

Design of a lifestyle intervention to slow menopause-related progression of intra-abdominal adipose tissue in women: The Women in the Southside Health and Fitness (WISHFIT) study



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ABSTRACT

Background: Changes in reproductive hormones during menopause are associated with accumulation of intra-abdominal adipose tissue (IAAT), a subclinical indicator of cardiometabolic disease risk. Independent of reproductive hormones, unhealthy lifestyle contributes to IAAT gain. The Women in the Southside Health and Fitness (WISHFIT) Study aims to develop a lifestyle approach to slowing IAAT accumulation as women begin the menopausal transition.

Methods: The primary aim is to develop and conduct a proof-of-concept test of a multi-component, multi-level behavioral intervention targeting jointly physical activity, diet, and psychological well-being. Participants attend group sessions over 2 years to experiment with healthy living through both experiential and didactic learning, cultivate a health network, and draw on community resources to sustain change. The primary endpoint is 2-year IAAT progression, assessed using computerized tomography. Behavioral targets of treatment and secondary endpoints will be evaluated at 6, 12, 18 and 24 months. Change in social networks and community support will be assessed at 2 years.

Results: WISHFIT recruited 71 pre- and peri-menopausal Caucasian and African American women (mean \pm SD age = 47.6 \pm 3.4 yrs; BMI = 33.6 \pm 7.3 kg/m²; 52% African American). Baseline IAAT was 2104.1 \pm 1201.3 cm³. IAAT, physical activity, BMI, and self-reported family income and resilience differed by ethnicity at baseline.

Conclusions: WISHFIT is a multi-component, multi-level intervention aimed at producing a sustained improvement in physical activity, diet, and psychological well-being early in the menopausal transition to slow menopause-related accumulation of IAAT. It provides a model for the process of developing a behavioral treatment to manage a chronic disease.

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1. Introduction

Midlife women gain approximately 3.8–4.4% intra-abdominal adipose tissue (IAAT) per year during the menopausal transition [1,2]. Adipose tissue redistribution is associated with increased cardiovascular and metabolic risk beyond that posed by increased

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body mass index (BMI) alone [3,4], IAAT, found in the mesentery and surrounding organs, can be differentiated from subcutaneous adipose tissue by radiographic imaging, making it more precise than waist circumference, which reflects total abdominal adipose tissue [5]. The accumulation of IAAT is precipitated by increases in bioavailable testosterone during menopause [6]. However, potentially modifiable lifestyle factors may slow this accumulation, including physical activity [7], healthy dietary intake [8] and managing psychological factors like depressive symptoms [9] and hostility [10]. Thus, a lifestyle intervention for women about to undergo the menopausal transition could reduce IAAT accumulation and, as such, reduce the menopause-related increase in cardiovascular risk [11–14].

Behavioral interventions have been successful in increasing physical activity [15–18], improving dietary intake [16–18], and improving well-being [19–21]. In midlife women, lifestyle interventions have also been successful in reducing weight [22–25] and waist circumference (WC) [22,24–26]. While both weight and WC are positively correlated with IAAT [27,28], no interventions have specifically aimed to prevent accelerated IAAT accumulation during menopause.

Prior studies have demonstrated, however, that maintenance of behavior change remains a difficult challenge [29]. One way of promoting sustained change in lifestyle is developing interventions that progress beyond individual targets and include the social and community levels. Health behaviors are transmitted in social networks, defined as webs of social relationships and social linkages [29–31]. Indeed, women who report consistent physical activity over 15 years were more likely to have a friend who is active [32]. Social network transmission is also evident in diet [33] and emotional states [34]. Moreover, promoting healthy choices can be fostered by drawing on community infrastructure and building community support for healthy living [35,36].

The Women In the Southside Health and FITness (WISHFIT) study is one of seven projects participating in the National Heart, Lung, and Blood Institute's Obesity-Related Behavioral Intervention Trials (ORBIT) Consortium, all of which are aimed at developing interventions for the prevention or management of obesity [37]. A series of preliminary studies identified: [1] links to basic and behavioral and social science theory and their recommended treatment strategies [23]; [2] the importance of positive framing over monetary incentives in preventing early dropouts [38]; and [3] activities and incentives that foster sustained lifestyle change using a "product-testing" qualitative approach from the marketing literature [39]. These data formed the basis of a multi-component, multi-level intervention. The individual level has three components: physical activity, diet, and psychological well-being. The social level encourages participants to build and increase the frequency of positive interactions with a health network. The community level aims to promote community support for midlife women who were in the process of pursuing a healthy lifestyle.

The goal of WISHFIT was to produce a 2-year sustained lifestyle change, thereby reducing by half the menopause-related progression of IAAT. This paper describes the study development, design, and baseline characteristics of the participants.

2. Methods

2.1. Study design

WISHFIT is a single site, quasi-experimental proof-of-concept study aimed at providing a preliminary test of treatment efficacy. The primary outcome of IAAT accumulation will be evaluated at baseline and 24-months. The proof-of-concept design is consistent with the ORBIT model of treatment development which advocates

quasi-experimental testing of new interventions to determine whether justification exists for more rigorous testing using a randomized design [37]. Fig. 1 outlines the hypothesized and exploratory pathways by which the WISHFIT intervention will prevent IAAT gain.

