ACTION (physicAl aCtiviTy In minOrity womeN with asthma) intervention

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Study Location(s):

1. University Illinois at Chicago
2. Chicago Park District

541 N Fairbanks Ct, Chicago, IL 60611

Sponsor: [National Heart, Lung and Blood Institute, Central Society of Clinical and Translational Research]

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LIST OF ABBREVIATIONS

AA	African American
ACQ	Asthma Control Questionnaire
ACTION	physicAl aCtiviTy In minOrity womeN with asthma
DSMP	Data and Safety Monitoring Plan
EHR	Electronic Health Record
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
ISWT	Incremental Shuttle Walk Test
NIH	National Institutes of Health
OPRS	Office for the Protection of Research Subjects
PA	Physical Activity
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event

1.0 Project Summary/Abstract

Physical inactivity in asthma is associated with worse asthma outcomes and African American women are disproportionately impacted by both physical inactivity and asthma. Research aimed at addressing the unique asthma-related and cultural-specific barriers to physical activity in this vulnerable population of women is needed. The proposed study will modify a validated community-based walking intervention specific to the needs of sedentary African American women with asthma and evaluate the impact of the intervention on physical activity and asthma specific indicators to reduce the burden of asthma in sedentary African American women.

2.0 Background/Scientific Rationale

Asthma is a highly prevalent chronic disease that disproportionately impacts African American (AA) women. AA women have poorer asthma-related quality of life and higher rates of asthma exacerbations, healthcare utilization and mortality compared to Caucasian women. Further, AA women are less physically active than any other subgroup of adults, which may help explain the asthma health disparities, found between AA and Caucasian women. Physical inactivity among individuals with asthma is associated with poor asthma control and respiratory function, greater health care utilization, and poorer quality of life. Given the connection between poor asthma outcomes and physical inactivity, addressing physical activity (PA) among sedentary AA women with asthma is imperative. Physical activity demonstrated improvement in asthma outcomes specifically asthma control, quality of life and healthcare utilization. Despite these benefits, fewer than 25% of AA women with asthma engage in regular physical activity. The **ACTION intervention: physicAl aCtiviTy In minOrity womeN with asthma** is a 8-month community-based walking intervention refined to be applicable for sedentary AA women with asthma.

This project will obtain and incorporate stakeholder input on the barriers and facilitators to engaging in physical activity with asthma to a validated community-based walking intervention. Once modified, we will pre-pilot the intervention in 10 participants, refine further in response to participant feedback and then test the feasibility, acceptability and estimate the efficacy of the intervention in a randomized controlled pilot of 80 participants within a pragmatic community setting convenient for sedentary AA women.

3.0 Objectives/Aims

The proposed study has 5 aims involving a total of 135 sedentary AA women with asthma.

NOTE: Aims 1 and 2 have been IRB approved and completed. Only data analysis of these 2 aims are still occurring. At this time, I am requesting approval for Aim 3 which entails pilot testing the intervention to assess the feasibility, acceptability and to estimate the efficacy of the ACTION intervention.

Aim 1: Use stakeholder input to modify a validated walking intervention for sedentary AA women with asthma.

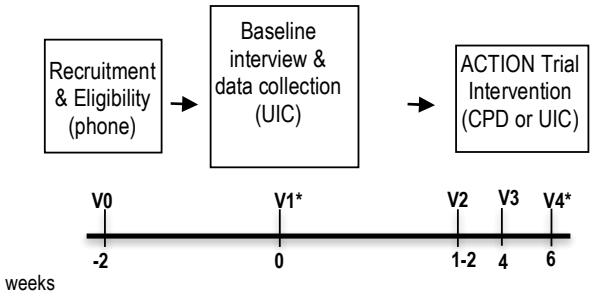
Aim 1a: Conduct focus groups in 30 sedentary AA women with asthma to assess PA barriers and facilitators.

Aim 1b: Adapt a validated walking intervention that addresses the barriers and facilitators to PA unique to sedentary AA women with asthma obtained from Aim 1A.

Aim 2: Pre-pilot test ACTION (physicAl aCtiviTy In minOrity womeN with asthma) intervention in up to 10 sedentary AA women with asthma to refine the recruitment

materials, approach, design, and intervention content.

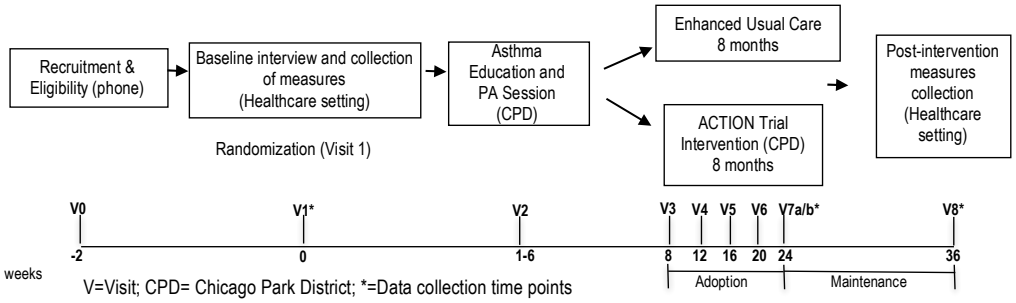
Figure 1. Study Design for ACTION Pre-pilot



V=Visit; *=Data collection;
UIC=University of Illinois at Chicago; CPD= Chicago Park District

Aim 3: Pilot test ACTION intervention in 80 sedentary AA women with asthma to assess acceptability, feasibility and estimate the efficacy to appropriately power a subsequent efficacy trial.

Figure 2. Study Design for Aim 3 (ACTION RCT Pilot)



V=Visit; CPD= Chicago Park District; *=Data collection time points

Aim 4: Modify and refine the video component of the intervention to address the asthma-specific barriers to walking in AA women with asthma.

Aim 4a: Conduct a focus group with an Asthma Advisory Council (AAC) that includes up to 15 AA women with asthma, to assess the appropriateness of the proposed asthma content, language and setting used in the videos.

Aim 4b: Adapt the video component of the intervention using an iterative approach to include appropriate asthma content, language and setting.

Aim 5: Assess the acceptability of the revised videos by the AAC using a mixed methods approach (qualitative and quantitative data).

Aim 6: Disseminate research findings and next steps to women that participated in Aims 1-3.

4.0 Eligibility/Inclusion and Exclusion Criteria (for Aims 1, 2 and 3)

Participants will be recruited from the UI Health System.

- **Eligibility considerations:** We chose to focus on sedentary AA women with sub-optimally controlled persistent asthma (based on ACQ score ≥1.5/Appendix 1 OR ACT score ≥20/Appendix 2) as long-term goal is to see an effect change in asthma control. During our focus groups, we will discuss if there is a preferred age range and will refine the intervention accordingly. Focus group participants did not express a preferred age range so a diverse age range of participants will be recruited to ensure representation from a diverse population of AA women with asthma. Women that have completed participation in Aims 1, 2, or 3 of this study will be able to participate in Aims 4 and 5 of the study.

