University of South Carolina Protocol v4

Study Title: Evaluation of a Phone-Based Walk with Ease Program in Adults with Arthritis

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A.SPECIFIC AIMS

Aim 1: Identify and incorporate best practices for recruiting and retaining participants in behavioral interventions and programs, particularly among hard-to-reach populations (e.g., low socioeconomic status). A literature review will be conducted to identify best practices and recommendations for recruitment and retention strategies for hard-to-reach populations including those with low socioeconomic status. Results will be published and will help guide recruitment strategies for the proposed project.

Aim 2: Evaluate the short-term (6 weeks and 6 months) and long-term (1 year) effects of a phone-based version of Walk with Ease (WWE-T) in adults with arthritis on primary (self-reported pain and objectively measured physical function) and secondary (objectively measured physical activity, self-efficacy, depressive symptoms, weight, blood pressure, work loss, and health care utilization) outcomes as compared to a wait list control. *We hypothesize that participants randomized to WWE-T will have greater improvements in outcomes at 6 weeks, 6 months, and 1 year than those in the wait list control.*

Aim 3: Determine the effectiveness of recruitment and retention strategies in WWE-T. We will examine recruitment rates by recruitment avenue and site to determine which strategies led to greatest reach, and whether this differed by sociodemographic characteristics (e.g., age, race, income). We will also examine retention rates and reasons for attrition at program completion (6 weeks) and follow-up assessments (6 months, 1 year) by recruitment strategy among the total sample and by demographic (e.g., socioeconomic status) and clinical (e.g., pain) variables.

B. BACKGROUND AND SIGNIFICANCE

Walk with Ease (WWE) is a 6-week evidence-based physical activity program developed by the Arthritis Foundation for people with arthritis.[1,2] WWE consists of 3 in-person group sessions each week (18 sessions total) with each session lasting approximately 60 minutes. WWE has led to improvements in arthritis symptoms,[1–4] physical activity levels,[3] self-efficacy,[1] depression symptoms,[1,2] and function,[1] and participants report high satisfaction,[3,5] including minority participants.[4] As a result of WWE's success, it is one of the arthritis-appropriate evidence-based programs (AAEBI) recognized and recommended by the Centers for Disease Control and Prevention (CDC).[6] WWE is currently being offered across the country, including by the South Carolina Department of Health and Environmental Control (DHEC).

Although effective, many populations face barriers to attending in-person group WWE sessions. To overcome some of these barriers of a face-to-face program; a self-directed WWE program was developed. To date, the self-directed WWE has resulted in beneficial effects[1,5] and participants report a high level of satisfaction;[5] however, unlike the group-based WWE program, classified as a "recognized program," the CDC classifies the self-directed adaptation as a "promising program." While promising, the self-directed format may lack the provision of social support and accountability, both of which may be important for physical activity in populations with arthritis.[7–9]

Having a variety of evidence-based formats to deliver WWE could maximize the reach of the program, allowing individuals with arthritis to participate in the WWE delivery format that is the most accessible based on their needs and preferences. Thus, we will develop and test a phone-based format of WWE, which has the ability to overcome the primary barriers of group, self-directed, online, and print-based formats of the program. A phone-based format of WWE may represent a translatable mode to deliver an arthritis-appropriate evidence-based physical activity program to increase the reach as well as better target those at the greatest need.

C. RESEARCH DESIGN AND METHODS AND DATA ANALYSIS

Study Design: To address Aims 2 and 3, we will use a randomized controlled trial. A total of 300 adults with arthritis, aged 18 and older, will be recruited throughout the community. Participants will be randomized to either Walk with Ease (WWE-T) or Wait list control. The WWE-T program will be 6 weeks in duration, like the AAEBI version of WWE, and will include two phone calls each week: one group call and one individual call. Assessments will be conducted before randomization, immediately after the 6-week program, and at 6 months and 1 year. There will be no intervention-specific contact with participants following the 6-week program. Primary outcomes are pain and physical function. Secondary outcomes are weight, objectively measured physical activity, depressive symptoms, self-efficacy, weight, blood pressure, work loss, and health care utilization.

Procedures:

Recruitment: Participants will be recruited using effective recruitment strategies used in the past as well as with the assistance of DHEC, the SC Department of Aging, and Lupus Foundation of America. All recruitment procedures are provided in more detail in section D.2.

