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

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

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Population: Participants will be 10 dyads of South Asian Indian (SAI) women aged 40-65 years living in Houston, Texas; insufficiently active (Physical activity (PA) <150 minutes/week); physically able to engage in moderate PA; and Blood pressure reading <160/100 mm Hg, or with medical clearance.

Number of Sites:*South Asian Indian Churches/faith organizations and community organizations*

Study Duration: *one year*

Subject Duration: *Three months*

General Information (Abstract)

South Asian Indians (SAIs) are diverse and come from different cultures, backgrounds, immigration histories, geographic regions, and experiences. Despite being the fastest growing ethnic/racial group in the U.S., Asian Americans have not been a focal group of scientific interest in psychological research and high-impact medical research studies, with only 0.17% of National Institutes of Health (NIH) expenditures allocated to projects since 1992. Most importantly, SAIs disproportionately experiences cardiometabolic health disparities, including a high prevalence of type 2 diabetes (T2D) and increased mortality from atherosclerotic cardiovascular disease (CVD) compared to non-Hispanic, White and other Asian American groups, despite having a lower body mass index (BMI) than other racial/ethnic minority groups. The objective of the proposed research is to adapt and evaluate a dyadic social support intervention to increase PA in SAI women. Social support, self-efficacy and behavioral skills are recognized correlates of PA across racially, ethnically, and socioeconomically diverse populations. Nonetheless, research is needed to better understand the most effective approaches for delivering social support interventions to increase PA in SAI women. The proposed research is able to leverage the knowledge and infrastructure from two ongoing studies of this research team, one involving qualitative focus groups with SAI women regarding barriers and facilitators to PA including the role of social support, and a large R01 efficacy trial testing a dyadic health coaching PA intervention in inactive Hispanic and African American women) in Houston, TX. Women will enroll with an eligible partner of their choosing (e.g., family member, friend). The intervention will consist of 6 dyad-based health coaching sessions, a Fitbit device for women to monitor their own and their partners' PA, and 6 electronic newsletters with PA-related health education. The health coaching will be delivered over Zoom by a certified holistic nurse using a motivational

interviewing approach to promote social support between dyad members as they practice how to be supportive partners. Participants will be recruited by leveraging the PI's relationships with community- and faith-based organizations, through advertisement flyers, on-site recruitment, presentations during/before church services, social media, email list-serves, local SAI newspapers, health fairs, and health screenings targeting SAIs in Houston. Participants will be eligible for inclusion in the study if they satisfy all the inclusion criteria including inactive SAI women aged 40-65 years living in Houston, Texas. Participants will be assessed at baseline and immediately post-intervention. Physical activity will be assessed using self-reported and objective measures. Detailed screening log and record consent rates including refusal reasons, retention rates including attrition reasons, and completion of questionnaires will be tracked. We will also monitor session attendance, and participants will complete brief, open-ended evaluations of their overall satisfaction of the program at the follow up to determine intervention acceptability.

Background and Significance

Asian Indians from the Indian subcontinent are at high risk for CVD and type 2 diabetes (T2D). Asian Indian immigrants are at greater risk for morbidity and mortality from these chronic diseases compared with whites and other immigrant groups in the U. S.[1-5]. Central obesity (accumulation of abdominal fat) is a significant risk factor for CVD, T2D and metabolic syndrome in Asian Indians, despite the fact that they have an average lower body mass index (BMI) than Whites[6]. Morbidity and mortality from CVD and T2D are higher in people of Asian Indian descent who live in the U.S. than those who reside in India[7] due to the metabolic impact of a westernized diet, sedentary lifestyle and unhealthy dietary habits. [8] Importantly, SAIs experience cardiometabolic health disparities, including a high prevalence of type 2 diabetes (T2D) and increased mortality from atherosclerotic cardiovascular disease (CVD) disproportionately compared to non-Hispanic, White and other Asian American groups, despite having a lower body mass index (BMI). [9-17] In addition, clinical consequences such as myocardial infarction and stroke tend to appear at an earlier age in this group than in any other ethnical/racial groups[18-20].The prevalence of diabetes among first generation Asian Indian immigrants is estimated to be two-to three-fold higher than in the general US population.[2] Moreover, risk factors are present in Asian Indians at a younger age compared to other populations, resulting in coronary artery disease at a younger age.[21] Because Asian Indians are one of the fastest growing populations, the population-attributable risk of these conditions is expected to increase over time. Asian Indians are the second largest Asian American group (4.6 million) after Chinese Americans (5.4 million) with a much faster growth rate.[22] Regular PA is essential for reducing the risk factors for CVD[23], T2D[24], obesity and metabolic syndrome[25]. Studies conducted in the U.S. and other western countries have shown a reduced level of PA among Asian Indians[26-31] and thus, increased risk for CVD, T2D and metabolic syndrome[5,8,31-33] in this population.

The major precursor to T2DM is abdominal obesity, which is associated with the most dangerous risk factors for CVD events and premature deaths in Asian Indians, e.g., insulin resistance, high cholesterol, and hypertension (HTN)[4,34].In the Diabetes Prevention Program (DPP),[35] moderate physical activity, i.e., ≥150 minutes per week of activity similar in intensity to brisk walking, and

losing a minimum of 7% of body weight through reduced caloric intake resulted in the largest reduction in diabetes risk (58%) in persons with impaired glucose tolerance (IGT). These findings were consistent across other ethnic groups, both genders, and all age groups. In other ethnic groups, small weight reductions (7%−10%) enhance insulin sensitivity and glycemic control and: (1) may reduce the need for medications in those diagnosed with T2DM or delay diabetes onset in those who are at high risk but not yet diagnosed.

Asian Indians are significantly different from the average values of body mass index for the world. World Health organization (WHO) modified BMI criteria for Asians as having normal weight (BMI of less than 23(BMI ≥23 kg/m^2) as compared with normal WHO criteria (BMI ≥25 kg/m^2)[36] because of the additional fat content, and a difference of fat distribution on the body in Asians and thus increasing tendency toward metabolic syndrome[37]. Recent study findings on the causality link between BMI and T2D, postulated that obesity may be involved in the etiology of T2D through interaction with ethnic-specific genetic factors in Asian Indians as compared other Asian subgroups[37]and other related complications at a much early age[38]. Most importantly, 60% of the world's diabetic population is Asians[39]. Moreover, Centers for Disease Control and Prevention (CDC) identified south Asian subgroups are at higher risk for diabetes and also changed the criteria of screening for T2D as Asian heritage with a BMI of 23 should be tested for type 2 diabetes[40,41].