4.1 Inclusion Criteria

4.1.a. Aims 1 and 2:

- Self-identify as female and black or AA
- Age 18-70
- Self-report <150 min/week of moderate intensity PA
- Sub-optimally controlled persistent asthma based on Asthma Control Questionnaire (ACQ ≥1.5) OR Asthma Control Test (ACT <20)
- Wiling to enroll and provide written-informed consent

4.1.b. Aim 3

- Self-identify as female and black or AA
- Age 18-70
- Sub-optimally controlled persistent asthma based on Asthma Control Test (ACT <20)
- Wiling to enroll and provide written-informed consent
- Have a smartphone or tablet device
- Willing to be randomly assigned to treatment or control group

4.1.c. Aims 4 and 5

- Self-identify as female and black or AA
- Age 18-70
- Wiling to enroll and provide written-informed consent

4.2 Exclusion Criteria:

4.2.a. Aims 1 and 2

- Plans to move from Chicago during the study period
- Unable to ambulate without human assistance
- History of significant mental illness (e.g. uncontrolled bipolar disorder, psychoses)

- Currently pregnant, planning to become pregnant over the next 3 months
- Diagnosis of COPD (emphysema or chronic bronchitis) suggested by patient report of doctor diagnosis or smoking history (>20 pack years)
- Family/household member of another study participant or staff member
- Inability to speak, read or understand English;
- Investigator discretion for safety or protocol adherence reasons

4.2.b. Aim 3

- Plans to relocate outside of the Chicagoland area during the study period.
- Unable to ambulate without human assistance (ie. use of a wheelchair, scooter)
- History of significant mental illness (e.g. uncontrolled bipolar disorder, psychoses)
- Currently pregnant, planning to become pregnant over the next 3 months
- Diagnosis of COPD (emphysema or chronic bronchitis) suggested by patient report of doctor diagnosis or smoking history (>20 pack years)
- Poorly controlled high blood pressure (BP >180/100 at baseline visit)
- Family/household member of another study participant or staff member
- Inability to speak, read or understand English;
- Investigator discretion for safety or protocol adherence reasons
- Participation in Aim 2 of this study

We will use the Exercise Assessment and Screening for You (EASY) questionnaire (Appendix 3 to detect the presence of conditions that could preclude study participation. Current physical activity (PA) screening guidelines from a consensus group from the American Heart Association and the American College of Cardiology no longer recommend routine stress testing for those initiating a PA program. The EASY questionnaire has clear recommendations for when evaluation by a physician is needed before beginning a PA program (e.g., when the individual reports new-onset shortness of breath, pain, or dizziness that has not been previously evaluated by a health care provider), and we will follow these recommendations.

If the EASY questionnaire recommends that a potential participant be evaluated by a health care provider prior to starting a PA program, the potential participant will be asked to contact their health care provider or we will obtain permission from the participant to contact their UI Health provider. We will send their UI Health provider a secure message describing the study and it's procedures and the results of their patient's EASY questionnaire. We will request a response regarding permission of entry into the study. Permission from their health care provider will be required prior to participation in any study activities.

Exclusion criteria for spirometry procedure only done at 1 data collection visit (Visit 1) in the pre-pilot and 3 data collection visits in the pilot: chest or abdominal surgery in previous 6 weeks, detached retina or eye surgery in previous month.

NOTE: This will be assessed at data collection visits only. If participant meets these exclusion criteria, then spirometry will not be performed.

4.2.c. Aims 4 and 5

- Plans to move from Chicago during the study period
- Diagnosis of COPD (emphysema or chronic bronchitis) suggested by patient report of doctor diagnosis or smoking history (>20 pack years)
- Inability to speak, read or understand English;
- Investigator discretion for safety or protocol adherence reasons

4.3 Excluded or Vulnerable Populations

EXCLUSION OF MINORS Although asthma is a disease that affects both children and adults the focus of this proposal is to specifically modify and pilot test an existing physical activity intervention in sedentary African American women with asthma. Children are intentionally being excluded, as currently there is insufficient data available in African American adults with asthma to judge the potential risk of this intervention in children.

INCLUSION OF WOMEN AND MINORITIES The focus population for this study is sedentary African-American (AA) women with asthma. All participants included in the study will self-identify themselves as female and black or AA. This study population was chosen as AA women are disproportionately impacted by physical inactivity and asthma compared to Caucasian men and women and AA men. In particular, AA women have the highest rates of asthma-related mortality and asthma-related health-care utilization. Physical inactivity in asthma is particularly relevant because it is associated with worse asthma outcomes, specifically, poor asthma control and respiratory function, greater health care utilization, and poorer quality of life. Research aimed at addressing physical inactivity and asthma control in this vulnerable population of women is needed.

5.0 Subject Enrollment

Potential participants will be identified using 3 methods: 1) Using a validated electronic health record (EHR) algorithm (Appendix 4) that identifies asthma patients with a high sensitivity and specificity (99% and 96%, respectively)[1]; 2) From healthcare providers in internal medicine, pulmonary and allergy/asthma clinics at UI Health; 3) From women that were screened in Aims 1-3 and provided permission to contact them for future studies.

5.1 Asthma algorithm identification

The EHR asthma algorithm will be performed by Dr. William Galanter, co-investigator. We have experience using this EHR algorithm at UIC for an ongoing asthma study, CAPriCORN (ChairB Protocol #14111301). A HIPAA waiver will be obtained for this research to allow us to gather information about potential study participants and contact the potential participants. Two methods of recruitment will be used: in-person and

mailings. In-person recruitment will occur in the UI Health outpatient clinics. We will approach potential participants who are already coming to UI Health for an appointment. In a given week, we will verify ahead of time what potential participants are coming to the clinics that have also been identified through the EHR asthma algorithm. A research assistant(s) will come to the outpatient clinic for the potential participant's appointment, obtain verbal agreement from potential participant's doctor/provider to approach the potential participant, then approach the potential participant and give a brief introduction about the study and ask screening questions to assess eligibility. If eligible and interested, the study will be introduced to the potential participant and if interested scheduled for a focus group session (Aim 1) or the first study visit (baseline interview and initial data collection) which will take place in the Clinical Research Center at UIC (Aim 2 and 3). Alternatively, the recruiter and potential participant can set up another day or a phone call to assess eligibility, describe the study and/or schedule the initial visit. All patients approached must be identified by our EHR asthma algorithm.

For mail recruitment, letters along with a response card will be sent to women identified by the algorithm. Within 1 week, telephone contact will be made unless the response card is returned indicating that they are not interested. Participants will be called up to 5 times to recruit a potential subject via telephone. If the potential participant doesn't answer the phone call, a recruitment voicemail will be left up to 5 times. A brief telephone screen will assess eligibility, describe the study and interest in participation. If interested and eligible, patients will be scheduled for a focus group (Aim 1) or the first study visit (baseline interview and initial data collection) which will take place in the Clinical Research Center at UIC (Aim 2 and 3). Written informed consent will be obtained in person in a private area prior to starting the focus group session (Aim 1) or the baseline interview and data collection (Aim 2 and 3) for all participants.

5.2 Healthcare provider identification

In our second selection strategy, a research assistant (RA) will work closely with healthcare providers who see a lot of patients with asthma in their clinics (Internal Medicine, Pulmonary and Allergy/Asthma).

1. The RA will go to Internal Medicine, Pulmonary and/or Allergy/Asthma clinics and introduce themselves to the healthcare providers and provide them a brief synopsis of the research study (See study synopsis V1 11_20_17).
2. The RA will ask healthcare providers for potential participant's that have physician diagnosed asthma and obtain verbal agreement from the healthcare provider to approach the potential participant.
3. The RA will approach the patient and give a brief introduction about the study and ask screening questions to assess eligibility using the in-person screening script.
4. If the patient is eligible and interested, the study will be introduced to them and if interested scheduled for the first study visit (baseline interview and initial data collection) which will take place in the Clinical Research Center at UIC (Aim 3).

5. Alternatively, the potential participant may be given a flyer about the study or the recruiter and potential participant can set up another time to assess eligibility, describe the study and/or schedule the initial visit by phone or in-person.

5.3 Women screened for Aims 1-3

1. Women that were screened for Aims 1-3 AND provided permission to contact them for future phases of this research will be contacted via preferred method of contact (phone/text/email). The RA will contact the participant and give a brief introduction about the study and ask screening questions to assess eligibility using the telephone screening script.
2. If the patient is eligible and interested, the study will be introduced to them and if interested the RA will obtain times that are ideal for the participant for the focus group.