Screening*:* Participants will be screened by telephone or online to ensure they meet study criteria. Interested and eligible participants will be scheduled for a baseline appointment and mailed an informed consent form and study materials to review prior to their baseline visit.

Informed Consent: At the baseline appointment, study staff will review the consent form with participants and answer any questions participants may have regarding their participation. To ensure the consent form is understandable to the study population, the consent form will be written using short sentences and non-technical terms, with a reading level at or below an eighth-grade level. Interested participants will sign the approved informed consent document and will be given a copy for their records.

Randomization: After completing the baseline assessment, participants will be randomized in a 1:1 ratio to either: (1) WWE-T or (2) Wait list control. Randomization, stratified by age (<65 years and ≥65 years) and sex, will be done using randomly permuted blocks. The study team member conducting the randomization phone call will open the sealed envelope and reveal randomization to the participant. The study team member will describe the condition, provide the appropriate program materials via mail, and review study expectations.

Randomized Conditions:

1.) **Walk with Ease by Telephone Program.** Our Walk with Ease by Telephone (WWE-T) program is adapted from the original 6-week community-based group walking program developed by the Arthritis Foundation for adults with arthritis. After randomization, all participants in WWE-T will be given an Arthritis Foundation Walk with Ease Guidebook and a brief overview of the program. The program uses motivational strategies, which includes action planning, goal setting, and social support. Additionally, WWE provides participants with appropriate health education necessary to safely increase walking and exercise into their daily lives and assists in tailoring the program to fit individuals' unique needs and goals. Examples of topics include exercise and arthritis, preparing to walk (e.g., identifying appropriate footwear, location, and walking pace), stretching, and overcoming barriers including pain and discomfort. Participants will work towards walking at least 30 minutes/day for 3 days/week, as this goal is consistent with the evidence-based WWE program.

Phone Sessions for WWE-T. Participants in WWE-T will receive 2 phone calls each week for 6 weeks. Each week, one phone call will be one-on-one with a WWE certified trained leader and the second call will be a group call led by the WWE leader and will include other WWE-T participants. During group phone sessions, the WWE-T leader will cover topics described above relating to exercise and arthritis. Group calls will include 12-16 participants, as recommended by previous studies. Group calls will last approximately 45 - 60 minutes in duration. During

individual phone sessions, the WWE leader will focus on tailoring the WWE-T program for the individual and setting weekly walking goals. The WWE leader will also ensure that safety issues are assessed and addressed. Individual calls will be approximately 10 – 15 minutes in duration. WWE leaders will document attendance, topics discussed, any participant symptoms/adverse events, and call durations.

2.) **Wait List Control.** Participants randomized to Wait List Control will receive the WWE-T program following the completion of the 1-year assessment. Besides scheduling for and sending reminders for each assessment, there will not be contact with participants in the Wait List Control.

Measures:

Assessments will be completed at baseline, 6 weeks, 6 months, and 1 year and will take place in the PHRC or Discovery I buildings at the University of South Carolina (Columbia, SC). Additionally, participants will be asked to report any injuries, illnesses, surgeries, or medication changes that occur between study assessments at each of the assessments. Staff completing assessments will be masked to randomization. Participants will receive $25 for completing the baseline and 6-week assessments, $40 for completing the 6-month assessment, and $50 for completing the 1-year assessment.