The trial is registered with ClinicalTrials.gov (NCT01778712). Approval for the use of human subjects was provided by the Institutional Review Board of Rush University Medical Center. The study is monitored by a data and safety monitoring board.

2.2. Eligibility criteria

Potential participants are African American or Caucasian women living in a geographically contiguous south-side Chicago community, aged 42 years or older, with an intact uterus, ≥ 1 functioning ovary, and ≥ 1 menstrual period in the last 12 months. Exclusion criteria includes: hysterectomy; no menstrual cycle in the past 12 months; pregnancy; self-reported physical activity >90 min per week; metabolic conditions or use of medications with direct impact on IAAT; history of major psychiatric condition in the last 6 months, anti-psychotic medications, or hallucinations; and being told by a physician to abstain from physical activity because of such circumstances as: heart failure, recent heart attack, liver cirrhosis, kidney failure, oncologic conditions, or history of heart surgery, angioplasty or coronary artery stenting. Participants weighing >300 pounds are excluded due to equipment limitations for IAAT measurement.

2.3. Setting and recruitment

The study neighborhood is demographically representative of Chicago with equal distributions of African American and Caucasian women across diverse socioeconomic strata. This area has local parks and community programs that support healthy lifestyles. The WISHFIT study capitalizes on long-standing community partnerships on the south side of Chicago through which the study investigators have evaluated biological, psychosocial, and cultural influences on the menopausal transition [40].

Recruitment includes several strategies to assess interest in WISHFIT including: 1) direct mail using lists from InfoUSA; 2) advertisements and articles in local newspapers; 3) flyers and brochures displayed in local businesses; 4) information tables at community events; and 5) family, friend, and research team referrals. Eligible women have two screening interviews by two WISHFIT staff members to assess motivation, readiness for making lifestyle changes and participating in a study, and serving as a community ambassador for healthy living. Women who are ready to make lifestyle changes are invited to a group-based orientation meeting where the rationale behind WISHFIT and tangible and non-tangible costs of study participation are presented. Women are given the opportunity to discuss among themselves the pros and cons of participating [41]. Participants who decide to participate undergo a baseline exam and are enrolled in six groups (waves) of approximately 10 women each. Recruitment was completed over an 18-month period.

2.4. Measures

Full assessments are conducted at baseline, 6, 12, 18 and 24 months, with an abbreviated assessment at 9 months. All study measures are assessed by trained study staff at a community-based intervention site, with the exception of IAAT and body fat measurements. Participants provide demographic information at baseline. Table 1 presents the complete assessment battery.

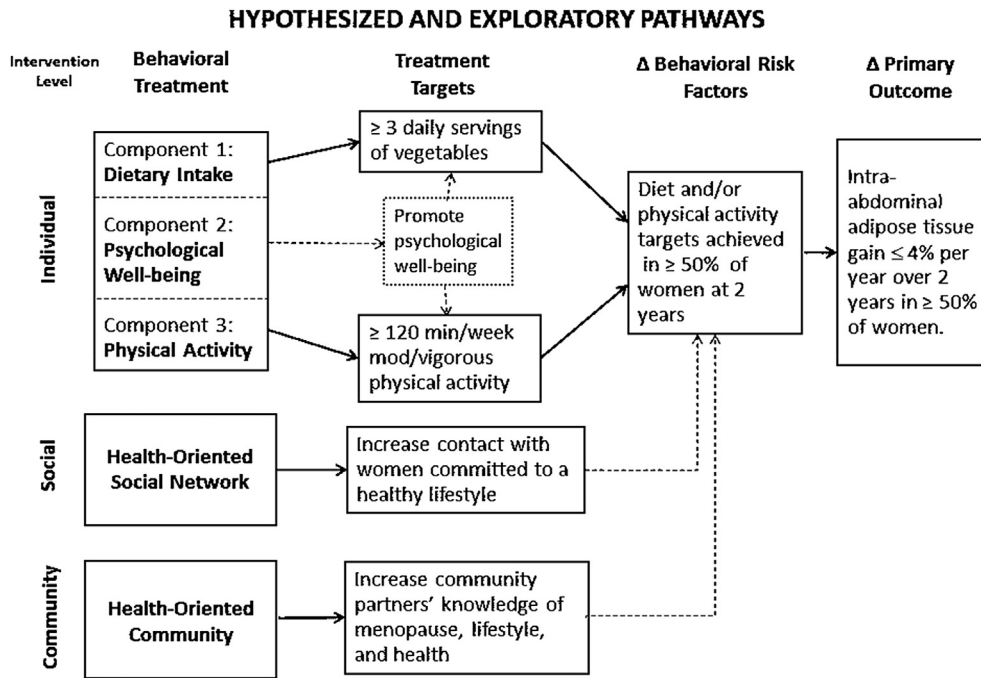


Fig. 1. Hypothesized and exploratory pathways with treatment targets, risk factors, and primary outcome. Solid arrows depict hypothesized pathways. Dotted arrows depict exploratory pathways.

