PROTOCOL TITLE:

Managing AsThma AnD Obesity Related Symptoms (MATADORS) study: An mHealth intervention to facilitate symptom self-management among youth (Phase II)

PRINCIPAL INVESTIGATOR:

Michelle Nichols, PhD, RN

1.0 Objectives / Specific Aims

Aim 1. Conduct feasibility testing of a mobile health (mHealth) app intervention (MATADORS) among a population of youth with asthma and obesity randomized to the intervention (n = 15) or control (n = 15) group.

Aim 2. Obtain estimates of variability and describe preliminary outcomes of MATADORS on fatigue, pain, self-efficacy, anxiety, sleep, depression, and quality of life measured at baseline, week 4, and an 8-week follow-up period.

2.0 Background

Youth with one or more chronic diseases (i.e., multimorbidity) are at increased risk of morbidity and mortality as they enter their adult years [1]. Recent increases in incidence of both asthma and obesity in youth correspond to increased health care use and subsequent health complications [2-5], as well as potentially iatrogenic parental and self-imposed limitations on activities due to respiratory symptom exacerbation and fatigue. Physical inactivity and increased steroid-based treatment of asthma symptoms contribute to increased weight gain, creating a problematic cycle that underscores the need to consider these two increasingly prevalent conditions together, as provider and caregiver efforts to address asthma (e.g., steroid treatment, restricted activity, respectively) may exacerbate weight gain and symptoms of obesity.

Research and clinical care for non-communicable diseases (NCDs), which contribute to 71% of deaths globally [6], are often focused on a single disease approach [7]. Failure to address the complexities and compounded influence of multimorbidity affects quality of life, healthcare utilization, increases disease burden, and contributes to premature death [7-9]. As asthma and obesity are among the most common chronic diseases, it is important for scientists to develop interventions that reduce the overall burden of each disease and the confluence of the two together [2, 10].

Current pharmacological and behavioral treatment approaches for asthma and obesity are complex, multi-faceted, demanding, and often result in high rates of non-adherence and non-adoption [2, 3, 11, 12]. Building on our team's prior work to enhance medication adherence via mobile health with children and youth and building on our expertise in weight management of children and youth through community-engaged research, we intend to develop a low-cost, easy to use and readily available MATADORS mHealth intervention that leverages key motivational enhancement (ME) principles using a behavioral activation (BA) framework to guide this intervention.

3.0 Intervention to be studied

MATADORS is a multi-component self-management intervention for youth with asthma and obesity that will be delivered via mobile device over a 4-week period and will include tailored content based on the existing SAMS (medication inhaler adherence for children with high-risk asthma) and SELFY (family-centered symptom self-management for children with sickle cell disease) mobile health applications and participation input from Phase I of this study. Participants randomized to the control arm (n = 15) will be enrolled in the existing SAMS symptom tracking and EMA assessment program to include baseline assessment, EMA symptom reporting, and repeated measures at 4 & 8 weeks. Participants randomized to the intervention arm (n = 15) will have continuous access to educational content within the app and weekly nurse-guided support available through videoconferencing support and text messaging to promote engagement.[32-33] Intervention procedures will include symptom monitoring through self-report and completion of measures (Table 1), accessing of educational content, engagement with study team to increase engagement, use of activity trackers, and photo/voice/video diary entries completed through the app. At study completion, youth and their primary caregivers from both the intervention and control groups will complete an end of study interview.

4.0 Study Endpoints

Study endpoints include:

- Successful completed of the 8-week study
- Participant consent withdrawal

- PI termination due to lack of adherence to the protocol
- Withdrawal due to adverse event
- Lost to follow-up

5.0 Inclusion and Exclusion Criteria/ Study Population

Youth-Caregiver Dyad Inclusion Criteria:

- Male and female youth aged 10 – 17 years
- Adult primary caregiver
- English speaking
- Youth diagnosis of asthma
- Youth Body Mass Index at or above the 85th percentile for age and sex based on the Centers for Disease Control (CDC) growth charts
- Must own a smartphone (iOS) with working Wi-Fi access and/or cellular data plan

Youth-Caregiver Dyad Exclusion Criteria:

- Diagnosis of cognitive impairment
- Inability or unwillingness of youth participant to assent and/or primary caregiver/legal guardian/representative to give informed consent.
- Inability or unwillingness to participate in the end-of-study interview session.