5.4 Eligibility Screening

If a participant does not meet eligibility criteria during screening, this will be indicated on an encrypted data sheet so that participants are not approached multiple times. The de-identified data collected from the screen failures will be entered into REDCap by key research personnel.

The principal investigator will separate clinical responsibilities and influence from the recruitment process by having key research personnel perform eligibility screening and informed consent of potential participants. The physicians will be informed of the study and its' objectives at a faculty meeting and will be asked if they have any concerns regard their patients' participation.

6.0 Study Design and Procedures

Aim 1 (focus groups)

We will randomly select 160 women with the goal of recruiting a random sample of 30 women. We will use the recruitment method described above in Section 5.0. Participants will be selected to ensure representation of a range of asthma severity and current age. The sample size is determined by the theoretical saturation or the point when no new ideas relevant to the question are obtained, which is generally 15[2]. However, a minimum of 20 is recommended for illness studies[3]. This study includes 30 participants in groups of 6-10 for focus groups. If redundancy is not noted in the focus group discussion, additional participants will be included until saturation is reached.

To ensure that the focus groups are responsive to the participants and unexpected themes that might emerge, data analysis will begin after the first focus group data are entered and continue throughout the focus group phase.

Study Procedures for Aim 1:

1. Complete eligibility screening.
2. Securing informed consent.
3. Complete a brief demographic form. (Appendix 5)
4. Attend one 2 hour focus group and provide perspective on issues such as physical activity and asthma. Provide feedback and recommendations on recruitment materials, content structure, and approach of ACTION intervention.

Drs. Nyenhuis and Sharp will moderate all focus groups using an interview guide (Appendix 6) with semi-structured open-ended questions. The interview guide will be pre-tested for clarity, comprehension, and sensitivity and will provide sufficient flexibility to pursue unanticipated facets of topics that emerge in focus group discussions[4].

Each group will last approximately 2 hours and be audio-recorded and subsequently transcribed by a member of the research team. Patients will complete written consent, receive $50 (gift card or cash) and light snacks/refreshments.

The focus groups will take place in a private space in one of 3 places:

1. Chicago Park District location that is in close approximation to where the participants live. The exact location will be determined with the help of the Chicago Park District liaison and will take into account safety of the participants and the location of where participants live.
2. The University of Illinois at Chicago Institute of Health Research and Policy
3. For participants that are interested but unable to any other the other scheduled visits, we will arrange for an individual interview at UI Health.

The Chicago Park District will only host focus groups and no Chicago Park District staff are involved in the research as recruiters or to collect data.

Key research personnel will send a reminder text and/or call the patient (based on patient preference) 24-48 hours prior to the focus group stating “UIC group will meet at X time and X place.”

Aim 2 (Pre-pilot)

We will select up to 10 women using the recruitment method described above in Section 5.0. Potential participants and participants for Aim 1 will be eligible to participate in Aim 2 if they expressed an interest to participate in future phases of the study. Participants will be selected to ensure representation of a range of asthma severity and current age.

Study Procedures for Aim 2 (Appendix 7- Table of study procedures):

Screening:

Potential participants will undergo eligibility screening either in-person (UI Health patients who are already coming to UI Health for an appointment) or over the telephone. If eligible and interested in participating in the study, they will be scheduled for their first study visit (Visit 1).

Visit 1: (See appendix 8 for measures)

At visit 1 the following procedures will take place at the Clinical Research Center at UIC:

1. Secure informed consent.
2. Complete a brief demographic form.
3. Spirometry performed according to American Thoracic Society guidelines. Participants will be asked to wear nose clips and to take a deep breath in and blow their breath out as fast as they can into the spirometer. We will perform repeated measurements (3 to 8 times) to ensure accuracy of results.
4. Height and Weight
5. Incremental Shuttle Walk Test (ISWT) performed according to American Thoracic Society guidelines
6. Physical activity questionaires
7. Asthma Control Questionnaire (ACQ)
8. Asthma-related quality of life questionnaire (AQLQ)
9. PROMIS measures (Global Health, social roles satisfaction, mood, sleep)
10. Asthma Knowledge and Self-efficacy questionnaire (KASE-AQ)
11. Dyspnea questionniare
12. Active Where Questionnaire
13. Self-efficacy for walking scale
14. Social support for exercise survey
15. Outcome expectation scale for exercise
16. Epworth sleepiness scale-pending permission
17. Sleep Apnea Scale of the Sleep Disorders Questionnaire- pending permission
18. Pittsburgh Sleep Quality Instrument
19. Schedule Visit 2 with participant

Key research personnel will obtain consent in a private room in the Clinical Research Center. After consent is obtained, the other study procedures will be completed. This visit will last approximately 2 hours and upon completion the participant will receive $25 cash or gift card. Patients will be offered light snacks/refreshments at this visit.

Participants will then be provided the following equipment at Visit 1:

Actigraph accelerometer: This will be given to participants to assess their baseline and post-intervention daily number of steps. Participants will be verbally instructed to wear it attached to their waist at all times while awake. The Actigraph accelerometer (Figure 3) is a research accelerometer (1.8 inches at its largest dimension, weight 19 grams). This will be returned at Visit 2. The data from the accelerometers will be downloaded to Actigraph software (ActiLife 6.13.3) when the accelerometers are returned. Only study ID will be used in the actigraph software. No identifiable information will be maintained in the Actigraph software.

Figure 3. Actigraph accelerometer

Visits 2-4 (1-2 weeks after each prior visit):

Visits 2-4 will take place at UI Health/UIC or a Chicago Park District (CPD) location that is in close approximation to where the participants live. The exact CPD location will be determined with the help of the Chicago Park District liaison and will take into account safety of the participants and the location of where participants live. The Chicago Park District will only provide space for these visits and no Chicago Park District staff are involved in the research as recruiters or to collect data.

At visits 2-4 the following procedures will occur:

1. Collection of accelerometers (Visit 2 only) and Fitbit (Visit 4 only).
2. Attend a 2 hour group session at the Chicago Park District or at UI Health/UIC. At the group session, participants will receive basic asthma education, physical activity education and watch a video on how to get started to walk. Participants will be asked to share their experiences with asthma and physical activity.
3. Each participant will be given an individualized step-goal not to exceed 3000 steps above their baseline calculated from accelerometer data. (Visit 2 and 3 only)
4. Each participant will be given an ACTION participant manual (Visit 2 only).
5. Participants will be asked to complete a session evalution form. (Appendix 9)
6. Summative evaluation (visit 4 only; Appendix 10)

Key research personnel will send a reminder text, call and/or email (based on patient preference) up to 3 times the prior week to the group session stating “ACTION group will meet at X time and X place.”

Reminder messages will also be sent via phone, text or email (based on participant preference) up to 3 times per week to help them attain their weekly step goal (See Appendix 11 for sample text messaging).

An interventionist and/or Dr. Nyenhuis will attend the group sessions. Each group will last approximately 2 hours and be audio-recorded to assess for intervention fidelity. If a participant declines audio-recording the session, then the session will not be recorded. The PI or co-investigator may then observe a group session intermittently to assess for intervention fidelity. If the session is recorded, the PI will review portions of the session. The sessions will be deleted once the pre-pilot is complete. These audio recordings will not be transcribed. Patients will receive light snacks/refreshments at each session.

Key research personnel will send a reminder text, email and/or call the patient (based on patient preference) 24-48 hours prior to each visit.