2.4.1. Intra-abdominal adipose tissue and waist circumference

The primary outcome of the study is two-year IAAT change. All women undergo Quantitative Computed Tomography (CT) imaging to assess IAAT at Rush University Medical Center in Chicago. Images are acquired in the supine position during a breath hold after exhalation. Images are analyzed for IAAT and subcutaneous abdominal adipose tissue (SAAT) by the same radiologist at a dedicated workstation (TeraRecon, San Mateo, CA, USA) at the Image Reading Center (New York, NY). IAAT (cm^2) and SAAT (cm^2) areas are measured applying pre-defined image display settings (window width -195 to -45 HU; center -120 HU). To separate IAAT from SAAT, the abdominal muscular wall separating the two compartments is automatically traced and subsequently adjusted manually. Volumetric estimates are calculated as they predict IAAT and SAAT more accurately than estimates from a planimetric quantitation [42,43]. Waist circumference is measured at baseline and all follow-up visits as a surrogate IAAT measure.

2.4.2. Behavior treatment risk factors

Objective, free-living physical activity, measured via accelerometry, and three separate 24-h dietary recalls, taken via interview, were collected at baseline and all follow-up visits to assess the behavioral treatment risk factors (Table 1).

2.4.3. Other outcome assessments and covariates

Multiple measures of psychological well-being are included to provide the opportunity to explore how aspects of well-being might promote or subvert success in making behavioral changes. Additional measures serve as covariates and/or explore mediator and moderator relationships, including menopausal status, age, race, body mass index, total body fat, subcutaneous abdominal adipose tissue, socioeconomic status, medical history, and use of medications. See Table 1 for other secondary outcomes. Social network assessment includes a subset of one's total connections, rather than a map of entire social networks [44]. Evaluation will

include any change in health-related function of the network and, in particular, any addition of a fellow WISHFIT participant to one's list. Health-orientation of the community is assessed at baseline and 24 months using a "man on the street" survey conducted at six sites across the community. Qualitative interviews assess the impact of WISHFIT on community-based organizations and businesses.

2.5. The WISHFIT intervention

2.5.1. Structure

The lifestyle intervention aims to produce sustained change, drawing its treatment strategies from self-determination and social cognitive theory, both of which speak to sustained change [45,46]. The key teaching technique is real time experimentation with cognitive and behavioral habits that are consistent with a healthy lifestyle. It is offered in three phases, each of which has a unique focus (Table 2). But the format of group meetings is consistent, regardless of the phase. At each session, a new activity (e.g., Zumba, line dancing) is introduced to expose participants to various options for enjoyable forms of physical activity. Participants then undergo a brief meal preparation or stress reduction exercise. The session closes with a review of progress, feedback and encouragement from group leaders and other group members, problem-solving for challenges, and goal-setting based on individual feedback and intervention targets. In response to participant feedback, the maintenance phase features half of its meetings off-site at a location, and in a format, chosen by the group members. This transfer of autonomy was consistent with self-determination theory and the development of a self-supportive, self-sustaining health network. If a participant misses a group session, the interventionist calls to review content, problem-solve any barriers to lifestyle change, and assist with goal setting. Additionally, a research assistant calls all participants every three months to identify any physical injury or study concerns.

Table 1
Description of outcomes and other measures.