Inclusion of a diverse population

Participants from all racial and ethnic backgrounds will be approached and invited to participate as research participants.

6.0 Number of Subjects

The target enrollment for this study is N=60. This includes 30 youth (10-17 years old) and their primary adult caregivers.

7.0 Setting

Study procedures will take place using virtually using communication means such as telephone, email or meeting platforms, such as Microsoft Teams or DoxyMe. In-person informed consent may be collected in a private MUSC clinic or office space, pending participant preference and current social distancing requirements. As an alternative to in-person consent, participants will be offered the option to provide e-consent via the MUSC e-consent REDCap template or DoxyMe. Initial study procedures (consent, basic demographic and baseline measures, and study instructions) and measure completion at 4-week intervention and 8-week follow-up will be completed remotely using REDCap. Post-exit interviews will be conducted via Microsoft Teams or DoxyMe.

8.0 Recruitment Methods

This study will use the following recruitment strategies:

- Youth and caregivers that participated in Phase I of the study and agreed to be re-contacted by the researchers regarding volunteering in Phase II will be approached about this part of the study.

- Youth and their caregivers that are seen in the clinics of research team members that are MUSC clinicians will be approached and given a study flyer.

- A BMIC query through honest broker services will be conducted and used to identify and contact families of youth that meet the study inclusion criteria and that have not opted-out of being contacted. Researchers will use a telephone script and contact with these individuals will follow MUSC policies and procedures for contacting patients for research purposes.

- Study flyers will also be placed in clinic and public areas throughout the Medical University of South Carolina Enterprise.

- Flyers, advertisements, and study information will be posted on social media channels, on Research Match, and will be sent to professional and community-based organizations focused on care of youth with asthma or obesity.

9.0 Consent Process

Research activities will not be conducted without the caregiver's written informed consent and youth's written assent. One caregiver per youth will be consented to participate in the study. The caregiver consenting and participating in this study will be the child's self-identified primary caregiver. Informed consent will be conducted by an approved member of the study team. As an alternative to in-person consent, participants will be offered the option to provide e-consent via the MUSC e-consent REDCap template or DoxyMe.

Prior to the consent meeting, potential participants will have already spoken with study personnel by phone or in person at a clinic visit, will have been introduced to the study and its demands, had initial questions answered, and will have received a copy of the informed consent for their review. Participants who are further interested will be allowed as much time as needed to read and review the consent document in the privacy of their own home or at a place of their choosing. They will be provided with the telephone and email contact details for study personnel, should they have any questions before to the consent meeting. Prior to providing their physical e-consent, IRB-approved study personnel will coordinate with participant so as to be on the telephone, online, or in-person (when appropriate given social distancing and current COVID-19 requirements/guidance) and be available to further answer any questions that they may have during the e-consent process.

After reviewing the consent document, the patient will be given the opportunity to ask any questions about the study that they may have. Participants will be requested to demonstrate what is expected from them should they agree to enroll in the study through verbal questioning of their understanding of study procedures and risks. Prior to consenting, all questions will be resolved to the patient's satisfaction. If a participant does not appear to understand the information contained within the Consent document or of what is expected of them as a study subject, then the study coordinator will review the consent document again with the participant. If after this second review, the subject does not demonstrate an understanding, they will not be enrolled in the study. Only participants, with no observed cognitive impairment, will be consented and enrolled into the study.

The consent form will meet the requirements of the Code of Federal Regulations and the MUSC Institutional Review Board; and, include the following elements:

- The purpose, nature, and objectives, potential risks and benefits of the intended study.
- The length of study and the likely follow-up required.
- The name and a contact of the investigator(s) responsible for the protocol.
- The right of the participant to accept or refuse study interactions and to withdraw from participation at any time.

All consented subjects will be given a copy of their executed and countersigned Consent form. The researchers will maintain a means of contact with all enrolled study participants in the eventuality that reconsenting of currently enrolled participants is needed and/or the disclosure of new study information is warranted to previously enrolled participants.