Gender influences levels of PA. Worldwide data of PA levels for adults confirm that women are generally less physically active than men. [29] A national survey indicated that women had a higher percentage of inactivity (22% to 47%) than men (14% to 32%).[30] With advancing age, women are less likely to participate in PA. **PA is unusually low in this at-risk population**[11,32-34] Studies conducted in the U.S. and other western countries have shown a reduced level of PA among Asian Indians.[4 ,24-26] It is also found that lower levels of PA are also associated with the development of diabetes, coronary artery disease,[7, 27- 28] and metabolic syndrome in Asian Indian women.[18] The high prevalence of chronic disease in Asian Indian women and their low PA level emphasize the need for developing culturally sensitive interventions that promote regular PA in these at-risk minority women.

Low PA among Asian Indian women is rooted in cultural factors that are unique to this population. Promoting PA among Asian Indian women poses a particular challenge, as the barriers to recreational PA may be culturally derived.[42-45] Presumably, Asian Indian women participate in less PA and recreational exercise than other women owing to the cultural barriers of religious modesty, avoidance of mixed-gender activities, fear of going outside alone and thus PA remains a function relegated to normal daily duties rather than for enjoyment.[43,46,47] Furthermore, Asian Indian women come from a patriarchal and collectivistic society and bear the responsibility of holding, teaching, and transmitting cultural traditions, values, and beliefs to their families[48,49]. Findings from a study in the U.K. showed that Asian Indian women were under considerable physical demands, including caregiving, housekeeping, and workday activities. This, in turn, resulted in less supplemental time for exercise, and activities such as aerobics classes were not seen as an acceptable part of family duties. The notion of exercise for oneself beyond daily work was perceived by some as a selfish activity or given little priority in the context of family and community expectations and needs.[47] Moreover, acculturation among Asian Indian women does not necessarily lead to greater PA, as is seen in other ethnic groups.

Earlier research by the PI found that lower levels of leisure time PA that were well below the recommended weekly exercise level in this at-risk population. Furthermore, the PI's secondary analysis of data from a national sample of Asian Indians showed that PA mediated the relationship between acculturation and cardiovascular risk factors.[8] in both in Asian Indian men and women.

Physical inactivity and increased sedentary time are major risk factors for obesity, CVD and T2D and are important contributors to preventable morbidity and mortality. Studies conducted in the U.S. show a reduced level of physical activity (PA) among SAIs, and that lower levels of PA are associated with T2D in SAI women in particular. These findings underscore the importance of developing culturally sensitive interventions to promote regular PA in these at-risk minority women. As a SAI woman and nurse researcher, PI understands that low PA among SAI women can be rooted in cultural and social factors that are unique to our population. Moreover, acculturation among SAI women does not necessarily lead to greater PA, as seen in other ethnic groups. In our previous study from a national sample of SAIs, PA mediated the relationship between acculturation and CVD risk factors in SAI women, suggesting an important role for community health care providers to improve the PA of SAI women in the U.S.

Social Environments and PA. Social environments are widely recognized to have an important impact on critical health behaviors.[50-53] Individuals are embedded within social networks, creating spheres of influence. Decisions about and participation in PA often involve other social network members, producing opportunities for behavioral impact, both positive and negative. Social support for PA, conceptualized as encouragement to be active, actions taken by others that facilitate being active, and having someone with whom to engage in PA, is positively associated with PA across racially, ethnically, and socioeconomically diverse groups of women.[53-57] Research has also shown that PA is heavily associated with social and cultural norms,[54,58-61] such as gender role expectations and cultural appropriateness of PA in adult women. Moreover, the potentially influential role of friends is illustrated by the finding that having a close friend who becomes obese increases an individual's chances of becoming obese by 57% within the same time period.[62] These findings underscore the notion that individuals' behaviors are strongly influenced by the actions and beliefs of others around them, pointing to social environments as an important lever for behavior change.

Despite this recognition, ***few studies intervene on the social contexts in which these behaviors occur***.[63,64] Most interventions remain focused on individuals. Although empirical evidence supports the efficacy of individually focused strategies that address key behavior change constructs (e.g., goal setting, self-monitoring), effects tend to be short-lived and maintenance is poor.[63,65-69] Studies of racially/ethnically diverse women provide support for the potential appeal of approaches that involve existing members of one's social network. These studies report that women desire encouragement and support for PA from important people in their lives; that they seek to exercise with others; that tangible support in the form of direct help or assistance can facilitate engagement in PA activities; and that seeing others in their communities and their social networks be active is important to feeling comfortable and confident about exercising.[53,54,56,69-72] Although some interventions aim to create social support for PA by bringing unconnected individuals together, research indicates that support tends to diminish upon the conclusion of the intervention.[73] This highlights a potentially unique and critical contribution of intervention approaches designed to enhance support within women's existing social networks

to promote health behavior change.

Social support, self-efficacy and behavioral skills are recognized correlates of PA across racially, ethnically, and socioeconomically diverse populations. However, research is still needed to better understand the most effective channel(s) for delivering social support interventions to increase PA in SAI women. ***Research is also needed to determine whether and how dyadic behavioral interventions can create supportive interpersonal environments to yield greater increases in PA in sedentary SAI women.***

Objectives and Outcome Measures

The objective of the proposed research is to adapt and evaluate a peer based dyadic social support health coaching PA intervention to increase PA in SAI women. Social support, self-efficacy and behavioral skills are recognized correlates of PA across racially, ethnically, and socioeconomically diverse populations[74-78] and motivational interviewing can enhance lifestyle behavioral change[79,80]. Nonetheless, research is needed to better understand the most effective approaches for delivering social support interventions to increase PA in SAI women. The proposed research is able to leverage the knowledge and infrastructure from two ongoing studies of this research team, one involving qualitative focus groups with SAI women regarding barriers and facilitators to PA including the role of social support, and a large R01 efficacy trial testing a peer based dyadic social support health coaching PA intervention in inactive Hispanic and African American women**.**

Hypothesis: We hypothesize that this innovative culturally adapted, social support-based intervention will be feasible and acceptable among sedentary population of SAI women in the U.S.