Variable	Measure	Description
Primary Outcome		
Inter-Abdominal Adipose Tissue	Quantitative Computed Tomography (CT) imaging (Siemens Definition Flash, Erlangen, Germany)	Volumetric quantification using five images (10 mm in thickness) were taken at 5 cm increments, one with the first planimetric image anchored at L ₄ –L ₅ vertebral interspace (120 KVP, 150 mA, gantry speed 0.5 s, standard reconstruction kernel (soft-tissue) without dose modulation). Volumetric estimate of IAAT (in cm ³) was calculated as: $V = (t + h) \sum_{i=1}^N A_i$ where V is volume, A _i is planimetric area, h is between-slice interval, and N is the total number of slices included [62].
Surrogate Outcome		
Waist Circumference	Gulick II Pro tape (model 67019)	Waist girth was measured above iliac crests to the nearest 1 mm with women in standing position at the end of exhalation.
Behavioral Treatment Risk Factors		
Physical Activity: Moderate to vigorous intensity physical activity minutes/week	Accelerometer	Accelerometer (Actigraph GT3X Accelerometer, Actigraph, LLC, Fort Walton Beach, FL) was worn at the hip for 7 days (≥ 10 h per day). Triaxial accelerometer captures acceleration in three axes (vertical, anteroposterior, mediolateral) and was initialized to collect data in 60-s epochs. Vector magnitude cut-points [63] were used to determine time spent in moderate and vigorous physical activity calculated from raw accelerometer data. Continuous bouts of moderate-to-vigorous activity were defined as ≥ 10 consecutive minutes above the moderate intensity threshold.
Vegetable Intake: Number of vegetable servings	24-Hour Dietary Recall	Dietary intake assessed through three 24-h dietary recalls using a multiple-pass interview approach. The Nutrition Data System for Research computer-based software application developed at the University of Minnesota Nutrition Coordinating Center facilitated a standardized recall collection.
Psychological Well-Being		
Stress	Perceived Stress Scale(64)	10-item questionnaire assessing the degree to which situations in one's life are appraised as stressful. Questions refer to frequency of feelings and thoughts during the past month with options ranging from 1 (never) to 5 (very often).
Depression	Patient Health Questionnaire Nine Item Depression Scale (PHQ-9) [65]	9-item questionnaire assessing presence and severity of depressive symptoms over the last 2 weeks. Total scores range between 0 and 27 points, with the presence of depression and its severity being defined by the following scores: 1–4 minimal depression, 5–9 mild, 10–14 moderate, 15–19 moderate to severe, and 20–27 severe.
Energy and Vitality	36-Item Short Form Health Survey (SF-36) Energy and Vitality subscale [66]	4-item subscale from the SF-36. Each item has 6 response options ranging from 1 (all of the time) to 6 (none of the time). Items are positively scored with higher scores indicating higher energy or vitality.
Fatigue	Patient Reported Outcomes Measurement Information System (PROMIS) Short Form V1.0 Fatigue [67]	4-item questionnaire evaluating self-reported fatigue symptoms over the past 7 days—from mild feelings of tiredness to an overwhelming and sustained sense of exhaustion. Item responses range from 0 (not at all) to 5 (very much) and are summed for a raw total score.
Anger	PROMIS Short Form V1.0 Anger [67]	8-item scale from the questionnaire measures self-reported angry mood, negative social cognitions and efforts to control anger over the past 7 days. Item responses range from 0 (never) to 5 (always) and are summed for a raw total score.
Resilience	Connor-Davidson Resilience Scale(68)	10-item scale assessing ability to cope with stress and adversity over the past month. Responses are on a 5-point Likert scale ranging from 0 (not at all true) to 4 (true nearly all the time). Total scores range from 0 to 100 with higher scores reflecting greater resilience.
Time Urgency	Time Urgency (Framingham) [69]	4-item questionnaire assessing time urgency and feeling pressed for time. Three of the items responses range from 0 (statements do not describe participant at all) to 3 (describe participant very well). The 4th item response ranges from 1 (never) to 2 (often).
Social Support	Social Support and Exercise Survey(70)	13-item survey regarding supportiveness for exercise behaviors, with separate responses for family and friends. Item response ranges from 1 (none) to 5 (very often). The word "exercise" was changed to "physical activity."
Motivation	Treatment Self-Regulation Questionnaire(71)	15-item questionnaire including 6 autonomous items regarding autonomous motivation for a target behavior (Physical Activity), 6 controlled items regarding controlled motivation for the target behavior, and 3 items regarding amotivation. Responses range from 1 (not at all true) to 7 (very true). Three subscale scores can be used separately, or a Relative Autonomy Index is calculated by subtracting the average for the controlled reasons from the average for the autonomous reasons.
Secondary Outcomes		
Total Body Fat	Dual-energy X-ray absorptiometry (DXA)	Images taken in the supine position during the breath hold in exhalation. Participants wore paper gowns and removed all jewelry. EnCore™ Software v13.6 (GE Medical Systems, Madison, WI) was used to determine the proportion of total body fat. Proportion of total body fat (%) was calculated as (fat mass divided by total soft tissue mass) \times 100. The precision limit for total body fat readings by technicians at our center are <2%.
Subcutaneous Abdominal Adipose Tissue		Subcutaneous abdominal adipose tissue was measured in the same manner as inter-abdominal adipose tissue, mentioned above.

(continued on next page)

Table 1 (continued)

Variable	Measure	Description
Physical Activity: Light intensity physical activity minutes/week, sedentary behavior, steps/day	Quantitative Computed Tomography (CT) imaging (Siemens Definition Flash, Erlangen, Germany) Accelerometer	As stated above in objectively measured physical activity, vector magnitude cut-points [63] were used to determine time spent in light, physical activity and sedentary behavior, while step counts were calculated from raw accelerometer data.
Daily Caloric Intake (kcal/day)	24-Hour Dietary Recall	As described above for vegetable intake, total caloric intake (kcal/day) was assessed using three 24-h dietary recalls using the Nutrition Data System for Research computer-based software application.
Healthy Eating Index (HEI) [72]	24-Hour Dietary Recall	The HEI quantifies adherence to federal dietary guidelines and assesses diet quality. Scores are derived using the Nutrition Data System for Research computer-based software application.
Social Level Health-Oriented Social Network	Social network survey-egocentric. Adapted from Valente [73]	Survey was developed as an egocentric social network data collection tool consisting of questions about persons with whom participants frequently spend their free time. Each WISHFIT participant could list up to 8 persons. For each person, questions asked how well the participant knows the person, how frequently they are in contact, the nature of the activities they do together (e.g., physical activity, sharing meals, and activities that promote well-being), and the participant's perception of the physical activity, healthy diet, and stress levels of each person. In follow-up questionnaires, these questions were asked specifically in a separate category for WISHFIT women.
Community Level Health-Oriented Community	"Man on the Street" community survey of knowledge of menopause and its health consequences; Qualitative studies	13 structured questions and one open-ended question, probing knowledge of menopause-related health issues, basic demographics of respondent and awareness of the WISHFIT study. Survey delivered in a "man-on-the-street" format by study staff at six randomly selected locations within the target community where women are known to congregate. Qualitative interviews were conducted with members of community-based organizations and health-oriented businesses.

2.5.2. Behavioral treatment targets

Table 3 summarizes the central focus and the tools and strategies used to achieve it within the physical activity, diet, and psychological well-being targets.

To encourage enjoyment of physical activity, participants are first sensitized to the goal. Sensitivity to moderately intense physical activity is developed by rating perceived exertion and noting bodily cues of increased respiratory rate [47]. Gradual build-up to 120 min per week [48,49] is cultivated through the use of pedometers (Omron model HJ-720ITC) and graduated goals toward 8000 to 10,000 steps per day [50]. Participants are then exposed to a variety of options for achieving goals emphasizing recognition of enjoyment, fun, benefits on mood, and the security of a strong body.