10.0 Study Design / Methods

This feasibility study is an 8-week, longitudinal randomized controlled trial (RCT) with 3 study visits (baseline, week-4, and week-8) among youth 10-17 years old (n=30) with asthma and >85% BMI and their primary caregivers (n=30). Eligible participants that agree to consent, will be randomized 1:1 into the MATADORS intervention or control group. Randomization will be performed by the study coordinator in REDCap utilizing a

scheme generated by the study biostatistician. The PI will be blinded to study allocation until the end of study follow-up interview. Participants randomized to the control arm (n = 15) will be enrolled in the existing SAMS symptom tracking and EMA assessment program to include baseline assessment, EMA symptom reporting, and repeated measures at 4 & 8 weeks. Intervention participants (n = 15) will have continuous access to educational content within the app and weekly nurse-guided support available through videoconferencing support and text messaging to promote engagement.[32-33] Intervention procedures will include symptom monitoring through self-report and completion of measures (Table 1), accessing of educational content, engagement with study team to increase intervention engagement, use of activity trackers, and photo/voice/video diary entries completed through the app. During engagement with study team, participants will receive feedback on the one-time video inhaler technique submitted via the MATADORS app. At study completion, youth and primary caregivers will complete an end of study interview. Interviews will be audio-recorded and professionally transcribed.

Data Collection/Measures

Data collection approaches, instruments, and interventions are outlined in Table 1. Primary intervention measures will be collected at baseline, end of study (week 4), and the week 8 follow-up.

Table 1. Data Collection/Measurement/Instruments/Interventions/Time Points

Data Collection	Measures	Data Sources	Time Point
Demographics/Clinical	Age, date of birth, gender, race, ethnicity, education, insurance, urban/rural residence, caregiver demographics, family characteristics, diagnoses, medications, Short Assessment of Health Literacy-English [40]	Medical record review, participant interview	Baseline
Exit Interview	Semi-structured interviews	Dyadic and 1:1 participant interviews	Post intervention follow-up (week 8 +/- 7 days)
Reach: Sample Recruitment	Monitoring of sample representativeness, types of recruitment activities, rate of recruitment, % eligible, and consented	Recruitment tracking form	Study initiation, daily, and study end
Efficacy:	PROMIS Pediatric Fatigue 10a [38-39] Self-Efficacy for Managing Chronic Disease-6 item Neuro-QOL Item Bank v2.1-Pediatric Fatigue PROMIS Pediatric Item Bank v2.0-Pain Interference Neuro-QOL Item Bank v.1.0-Pediatric Pain-Short Form PROMIS Pediatric Emotional Distress: Anxiety [38-39] PROMIS Pediatric Emotional Distress: Depression [38-39] # days reporting symptoms (fatigue, pain, anxiety, depression) Self-report medication adherence (rescue/controller) from SAMs study Self-report missed school/work/activity Activity tracker-step count & sleep patterns (hours per day) Physical activity patterns (# of minutes active/day per Fitbit) Inability to concentrate/sleepiness during the day Pediatric Quality of Life Inventory 3.0 Asthma Module [42] Asthma Belief Survey [43] Asthma Control Test Inhaler technique video (one time video during 4 week study period)	Participant interviews, self-report, diary entries (video/voice/photo entries), and activity tracker data	Baseline, daily, end of study, and post-intervention follow-up

Adoption:	# days reporting symptoms (fatigue, pain, anxiety, depression) # times educational modules accessed (time in minutes) # diary entries Activity tracker-step count Activity-self report (PA)	Tracking forms, activity tracker reports, diaries, app access counts, symptom reporting	Daily
Implementation:	# problems with mobile device/app/fitness tracker; fidelity to intervention; participant/caregiver recommendations; acceptability of intervention; participant burden (time) spent completing dependent measures.	Tracking forms and study team meetings	End of study interviews and satisfaction questionnaires
Maintenance:	# youth who would continue post intervention; youth & caregiver perception of intervention; recommendations for revision	Youth-caregiver end of study interview	End of study interviews and satisfaction questionnaires

Measures of feasibility, including recruitment, reach, adherence, satisfaction, participant burden of data collection procedures, and fidelity to interventions will be evaluated. Quantitative measures will be entered into REDCap [47] and analyzed using SPSS.[48] Univariate descriptive statistics and frequency distributions will be calculated, as appropriate, for all variables. Demographic variables will be described via measures of central tendency (mean, median), variability, and frequency distributions, as appropriate. Demographic and clinical characteristics from completers/non-adherent/non-completers will be compared to better understand and describe the population. Confidence intervals (95%) will be used to estimate dichotomous outcomes (e.g., proportion completing intervention, proportion adherent to the intervention, proportion providing daily symptom reporting and diary entries) and continuous feasibility measures (e.g., satisfaction scores and end of study interview). Qualitative data from end of study interviews and video/voice diaries will be analyzed using directed content analysis [44] and transcripts will be entered into MAXQDA Analytics Pro software.[46] A priori and emergent codes will be analyzed using the RE-AIM theoretical framework.[28]