1. **Pain and Physical Function**.
Symptoms of arthritis: pain, fatigue, stiffness. A visual analog scale (VAS) will be used to assess the arthritis symptoms of pain, fatigue, and stiffness. VAS's have been previously used to measure reduction in symptoms of arthritis in physical activity interventions.[1,10,11] Participants will be asked to mark their experience with symptoms over the past 7 days on a 100-mm line. Each line is anchored with "no pain" and "severe pain." Pain, fatigue, and stiffness will be assessed using this format. Participants responses for each arthritis symptom are measured in millimeters from the left anchor (no pain, 0) to their mark, with higher scores indicating higher levels of pain, fatigue, or stiffness.
Physical function – 30 Second Chair Stand Test and Six-Minute Walk Test. The 30-second chair stand test evaluates sit-to-stand activity, lower body strength and dynamic balance. Participants are asked to complete as many chair stand repetitions as possible during a 30 second period. This test has been found to be a reliable and valid measure.[12,13] The six-minute walk test assesses aerobic capacity and has been found to be a valid and reliable measure of functional ambulation in populations with arthritis.[14,15] Participants will be asked to walk between two cones 50 feet apart for 6 minutes. The maximal distance in feet a participant can walk during the 6-minute period will be calculated. Any use of assistive devices will be recorded and scores will be adapted accordingly.[16]
2.) **All-Cause Pain – PROMIS Pain Intensity and Pain Interference.** General pain and pain interference will be assessed using the PROMIS pain intensity[17] and interference.[18,19] PROMIS[20] pain intensity and interference surveys utilize a non-computerized test and generates a t-score, whereas 50 is the mean of the reference population and 10 is the standard deviation (SD). PROMIS pain and interference have demonstrated test-retest reliability and is sensitive to change in adults with arthritis.[21,22]
3.) **Physical Limitations - Health Assessment Questionnaire (HAQ).** The Health Assessment Questionnaire (HAQ) was developed as a comprehensive measure of outcome in patients with a wide variety of rheumatic diseases, including rheumatoid arthritis, osteoarthritis, lupus, fibromyalgia, and psoriatic arthritis.[23,24] It is widely used as an outcome in physical activity interventions for people with arthritis.[25–27] The HAQ Disability Index assesses eight categories of activities of daily living (i.e., dressing, arising, eating, walking, hygiene, reach, grip, and common activities). There are 20 questions using a scale of 0 (without difficulty) to 3 (unable to do). These items will be averaged for a total score of 0-3, with a higher score indicating more impairment or disability. The HAQ is correlated with several clinical and laboratory measures[23,28,29] and has also demonstrated test-retest reliability.[30]

4.) **Psychosocial Function - Arthritis Management Self-Efficacy.** The Arthritis Self-Efficacy Scale (ASE) will be used to assess participants' confidence to manage symptoms of arthritis.[31] We propose to use an 8-item version of the ASE as recommended by Lorig et al. given the overlap with the HAQ,[32] with each item answered on a 1 (very uncertain) to 10 (very certain) point scale. The items are averaged to calculate a score. Higher scores indicate higher levels of self-efficacy for managing arthritis. The ASE is commonly used in arthritis intervention studies[33] and has been shown to have acceptable levels of construct and concurrent validity as well as reliability.[31] Our previous work suggests the 8-item version is also a valid and reliable tool to measure arthritis self-efficacy.[34]

5.) **Physical Activity -** Minutes of moderate-intensity physical activity will be assessed objectively using accelerometry. At each data collection visit, participants will be given an Actigraph GT3X link accelerometer to wear around the waist during waking hours for 7 days. Non-wear time will be defined as ≥90 minutes with zero activity counts, allowing for up to 2 minutes of <100 counts/min.[35] Physical activity will be categorized as sedentary (<100 counts/min), light (100-2019 counts/min), and moderate-to-vigorous (MVPA) (≥2020 counts/min).[36] Total MVPA/week will be calculated. Only those with ≥4 valid monitoring days (≥10 wear-hours/day), including one weekend day will be included in the analyses.[36,37] Participants will also be asked to complete a log indicating times the accelerometer was worn and taken off over the 7-day assessment period. Using procedures successfully implemented in our previous studies, following the 7-day wear period, participants will return the accelerometer and log by mail using a pre-paid addressed padded envelope.

6.) **Body Weight.** Height and weight will be measured by trained research staff using equipment that is regularly calibrated. The participant will be weighed wearing a light layer of clothing with shoes and belt removed and pockets emptied and the value to the nearest 0.1 lb. will be recorded. Height and weight will be used to calculate body mass index (BMI).

7.) **Mental Health Status - Center for Epidemiological Studies – Depression (CES-D).** The Center for Epidemiological Studies-Depression (CES-D) index is a widely-used measure of depression symptoms[38] and is frequently used in activity and arthritis studies.[27,39,40] We will use a 10-item version of the CES-D[41] in which participants rate the frequency of symptoms using a 4-point Likert scale (0=rarely or none of the time to 3=most or all of the time). Responses are summed to yield a total score ranging from 0 to 30, with a higher score indicative of higher levels of depressive symptoms. The CES-D demonstrates high internal consistency, is correlated with other measures of depression, and can classify patients by level of depression.[39,42]