To encourage interest in vegetables and cooking at home, participants are sensitized to the Perfect Plate method, modified from the United States Department of Agriculture MyPlate Nutrition Guide [51]. The Perfect Plate directs individuals to consume portions of non-starchy vegetables comparable to two fists, or approximately a half plate, at daily lunch and dinner. To encourage eating at home as a way to improve nutrition quality, experiential cooking activities take place during group sessions. Participants practice cooking easy-to-prepare foods, share recipes, exchange

substitutions to promote healthy cooking and join in cooking competitions. Participants are encouraged to self-monitor their dietary intake daily.

To encourage a reprioritization of time and to place important over urgent activities, participants are asked to set aside one hour per day (i.e., "The WISHFIT Hour") to practice skills learned during group sessions. Mindfulness exercises helped participants to manage negative emotions and re-conceptualize stressful events [21]. A breathing technique called "Stop, Breathe, Be" and guided meditations are invoked to reduce reactivity to daily stressors [52]. Recognizing 'hooks' is a cognitive restructuring exercise that helps participants replace thoughts associated with emotional reactivity with alternatives [53]. The Williams Life Skills technique 'I am worth it™' helps participants identify whether it is worth taking action when balancing the needs of self and others [54]. A set of twelve affirmations, Words of a WISHFIT Woman, are reviewed in group sessions to promote enjoyment and inspiring others.

2.5.3. Fidelity

The intervention team features two Master's level group leaders. A leader's guide insures standardized content delivery. All group sessions are recorded using a digital voice recorder and are randomly reviewed using a fidelity check list. Supervisors review

Table 2
Intervention format and focus by phase.

Phase	Phase length	Group session frequency	Phase focus	Group session format (all phases)
Skill Acquisition	4 Months	Weekly	Four Week blocks Focusing on: <ul style="list-style-type: none"> Physical Activity Dietary Intake Psychological Well-being Combining Lifestyle Skills 	1 30 min of guided, moderate-intensity physical activity 2 Brief nutrition lesson OR mindfulness exercise for stress-reduction 3 Review of goal progress with feedback and encouragement 4 Presentation specific to phase
Skill Application	8 Months	Monthly	Integrating habits into daily life	
Skill Maintenance	12 Months	Monthly	Maintenance and repetition to sustain habits	

Table 3
Intervention strategies by component.

Component	Central focus	Tools and strategies
Physical Activity	<ul style="list-style-type: none"> Enhance motivation through immediate reinforcers: enjoyment, fun, positive mood, and strong body. 	<ul style="list-style-type: none"> Pedometer with individual step goals Group sessions focused on having fun Participation in community events Ongoing objective feedback reports
Dietary Intake	<ul style="list-style-type: none"> Recognize the value of eating vegetables and cooking at home 	<ul style="list-style-type: none"> Perfect Plate guide for balancing meals with ½ plate vegetables Experiential cooking sessions Cooking competitions Nutrition education with food journaling
Psychological Well-being	<ul style="list-style-type: none"> Make time for healthy living by prioritizing important over urgent 	<ul style="list-style-type: none"> Daily WISHFIT hour Recognizing “Hooks” “Stop, Breathe, Be” Guided mindfulness meditations “I am worth it™” Words of a WISHFIT Woman

fidelity data and provide group leaders with feedback. Supervision meetings are held weekly during each phase of the intervention, including 1-on-1 supervision of each group leader by a supervisor and/or group supervision sessions including the entire intervention team. Implementation of feedback is assessed at subsequent intervention sessions.

2.5.4. Health network

WISHFIT is exploring ways to encourage each woman to develop a health network in several ways. First, interpersonal skills are cultivated during group meetings. Second, participants are sensitized to the health nature of their existing social networks by identifying the people who comprise them and the type of activities in which participants engage with these people. Third, participants are encouraged to create additions to their social networks to fulfill voids in the area of health. Connections with other WISHFIT women are encouraged through a study website and various seminars and events where WISHFIT women interact with each other and connect members of their own networks to the WISHFIT network. Upon transition to maintenance, small groups are combined to form a large group of WISHFIT women for the purpose of developing a WISHFIT identity. Fourth, participants are encouraged to serve as leaders within their own social networks and ambassadors in their community. They are offered opportunities to host small gatherings where study staff is invited to talk about topics of interest. They are given opportunities to sit on panels and participate in newspaper interviews to describe their experiences with lifestyle change.

2.5.5. Health-oriented community

The community level of the intervention seeks to explore whether or not community awareness of menopause and its associated cardiovascular risk in midlife women can enhance community support for midlife women who are pursuing healthy lifestyles. Among the activities pursued are partnering with local businesses, community centers, educational organizations, and women's groups to increase awareness. For example, partnering with the local running shoe store exposes proprietors and patrons to menopause-related health issues and participants to new resources, opportunities for physical activity, and health-minded people. Co-sponsorship of community events which have a health focus is aimed at increasing the visibility of WISHFIT and WISHFIT women to the community. Regular newspaper articles in local newspapers about WISHFIT, specific WISHFIT women, and pertinent research findings are aimed at enhancing visibility to a wide audience.