Participant Compensation: Aim 2 Control participant dyads (n =15) will receive checks for completion of study activities ($30 each for baseline data collection and training for both youth and caregiver participants; $25 for each participant for weeks 4 & 8 measures; $25 for each member of the dyad for post-study key informant interviews; $10 for a one-time video upload of inhaler technique; and up to $1/day for symptom reporting/EMA entries and Fitbit usage x 30 days maximum) (control group youth maximum remuneration = $175/participant; control parent maximum remuneration = $105). Intervention participant dyads (n=15) will receive ($30 each for baseline data collection and training for both youth and parent participants; $25 each for weeks 4 & 8 measures; $25 for each member of the dyad for post-study key informant interviews; $10 for a one-time video upload of inhaler technique; and up to $4/day for symptom reporting/EMA entries, medication reporting, Fitbit usage, and video/voice/photo diary entries x 30 days maximum) (intervention group youth maximum remuneration = $235/participant; intervention group caregiver maximum remuneration = $105).

12.0 Data Management

Audio-recordings and transcripts will be stored on a secured MUSC server. Demographic and clinical data will be entered into REDCap [(13)] and analyzed using the Statistical Package for the Social Sciences (SPSS) [(14)]. All hardcopy documents (consent forms and data collection instruments) will be stored in a locked cabinet inside a locked office at the College of Nursing. Access will be limited to authorized study personnel.

Protecting Confidentiality of Participant Data:

Certificate of Confidentiality. This study will be conducted in accordance with recently enacted policy regarding the automatic granting of Certificates of Confidentiality to NIH/NINR federally funded research. Participants will be made aware of their rights and the limitations of the release of Protected Health Information during the Informed

Consent process.

Participant Screening and Enrollment. All data from participants screened for the study will be entered into an electronic study database. Designated research staff will collect, gather, and enter required data (written informed consent, documented assent for youth participating, HIPAA Authorization, and demographics) onto study data forms. Screened patients who do not meet study eligibility will have specific screening data entered into the study database. The collected data will be helpful in examining the patient population and feasibility of enrollment criteria and will include reason for exclusion. All dates will be shifted and other Personal Health Information (PHI) will be removed from the study database upon study completion. All data obtained from this study will be used for research purposes only and will comply with Federal HIPAA regulations. Master Screening and Enrollment Logs will used by the PM to prepare reports on accrual and attrition for the PI and SMC.

Case Report Forms (CRF). All proposed study specific case report forms (source documents) for data collection will be designed by the PI, and, when possible, transferred into electronic Case Report Forms (eCRFs) for use in the study's REDCap database. These study specific eCRFs source documents (study logs for correspondence, compensation and other forms such as pre-eligibility screens) will be coded by the participant's unique study ID# for all data collected including study instruments will be maintained in the participant research record. Completed instruments that require signature on a paper CRF will be scanned and uploaded into the study database to all for remote electronic safety monitoring as well as maintained on file in accordance with MUSC policies and applicable Federal Regulations for the Conduct of Human Participant Research.

Binders. The PC will prepare and maintain a participant-specific CRF binder for each participant containing all non-eCRFs records. A regulatory file will be maintained by the PM to include the IRB-approved Protocol, original Informed Consent documents, HIPAA forms and other required study-related regulatory documents. All paper research records and CRFs will be maintained in a locked file cabinet, stored in a room for research files that is accessible only via a password protected entry system that features security cameras, within the College of Nursing. Access to the research records, study database and PHI will be restricted to authorized study personnel as approved by the PI and MUSC IRB. As with all studies conducted at MUSC, this study is also eligible for a random audit by MUSC Office of Compliance.

