UTHealth Houston

# A Culturally Adapted, Social Support-Based, Physical Activity Interventions for South Asian Indian Women in the United States: A Feasibility Study

**NCT05966506**

**Version Date: 01/11/2024**

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**Appendix -C**

**CONSENT TO TAKE PART IN RESEARCH**

**Full Study Title:** A Culturally Adapted, Social Support-Based, Physical Activity Interventions for South Asian Indian Women in the United States: A Feasibility Study

**Principal Investigator:** Nitha Mathew Joseph, PhD, RN, CNE,
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**Study Contact:** Nitha Mathew Joseph, PhD, RN, CNE, Associate Professor, [redacted]

The purpose of this study is to determine whether a culturally adapted, social support-based physical activity intervention can be done among inactive South Asian Indian women. If you choose to participate in this study, you will be asked to complete a 12 -week zoom based counseling intervention by a certified nurse health coach. During the counseling intervention, you will be given information on increasing your motivation for positive behavior change and promote self-efficacy and competence to make change in your exercise behavior. It will also help for goal-setting, self-monitoring, identification of barriers and facilitating factors of exercise, your past and present experiences with physical activity, social support, and problem-solving abilities. Moreover, you will work with the coach to develop a Wellness Plan that outlines what you want to work on and will serve as a guide throughout the intervention. During the dyad intervention, you and your partner will be asked to support each other and encourage you and your partner to engage in at least one exercise -related activity together each week (or on a regular basis agreed on by participants). You will also be given with Fitbit activity monitor and will be asked to wear the device on most days and including while you sleep.

Taking part in this study may help you be more physically active. Future women may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment.

You can read a list of potential risks below in the Possible Risks section of this consent.

Your participation on this study will be over after you complete the 12-weeks follow-up visit (described below).

There is no cost to you for taking part in this study.

Participation in this research study is voluntary. You may choose not to take part in this research study or you may choose to leave the research study at any time.

If you are interested in participating, please continue to read below.

**Who is being asked to take part in this study?**

- *If you are Asian Indian woman between 40 and 65 years of age*
- *Can you speak, and read English?*
- *Insufficiently active physical activity <150 minutes/week)*
- *Physically able to engage in moderate physical activity*
- *Able to enroll with an eligible adult female partner who does not live in the same household*
- *Willing to use the Fitbit app/device*
- *Own a smartphone that is compatible with Fitbit software*
- *Able and willing to send and receive text messages*
- *Blood pressure reading <160/100 mm Hg, or with medical clearance*

**What will happen if you take part in this study?**

If you agree to take part in this study, you and your study partner will be assigned to one group in the first study visit. You and your study partner will be in the PARTNER COACHING group. In this group, you and your study partner will participate in the study together. You and your partner will have 6 Zoom meeting video sessions with a health coach over the course of 3 months. It is important that both you and your study partner are able to speak with the health coach at the same time. These calls will last about 30-45 minutes. The health coach will talk to you both about how you can be more physically active and support one another. In this group, you will also receive 1-2 text messages per week asking you about activities you have done with your partner.

If you are not able to connect to the Zoom meeting video sessions, you can call in using your phone. All participants will receive a Fitbit device to track your physical activity and will also receive 6 newsletters (sent electronically or in the mail) over 3 months with tips for increasing physical activity and information about online and community resources.

Up to 10 dyads (20 participants) may be enrolled in this study. All will take part at Cizik School of Nursing at UTHealth Houston.

**<u>Study Visits</u>**

You will have 3 visits during the study: 1 time at the beginning of the study, 1 time about 3 months after you begin the study, and 1 time about 12 months after you begin the study. Study visits will take place at a community center or at religious organizations. The first study visit may last 1.5-2 hours. The visits at 3 months may last 1-1.5 hours. The following procedures will be performed at each study visit:

- Your blood pressure will be measured. If you have a blood pressure reading of 160/100 mm Hg or higher at this first visit, you will not be able to participate in this study until you have written permission from a healthcare provider.
- You will complete questionnaires about your physical activity habits and other behaviors, your beliefs and attitudes, your neighborhood, and your household. The questionnaires should take about 45 minutes to complete and you will have the option of completing the questionnaire online before your scheduled visit. This may reduce the length of your visits.