Specific Aims: This project is built on evidence that peer-based social support, motivational interviewing, and mobile technologies can be utilized to strengthen self-efficacy and social supports to promote increased PA in minority women. This study is able to leverage two ongoing studies, one that involves qualitative focus group research specifically with SAI women regarding barriers and facilitators to PA, and a large R01**(R01HL155310)** efficacy trial testing a dyadic health coaching intervention in inactive Hispanic and African American women**.**

Aims are: 1) Assess the feasibility of recruitment, retention outcomes, intervention engagement (i.e., number of counseling sessions completed, use of Fitbit, review of newsletters), and completion of study procedures in a preliminary group of a social network-based 12-week dyadic behavioral PA intervention in sedentary SAI women. 2) Explore preliminary effects of receiving the intervention on intermediate outcomes: self-reported and objective moderate-to-vigorous physical activity (MVPA), social support, and self-efficacy at 12 weeks.

OBJECTIVES	OUTCOME MEASURES (a.k.a. ENDPOINTS), with TIMEPOINTS for each

Primary	
Assess the feasibility of recruitment, retention outcomes, intervention engagement (i.e., number of counseling sessions completed, use of Fitbit, review of newsletters), and completion of study procedures in a preliminary group of a social network-based 12-week dyadic behavioral PA intervention in sedentary SAI women	The feasibility of the intervention will be determined by comparing the percentages for overall recruitment and retention at week 12 to their target values of 80% and 70%, respectively. A secondary feasibility assessment will determine the proportion of intervention participants who take part in each of the intervention components (i.e., number of counseling calls completed, use of Fitbit, receipt and review of newsletters). In addition, every attempt will be made to query subjects lost to follow-up to ascertain the reason for drop out or barriers to participation. Feasibility will be measured by calculating the rates of enrollment, retention, assessment completion, and treatment adherence. The enrollment rate will be the proportion of those meeting inclusion criteria that enrolled, while the retention rate will be the proportion enrolled that complete the study. Assessment completion will be calculated as the proportion of assigned data collection forms that were completed. Treatment adherence will be calculated as the proportion of intervention sessions attended.
Secondary	
Explore preliminary effects of receiving the intervention on intermediate outcomes: self-reported and objective moderate-to-vigorous physical activity (MVPA), social support, and self-efficacy at 12 weeks.	Secondary outcome measure(s) should be clearly specified, and a timepoint should be listed for each secondary outcome measure). Secondary outcome measure(s) are those that may provide supportive information about the study intervention's effect on the primary outcome measure or demonstrate additional effects on the disease or condition.

Study Design

The proposed single-arm pilot study will test the feasibility of recruitment, retention, acceptability and implementation of study procedures of a 12-week dyadic behavioral intervention to promote positive and sustained change in MVPA, social support, and self-efficacy among inactive SAI women in Houston, TX. The intervention will target 10 dyads of inactive SAI women and will include dyad-based Zoom coaching delivered by a certified holistic nurse coach using a motivational interviewing approach to promote social support between dyad members as they practice how to be supportive partners; employing a Fitbit device to monitor one's own and one's exercise partner's PA; and dissemination of PA-related health education.

Study Population and Eligibility

For this study, participants will be SAI women aged 40-65 years living in Houston, Texas; insufficiently active (PA<150 minutes/week); physically able to engage in moderate PA; speak and read English; 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 (up to 223.3 MB on iPhone or 165 MB on Android) 9); able and willing to send and receive text messages; and Blood pressure reading <160/100 mm Hg, or with medical clearance. Exclusion criteria include SAI women with a current/planned pregnancy; cannot speak and read English, those participating in a PA or weight loss program, and those diagnosed with a physical disability that interferes with their ability to be physically active.

Recruitment: To facilitate sustainability, we will pilot this intervention with SAI women recruited from religious organizations. Faith is a significant component of many SAIs, and churches are an important element of SAI community. The Houston metropolitan area is home to many Asian Indian females in a close-knit community. According to the 2020 census data, Texas is one of the top three states in the U.S. with the largest number of Asian Indians (n=245,981, i.e., 0.9% of 25,145,561)[81]. The majority of the Asian Indian population resides in Houston (1.21% of 2,571,090), Stafford (7.35% of 27,677), Sugar Land (7.20% of 108,607), Missouri City (3.4% of 65,701), and surrounding neighborhoods of Houston[82]. The study will use purposive sampling of women who meet the study eligibility criteria. IRB approval will be obtained from the Committee for the Protection of Human Subjects (CPHS) at the University of Texas Health Science Center at Houston. Study participants will be recruited from Indian community churches that the PI used previously to successfully recruit the population of interest and we anticipate no challenges to recruiting for this study given previous experience and established contacts[27,83]. Participants also will be recruited through advertisements through flyers (Appendix-A) on-site recruitment, presentations during/before church services, email list-serves, health fairs, and health screenings targeting Asian Indians in Houston. As the study progresses, snowball sampling may be employed in cases where a study participant wishes to recommend other Asian Indian women to ensure that the sample is not limited to those who are socially engaged and attend religious facilities.

Trained research staff will screen potentially eligible participants. Screening may be performed in person or over the phone. At this time, staff will explain the study, assess interest in participation, and for those interested, screen for inclusion/exclusion criteria. Determination of preliminary eligibility will be based on participants' self-reported responses to the screening

questions (Appendix -B). Participants will be informed that eligibility will be finalized with the measurement of blood pressure at the in-person baseline visit. Prospective participants will select their study partners. Screening of both dyad members is required prior to enrolling in the study. Informed consent (Appendix -C) will be collected from both partipcants and their study partners.