Data Processing. This study will use Research Electronic Data Capture (REDCap) for data capture and management. REDCap is a software toolset and workflow methodology for the electronic collection and management of research and clinical trials data. REDCap provides secure, web-based, flexible applications, including real-time validation rules with automated data type and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, SATA, R and Microsoft Excel. The study-specific REDCap electronic database will be designed and developed by the PI, CI, or PC. The provision of REDCap is made available through the South Carolina Clinical & Translational Research (SCTR) Institute at MUSC with NIH Grant awards UL1RR029882 and UL1TR000062. This study will also use Doxy.me, a secure video conferencing platform that is HIPAA compliant and freely available to MUSC researchers through SCTR.

Data Security. Ensuring data security, compliance with 45 CFR 46 and maintaining the integrity of PHI is a top priority. MUSC has Standard Operating Procedures (SOP) to ensure a high level of data security while coordinating electronic and paper data management activities for clinical research trials. The REDCap study database will be hosted in the Biomedical Informatics secure data center at MUSC, a secure environment for data systems and servers on campus, and includes firewall, redundancy, failover capability, backups and extensive security checks. The secure data center has strict access control; only authorized core personnel may access the facility un-escorted. Only authorized users are allowed to connect to the network, and the security of the network is actively monitored. Power and environmental controls have several layers of backups, from interruptible power supplies to alternate and redundant feeds to the local utility company. The REDCap system administrator contributes to the maintenance of institutional disaster recovery and business continuity plans. Load balancers and a highly fault tolerant SAN infrastructure contribute to high availability.

The REDCap system itself has several additional layers of protection including password protection. Access to the data and its security is managed institutionally by sponsored login IDs through a Shibboleth login with an MUSC

issued NetID and features a user account management filter that controls who can access the data and to what degree. All personnel must pass an employment background check before being issued an ID. Password complexity, history and expiration standards are implemented at the institutional level. Access to individual REDCap projects and their data is managed by the owner of the project. All transactions are securely delivered to the application using Secure Sockets Layer (SSL – SHA-1 with RSA Encryption; 2048-bits). It is then transmitted internally (behind the firewall) to the database server. All transactions are logged at the server layer (httpd logging), application layers (REDCap logs activity to a database table), and the database layer, using both query and binary logging. This feature provides audit trails for all changes, queries, data exports and reports. MUSC Information security policies are available at: https://mainweb-v.musc.edu/security/policy/

Data Entry. Only MUSC IRB approved study personnel that are authorized to have access to the REDCap study database will be granted password access. Study personnel using computers that are connected to the Internet will directly enter data into the remotely housed database. As such, no electronic study data will be stored on hard drives and/or any portable electronic devices. Additionally, all personnel with access to the database will have current University of Miami CITI training in the Conduct of Human Subject Protections, and HIPAA and Information Security trainings that are completed annually. Each participant will be assigned a unique study identifier, all PHIs will be masked, and data exports will be limited to the PI or the PC for generating reports and the conduct of statistical data analysis.

Data Monitoring. Ongoing quality control procedures will be implemented for data collection, storage and processing. The PM will conduct routine monitoring of the study database and generate a monthly report for review at study team meetings. Standing agenda items for these meetings will include participant recruitment and retention, AE's, protocol deviations, data integrity and overall study conduct. The PI and PC will work to resolve and validate discrepant data. Discrepancies that warrant clarification will be sent to appropriate parties for review and resolution. All data entry and changes made in the study database by authorized study personnel will be automatically logged by REDCap, which will provide a transparent visible audit trail for reviewers.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

We have a well-developed and NIH/NINR prepared Data Safety Monitoring Plan (DSMP) that involves the use of a Safety Monitoring Committee (SMC) that shall meet semi-annually following study initiation (i.e., recruitment of first participant). The Committee is comprised of key individuals that include: an independent safety monitor (ISM), a biostatistician (BS), and the Program Manager (PM). All reports will be forwarded to the IRB and Sponsor in accordance with institutional policies and sponsor requirements.

Safety Monitoring Committee (SMC):

The study's SMC will be comprised of the following individuals, who will perform data safety management and monitoring of the study:

Principal Investigator, (PI). Although not part of the SMC, as PI, Dr. Nichols will overall be responsible for the immediate protection of all human participant study participants enrolled in the study.