Participants will then be provided the following equipment at Visit 2 and will be asked to return on Visit 4:
1) Fitbit® physical activity monitor: Participants will be verbally instructed to wear it on their wrist at all times while awake. The Fitbit (Figure 3.a) is a commercially-available physical activity monitor (0.83 inches wide, weight 0.8 ounces). The wristbands are adjustable and data from our focus groups revealed that participants would prefer a wrist-based than a waist-based physical activity monitor. Participants will be asked to download the fitbit app to their smartphone or tablet and asked to create an account. Participants will be referred to the Fitbit website for troubleshooting. This will allow for physical activity data transmission to the Fitbit study database which will not contain any identifiable information. A previous survey found that over 90% of our patients had a smartphone or tablet. If a participant is unable to or does not want to download the fitbit app then they will write their daily steps into a journal which they will bring to each study visit. Participants will not be responsible for the cost of the Fitbit if it is lost or stolen.

Figure 4. Fitbit physical activity monitor

Daily physical activity, heart rate and status of the Fitbit (e.g., battery) will be monitored in real time using a Fitbit study database. Only physical activity data (i.e., step counts, time worn using heart rate, minutes active, distance walked) of the participant will be kept in the Fitbit study database. This is necessary for recording of detailed physical activity data as the pedometers have limited data storage capacity. Only study ID will be used in the Fitbit study database. No identifiable information will be maintained in the Fitbit database.

Participants will be given a $25 gift card or cash after completion of study visit 4.

Aim 3 (Pilot)

We will randomly select 800 women with the goal of recruiting a random sample of 80 women. We will use the recruitment method described above in Section 5.0. Participants will be selected to ensure representation of a range of asthma severity, BMI and current age. Potential participants for Aim 1 and 2 will be eligible to participate in Aim 3 if they did not participate in the focus groups or the pre-pilot but expressed an interest to participate in future phases of the study.

Study Procedures for Aim 3 (Appendix 7- Table of study procedures):

Screening:

Potential participants will undergo eligibility screening either in-person (UI Health patients who are already coming to UI Health for an appointment) or over the telephone. If eligible and interested in participating in the study, they will be scheduled for their first study visit (Visit 1).

3 Data Collection Visits: Baseline (week 0/Visit 1), post adoption phase (week 24/Visit 7a/b) and post maintenance phase (week 36/Visit 9) in all participants (See appendix 8 for measures)

At the data collection visits, the following procedures will take place at the Clinical Research Center at UIC or Chicago Park District location:

1. Secure informed consent (1st visit only).
2. Complete a brief demographic form.
3. Spirometry performed according to American Thoracic Society guidelines. Participants will be asked to wear nose clips and to take a deep breath in and blow their breath out as fast as they can into the spirometer. We will perform repeated measurements (3 to 8 times) to ensure accuracy of results.
4. Height and Weight
5. Incremental Shuttle Walk Test (ISWT) performed according to American Thoracic Society guidelines
6. Physical activity questionaires

7. Asthma Safety Measures
8. Asthma Control Questionnaire (ACQ)
9. Asthma-related quality of life questionnaire (AQLQ)
10. Adult Asthma Adherence Questionnaire (AAAQ)
11. PROMIS measures (Global Health, social roles satisfaction, mood, sleep)
12. Active Where Questionnaire
13. Self-efficacy for walking scale
14. Social support for exercise survey
15. Outcome expectation scale for exercise
16. Sleep Apnea Scale of the Sleep Disorders Questionnaire
17. Pittsburgh Sleep Quality Instrument
18. Neighborhood safety and social cohesion questionnaire
19. Study randomization (1st visit only)
20. Schedule asthma and physical activity (PA) education session with participant (1st visit only)

Key research personnel will obtain consent in a private room in the Clinical Research Center. After consent is obtained, the other study procedures will be completed.

This visit will last approximately 2 hours and upon completion the participant will receive $35 cash or gift card. Patients will be offered light snacks/refreshments at this visit and given a visit summary sheet with their blood pressure, heart rate, weight, height, oxygen level, date of next study visit and a copy of spirometry results if desired.

Participants will then be provided the following equipment at these data collection visits:

Actigraph accelerometer: This will be given to participants to assess their baseline and post-intervention daily number of steps. Participants will be verbally instructed to wear it attached to their wrist at all times while awake. The Actigraph accelerometer (Figure 3) is a research accelerometer (1.8 inches at its largest dimension, weight 19 grams). This will be returned within 2 weeks of the data collection visit. The accelerometers can be returned either in person at the asthma and PA session, in a postage paid envelope or the participant and the research assistant will find a mutually agreeable place to pick up the accelerometer from the participant. The participant will not incur any charges if the accelerometer is lost or stolen. The data from the accelerometers will be downloaded to Actigraph software (ActiLife 6.13.3) when the accelerometers are returned. Only study ID will be used

in the actigraph software. No identifiable information will be maintained in the Actigraph software.

Participants are typically asked to wear the accelerometer for 7 days (does not have to be consecutive). However, valid baseline measurement of activity can be obtained with an average of 10 hours per day for 4 days. This is the minimum amount of accelerometer data required to continue participation in the intervention. If the participant does not wear the accelerometer for sufficient time to provide valid baseline measure (ie. an average of 10 hours per day for 4 days), they will be offered a second opportunity to wear the accelerometer. If the participant declines or is unable to wear the accelerometer again within 3 weeks of returning the accelerometer, then the participant will be withdrawn from the study.

Enhanced Usual Care Group (home-based walking program): The comparison group will be instructed to achieve a static goal of 10,000 steps per day. The US Surgeon General recommends accumulating 30 minutes of activity most days of the week. Assuming that an individual gets 6,000 steps from their other daily activities, 30 minutes of walking can help one achieve a goal of approximately 10,000 steps per day.

Participants will be given a Fitbit Charge HR® which will measure their daily steps (see more detail below under visit 2). In order to attention-match for interactions with study staff, participants will attend an asthma education and physical activity training session. Newsletters with walking tips for AA women and asthma education topics will be sent twice during the intervention phases to participants in this group. Participants will come to the Clinical Research Center for data collection at weeks 24 (Visit 7b) and 36 (Visit 9) described in more detail below.

Asthma and physical activity (PA) education session for all participants (1-6 weeks after baseline data collection visit)

The asthma and PA education session will take place at UI Health/UIC or a Chicago Park District (CPD) location that is in close approximation to where the participants live. The exact CPD location will be determined with the help of the Chicago Park District liaison and will take into account safety of the participants and the location of where participants live. The Chicago Park District will only provide space for these visits and no Chicago Park District staff are involved in the research as recruiters or to collect data. Two separate asthma/PA education sessions will take place, one for enhanced usual care group and one for those randomized into the intervention group.

At the asthma/PA education session the following procedures will occur:

1. Collection of accelerometers for those that have not already returned it.

2. Attend a 2 hour group session at the Chicago Park District or at UI Health/UIC. At the group session, participants will receive didactic asthma education and information on how to engage in physical activity with their asthma.
3. Participants will be asked to complete a session evalution form. (Appendix 9)
4. Participants will be given $5 cash to assist with travel expenses incurred for the visit.

Key research personnel will send a reminder text, call and/or email (based on patient preference) up to 3 times the prior week to the group session stating “Asthma and physical activity session will meet at X time and X place.”

An asthma educator, a research assistant(s) and/or Dr. Nyenhuis will attend the education session. Each education session will last approximately 2 hours. Patients will receive light snacks/refreshments at each session.

For missed sessions, make-up sessions will be offered (in-person or by video). Continuation in the program will be decided by the PI on a case by case basis. Participants will be strongly encouraged to make up missed sessions prior to the next scheduled group session (intervention group) or data collection visit (enhanced usual care group).