- Your height, weight, body composition, and waist circumference will be measured. To measure your waist circumference, you may be asked to lift your shirt to expose your stomach area. The height, weight, and waist circumference measurements should take about 10 minutes and will be performed in a private area.
- To measure your fitness, the research staff will ask you to march in place for 2 minutes and will count the number of times your knee goes above a certain height.
- At the first visit, the study staff will set up your Fitbit. The study staff will ask to access and download your Fitbit physical activity data through a secure system called Fitabase. This authorization will not require you to give your password or other personal information to the research staff. After you complete the study, you will keep the Fitbit. The research staff will delete your authorization so that your Fitbit information cannot be collected after the study.

**Contacting You**

To remind you about study visits, study procedures, and sessions with a health coach, you may be contacted by text message or email unless you prefer to be contacted by phone. You will be asked to give the names and contact information of family members and/or friends for the study staff to contact if the study staff cannot reach you first.

**Additional Information and How Your Data Is Used**

- You and your partner's height, weight, blood pressure, and physical activity behavior will be shared with your health coach so it can be discussed during your phone calls.
- The sessions with the health coach will be audio recorded for quality improvement purposes. This will help researchers improve the quality of the program. Only the research team will have access to these recordings. These recordings will be stored securely until the study has been completed and the data has been analyzed, after which point the recordings will be deleted.
- Your home address may be used to access public information about the area where you live. This is to help researchers learn about how your neighborhood encourages physical activity. The results from this study will only be reported as a group and you will not be identifiable from any products resulting from this study (such as research papers). Your home address will never be released or published in any form. Your address will be stored separately from other study data, and only the study chair, the research team, and the community health workers will be able to see the data after the neighborhood information has been collected.
- If your blood pressure reading is ever 180/120 mm Hg or higher, the study staff will call 911. If you do not want 911 to be called, you must sign a waiver stating this decision.
- You may be contacted in the future to see if you would agree to take part in other research studies.

**Possible Risks**

While on this study, you are at risk for side effects. You should discuss these with your doctor. The known side effects are listed in this form, but they will vary from person to person.

**Questionnaires** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you are encouraged to contact your doctor or the study chair. If your questionnaire responses suggest signs of depression, you will be given a list of resources for mental health services.

There is some small privacy risk associated with **text messaging and email**. Messages may not be encrypted and may not be completely secure in transit. Text messages are being sent through a third-party company, which may have access to the content of the messages your name, and your phone number. Your name will be included in the text messages but will not contain any of your health information. Standard text messaging rates will apply, and you will be responsible for this cost unless you currently have an unlimited text messaging plan.

Although every effort will be made to keep **study data** safe, there is a chance that the information you share could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets.

If the **Fitbit** is lost or stolen, you will not be responsible for the replacement cost, but you should tell the study staff right away.

This study may involve unpredictable risks to the participants.

**Pregnancy Related Risks**

Because being pregnant could change your physical activity level, women who are pregnant or thinking about becoming pregnant during the study will not be able to participate. If you become pregnant during this study, please tell the study staff right away. You will no longer be able to complete the study visits, but you will still be able to participate in the telephone calls with the health coach if you were assigned to that group and choose to continue.

**Injury**

If you suffer injury as a direct result of taking part in this study, UTHealth Houston health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by UTHealth Houston health for this injury. You may also contact the Chair of UTHealth Houston IRB at [redacted]. with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Costs And Compensation

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You and your study partner will each receive gift cards upon completion of study procedures. At the first visit, you will receive $40 in the form of an electronic gift card at the time of the in-person visit. You will receive another $50 after your complete study at 12weeks (3rd visit), and the study staff have determined that you wore the device for a sufficient amount of time. If you complete all procedures for all the visits, you will receive a total of up to $90 on your gift card. You will also receive compensation for parking, if needed.

**Additional Information**

You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

UTHealth Houston may benefit from your participation and/or what is learned in this study.

**Future Research Using Data**

Your personal information is being collected as part of this study. These data may be used by researchers at UTHealth Houston or shared with other researchers and/or institutions for use in future research. Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

**Whom can you contact if you have questions about the study?**

If you have questions at any time about this research study, please feel free to contact Dr. Nitha Mathew Joseph at [redacted], as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted].

## CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

| Printed Name of Subject | Signature of Subject | Date |
|---|---|---|

| Printed Name of Person Obtaining Informed Consent | Signature of Person Obtaining Informed Consent | Date |
|---|---|---|