3. Statistical analysis

Baseline descriptive statistics were conducted to describe the study sample using two-sided t-tests for continuous variables, chi-square tests or Fisher's exact tests for categorical variables. Regarding the primary outcome of interest, at the end of the two-year assessment, statistical analyses will be conducted to assess whether $\leq 4\%$ increase in IAAT was achieved in 50% of the population. Both planimetric and semi-volumetric (5-slice) CT scan measurements of the abdomen will be used in analyses. It will be determined whether achievement of IAAT goal differs by wave, race, menopausal status, and percent body fat using chi-square tests and t-tests.

Regarding secondary outcome measures, a series of linear mixed effects models will assess changes over time of weekly moderate to vigorous intensity PA minutes and number of daily servings of vegetable. For psychological well-being, different psychosocial constructs will be assessed throughout the course of the study (see Table 1).

The base set of mixed models will include time with a random intercept and slope. The second set will include the base model with the addition of covariates wave, race and age. A third set will include other confounding factors such as family income. The final set will test for interactions between time and race and wave. Assumptions and goodness-of-fit will be assessed. If assumptions for a specific statistical test are not satisfied, transformations of the data or non-parametric alternatives will be considered. If missing data exceeds 10%, we will assess various missing data techniques (i.e. multiple imputation, maximum likelihood, Heckman's sample selection bias model, etc.) to evaluate the influence of missing data. All statistical analyses were and will be done in SAS 9.3.

4. Results

A total of 355 participants were screened for eligibility in WISHFIT (Fig. 2). Of these, 137 women met inclusion criteria, 95 continued to be interested after the recruitment interview, and 71 women ultimately enrolled into the study. Baseline characteristics of the enrolled participants are presented in Table 4. The mean age (\pm SD) was 47.6 ± 3.4 years, mean BMI (\pm SD) was 33.6 ± 7.3 kg/m² and 52% were African American. Approximately 40% of participants reported that it was “somewhat hard” or “very hard” to pay for basics, though Caucasian women had significantly higher family income. While almost three-quarters of the Caucasian women reported being married or living with a partner, this was the case for only about half of the African American women. Approximately half of the African American women and two-thirds of the Caucasian

women had a child or children under 18 living at home. Caucasian women spent more minutes in moderate-intensity PA per day, and also had more steps per day than African American women but there were no differences by ethnicity for daily caloric intake or daily vegetable servings. Baseline volumetric IAAT for the study participants was $2121.7 \pm 1189.2 \text{ cm}^3$ as assessed by CT imaging. African American women had significantly higher BMI than Caucasians, though Caucasian women had significantly higher IAAT than African American women. African American women were more resilient than Caucasian women. The number of individuals reported in participants' social networks did not differ by ethnicity.

A total of 99 people completed the “man on the street” community survey. Approximately half were women and 41% were African American. Mean age (\pm SD) was 50 ± 15 years. When asked about menopause, 58% answered that it is the time “when women stop having periods”. When asked in what way “going through menopause affects a woman’s long term health”, only two people answered “increases the risk of heart disease” and no person referred to ‘increase in visceral fat’.

5. Discussion

WISHFIT is one of seven projects that comprised the ORBIT Consortium which was funded by the National Heart, Lung, and Blood Institute to provide support for the development of behavioral interventions for obesity [37]. In contrast to the widely-accepted process for drug development, no such process exists for development of behavioral treatments aimed at improving chronic disease outcomes. In contrast to the \$140 billion/year invested in drug development by industry, no such benefactor exists for behavioral treatments. The ORBIT Consortium was developed to respond to these deficits. The product of the work of the Consortium has been presented as the ORBIT model for behavioral treatment development, and NIH support for mechanisms aimed at behavioral treatment development is increasing. The development and design of WISHFIT follows closely the ORBIT model and exemplifies what can be accomplished with sufficient support for developmental work.

The ORBIT model emphasizes the importance of a clinically significant question. The significance of WISHFIT lies in the problem of the post-menopausal increase in cardiovascular disease in

women [55]. Through a series of preliminary epidemiological studies, we have shown that a shift in the androgency of the hormonal milieu at the menopause promotes an increase in IAAT [6] which can in turn increase risk for cardiovascular and metabolic diseases in women [3,4,56], but that a lifestyle that reduces behavioral risk factors can reduce this menopause-related progression of IAAT. These findings gave rise to the hypothesis that enhancement of healthy living at the time of the menopausal transition could slow the progression of IAAT in women.

The ORBIT model emphasizes the importance of specifying a priori hypothesized pathway by which treatment translates into benefit on a primary outcome. The WISHFIT hypothesized and exploratory pathways are presented in Fig. 1. Because physical inactivity, excess caloric intake, and aspects of psychological distress are each associated with IAAT gain, independently of each other and of changing reproductive hormones [7–10], the individual level of this treatment was conceptualized as having three components—physical activity, diet, and psychological well-being. The need for improvement in each of these three areas is evident from national statistics. Less than half of the US population participates in regular PA, with adherence being lower among adult women than men [49], and decline in leisure time throughout adulthood being more rapid in women than in men [57]. Approximately three-quarters of US adults do not meet government recommendations of consuming three or more servings of vegetables per day [58]. One in four women report insufficient management of stress, compared to only 17% of men [59].