Data Collection and Study Procedures

Intervention: The intervention draws from social cognitive theory, self-determination theory, and interdependence theory, which informed the individual and interpersonal constructs of importance for behavior change within a dyadic context. Intervention components include dyad-based Zoom coaching delivered by a certified nurse coach who is certified in holistic nursing using a motivational interviewing approach to promote positive communication between dyad members as they learn and practice how to be a supportive partner; a Fitbit device to monitor one's own and one's partner's PA; and electronic newsletters to disseminate PA-related health education. Holistic care in nursing is important to enhance the health of all populations, improve preventive care, and reduce treatment costs. Motivational interviewing by a certified holistic nurse health coach in a dyad-centered behavioral intervention can create supportive interpersonal environments to yield greater increases in PA. If results are meaningful, this nurse-driven intervention could be used as a guide for health researchers in areas of preventive research for enhancing minority health and ultimately reduce health inequities.

The goal of the intervention is to increase participants' PA, working towards meeting national PA guidelines for adults that recommend 150 minutes of at least moderate intensity activity per week, by building behavioral skills and increased social support through social network dyads. The intervention will draw upon Social Cognitive Theory (SCT), a robust framework for behavior change that explains behavior within a dynamic and reciprocal model where a person's behavior, personal factors, and the environment continuously interact. The intervention design was informed by the literature highlighting the importance of social support and enhanced behavioral skills and motivation, while incorporating the use of a mobile app to reflect the new ways in which PA-related information can be tracked and how women communicate with social network members. The intervention builds off of women's existing social networks, enrolling women as dyads to enhance the social support provided and received. The 12-week intervention will focus on behavior change strategies and principles derived from SCT, with a particular emphasis on developing skills related to the constructs of self-efficacy, and social support. Specific skills that will be targeted include goal setting, self-monitoring, problem solving, and drawing upon one's social networks to both receive, and provide, social support.

Dyad-based Zoom health coaching: Zoom based coaching is selected because it demonstrates more feasibility in diverse populations with busy life schedule and thus it can help people initiate PA. Trained holistic nurse health coach will provide 6 sessions of Zoom health coaching over 12 weeks to dyads, biweekly (weeks 1, 3, 5,7, 9 &11) for 45 minutes, and dyad members do not need to be physically together; they can both participate via zoom meeting. Moreover, PI's ongoing qualitative focus group study explores how natural dyads of women can help each other to promote greater PA, and in particular, how mobile phone technology can facilitate the provision of support for PA within women's social networks, how women can share information

within their social networks, how they provide support to one another, as well as potential challenges that may arise in an intervention that emphasizes mobile technology to promote PA within dyads of women. This component of the intervention will be adapted and modified based on the qualitative data collected from the PI's ongoing focus group study and it is intended to help women gain the knowledge and skills needed for behavior change and maintenance, and to build women's capacity to act as sources of support to facilitate PA participation among dyad members. Dyad based Zoom coaching will be delivered by a certified nurse coach who is also certified in holistic nursing with specific training and experience in motivational interviewing (MI). MI is a collaborative, goal-oriented, person-centered approach designed to elicit and strengthen autonomous motivation for change.[84,85] Consistent with SCT, MI represents an orientation or interpersonal style in which the health coach respects the client's autonomy and freedom of choice regarding her own behavior. The primary purpose of the coaching calls will be to increase autonomous motivation for positive behavior change and promote self-efficacy/competence to make change. Coaching calls will address constructs aligned with the guiding theoretical frameworks using established techniques for PA behavior change.[86] Zoom coaching will focus chronologically on goal-setting, self-monitoring, identification of barriers and facilitating factors, social support, and problem solving. The nurse health coach will first inquire about participants' past and present experiences with PA including barriers and facilitators to get to know participants, build rapport, and inform future discussions. The nurse health coach will explore participants' personal motivations for PA, identify outcome expectancies, and connect motivation for PA with personal values. Participants will work with the coach to develop a Wellness Plan that outlines what participants want to work on and will serve as a guide throughout the intervention. To promote self-efficacy, nurse health coach will work with participants to build key behavioral skills such as self-monitoring of PA with the Fitbit, setting incremental and achievable goals to facilitate mastery and competence, and problem solving to overcome identified barriers. Each zoom meeting will include discussion about progress since the last call, strategies that worked well and those that did not, possible modification of participants' goals, and continued problem solving. During all sessions, the nurse health coach will provide positive feedback and reinforcement using MI techniques such as active listening, asking rather than making assumptions, offering empathy, and speaking in a non-judgmental manner. These positive communication strategies will serve as a guiding framework for discussions during coaching calls and will be encouraged between partners on their own. Nurse health coaches will model these approaches, and participants will practice them during calls, beginning with role play scenarios and later in discussions of their own progress. Role play scenarios will provide examples of both positive (e.g., asking open questions, reflection, support for partners' decisions) and negative (e.g., interruption, telling partner what to do, critical and pressuring language) communication patterns to illustrate differential reactions and outcomes. Dyads will also develop a mutual support plan that describes each participant's support needs and ways for the partner to be supportive. Partner support actions may include those that provide direct/tangible support (e.g., actions that facilitate a partner being active) as well as autonomy support (e.g., expressing support for her partner's behavior change plans). On each zoom meeting, the nurse health coach will check in with participants regarding communication between dyad members, support that has been helpful, support or actions that have not been helpful, and support needs. Mutual support plans will be reviewed and modified as needed. Recognizing that relationships may encounter challenges, the nurse health coach will also reach out to participants individually throughout the study to see if they would like to speak

privately. Finally, the nurse health coach will encourage dyads to engage in at least one PA-related activity together each week (or on a regular basis agreed on by participants). Consistent with SCT, dyads can choose from a menu of options or develop an activity on their own. Options may include exercising together, planning to be active during the same day/time even if physically apart, participating in a challenge or friendly competition together (e.g., through the Fitbit app), and trying a new type of activity or exercise class. Nurse health coach will encourage dyads to engage in a virtual or in-person activity together one time per week to promote interaction and enjoyment and will record women's experiences and satisfaction. During coaching zoom meeting calls, nurse health coaches will record the activity engaged in, overall enjoyment, and aspects participants liked and did not like to inform future activity planning. Participants will also be advised to set small, achievable PA goals to promote mastery and build self-efficacy. All calls will be digitally recorded to monitor coaching procedures and for future evaluation. Zoom audio recordings will be erased once the data have been published. Nurse health coach will communicate with participants using institutionally-managed devices (e.g., iPhones managed with institutional information security software). For reminders and rescheduling of calls, nurse health coach may communicate with participants over the zoom and via text messaging. Text messages will include information about the time and date of calls but names will not be used. No protected health information will be included in the text messages. Messaging history will be deleted at weekly intervals.