8.) ***Work Loss – Work Productivity and Activity Impairment Questionnaire.*** The Work Productivity and Activity Impairment (WPAI) Questionnaire[43,44] will be used to assess patient-reported amount of absenteeism, presenteeism and daily activity impairment attributable to general health as well as specifically for arthritis. The WPAI includes 6-items that assess current employment status, number of hours missed due to a health problem or other reasons, hours actually worked, degree to which health affected productivity while working, and the degree to which health affected regular (nonwork) activities. Four outcome scores will be calculated: percent work time missed due to health, Q2/(Q2 + Q4) (percentage of absenteeism); percent impairment while working due to health, Q5/10 (percentage of presenteeism); percent overall work impairment due to health, Q2/(Q2 + Q4) + [(1 − Q2/(Q2+Q4)) × (Q5/10)]; percent activity impairment due to health, Q6/10. Higher scores for each outcome score (range 0–100%) suggest a greater impact of health. The WPAI has found to be a valid assessment of work-related impairments in populations with arthritis[45] and its use is recommended by the rheumatology community.[46]

9.) **Health-care utilization and Medical Expenditures.** While access to medical records would provide a more accurate assessment of healthcare utilization and expenditures, it would not be feasible to obtain among our community-dwelling population due to the time and costs associated with obtaining and reviewing charts, healthcare visits may be with multiple providers and not all tracked, and due to privacy concerns.[47] Self-report assessments of healthcare utilization have been found to be both valid and reliable among older adults[48] and have a low likelihood of bias by demographic factors including socioeconomic status.[47] Therefore, we

propose to use the UCSD Healthcare Utilization Questionnaire[49] to estimate health care utilization during the study. This survey consists of 12 questions that asks participants to report the number of times they used different healthcare services within a specific timeframe. Specifically, questions assess physician visits or telephone calls with health care providers, home-care visits, ambulance use, inpatient hospital days, surgeries, emergency room visits, and medication use. The costs associated with each health care utilization will be obtained from the Medical Expenditure Panel Survey (MEPS).[50]

10.) **Physiological outcomes – Blood Pressure**. Systolic and diastolic blood pressure will be measured according to the American Heart Association guidelines in triplicate each visit using an osillometric blood pressure cuff (Omron, Tampa Bay, FL) on the left arm at each visit in the supine position after a 5-minute rest in a quiet room. The average of the all three measures in mmHg will be used in analyses.[51,52]

11.) **Demographic and Health Variables.** At baseline, participants will be asked to complete general demographic and health history surveys. The demographic variables to be assessed include age, sex, race, ethnicity, education, income, and marital status. The health history survey will include an assessment of arthritis type, years since arthritis diagnosis, presence of comorbid chronic health conditions (e.g., hypertension, hyperlipidemia), prescription and over-the-counter medications and doses, number of physician visits in the past 4 months, hospitalizations in the past month, and smoking status.

12.) **Process Measures & Program Evaluation.** WWE-T leaders will track phone session attendance for both individual and group calls. The percentage of calls attended will be calculated for each participant (total calls attended/12 calls). Topics discussed and duration of each call will also be tracked. Following the completion of WWE-T, participants will complete the Walk with Ease Post-Program Evaluation.[53] This evaluation asks participants to rate usefulness of tools and strategies provided, knowledge obtained, length of the program, and their overall satisfaction with the program using a Likert scale from 0 (not at all) to 3 (very well). Additional questions will be added specific to the phone-based program including satisfaction with group and individual calls, length of group and individual calls, and rapport with WWE-T leader.

Data Analysis: After data collection and cleaning, baseline characteristics of the groups will be compared. Variables which differ between the groups at baseline will be used as covariates in the outcome models. For each of the Aim 2 primary and secondary outcomes, a generalized linear model will estimate group means at baseline, six weeks, six months and one year. Each model will include factors for group (2 levels), time (4 levels), group-by-time interactions and the required covariates. In the event of participants being lost to follow-up or otherwise missing data from the 6-week, 6-month and/or 1-year times, the models will provide estimates using Full Information Maximum Likelihood with robust standard errors, interpretable under an Intent to Treat principle.