The ORBIT model encourages reliance on basic behavioral and social sciences to achieve a treatment that has sufficient strength to affect a biologic outcome such as IAAT. In preliminary studies, the value of social cognitive and self-determination theory in the promotion of sustained change in physical activity was supported [33] thus giving rise to treatment strategies advocated by these theories including repeated objective feedback and autonomy of choice. The value of a health-oriented network was also supported by a preliminary study [32] thus giving rise to a social network level of the intervention. But, because the methods for facilitating the development of a health-oriented network are not well established, this was deemed to be an exploratory pathway. A preliminary experiment supported the value of immediate reinforcers such as having fun during physical activity [38] which gave rise to the design

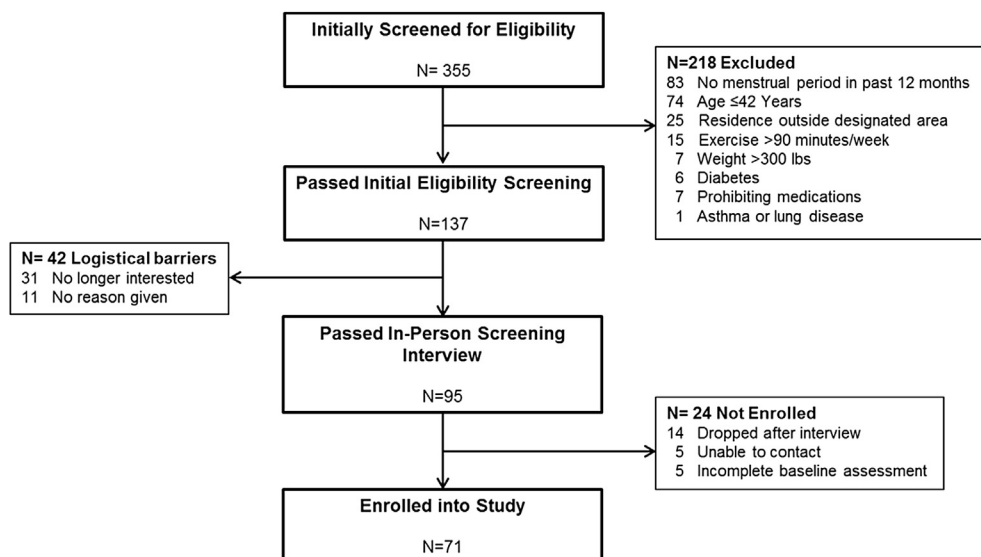


Fig. 2. Eligibility and enrollment flow diagram for the WISHFIT study.

Table 4
Baseline characteristics.

	All women N = 71	Caucasian N = 34	African-American N = 37	P-value ^a
Age in years, mean ± SD	47.6 ± 3.4	47.9 ± 3.5	47.3 ± 3.2	0.491
Education, n (%)				
HS Diploma, Vocational/Training School	6 (8.4)	2 (5.9)	4 (10.8)	0.833
Some College/Associate Degree	17 (23.9)	8 (23.5)	9 (24.3)	
Baccalaureate Degree	22 (31.0)	12 (35.3)	10 (27.0)	
Graduate School	26 (36.2)	12 (35.3)	14 (37.8)	
Marital Status				
Single	15 (21.1)	4 (11.8)	11 (29.7)	0.283
Married/Living w/partner	46 (64.8)	25 (73.5)	21 (56.8)	
Divorced	8 (11.3)	4 (11.8)	4 (10.8)	
Widowed	2 (2.8)	1 (2.9)	1 (2.7)	
Family Income				
< \$50,000	17 (23.6)	5 (14.3)	12 (32.4)	0.010
\$50 to < \$99,999	23 (31.9)	8 (22.9)	15 (40.5)	
≥ \$ 100,000	24 (33.8)	18 (52.9)	6 (16.2)	
Refused/Don't know	7 (9.7)	3 (8.6)	4 (10.8)	
Employment Status				
Full-time	44 (62.0)	21 (61.8)	23 (62.2)	0.206
Part-time	17 (23.9)	10 (29.4)	7 (18.9)	
Unemployed	3 (4.2)	2 (5.9)	1 (2.7)	
Other	7 (9.9)	1 (2.9)	6 (16.2)	
Difficulty Paying for Basics				
Very hard	8 (11.1)	7 (20.0)	1 (2.7)	1.0
Somewhat hard	21 (29.2)	8 (22.9)	13 (35.1)	
Not hard at all	40 (56.3)	19 (55.9)	21 (56.8)	
Refused	2 (2.8)	0 (0.0)	2 (5.4)	
Having Health Insurance	62 (87.3)	30 (88.2)	32 (86.5)	1.0
Number of Children under 18 at Home	1.1 ± 1.1	1.3 ± 1.2	0.9 ± 0.9	0.160
Have Children under 18 at Home	41 (66.1)	22 (64.7)	19 (51.3)	0.255
Current Smokers	2 (2.8)	1 (2.9)	1 (2.7)	1.0
Menopausal Status				
Premenopausal	28 (39.4)	13 (38.2)	15 (40.5)	0.346
Early peri-menopausal	35 (49.3)	19 (55.9)	16 (43.2)	
Late peri-menopausal	8 (11.3)	2 (5.9)	6 (16.2)	
Body Mass Index (kg/m ²)	33.6 ± 7.3	31.8 ± 6.6	35.4 ± 7.6	0.039
Waist Circumference (cm)	102.1 ± 14.6	100.2 ± 12.9	103.9 ± 15.9	0.291
Total % Body Fat	47.5 ± 6.0	46.6 ± 5.6	48.3 ± 6.3	0.240
Intra-Abdominal Adipose Tissue (cm ³)	2121.7 ± 1189.2	2425.1 ± 1299.4	1835.1 ± 1011.1	0.041
Physical Activity: Moderate min/week, median (Q1, Q3)	18.0 (0, 61)	30.0 (0, 137)	12.0 (0, 36)	0.034
Daily Average Steps	5864.1 ± 2182.5	6535.7 ± 2638.5	5254 ± 1322	0.021
Perceived Stress ^b	15.6 ± 5.2	16.3 ± 4.5	14.9 ± 5.7	0.257
Depression Severity ^c , median (Q1, Q3)	4.0 (3.0,7.0)	4.0 (3.0, 7.0)	4.0 (2.0, 6.0)	0.341
Energy/Vitality ^d	56.3 ± 16.5	52.4 ± 15.1	59.9 ± 17.1	0.055
Fatigue ^e	6.3 ± 3.5	7.0 ± 3.1	5.7 ± 3.7	0.132
Anger ^f	9.7 ± 5.4	9.8 ± 5.2	9.6 ± 5.7	0.861
Resilience ^g	29.4 ± 5.9	27.2 ± 5.6	31.3 ± 5.6	0.003
Time Urgency ^h , median (Q1, Q3)	1.0 (0, 1.0)	1.0 (0, 1.0)	1.0 (0, 1.0)	0.657
Social Support – Family ⁱ	27.5 ± 10.2	27.0 ± 9.9	28.0 ± 10.6	0.696
Social Support – Friends ⁱ	23.4 ± 8.6	21.6 ± 7.5	25.0 ± 9.3	0.119
Autonomous Motivation–Physical Activity ^j , median (Q1,Q3)	6.3 (6.0, 7.0)	6.3 (6.0, 6.8)	6.5 (6.0, 7.0)	0.360
Daily Total Caloric Intake (KCAL/day)	2013.2 ± 561.9	2004.0 ± 477.4	2021.7 ± 636.3	0.891
Daily Vegetable Servings, median (Q1, Q3)	2.5 (1.4, 4.1)	2.5 (1.3, 4.3)	2.6 (1.6, 4.0)	0.867
Average number of people in Social Network	5.2 ± 2.5	5.3 ± 2.2	5.2 ± 2.8	0.865