Participants will be given the following equipment at the asthma/PA education session: 1) Fitbit® physical activity monitor: Participants will be verbally instructed to wear it on their wrist at all times while awake. The Fitbit (Figure 4) is a commercially-available physical activity monitor (0.83 inches wide, weight 0.8 ounces). The wristbands are adjustable and data from our focus groups revealed that participants would prefer a wrist-based than a waist-based physical activity monitor. Participants will be asked to download the fitbit app to their smartphone or tablet and asked to create an account. Participants will be referred to the Fitbit website for troubleshooting. This will allow for physical activity data transmission to the Fitbit study database which will not contain any identifiable information. If a participant is unable to or does not want to download the fitbit app then they will write their daily steps into a journal which they will bring to each study visit. Participants will not be responsible for the cost of the Fitbit if it is lost or stolen.

Daily physical activity, heart rate and status of the Fitbit (e.g., battery) will be monitored in real time using a Fitbit study database. Only physical activity data (i.e., step counts, time worn using heart rate, minutes active, distance walked) of the participant will be kept in the Fitbit study database. This is necessary for recording of detailed physical

activity data as the pedometers have limited data storage capacity. Only study ID will be used in the Fitbit study database. No identifiable information will be maintained in the Fitbit database.

Group sessions (Intervention group only): Women randomized into the intervention group will also attend group sessions in 2 phases: Adoption and Maintenance (See Figure 2).

Adoption phase (5 sessions every 4 weeks)

The group session will take place at UI Health/UIC or a Chicago Park District (CPD) location that is in close approximation to where the participants live. The exact CPD location will be determined with the help of the Chicago Park District liaison and will take into account safety of the participants and the location of where participants live. The Chicago Park District will only provide space for these visits and no Chicago Park District staff are involved in the research as recruiters, interventionists, asthma educators or to collect data.

At each group session the following will occur:

1. Women will attend a 2 hour group session at the Chicago Park District or at UI Health/UIC. At the group session, participants will continue to receive asthma education (short videos and/or didactic session), watch a video on how to get started to walk and what barriers they may face. Participants will be asked to share their experiences engaging in physical activity with asthma.
2. Participant will be given an individualized step-goal not to exceed 3000 steps above their baseline calculated from accelerometer data over the entire course of the study.
3. Each participant will be given an ACTION participant manual (1st group session only).
4. Participants will be encouraged to walk during the group session for up to 15 minutes. The interventionist and Chicago Park District liaison will identify safe locations for the women to walk at the group session site. Women will be able to walk at their own pace and stop at anytime. If the participant does not want to participate in the walking portion of the group visit they may opt-out by verbally telling the interventionist that they do not want to participate.
5. Participants will be asked to complete a session evaluation form. (Appendix 9).
6. Participants will be given $5 cash to assist with travel expenses incurred for each group visit.

At the last group session in the adoptive phase, the following procedures will occur and the participant will receive $35 cash or gift card for this visit only:
:

1. Spirometry performed according to American Thoracic Society guidelines. Participants will be asked to wear nose clips and to take a deep breath in and blow their breath out as fast as they can into the spirometer. We will perform repeated measurements (3 to 8 times) to ensure accuracy of results.
2. Weight
3. Incremental Shuttle Walk Test (ISWT) performed according to American Thoracic Society guidelines
4. Accelerometer distribution
5. Summative evaluation (visit 7 only; Appendix 10)

If a participant is not able to attend this session, we will contact the patient to scheduled an in person data collection visit at UI Health/UIC where the above procedures (#1-3) will be completed.

During or after Visit 7a is complete, participants will complete REDCap paper surveys (in person) or will be sent a link (email or text) to complete the following REDCap surveys electronically:

1. Physical activity questionaires
2. Asthma Safety Measures
3. Asthma Control Questionnaire (ACQ)
4. Asthma-related quality of life questionnaire (AQLQ)
5. Adult Asthma Adherence Questionnaire (AAAQ)
6. PROMIS measures (Global Health, social roles satisfaction, mood, sleep)
7. Active Where Questionnaire
8. Self-efficacy for walking scale
9. Social support for exercise survey
10. Outcome expectation scale for exercise
11. Sleep Apnea Scale of the Sleep Disorders Questionnaire
12. Pittsburgh Sleep Quality Instrument

Key research personnel will send a reminder text, call and/or email (based on patient preference) up to 3 times the prior week to the group session stating “ACTION Asthma group will meet at X time and X place.”

Reminder messages will also be sent via phone, text or email (based on participant preference) up to 3 times per week to help them attain their weekly step goal (See Appendix 11 for sample text messaging).

An interventionist and/or Dr. Nyenhuis will attend the group sessions. Each group will last approximately 2 hours and may be audio-recorded to assess for intervention fidelity. If a participant declines audio-recording the session, then the session will not be recorded. The PI or co-investigator may then observe a group session intermittently to assess for intervention fidelity. If the session is recorded, the PI will review portions of the session. The sessions will be deleted once the pilot is complete. These audio recordings will not be transcribed. Patients will receive light snacks/refreshments at each session.

If any of the group visits 3-7 are missed, the woman is asked to arrive 15 minutes early for the next meeting to receive an update. Her report will be emailed/phones/texted to her depending on her preference.

If a woman has missed several group visits and we have been unable to contact her, we will mail her a letter indicating to call us.

Visit 7b: 24 week data collection (Enhanced Usual Care only)

At Visit 7b the following procedures will take place at the Clinical Research Center at UIC:

1. Spirometry performed according to American Thoracic Society guidelines. Participants will be asked to wear nose clips and to take a deep breath in and blow their breath out as fast as they can into the spirometer. We will perform repeated measurements (3 to 8 times) to ensure accuracy of results.
2. Weight
3. Incremental Shuttle Walk Test (ISWT) performed according to American Thoracic Society guidelines
4. Accelerometer distribution
5. Physical activity questionaires
6. Asthma Safety Measures
7. Asthma Control Questionnaire (ACQ)
8. Asthma-related quality of life questionnaire (AQLQ)
9. Adult Asthma Adherence Questionnaire (AAAQ)
10. PROMIS measures (Global Health, social roles satisfaction, mood, sleep)
11. Active Where Questionnaire
12. Self-efficacy for walking scale
13. Social support for exercise survey
14. Outcome expectation scale for exercise
15. Sleep Apnea Scale of the Sleep Disorders Questionnaire
16. Pittsburgh Sleep Quality Instrument

This visit will last approximately 2 hours and upon completion the participant will receive $35 cash or gift card.

Participants will be given a postage paid envelope and be asked to mail the accelerometer back to study team after wearing it for 1 week. Reminder calls/texts/emails will be sent if we have not received the accelerometer within 2 weeks of completion of visit 7. If needed, a central location for drop-off of the accelerometer may be arranged with the participant.

Maintenance Phase: During the maintenance phase, participants will continue to receive reminder text messages to help them attain their weekly step goal no more than once a week.

Visit 8: Post-maintenance booster session and data collection (12 weeks after Visit 7) Booster session will only be for intervention group.

At visit 8 booster session the following procedures will occur:

1. Attend a 2 hour group session at the Chicago Park District or at UI Health/UIC. At the group session, participants will review successes attained and barriers, lapses, and relapses encountered.
2. Participants will be asked to complete a session evalution form. (Appendix 9).
3. Participants will be given $5 cash to assist with travel expenses incurred for the group visit.

An interventionist and/or Dr. Nyenhuis will attend the group session. The group will last approximately 2 hours and may be digitally recorded to assess for intervention fidelity. If a participant declines audio-recording the session, then the session will not be recorded. The PI or co-investigator may then observe a group session intermittently to assess for intervention fidelity. If the session is recorded, the PI will review portions of the session. The session will be deleted once the pilot is complete. These audio recordings will not be transcribed. Patients will receive light snacks/refreshments at the session.

Post-maintenance data collection (all participants)

The following procedures will take place at the Chicago Park District (intervention group) or Clinical Research Center at UIC (enhanced usual care):

1. Spirometry performed according to American Thoracic Society guidelines. Participants will be asked to wear nose clips and to take a deep breath in and blow their breath out as fast as they can into the spirometer. We will perform repeated measurements (3 to 8 times) to ensure accuracy of results.