Safety Monitor, (SM). Dr. Susan Newman is an Associate Professor and the Director of the Ph.D. in Nursing Science program in the College of Nursing. She received her Ph.D. in Nursing and Bachelor of Science in Nursing from the Medical University of South Carolina, and a Bachelor of Fine Arts from Clemson University. Dr. Newman is a Certified Rehabilitation Registered Nurse. Dr. Newman's current research investigates the role of peer mentoring in the process of adapting to life with a spinal cord injury and learning to self-manage consequences of the injury successfully. Her research includes application of community-engaged research approaches to address issues affecting community participation, health, and overall quality of life of individuals with spinal cord injury. She has received funding from the National Institutes of Disability, Independent Living and Rehabilitation Research, National Institutes of Health, the Agency on Healthcare Research and Quality, the SCTR Pilot Projects Program, and the Rehabilitation Nursing Foundation.

As the SM, he/she will be responsible for reviewing all cumulative reported Serious Adverse Events related to study intervention/participation and data safety monitoring reports generated by the BS to provide study recommendations to the PI, MUSC's IRB and NINR. Dr. Newman will be immediately notified of the occurrence of any SAE by the PI or PM and will be provided with the necessary study information to provide an informed recommendation in real-time regarding the protocol and human participant safety.

Martina Mueller PhD, Biostatistician (BS). Dr. Mueller is a Professor in the College of Nursing with a joint appointment in the Department of Biostatistics, Bioinformatics and Epidemiology (DBBE) at MUSC. Dr. Mueller has served and is currently serving as a member of several NIH/NINR R01/R21 DSM Boards, and Committees. Dr. Mueller will be responsible for conducting semi-annual interim analyses, generating semi-annual AE safety reports from the electronic study research database and disseminating de-identified information to the ISM and other members of the SMC. The interim data analyses will only include safety related results; analyses in regard to study outcome will not be performed. The interim AE reports will provide typology, frequency data and outcomes of all reported and documented AE in the electronic study database. With no patient contact, Dr. Mueller has no apparent conflict of interests to serve in this capacity.

Mohan Madisetti MSc, Program Manager (PM). Mr. Madisetti is the P20 Program Manager at the College of Nursing and a member of MUSC Institute of Human Values with Fellowship certification in Research Ethics. Mr. Madisetti has served and is currently serving as a member of several NIH/NINR R01/R21 DSM Boards and Committees, and FDA Industry Sponsored Clinical Trials. With no patient contact, Mr. Madisetti has no apparent conflict of interests to serve in this capacity. Mr. Madisetti will be responsible for the classification of all reported adverse events (AE) and for ensuring that all serious adverse events (SAE) are forwarded to the PI and ISM in real time and in compliance with MUSC IRB policies and procedures. In addition, and in conjunction with the PI, Mr. Madisetti will be responsible for amending the protocol in accordance with the ISM recommendations, submitting reportable SAEs and protocol deviations to MUSC IRB, and, submitting annual Progress Reports to the NIH/NINR through MUSC's OSRP. He will also be responsible for maintaining the regulatory binder, ensuring data management validation and verification of the electronic study research database, conducting monthly internal quality control audits on all participant records, notifying the PI of any deficiencies, and the forwarding of reportable SAE to the NIH/NINR Program Official through MUSC's OSRP within 72hrs of IRB review and acknowledgement

Monitoring Study Safety

Good Clinical Practices (GCP) will be followed throughout this study. From the initial screening of participants through review of inclusion and exclusion criteria to the informed consent process to the provision of participant study instruction to staff training in Good Clinical Practices (GCP) and regulations pertaining to the Conduct of Human Participant Research to study contact with participants to internal monthly quality control audits and protocol fidelity monitoring to the real-time review of Adverse Events (AEs) and SAEs by the SM to the oversight of MUSC's IRB, procedures for monitoring study safety are consistently afforded throughout study. Specific study safety procedures include:

- Participants will be screened for inclusion and exclusion per the protocol; the PI or Research Coordinator (RC) shall verify potential participant eligibility prior to study enrollment.
- Participants will be fully informed as to all know risks and the possibility of risk from study participation during the informed consent process. Youth interested in participating will be asked to provide documented written assent, along with parental consent prior to enrollment. All adult participants will provide written informed consent prior to participating in any study procedures. Study risks will be provided in writing to participants via the informed consent document and will be reviewed verbally as part of the informed consent procedures. Participants will have the opportunity to ask questions prior to making a decision regarding whether they wish to volunteer for this research study. Study risks are minimal.
- Participants will be instructed to notify the researchers of any/all suspected or experienced adverse events whether they believe them to be related or not to the intervention.
- All reported participant AEs will be tracked through to resolution and reported to the IRB and Sponsor, as required per GCP and regulatory requirements.