^a P-value pertains to the difference between Caucasian and African American participants, using t-tests for continuous variables, chi-square tests for categorical variables and Fisher's exact test for categorical variables who cell size is < 5. All tests based on two-sided probabilities.

^b Perceived Stress Scale [64]; possible scores range from 0 to 40 with higher scores indicating greater perceived stress.

^c Depression severity assessed by the PHQ-9 [65]; possible scores range from 0 to 27 with higher scores indicating more depressive symptoms.

^d Energy/vitality subscale assessed by SF-36 [66]; possible scores range from 0 to 100 with higher scores indicating more energy/vitality.

^e PROMIS fatigue [67]; possible scores range from 0 to 16 with higher scores indicating more fatigue.

^f PROMIS anger [67]; possible scores range from 0 to 32 with higher scores indicating more anger.

^g Connor-Davidson Resilience [68]; possible scores range from 0 to 40 with higher scores indicating more resilience.

^h Score from Framingham Time Urgency [69]; possible scores range from 0 to 11 with higher scores indicating more urgency.

ⁱ Score from Social Support and Exercise [70]; possible scores from 10 to 50 with higher scores indicating more support.

^j Treatment Self-Regulation Questionnaire [71]; possible scores range from 1 to 7 with higher scores indicating more motivation.

emphasis that each group meeting be enjoyable and expose participants to a range of activities that they might enjoy and thus sustain over a lifetime. These activities were identified in preliminary qualitative studies, drawing on the marketing method of “product testing”, in which the target population experimented

with and rated a variety of options [39].

The decision to conduct a preliminary, proof-of-concept test of the intervention using a quasi-experimental design was made in light of team science feedback from the entire ORBIT Consortium. The reasoning was that if the intervention, as currently designed,

could hit a priori, clinically significant targets in a small, carefully studied sample, it would provide the justification for proceeding to a larger, more diverse, more complex, and more costly randomized design. If it could not hit these targets, revision and optimization and, possibly, retesting in a new proof-of-concept design would be advisable before undertaking such a step. In this proof-of-concept, we deliberately aimed to recruit equal numbers of African American and Caucasian women because of potential moderator effects. Ethnic differences exist at baseline in sociodemographic factors, physical activity, and adiposity measures. Caucasian women are more physically active but have higher IAAT compared to African American women, consistent with others' observations [6,60] but the annualized IAAT gain across the menopause is similar in African American and Caucasian women [2]. This potential moderation is, at this point, not well understood.

In summary, WISHFIT aims to answer the important question of how to enhance cardiometabolic health in women as they traverse the menopause. Women cannot avoid going through the menopause. But they can use this transition as a critical moment in life when making changes in lifestyle could be particularly important. Moreover, this may be a particularly opportune time for change since many women are now free of the child-rearing responsibilities they had when younger and have more time to devote to themselves. The systematic, progressive approach to developing this treatment which provides time for failure and optimization is modeled after the procedures for drug development which have gradually been put in place beginning in the early 1900's [61]. As WISHFIT progresses, it is our hope that it will contribute not only to answering the clinically important question at hand but also to promoting advances in the field of behavioral treatment development.

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