2. Weight
3. Incremental Shuttle Walk Test (ISWT) performed according to American Thoracic Society guidelines
4. Distribution of accelerometer

The following questionnaires will be completed by REDCap survey:

1. Physical activity questionaires
2. Asthma Safety Measures
3. Asthma Control Questionnaire (ACQ)
4. Asthma-related quality of life questionnaire (AQLQ)
5. Adult Asthma Adherence Questionnaire (AAAQ)
6. PROMIS measures (Global Health, social roles satisfaction, mood, sleep)
7. Active Where Questionnaire
8. Self-efficacy for walking scale
9. Social support for exercise survey
10. Outcome expectation scale for exercise
11. Sleep Apnea Scale of the Sleep Disorders Questionnaire
12. Pittsburgh Sleep Quality Instrument

This visit will last approximately 2 hours and upon completion the participant will receive $35 cash or gift card. Patients will be offered light snacks/refreshments at this visit.

Participants will be given a postage paid envelope and be asked to mail the accelerometer back to study team after wearing it for 1 week. Reminder calls/texts/emails will be sent if we have not received the accelerometer within 2 weeks of completion of visit 8. If needed, a central location for drop-off of the accelerometer may be arranged with the participant.

Aims 4 & 5 (Adapting Intervention Tools)

We will recruit up to 15 AA women with asthma from our database of ~80 AA women with asthma that have given us permission to contact them for research studies. These women have already been identified as having asthma either through physician diagnosis and/or the use of a validated electronic health record (EHR) algorithm that identifies asthma patients with a high sensitivity and specificity (99% and 96%, respectively)[15, 16]. Potential participants will be contacted and asked screening questions to ensure they are still in our target age range of 18-70 years. Participants will be selected to ensure representation of age ranges. The sample size is determined by the theoretical saturation or the point when no new ideas relevant to the question are

obtained, which is generally 15[17].

Study Procedures for Aims 4 and 5:

1. Complete eligibility screening.
2. Securing informed consent.
3. Complete a brief demographic form. (Appendix 5)
4. Attend three 90 minute focus groups and provide perspective on issues such as video content, video scene selection and final video product.

Drs. Nyenhuis and a nurse interventionist will moderate all focus groups using an interview guide (Appendix 12) with semi-structured open-ended questions. The interview guide will be pre-tested for clarity, comprehension, and sensitivity and will provide sufficient flexibility to pursue unanticipated facets of topics that emerge in focus group discussions[4].

Each group will last approximately 90 minutes and be audio-recorded and subsequently transcribed. If one of the focus group members decline to be audio-recorded the session will not be audio-recorded and only field notes will be collected. Patients will complete written consent (1st session only), receive $50 (cash) and light snacks/refreshments at each focus group.

The focus groups will take place in a private space at the University of Illinois at Chicago.

Key research personnel will send a reminder text and/or call the patient (based on patient preference) 24-48 hours prior to the focus group stating “ACTION asthma group will meet at X time and X place.”

Aim 6 (Dissemination of study findings to study participants)

We will disseminate our study findings and next steps to study participants by way of a newsletter. Using feedback from the CCTS Community Advisory Board we developed three newsletters to be disseminated to our study participants. The newsletters focus on thanking our participants, study findings, next steps and educational content related to physical activity and/or asthma. The newsletter will be sent on a monthly basis for 3 months and will be disseminated by email, text or mail based on the preferred communication each participant indicated in the study. A pdf of the newsletters will be also available on Dr. Nyenhuis’ Department of Medicine Research Page.

7.0 Expected Risks/Benefits

The research involves minimal risk:

1. There is a chance that answering questions about their health may cause participants to become upset or distressed. If this should happen during a focus group or group session, the participant may take a break from the group or leave the group entirely.
2. Questionnaires: given that some questions ask personal information; it is possible that participants will be uncomfortable answering them. Participants will be explained they do not have to answer any question they are uncomfortable with.
3. There is also a chance for loss of privacy and loss of confidentiality in the unlikely event that unauthorized persons should see study data. Many protections will be taken to decrease the chances that this happens.
4. Spirometry (lung function test): risks associated with spirometry are minimal for most people. Because the test involves rapid and forced breathing, some people may experience temporary (lasting up to a few minutes) shortness of breath, lightheadedness and minor chest soreness. In rare cases, the participant may hyperventilate and become dizzy during spirometric testing. Any participant who feels faint should be guided onto the chair with her head down towards the knees, and encouraged to breathe slowly and deeply until she recovers. If the participant fails to recover normal breathing, faints, or reports feeling ill, the research assistant will summon the CRC nurse manager and physician immediately. The physician should always be consulted if there is any question regarding the participant's safety status during the exam.
5. Risk of pulmonary event: subjects will be asked to increase their daily physical activity and will perform up to 15 minutes of walking during the intervention group sessions, so there is the possibility of a pulmonary complication, such as an increase in respiratory symptoms (shortness of breath, cough, wheezing). We will minimize this risk by careful participant selection. Previous studies have shown the safety of increasing physical activity in sub-optimally controlled persistent asthma (Ma J et al. Ann Am Thorac Soc. 2015; 12(1): 1–11.)

Participants may have direct personal benefits from participating in the pre-pilot and pilot, as they will receive asthma education and learn how to best exercise with asthma. Further, participants may enjoy talking with other people about their experiences with asthma and physical activity. The participant's involvement will offer important information that will help refine and test the feasibility and acceptability of a physical activity program to improve the life of women with asthma.

8.0 Data Collection and Management Procedures

Data collected during screening of participants will be entered into REDCap by key research personnel. For subjects that are interested in participating in future studies or future phases of the study, their contact information will be entered and secured in a

REDCap database. The asthma algorithm output (raw data) will only be seen by Dr. Galanter. The data from the algorithm that is needed to contact the potential participants (name, address, phone number, date of birth and medical record number) will be kept within the hospital intranet, behind the clinical hospital firewall that is password protected and will be accessed only by the PI and selected key research personnel.

The data from the focus groups (Aims 1, 4 and 5) will be in the form of audio recordings with no use of names. Drs. Nyenhuis and Sharp will review focus group transcriptions to identify recurring themes especially those focused on barriers and enablers to PA/walking and video adaptation and video acceptability. We will explore the distribution across the groups by key variables such as asthma severity and age. In this manner, analysis will consider the context of the responses including characteristics of the participants[5]. Information drawn from focus groups will not be shared with group participants. The audio of the focus groups will be destroyed after transcription. The transcript data will be destroyed immediately before the research has been closed via a Final Report.

The data from the pre-pilot and pilot will be in the form of a demographics form, surveys, Fitbit data (step counts, time worn using heart rate, minutes active, distance walked), accelerometer data and spirometry results. Each form, survey or report will have the participant's study ID only. The participant's height and weight will be directly entered into REDCap by key research personnel. After each study visit, key research personnel will ensure that the data is entered into the REDCap database. Paper copies of the demographics form, paper surveys (if used), and spirometry results will be kept in a locked cabinet or drawer separate from the study ID code. The paper copies will be destroyed immediately before the research has been closed via a Final Report. Electronic REDCap surveys will also be used and once complete will be automatically transferred into REDCap.

Other clinical data (ie. laboratory data, pulmonary function tests, sleep tests) will be obtained from the participant's UI Health electronic medical record (EMR). This data will be entered into REDCap and will have the participant's study ID only. This data will be used to assess the feasibility and preliminary efficacy of the PA intervention in different phenotypes of asthma.

