomes and t-test for continuous outcomes for baseline demographics and BMI, as well as study outcomes. An a priori value of $p<0.05$ was set for statistical significance.

XVI. References

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