Fitbit activity monitor. Fitbits have been used extensively in research with adequate feasibility. Fitbits will be provided to all participants to ensure consistency in devices and data monitoring. The increasing availability of wearable activity monitors (e.g., Fitbit, wearable devices) limits the expectation of a dyad group that lacks access to this form of monitoring. Participants in the dyadic intervention will be instructed to use the Fitbit to monitor their partners' PA in addition to their own. All participants will be instructed to "friend" their health coach to enable real-time monitoring of PA to inform coaching zoom calls. Women will receive an activity tracker/Fitbit and instruction in their use to facilitate monitoring of PA. The Fitbit will provide feedback on steps, active minutes, and calories burned. Participants will be instructed in how to use the Fitbit to monitor their PA. Participants will be asked to wear the device on most days and while they sleep. Fitbit physical activity data will be collected through a secure system called Fitabase. Although studies suggest that activity monitors can lead to increased PA, these effects tend to be short term, with multifaceted interventions that include monitors and personalized coaching leading to greater, sustained effects.[87,88] Researchers have suggested that activity monitors like Fitbit should be integrated within a lifestyle intervention to yield meaningful benefits.[89-91]

Electronic newsletters. Newsletters will be sent twice monthly during months 1-3 via email or text with an online link. Newsletters will be designed to share educational PA-related information from publicly available resources (e.g., the Physical Activity Guidelines for Americans, 2nd edition,[92] the Centers for Disease Control and Prevention, "Move Your Way" campaign materials). Newsletters will also contain tips for overcoming barriers to PA that may be common in our target population, e.g., finding time to exercise, low-cost ways to be active, being active with kids. Newsletters will also contain links to brief exercise routines that participants can do in their homes and information on low cost/free exercise classes in the community, which may help to overcome perceived access barriers. Participants who do not use email and do not want to receive the newsletter link via text will be sent newsletters in the mail.

Cultural sensitivity. The proposed intervention integrates cultural values and norms of South

Asian Indians into aspects of the design and delivery to enhance intervention relevance, appeal, and engagement. This includes "surface structure" approaches that emphasize the importance of having intervention materials and research/intervention staff reflect the characteristics of the target population (e.g., availability of Indian language materials, images of SAI women, bilingual and bicultural staff).[93] In addition, the intervention aims to address "deep structure" elements by focusing on issues of salience to the target population including cultural values and beliefs pertinent to health generally and PA in particular and these specific knowledge will be incorporated from the PI's ongoing qualitative focus group research with SAI women regarding barriers and facilitators to PA. Examples of deep structure elements for SAI women include the importance of family and the role of women as caregivers, religion/spiritualism, perceived norms around women exercising, body image, concerns regarding safety and access to PA opportunities. Although the intervention does not intervene directly on potential barriers such as access to opportunities for PA, MI is well-suited for problem solving to address the varied barriers that participants may face. The nurse health coach will be well trained to delve deeper into potential barriers and engage dyads to elicit participant-identified solutions. In addition, PI who represent SAI women will be involved in the planning process and will help to identify other possible cultural factors of relevance. An in-depth understanding of the factors associated with PA engagement and common barriers in our target population will be an important component of nurse health coach training.

Quality Control. Nurse health coach have a masters and doctorate degree in nursing (DNP) and is – is or are double certified in holistic nursing and health coaching. The nurse health coach will receive 20 hours of training in MI, which combines didactic and experiential activities. The nurse holistic health coach will also receive training in cultural competency and cultural and behavioral factors relevant to SAI women.

Data collection and study procedures are shown in Table 1 (Appendix -D). Data collection will take place at baseline and immediately post-intervention (approximately 3-months after baseline). Each participant will be compensated for their time with $40 (at baseline) and $50 (at 12-week follow-up) in gift cards upon completing study procedures and parking (as needed) for each visit.

All participants will also be provided with a Fitbit device that will enable participants to monitor their own and their partner's PA, and will also allow research staff and the nurse health coaches to monitor participants' PA. Data collection will be conducted in-person by UTHealth staff (research assistant) at community sites (e.g., Indian community center, churches, other religious organizations, health fairs, and health screenings targeting Asian Indians in Houston etc.) depending on participants' preference.

At baseline study staff will first request permission to take participants' blood pressure to confirm eligibility. Following the measurement, all participants will be provided with health education on blood pressure. Participants with elevated and high blood pressure (≥120/80 mm Hg), as defined by the 2017 American College of Cardiology and American Heart Association, will be encouraged to see a healthcare provider. Participants with BP readings ≥160/100 mm Hg will be informed that they can participate in the study only with a letter from a healthcare provider clearing them for participation. If participants do not have a healthcare provider, a list of low-cost clinics in Harris County will be provided. Participants with pressure readings ≥180/120 mm Hg will be informed that study staff must contact 911 due to their BP being

dangerously high. If participants decline to have 911 called, they will be required to sign a waiver indicating this decision. Participants will be advised to seek medical care immediately. Research Electronic Data Capture (REDCap), a secure, HIPAA-compliant web application for managing online surveys and databases, will be used to administer questionnaires. For participants who are eligible, study staff will describe the study and obtain informed consent. Participants will complete questionnaires on a laptop/tablet device, provide anthropometric measures, complete the fitness measures. Anthropometric measures include measured height, weight, waist circumference, and percent body fat. Height and weight will be measured using a stadiometer and digital scale, respectively. During the baseline assessment, study staff will work with participants to create a Fitbit account.