- All investigators and researchers will maintain active CITI Human Subject Research and Good Clinical Practice training.
- The PM will conduct a monthly internal quality control audit of all participant records to ensure compliance with MUSC IRB regulations; the PI and Program Coordinator (PC) will work together to correct any errors.
- The PI and/or designee will observe and evaluate ten (10%) percent of eligibility screening visits, informed consents and study instructions performed by IRB approved study personnel and provide feedback and/or retraining of study personnel if fidelity to both applicable federal regulations and the protocol is not observed.
- The BS will generate semi-annual AE reports for the PI and SMC to review.
- The SM will have access to real-time study data and will be able to provide immediate recommendations to the PI.
- Investigator performance and compliance will be provided for through MUSC IRB and ORI study oversight.
- This protocol will be conducted fully in keeping with the signed MUSC IRB Principal Investigator Statement of Assurance and Department Chair's Statement of Assurance, when submitted to the IRB as a required component of the MUSC IRB Human Research Review Application. Diligent study safety monitoring will be conducted by all member of the research team and the SMC throughout the conduct of this study in compliance with the following required elements of MUSC IRB's continuing review process:
- Tracking and follow-up of participant accrual (including withdrawn consents) will minimize risk by identifying, disclosing, and mitigating any potentially unknown risk(s) of harm to study participants.
- Timely and appropriate reporting of informed consent process deficiencies, protocol deviations, privacy breaches, conflicts of interest, and/or changes in personnel.
- Ongoing soliciting, monitoring and appropriate reporting of adverse event activities.
- Timely and appropriate IRB submission of safety-related documents such as audit reports, sponsor progress reports, SM reports, and other materials or communications that might impact the safe conduct of this study.
- Active cooperation with the IRB, ACO, sponsor, and other applicable entities in the event of a random or for-cause internal or external audit.

14.0 Withdrawal of Subjects

Participants may voluntarily elect to withdraw their consent at any time for any or no given reason while enrolled in the study. The PI may withdraw participants from the study at any time if they decide it is in the participant's best interest, if they do not follow the investigator's instructions, and/or if they fail to maintain to contact with the researchers or attend study visits. Withdrawals of participants may also occur if there is a protocol violation or early study closure. All data gathered from withdrawn participants will be used in the analysis plan under an Intention-to-Treat (ITT) model.

15.0 Risks to Subjects

The risks associated with this study include:

Loss of privacy: PHI from participants will be gathered and stored electronically on secure and encrypted servers and there are risks associated for the loss of privacy and confidentiality. We will further minimize the potential for loss of confidentiality through the physical separation of participant names from their research record. Audio recordings of participants interviews will be uploaded for transcription within 48 hours to an outside agency with which MUSC has established a Business Associates Agreement (BAA). Once uploaded, all audio recordings will be deleted from any portable storage device.

Emotional distress: Some of the questions asked may be upsetting to participants or make them feel uncomfortable answering them. Participants will be instructed that if they do not wish to answer a question, they can skip it and go to the next question.

Physical fatigue: Completion of the questionnaire, measures and interviews may be tiring to some participants. Participants will be given ample time to complete the questionnaire and may take breaks as necessary throughout the process.

Randomization: Participants are being assigned to a study group by chance. The intervention included in the first study arm may prove to be less or more effective or have more or less or unknown side effects than the second study arm or other available treatments.

16.0 Potential Benefits to Subjects or Others

There is no direct benefit to participants enrolled in this study. It is hoped that this research will contribute to generalizable scientific knowledge and the development of content to be used in a future mobile health intervention to promote symptom self-management among youth with asthma and obesity. A product developed with patient/provider engagement could have larger scale adoption and improve outcomes for caregivers, children, and families impacted by asthma and obesity.

17.0 Sharing of Results with Subjects

Results from this study will not be directly shared with participants. Results will however be published and made publicly available in accordance with the NIH/NINR Open Access Policy through posting on ClinicalTrials.gov.

18.0 Drugs or Devices

This study does not involve the use or storage of any drug product. All investigational supplies and materials are readily commercially available and are not industry regulated. All study supplies (physical activity trackers) will be inventoried and stored in a locked cabinet, behind a locked door by the researchers at CON. Study supplies will be dispensed individually to each participant after enrollment and group assignment.

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