Actual data and information connecting a study participant's name and study identifying number is kept in a locked file drawer in the PI's office. The coding system will be kept in a locked cabinet or drawer separate from the actual data. Research investigators performing the statistical analyses data will not have access to information that can connect up the actual identity of a study participant and their data. All workstations require the use of a password in order to gain access. When leaving a workstation unattended, the user must log-out or lock their computer. Users are required to use

screen savers that will be activated after ten minutes of inactivity and are password protected.

9.0 Data Analysis/Quality Control

Aim 1: Focus Group Data Analysis/Quality Control

To ensure that the focus groups are responsive to the participants and unexpected themes that might emerge, data analysis will begin after the first focus group data are entered and continue throughout the focus group phase. Drs. Nyenhuis and Sharp will review focus group transcriptions to identify recurring themes especially those focused on barriers and enablers to PA/walking and explore the distribution across the groups by key variables such as asthma severity and age. In this manner, analysis will consider the context of the responses including characteristics of the participants[5]. The list of themes will serve as the data for the intervention refinement, which will occur as part of Aim 1b.

The intent of Aim 1b is to integrate the barriers and facilitators to PA unique to sedentary AA women with asthma obtained from Aim 1a to adapt a validated walking intervention. A multi-disciplinary asthma advisory team, consisting of kinesiologist- Dr. Marquez, exercise-induced asthma specialist- Dr. Moy, PA in women specialist- Dr. Wilbur and behavioral scientist- Dr. Sharp will meet to review the results and generate independent suggestions related to safe and effective PA with asthma and asthma-related barriers and enablers to PA. This team will also address modifications specific to asthma such as: 1) identification of asthma triggers (exercise, pollens, cold-air); 2) adequate warm-up prior to physical activity; 3) medication pre-treatment prior to physical activity; 4) adequate cool-down after physical activity; 5) use of breathing exercises. The group will review and rank order all suggestions for intervention modifications. Final decisions will be determined by the Asthma Advisory Team: Drs. Marquez, Sharp, Moy, Wilbur and Nyenhuis. The resulting intervention will be used in Aim 2 (Pre-pilot).

Aim 2: Pre-pilot ACTION Intervention: The qualitative data collected during pre-pilot will include but not be limited to, measures of time to administer and recruitment, exploration of variance on measures (ceiling and floor effects), formative evaluations from group sessions and issues with data collection and entry. The asthma advisory team will review all aspects of the pre-pilot and recommend refinement of the content, logistics, or process of the intervention. No further modifications will be made and we will proceed to obtaining IRB approval for the final aim of the study (Aim 3).

Aim 3: Pilot ACTION Intervention: The qualitative data collected during pilot will include but not be limited to, measures of time to administer and recruitment, exploration of variance on measures (ceiling and floor effects), formative evaluations from group sessions and issues with data collection and entry. The quantitative data collected will include lung function, height/weight, body mass index, shuttle walk test time, surveys/questionnaires, EMR data (laboratory data, pulmonary function tests and sleep

tests). This data will be stored in REDCap and will be monitored periodically by the study statistician.

Aim 4: Adapting Intervention tools: Audio recordings of the focus groups will be transcribed and compared to field notes collected during the focus group meetings. An initial list of codes will be used based upon the facilitator guides used in the focus groups. The meeting transcript will be coded independently by the PI and a research assistant and will meet several times to group the codes into categories and add definitions for each code so that the coding process is consistent. The list of themes will serve as the data for the video refinement. Data analysis strategies for demographic data will use descriptive statistics.

A multi-disciplinary research team, consisting of an asthma specialist- Dr. Nyenhuis, PA in women specialist- Dr. Wilbur (mentor on Dr. Nyenhuis' K award) and behavioral scientist- Dr. Sharp (primary mentor on Dr. Nyenhuis' K award) will meet to review the results from the initial focus group meeting. The group will review and rank order all suggestions for video modifications. Final decisions will be determined by Drs. Nyenhuis, Wilbur and Sharp. The resulting suggestions of asthma content, setting and language will be used to develop the script for the videos working with an experienced videographer and filming will begin.

The relevant raw video footage will be presented at the second focus group meeting. The women will be asked to provide feedback (written and oral) on the selection of video scenes from the raw video footage clips that are relevant to the added asthma video content. The written feedback includes a scoring sheet for each video. Each video will be scored two times. Once for relevance of the asthma content to engaging in physical activity and second for the usefulness in stimulating group discussion. Each score will be on a 5-point scale from not relevant to very relevant or not useful to very useful. Field notes will be taken during the meeting and the session will be audio recorded and subsequently transcribed. The field notes and meeting transcript will be reviewed by the PI and research assistant independently. The mean ratings of video scenes' relevance and usefulness will be calculated. The mean scores for each video will be used as rationale for replacing unacceptable scores (<3) The suggestions for scene inclusion will be reviewed and finalized with the multi-disciplinary research team and reviewed with the videographer. The resulting video will be used in Aim 5.

Aim 5: During the third focus group the women will review the six edited videos and provide feedback on the acceptability of the videos. Acceptability will be measured for each video using a 4-item summative evaluation using a 5-point scale, which will address overall satisfaction, content and language used in each video. Open-ended questions asked by the moderators will capture participants' thoughts on what their likes and dislikes about the videos. This session will be audiotaped and transcribed.

The PI and RA will review the transcribed discussions and the mean scores from each question on the questionnaire will be calculated.

Aim 6: No data will be collected in this aim.

10.0 Data and Safety Monitoring

During this study, data and safety-monitoring will occur to to ensure the safety of study participants and the validity of data in compliance with the National Institutes of Health (NIH) requirement of Data and Safety Monitoring for Clinical Trials. The Data and Safety Monitoring for the proposed project has three goals: (1) to insure the safety of the participants; (2) to produce high quality research while considering both risks and benefits.

This section outlines essential elements of the Data and Safety Monitoring (DSM) for this study.

a) Monitoring the Progress of the Trial and Safety of Participants: This study poses minimal risk to the participants, as it involves getting the participant's opinions on the use of behavioral counseling and low-impact exercise, walking. Drs. Sharp and Nyenhuis will perform local monitoring of the progress of the trial and the safety of participants.

b) Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events (AE):
Participants will be given the study office phone number (24-hour coverage) to contact study staff and/or investigators to report adverse events. All adverse events will be reported to the IRB and study sponsor (NIH).

Information about adverse events experienced by study participants will be monitored by the following means:

- Report given by study participants to study staff, either in person or by telephone.
- Report given to study staff by study participants' family or friends, either in person or by telephone.
- Report by the participant's physician or other health care provider involved in her care.
- Report from a hospital or other healthcare facility where the study participant(s) is being treated for the serious adverse event.
- Other persons who may have knowledge of such a serious adverse event.

Upon receiving a report of a serious adverse event:

- The study staff will contact Dr. Nyenhuis (at 312-572-9179) or Dr. Sharp (312-355-3569) as soon as possible.
- Drs. Nyenhuis or Sharp will complete the Adverse Event Report and submit the completed form to the Human Subjects Committee of the University of Illinois at Chicago and the NIH within 24 hours of learning of the adverse event.
- A copy of the adverse event form will be kept in the study file.

Drs. Nyenhuis and Sharp will assess recruitment flow, attendance, retention rates, and AE summaries weekly during team meetings. Data from the focus groups will be recorded and transcribed by a member of the research team for review by Drs. Nyenhuis and Sharp. Procedures will be reviewed to insure that the data collected are collected in a manner consistent with the confidentiality of the participants involved.

Monitoring the Progress of the Trial and the Safety of Participants.