Process Evaluation. Process evaluation will be used to monitor and document program implementation via assessment of intervention dose (amount of intervention delivered and received), reach (extent of intervention participation by the target population), and fidelity (extent to which the intervention was implemented as planned). For dose, we will track the extent to which coaching session was completed, intended content was covered, and newsletters were received and read. Reach will be assessed by tracking participation of dyad members for each session (0, 1, or both) along with barriers to participation, dyad interaction, and use of the Fitbit, including frequency of monitoring partner's PA. Individual participants' Fitbit data from Fitabase dashboard will be used by intervention coaches to review participants' data and aid them with providing feedback. We will also use this information to evaluate participants' adherence to self-monitoring. To assess fidelity, all coaching sessions will be digitally recorded. Holistic nurse health coach will be required to keep detailed implementation logs showing the date and start and end times of sessions, individuals present, the content discussed, goals set by participants that will be followed up on the next session, dyad support plans, and any qualitative observations.

Measures: Surveys will be administered using Research Electronic Data Capture (REDCap), a secure, HIPAA- compliant web application. Table 1 (Appendix-D) shows the schedule of study procedures and constructs to be assessed, proposed measures, and the timing of assessment.

Physical Activity. Fitbit data include daily step counts, floors climbed, activity intensity, heart rate, and sleep data along with wear/usage data. If participants do not wear the Fitbit as recommended, this will not be recorded as a deviation Fitbit data will be PA will be described in terms of step count per minutes and total minutes being in moderate, and vigorous PA. Self-reported PA will be assessed with the Godin Leisure Time Exercise Questionnaire,[94] which assesses episodes, intensity, and duration of PA during a typical 7-day period. Good test-retest reliability has been observed, with test-retest correlation coefficients ranging from 0.48 for light activity to 0.94 for strenuous activity.[94]

Anthropometry. Non-fasting weight in light clothing, height without shoes, waist (at the iliac crest) circumference, and percent body fat will be measured by trained staff. Measurements will be assessed in duplicate or until two measurements are within the permitted variance (weight, 0.2 kg; height and waist circumference 0.3 cm) using a calibrated digital floor scale, a stadiometer, and a Gulick tape measure with a 6 oz. tension meter. Percent body fat is assessed using the digital Tanita scale.

Blood Pressure (BP). Participants will have their BP taken by a trained staff member with an arm blood pressure monitor. Participants will be provided with a written recording of their

blood pressure and will be referred to the information sheet (see "Participant Measures and BP Report") regarding recommendations. Participants with elevated and high blood pressure (≥120/80 mm Hg), as defined by the 2017 American College of Cardiology and American Heart Association, will be encouraged to see a healthcare provider. Participants who do not have a regular healthcare provider will be provided with a list of low-cost clinics in Harris County. Participants with BP readings ≥180/120 mm Hg will be informed that study staff must contact 911 due to their BP being dangerously high. If participants decline to have 911 called, they will be required to sign a waiver indicating this decision. Participants will be advised to seek emergency care or follow up with their healthcare provider immediately.

Questionnaires. Questionnaires to be completed by participants are listed in Table 2 (Appendix-E) and briefly described below. REDCap (Research Electronic Data Capture) will be used to administer questionnaires.

Screening

- The *Physical Activity Readiness Questionnaire (PAR-Q)* is a pre-activity screening tool recommended by the American College of Sports Medicine as a minimal standard for entry into low and moderate intensity exercise programs.[95] The PAR-Q serves to identify individuals who should consult a medical practitioner prior to participation in an exercise program.
- *The Godin Leisure Time Exercise Questionnaire*[94] assesses episodes, intensity, and duration of PA during a typical 7-day period. Good test-retest reliability has been observed, with test-retest correlation coefficients ranging from .48 for light activity to 0.94 for strenuous activity.[94] Other studies have confirmed reliability and validity,[96] and this measure has been validated with accelerometers.[97]

Demographics and Health

- *Demographic characteristics* are drawn from the Behavioral Risk Factor Surveillance System and will include variables such as participants' age, gender, race/ethnicity, country of birth, marital status, highest level of education, current employment status, and household income.

- Chew's one-item *Health Literacy Screening Question*[98] assesses individuals' self-reported ability to perform health literacy-related tasks. Participants respond to one question on a 5-point Likert scale (scores range from 1 to 5). Several studies have found that the question "How confident are you filling out medical forms by yourself" has the greatest accuracy in identifying individuals with limited and marginal health literacy.[99,100]

- *Self-Rated Health* is a one-item measure that asks participants to rate their health on a continuum ranging from excellent to poor. Self-rated health has been shown to be a consistent predictor of mortality in diverse populations and sensitive to health indicators and social factors.[101]

- *Health History* is a one-item measure that asks participants to indicate whether they have had specific medical problems in the past 12 months. These medical problems include diabetes, cancer, high blood pressure or cholesterol, stroke, asthma, thyroid problems, and heart, kidney, or lung disease.

- *Online Access* questions from the Pew Research Center assess the ways in which participants access the internet.

- *Value Assessment:* At the baseline assessment, we will ask participants about their top three *values* from a pre-selected list of 22 values (e.g., good parent, responsible, caring). These values will be provided to the health coaches to inform the health coaching sessions.

Social Context

- The *Interpersonal Support Evaluation List* (ISEL-12) is a 12-item measure of perceived social support overall and within three dimensions: appraisal support, belonging support, and tangible support. The ISEL-12 and its subscales have demonstrated adequate test-retest reliability and internal consistency, and good convergent and criterion validity.[102]
- The *Social Support* measure for PA assess family and friend social support specific to exercise behaviors.[103] These scales exhibit good reliability (e.g., α=0.83) and have been used with minority populations.[57,104]
- *Important Others Climate Questionnaire (IOCQ; Autonomy Support*) measures the perception of the autonomy supportiveness of an "important other" with respect to an identified behavior.[105] In this study, we will assess perceived autonomy supportiveness of the study partner from the perspective of the participant, and the perceived autonomy supportiveness provided by the study participant to her study partner.

- *Partner Characteristics and Relationship Quality*: We propose to ask a series of questions to collect information on participants' study partners and to characterize the relationship between dyad members. This includes such information as the type of relation, frequency of interaction, strength of relationship, and content and format of communication. These questions were adapted from egocentric questions.[106] Overall *relationship quality* will be assessed with a global rating item from the National Survey of Families and Households, with response options ranging from 1 (poor) to 5 (excellent).