For each outcome at each follow-up time, a statistically significant (at the 0.05 level) group by time interaction in the hypothesized direction will be interpreted as supporting the research hypothesis. The magnitude of each intervention effect will be computed by a pre-defined contrast of baseline to follow-up change in the group minus baseline to follow-up change in the Wait List Control, adjusted for covariates. All four time points for each outcome will be examined with a single model to best account for the full covariance structure over time. All analyses will be completed using SAS (SAS Institute Inc, Cary, NC).

We will evaluate the recruitment and retention strategies used during the proposed study, focusing on successful strategies used to increase participation of adults with arthritis, particularly among those with low socioeconomic status. During the recruitment and screening of participants, participants will be asked to report how they heard of the program. We will also examine recruitment numbers over time in relation to recruitment activities. Following the completion of the program, we will categorize recruitment avenues (e.g., saw flyer, word of mouth) and sites (e.g., local rheumatologist site, lupus support group) and calculate the percentage of those screened, not interested, ineligible, and enrolled. Percentages will be calculated among the total sample recruited as well as specifically for those of low

socioeconomic status (i.e., income <150% of poverty guidelines) and other demographic (e.g., race) or clinical variables (e.g., pain). We will compare enrollment yields by avenues and sites, using total sample and those with low socioeconomic status, using chi-square tests or Fisher's exact test if cell frequencies are less than 5. Identifying the highest yielding recruitment sources, especially for those with low socioeconomic status, will help to inform recruitment strategies used in future programs. Retention of participants in WWE-T will be examined at program completion (6 weeks) and each follow-up assessment (6 months and 1 year). Overall retention rates and percentages of specific reasons for attrition (e.g., loss to follow-up, no longer interested, medical issues) will be calculated among the total sample and by those with low socioeconomic status (i.e., income <150% of poverty guidelines), and other demographic (e.g., race) or clinical variables (e.g., baseline pain). We will also examine retention and specific reasons for attrition based on recruitment avenue and site. Independent samples t tests and chi-square tests (or Fisher's exact test for those with cells less than 5) will be used to examine differential attrition.

Data Management: All surveys will be administered via paper or online via REDCap (secure, web application for building and managing online surveys and database – managed by Health Sciences South Carolina). Any paper documents will be stored in a locked filing cabinet at the TecHealth Center at University of South Carolina. All computer files will be password protected. Only the study team will have access to the data.

D. PROTECTION OF HUMAN SUBJECTS

1.TARGET POPULATION

Inclusion Criteria: The target population will include adults ≥18 years old who meet criteria for the CDC's definition of self-reported arthritis.[54,55] Specifically, participants who respond yes to the following question will be eligible: "Have you ever been told by a doctor or other health professional that you have some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?" Additionally, participants must be able to read and write in English, plan to live in the Columbia, SC region for the next year, complete all baseline measures, and be willing to be randomized to either study condition.

Exclusion Criteria: Participants will only be excluded if they have any contraindications to exercise (besides arthritis) per the Physical Activity Readiness Questionnaires,[56] are pregnant, breastfeeding, or planning to become pregnant in the next year, have a serious cognitive impairment, or are currently or have previously participated in a WWE program within the last 12 months.

Sample Size: In order to assure sufficient statistical power to detect clinically meaningful effects, we relied on information from a previous study by Wilcox, et. al.[11] for an estimate of variability in the VAS Pain scale and physical function tests including the 30-second chair stands and six-minute test. The Steps to Health study evaluated two 12-week self-directed multicomponent exercise programs for adults with arthritis.[11] Clinically meaningful magnitude of changes were suggested by Bennell et al.[57] as 11 points for VAS pain, 1.3 repetitions for the chair stand test and 20-50 meters for the six-minute walk. Estimated power is based on a simplified analysis (t-tests) without covariate adjustments. A statistical significance level of 0.05 was used.

A sample of 120 participants per group would provide 80% or greater power to detect a clinically meaningful difference in each primary outcome, with a minimum effect size of d=.37, assuming that the variability within our sample is comparable to that observed in the earlier study from a similar population (see Table 2). We anticipate that some participants may be lost to follow-up before the conclusion of the study. Therefore, we propose inflating the required sample size by 25% to account for potential attrition and recruiting 300 participants total, with 150 to be randomized into each treatment condition.