Overall, the study poses minimal risk to participants. A safety office will be named and reports will be tendered every quarter to monitor progress and problems. The report provided to the safety office will including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, participant complaints (if any), adverse events, and other factors that can affect study outcomes. Summaries of enrollment, attendance, and withdrawals will be reviewed. If we are not meeting our recruitment/retention goals we may consider the following retention methods that have been used by other co-investigators in this patient population such as: 1) Sending notes of appreciation, birthday cards or holiday cards; 2) Small tokens of appreciation. If a participant is unable to provide acceptable accelerometer data (as described above) or is withdrawn from the study, a final letter will be mailed to the participant (See *Letter to participants that are withdrawn)*. The research team will report any problems expressed by participants to the PI either in person or by telephone within 24 hours of the problem. She will then pass this on to the IRB and other appropriate oversight bodies.

Reporting Adverse Events.

The safety officer will be immediately notified of any adverse events. All adverse events will be reported to the Institutional Review Board (IRB).

11.0 Statistical Considerations

Aim 1: Focus Groups

We will randomly select 160 women with the goal of recruiting a random sample of 30 women. Participants will be selected to ensure representation of a range of variables including asthma severity, current age and menopausal status. The sample size is determined by the theoretical saturation or the point when no new ideas relevant to the question are obtained, which is generally 15[53]. However, a minimum of 20 is recommended for illness studies[54]. This study includes 30 participants in groups of 6-10 for focus groups. If redundancy is not noted in the focus group discussion, additional participants will be included until saturation is reached.

Qualitative analysis will occur after the focus groups. We will review focus group transcriptions to identify recurring themes especially those focused on barriers and enablers to PA/walking and explore the distribution across the groups by key variables such as asthma severity and age.

Aim 2: Pre-pilot ACTION Intervention

One hundred women will be screened and up to 10 women will be selected to participate in the pre-pilot. Participants will be selected to ensure representation of a range of variables including asthma severity, current age and menopausal status. As the goal of this portion of the study is to test run the intervention and inform further refinement of the study methods no specific sample size calculations were performed.

Aim 3: Pilot ACTION intervention

Eight hundred women will be screened and up to 80 women will be selected to participate in the pilot. Participants will be selected to ensure representation of a range of variables including asthma severity, current age and BMI. Participants will be randomized using REDCap randomization program. As the goal of this portion of the study is to test the feasibility, acceptability and estimate the efficacy of the modified intervention thus no specific sample size calculations were performed.

Aims 4 and 5: Adapting Intervention tools

We will recruit up to 15 AA women with asthma from our database of ~80 AA women with asthma that have given us permission to contact them for research studies. These women have already been identified as having asthma either through physician diagnosis and/or the use of a validated electronic health record (EHR) algorithm that identifies asthma patients with a high sensitivity and specificity (99% and 96%, respectively)[15, 16]. Potential participants will be contacted and asked screening questions to ensure they are still in our target age range of 18-70 years. Participants will be selected to ensure representation of age ranges. The sample size is determined by the theoretical saturation or the point when no new ideas relevant to the question are obtained, which is generally 15[17].

Qualitative analysis will occur after the focus groups. We will review focus group transcriptions to identify recurring themes especially those focused on video adaptation and acceptability of the final product.

Aim 6: Dissemination of study findings

As no data is collected there will be no statistical analysis performed.

12.0 Regulatory Requirements

12.1 Informed Consent

As Aims 1-3 of this research involves no greater than minimal risk, we will obtain eligibility and interest in participation over the phone or in person. All participants that attend the focus group will provide written informed consent will be obtained prior to

starting the focus group. All participants involved in Aims 2 and 3 of the intervention will provide written informed consent prior to any study procedures taking place.

Informed consent will be obtained by key research personnel that have completed training in human subjects research and obtaining informed consent.

We request a HIPAA Preparatory to Research, a waiver of informed consent for the identification of potential participants in the recruitment phase of research.

This request is based on the following criteria that we will follow:

a. Use is sought solely to review protected health information as necessary to perform the asthma algorithm in the UI Health EHR. prepare a research protocol or for similar purposes preparatory to research (in this case identify participants for recruitment);

b. No protected health information is to be removed from the covered entity by the researcher in the course of the review and PHI will not be retained long term if patient decide not to participate; and

c. The protected health information for which use or access is sought is necessary for the research purposes.

The following criteria for the waiver of informed consent for the identification of potential participants in the recruitment phase of the research will be met:

a. The recruitment phase of the research involves no more than minimal risk to the participants;
b. The waiver of informed consent for the identification of potential participants in the recruitment phase of the research will not adversely affect the rights and welfare of the participants;
c. The recruitment phase of the research could not practicably be carried out without the waiver of informed consent for the identification of potential participants in the recruitment phase of the research; and
d. If appropriate, the participants will be provided with additional pertinent information after the recruitment phase of the research.

A waiver of documentation and an alteration of consent is requested for the eligibility screening portion of the study.

12.2 Subject Confidentiality

Each participant will be given information about the purpose of the study and will participate only after having signed the informed consent. Confidentiality will be maintained by keeping research records in locked file drawers and all data will be maintained on a secured network maintained in the Department of Medicine. We will use identification numbers to insure confidentiality of the data files. Once collected, an individual's data will not be available to anyone other than an authorized person on the proposed project.

Participants will receive a thorough introduction to the study preparing them for the nature of the questions that will be asked in the focus group. Such preparation often decreases the risk for becoming unduly distressed. If a participant does become distressed, study staff will be trained to respond in a supportive, empathic way and to give the participant the opportunity to take a break.

Formal training on data and participant safety is provided to all research staff involved in the data collection process. All staff and students involved in our research studies sign a confidentiality agreement stating that they are aware that any data they come in contact with is strictly confidential and is not to be discussed outside of the research project. They also complete the University of Illinois at Chicago online training on Human Subjects Protection (101) and the HIPAA Privacy Act.

12.3 Unanticipated Problems

Unanticipated problems involving risks to participants or others (including adverse events), will be reported to the UIC IRB and study sponsor (NIH) in a timely manner.

13.0 References

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APPENDICES

Appendix 1: Asthma Control Questionnaire (ACQ)

Appendix 2: Asthma Control Test (ACT)

Appendix 3: EASY Questionnaire

Appendix 4: Asthma Algorithm

Appendix 5: Basic Demographics Information

Appendix 6: Focus Group Guide/Questions

Appendix 7: Table of study procedures (pre-pilot 7a and pilot 7b)

Appendix 8: Survey measures

Appendix 9: Evaluation of group session

Appendix 10: Summative evaluation of intervention

Appendix 11: Text message content

Appendix 12: Focus group guide for adapting intervention tools

Appendix 13: Video Acceptability measure

Appendix 14: Sample dissemination newsletters

Appendix 15: Cover letter/email to accompany dissemination newsletter

Other documents

Blank Output from Asthma Algorithm V1

Sample CRF for REDCAP V1

Link to videos used in group sessions:

https://www.rushu.rush.edu/womens-walking-program

Link to Asthma Education content: American Lung Association Asthma Basics

http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/asthma/asthma-education-advocacy/asthma-basics.html

Sample participant walking program manual

Permission to contact health care provider

Email to UI Health provider for medical clearance

Participant letter for missed visits

Participant letter if withdrawn

Recruitment Documents

Patient Letter

#1-Focus Groups

#2-Pre-pilot intervention

#3- Pilot intervention

#4- Adapting tools- Focus Groups

Return Postcard

Eligibility Script

#1-Focus Groups: Phone and in-person

#2-Pre-pilot intervention: Phone and in-person

#3-Pilot intervention: Phone and In-person

#4- Adapting tools- Focus Groups: Phone and in-person

Eligibility Screening Form

#1-Focus Groups

#2-Pre-pilot intervention

#3- Pilot intervention

#4- Adapting tools- Focus Groups

Informed Consent Document

#1-Focus Groups

#2-Pre-pilot intervention

#3- Pilot intervention

#4- Adapting tools- Focus Groups