PA-related Measures

- *Self-efficacy for PA* assesses confidence in one's ability to be physically active on a regular basis in the face of various barriers. This construct is one of the most consistent correlates of PA behavior in diverse samples of adults.[107]

- The *Stage of Change* questionnaires for PA consists of 2 questions assessing readiness to engage regularly in PA,[108-110] Participants can be classified into one of five stages of change: pre-contemplation, contemplation, preparation, action, and maintenance. Concurrent validity tests indicate strong validity evidence for this staging measure.[111]

- The *Behavioral Regulation in Exercise (BREQ-3)* questionnaire assesses motivation to exercise. The questionnaire contains 24 items within six subscales, all of which have acceptable internal reliability (α=0.73-0.86).[112]

Physical Activity Outcomes

- *The Godin Leisure Time Exercise Questionnaire*[94] assesses episodes, intensity, and duration of PA during a typical 7-day period. Good test-retest reliability has been observed, with test-retest correlation coefficients ranging from .48 for light activity to 0.94 for strenuous activity.[94] Other studies have confirmed reliability and validity,[96] and this measure has been validated with accelerometers.[97]

- The *Multi-Context Sitting Time Questionnaire* (MSTQ) assesses time spent sitting on both work and non-work days.[114] The MSTQ assesses common sedentary behaviors such as watching television, computer use, reading, socializing, and transport. Intraclass coefficients for the MSTQ demonstrated acceptable reliability (ICCs>0.70), and the MSTQ performed similarly to other measures of sedentary behavior.

Other Behaviors

- We will assess diet using items from the BRFSS. Six items assess fruit and vegetable intake.

- We will also assess Cognitive function using Montreal Cognitive Assessment: MoCA Version 7.1 (Original Version)[115](Appendix-E). The MoCA is a screening test assessing global cognitive function that assesses memory, visuospatial ability, executive function, attention, concentration, working memory and orientation. This can be used for screening for mild cognitive impairment (MCI). The MoCA takes approximately 10 minutes to administer. The total possible score is 30 points with a score of 26 or more considered normal. To better adjust the MoCA for lower educated individuals, 2 points should be added to the total MoCA score for those with 4-9 years of education and 1 point for 10-12 years of education. The score range for MCI is 19-25.2 and for Alzheimer's dementia. The MoCA detected MCI with 90%-96% range sensitivity and specificity of 87% with 95% confidence interval. The MoCA detected 100% of Alzheimer's dementia with a specificity of 87%[116]. A trained research assistant who has successfully completed official MoCA training and certification module will administer this test.

Ethics

The study team will get approval from the Committee for the Protection of Human Subjects (CPHS) at the University of Texas Health Science Center at Houston before the recruitment of study participants. Potential participants will be informed regarding the overall goals of the study and stated that the data collected will remain confidential, and used strictly for research purposes and will get an informed consent (Appendix-C).

Potential Challenges and Risks and Procedures for Minimizing Risks

Risks associated with study participation are minimal as all data collection is non-invasive and

primarily non-personal. Minimal risk is defined as the probability and magnitude of physical or psychological harm that does not exceed that encountered in ordinary, everyday life or in the performance of routine medical or psychological examinations. Risks include: becoming fatigued when participating in sessions, feeling uncomfortable interacting with the study team during sessions, and breach of confidentiality. Participants will be notified of these risks during the informed consent process. If any concerns arise during study procedures, participants will be reminded that participation is voluntary and they may refuse to answer any questions, end the session, or withdraw from the study at any time without fear of repercussion. If a participant is too tired or ill to continue with a scheduled session, the session will be ended and if (and only if) the participant is willing and able the session will be rescheduled. All attempts possible will be made to minimize the risk that a participant's data will become known to others outside the approved research team (see Data Management). The research team will ensure the anonymity of the participants by protecting personally identifiable information. The proposed study will be conducted in English; India is a linguistically diverse country with 22 languages recognized by the constitution of India[117] and it is not feasible to conduct focus groups in multiple languages. However, English is also considered a popular second language in India [118] and is used as the language for communication in U.S. Asian Indians speak English very well (57.7%)[117]and limited English proficiency is fairly low (7.3%) and are bilingual since they speak another language at home[117].

Height/Weight/Waistline Measurements

Having weight or waistline measurements taken may make participants feel uncomfortable. Participants may refuse to complete any procedure that makes them feel uncomfortable.

Physical Activity Side Effects

This study encourages increased participation in physical activity of a moderate nature. This activity may result in mild physical discomfort (e.g., sore muscles, stiffness) for some participants. These effects have no long-term negative health implications and are a normal consequence of activity. However, more serious potential risks include pulled muscles, heart problems, chest tightness or discomfort, shortness of breath, and accidental injuries, such as falling. Possible outcomes could include referral to the participant's primary care physician and/or other physician. Our inclusion/exclusion criteria were designed to exclude participants who should not participate in regular light-to-moderate physical activity based on their responses to the PAR-Q and blood pressure measures without the authorization of a healthcare provider.

Study Withdrawal/Discontinuation

Participants may withdraw from this study at any point in time without repercussion, by simply indicating their desire to withdraw to a study team member.

Criteria for Removal from the Study:

- Participant or clinician request
- Inability to contact the patient for 1 month (up to 6 attempts will be made)
- Completion of study
- Study team determined the patient was no longer eligible

- Sessions were not productive
- Deceased
- Health status declined

All data captured from withdrawn participants will be considered evaluable and used for this study, unless a withdrawn participant requests to have their data destroyed.

Data and Safety Monitoring

Study team members will continuously monitor participant safety and data quality whenever conducting study activities. Study personnel will maintain quality assurance procedures for all data. Survey data will be collected and managed using REDCap (Research Electronic Data Capture). All protected health information (PHI) will be removed from the data when it is exported from REDCap for analysis. Those having access to the data file include the study Principal Investigator (PI) and research team personnel and will monitor recruitment, data quality, data management, and human subjects' protection at least bi-weekly. Logs will be maintained of refusals during recruitment, any participant complaints, and other adverse events and will be reported according to Institution Review Board (IRB) requirements. Dr. Mathew Joseph will work to address and resolve any concerns in the most expeditious manner possible. In particular, participant responses to recruitment attempts will be tracked in terms of methods of contact, and reasons for refusal (if available) and contact attempts made by the study team. This information will be reviewed on a bi-weekly basis, and if any concerning trends are noted in recruitment refusals, the IRBs will be notified and adjustments made to recruitment strategies and / or study procedures (as indicated).