2.RECRUITMENT PLANS:
Participants will be recruited using effective recruitment strategies used in the past as well as with the assistance of DHEC, the SC Department of Aging, and Lupus Foundation of America across Richland,

Lexington, and Fairfield Counties in South Carolina. Specifically, participants will be recruited from programs affiliated with the DHEC SNAP-Ed program (e.g., group dining programs, Text2bWell program). We will promote the study through local lupus support groups and the SC Lupus Events Facebook page, which has over 1,200 followers in SC. Additionally, participants will be recruited from community flyers (e.g., posted in the Drew Wellness Center in Columbia, SC, Fairfield County Parks & Recreation), University of South Carolina emails and flyers, local arthritis-related support groups, including the Arthritis Foundation website and Facebook pages, paid recruitment ads in newspapers and radio.. We will also share information with the UofSC PRC Community Advisory Board to share information with communities. All recruitment materials will include details about the study, eligibility criteria, and contact information. We will recruit at least 50% of participants who are between 18-64 years old and have low socioeconomic status. Low socioeconomic status will be defined by an annual household income <150% of the US Department of Health & Human Services 2021 poverty guidelines.[58]

3.EXISTING DATA/SAMPLES:

N/A

4. CONSENT/ASSENT:

Eligible participants will be scheduled for a baseline visit where full details of the study will be reviewed, questions will be answered, and an equipoise induction reviewing the pros and cons of participating in the study will be conducted. Interested participants will sign an informed consent document approved by the Institutional Review Board. Participants will be provided a copy of the signed consent form.

5. POTENTIAL RISKS:

1. Muscle soreness or pain from increasing physical activity. To minimize the risk, participants will regularly discuss activity with WWE certified leaders to ensure they are increasing their activities at a level appropriate.
2. An injury or fall during the physical function tests at the in-person assessments. All physical function tests will follow OARSI recommended procedures and assessment staff will be trained to respond appropriately in the event of an injury or fall. In the event that a severe or unanticipated adverse event (AE) occurs, 9-1-1 or a physician (depending on the severity) will be called. To minimize risk, participants will be encouraged to go at a pace they feel comfortable with and to stop when necessary. In the event a participant currently uses an assistive device, the participant will be asked to use it for the test and will be noted on study records. Further, two chairs will be placed near the 6-minute walk test area, in the event a participant needs to sit down or rest. We will also have apple juice and snack bars available, if needed.
3. An injury as a result of their physical activity. Participants are encouraged to stop exercising immediately if at any time they are injured or are encouraged to stop engaging in physical activity from a physician/medical professional. Since this is a telephone delivered intervention, WWE-T leaders will ask about symptoms or adverse events on individuals calls. Participants will also be encouraged to notify us of any injuries that occur in between calls or following the 6-week program. Additionally, we will ask participants to report any injuries, illnesses, surgeries, or medication changes that occur between study assessments at each of the assessments.
4. Some of the questions asked may be upsetting or may make participants feel uncomfortable answering them. Participants will have the option to skip any questions they do not feel comfortable answering.

6. POTENTIAL BENEFITS:

Participants may or may not directly benefit from participating in this study, however the risks of participating are considered minimal. If participants modify their activity, they may experience positive changes to their physical, psychological, or physiological health. Additionally, this research may be valuable in determining the effects of an alternatively delivered format of the Walk with Ease program.

7.) CONFIDENTIALITY

To ensure participants information is confidential, all participants will be assigned a study ID, which will be used on all paper or electronic forms. All study files will be stored in locked cabinets or on password-protected computer data files or secure-websites that only authorized study personnel can access. All results will be presented in aggregate form and participants will not be identified personally in any scientific report or presentation. All study personnel will undergo or have completed the most up to date clinical training, human subjects, and confidentiality training prior to assisting with any aspect of the study.

8. COMPENSATION

Participants will receive $25 for completing the baseline and 6-week assessments, $40 for completing the 6-month assessment, and $50 for completing the 1-year assessment. Payment options will be in the form of a physical gift card or an e-gift card from Amazon, a retail store or grocery store.

9. WITHDRAWAL:

Participants will be informed they can leave the research at any time without penalty. If a participant decides to withdraw, no more information will be collected. The participants will be made aware of this during the consent process.

Any data collected during their participation may be used by the investigators for the purposes described above. Choosing not to be in the study will not result in any penalty or loss of benefit to which participants are entitled. Specifically, the choice not to be in this study will not negatively affect a participant's right to any present or future medical treatment or his/her present or future employment.

E. REFERENCES/LITERATURE CITATIONS

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