Several procedures will be used to maintain the integrity of the data. Quality assurance procedures will include a data collection protocol documented in a protocol manual, and regular meetings among the investigators and project staff to review problems and solutions and discuss concerns. A specific audit trail system that identifies the date, time, and individual making changes on the database will be part of the data management system.

No protected health information will be included in the text/email messages (as there will be no health information in the message). Although participants' phone numbers and the content of the text messages will be disclosed to the automated text messaging service, no protected health information will be disclosed to the automated text messaging service. Participants will be informed that unencrypted text and email messages are not secure and may choose not to receive them.

To minimize the possibility of a breach in confidentially, data for this study will only be accessible by study team members. Communication with participants may occur in-person or via electronic mail or telephone calls. Voice mails left for participants will contain just the information necessary to return the contact (no identifiable or confidential information). Only UTHealth or site institutional email addresses will be used to communicate with participants.

Data Handling and Record Keeping

Identifiable participant data will be kept in secure locked areas at the Cizik School of Nursing or in password-protected electronic files accessible only by study staff. All identifiable electronic

data (including original recordings and participant contact information) will be stored and managed in a secure, password-protected folder on a server approved for the storage of protected health information or in a secured Research Electronic Data Capture (REDCap™) database, per UTHealth policy. Participants' names and identifiers will be linked to the study identification number in a database that will be password protected, with access restricted to the PI and designated research staff. Paper records (e.g., signed ICDs, completed screening forms) will be kept in a locked file room. All signed informed consent documents and/or HIPAA authorizations will be securely maintained for at least 6 years after the close of the study. Recruitment data will be stored separately from the data of participants who enroll in the study. In particular, a full list will be maintained of participant responses to recruitment attempts by site study team members on a secured and password-protected server managed by that site.

Mr. Stan Cron, statistician of the study, will have access to identifiers needed for analysis such as date of birth (to calculate age) and assessment dates. Other collaborators will have access to de-identified data only. Participants' residential addresses will be collected to access publicly available information about the area in which participants live. This can help us understand how their neighborhood is conducive to physical activity. Results from data analyses using this information will only be reported in aggregate form, and no participants will be identifiable from any research products resulting from this protocol. Participants' residential addresses will never be released/published in any form (e.g., maps, graphs/charts). Addresses will be stored separately from other study data, and following the procurement of neighborhood information, access to participants' addresses will be limited to the PI. Although every effort will be made to keep study data safe, there is a chance that personal health information could be lost or stolen.

After the research described here is complete and the manuscript/s written, access to the de-identified data files will be limited to the PI and research staff/collaborators, who will maintain the files on the institutional server in case any questions emerge from peers or regulatory agencies regarding the resulting publications. Recordings of coaching sessions will be deleted following the completion of analysis. Following study termination, data and identifiers will be handled as per applicable policies and regulations.

Statistics

The feasibility of the intervention will be determined by comparing the percentages for overall recruitment and retention at week 12 to their target values of 80% and 70%, respectively. A secondary feasibility assessment will determine the proportion of intervention participants who take part in each of the intervention components (i.e., number of counseling calls completed, use of Fitbit, receipt and review of newsletters). In addition, every attempt will be made to query subjects lost to follow-up to ascertain the reason for drop out or barriers to participation. Feasibility will be measured by calculating the rates of enrollment, retention, assessment completion, and treatment adherence. The enrollment rate will be the proportion of those meeting inclusion criteria that enrolled, while the retention rate will be the proportion enrolled that complete the study. Assessment completion will be calculated as the proportion of assigned data collection forms that were completed. Treatment adherence will be calculated as the proportion of intervention sessions attended.

To explore trends in the outcomes data, means and standard deviations will be calculated for the instrument scores at baseline and week 12. As hypothesis testing is not the objective of a pilot

study[118], these descriptive statistics will only be used to inform effect size estimation. Since the effect sizes in a pilot study may overestimate or underestimate the true effect sizes [120] the obtained effect size estimates will be considered in combination with clinically significant effect sizes for the outcome variables in determining the sample size for a future trial.

Power Analysis: The primary aims do not require power calculations given the focus on feasibility study.

Anticipated Results: This study will provide the foundation for further large-scale efficacy testing of the dyadic social support PA intervention with the ultimate goal of improving the health and well-being of SAI women. The proposed intervention also integrates cultural values and norms into aspects of the design and delivery to enhance intervention relevance, appeal, and engagement of PA to yield long-term positive impact on the health of SAI women. The results of the study will be published in the scientific journals in a manner that will be accessible to other academic institutions and researchers. We also plan to model with SAI community organizations and health clinics that serve this population and would benefit from the study's outcomes largely. Our project is timely and urgent for at risk SAIs women as it can improve PA to build healthy new habits that last a lifetime. Moreover, the nurse coach will help you learn new skills, encourage to set and meet goals, and keep motivated. Moreover, dyad partners can share ideas, celebrate successes, and work to overcome obstacles. Our study is related to current national priorities. The major goal of Healthy People 2030 is to reduce health disparities among racial and minority groups especially SAIs and to reduce obesity and diabetes by promoting physical activity. The National Institute of Health also encourages investigator-initiated research on minority health and health disparities.

Publication Plans

We will submit abstracts of the study findings for presentation at the conferences of Society of Behavioral Medicine and American Heart Association and plan to submit a manuscript for publication in *the American Journal of Public Health and Journal Preventive Medicine Reports* as second choice.

Potential for Extramural Funding

The data gathered in this study will allow us to understand the provides preliminary support for the feasibility and effectiveness of the peer-based dyadic behavioral intervention among SAI women. We will use the study findings as preliminary results to apply for National Institute of Health RO1 grant to test the effectiveness of a peer-based, dyadic behavioral intervention that emphasizes support between partners for promoting adoption and maintenance of PA intervention among SAI women. Major goals of Healthy People 2030 are to reduce health disparities among racial and other minority groups and obesity and diabetes by promoting PA. The National Institute of Health also encourages investigator-initiated research on minority health and health disparities.

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