Cherokee Health for Elderly Residents with Osteoarthritis of the Knee in the Easter band. The Cherokee Study (WE CAN Pilot)

STUDY PROTOCOL

9.9.2022

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Project Description:
The global prevalence of knee osteoarthritis (OA) is estimated at greater than 250 million persons or 3.6% of the world population, ranking 23rd on the list of the most common sequelae [1]. Knee OA is the most prevalent cause of mobility dependency and disability, with the time spent living with symptoms averaging 26 years [2]. Two in three people who are obese will develop symptomatic knee OA in their lifetime [3].

In 2004 we reported that a 5% weight loss, when combined with exercise, resulted in a 30% decrease in pain and a 24% improvement in function [4]. Our recently completed trial entitled Intensive Diet and Exercise for Arthritis (IDEA) sought to improve on our work with a more intensive weight loss intervention, 2 to 3 times the weight loss we had recently achieved [5]. IDEA compared intensive diet (D) and exercise (E) interventions, separately and in combination, across an 18-month intervention period in 454 overweight and obese older adults with radiographic knee OA. An intent-to-treat analysis revealed that after 18 months the D+E group reduced pain by 51% compared to 25% and 28% for the D only and E only groups, respectively. The D+E group was also superior to the E group on self-reported physical function, health related quality of life, and walking speed, and had significantly lower knee joint loading and serum levels of IL-6, a pro-inflammatory cytokine. On average, our D+E intervention was twice as effective at relieving pain as previous long-term OA trials. We concluded that wider adoption of intensive weight loss with a goal of at least 10% of baseline body weight combined with exercise could reduce the burden of disability related to knee OA.

IDEA was an efficacy study with impressive results, a trial designed to determine the effects of intensive diet and exercise *under ideal circumstances*. However, a common concern from physicians who treat people with knee OA is lack of practical means to implement this treatment in the clinical environment. Indeed, there is no evidence regarding how this efficacious intervention could be successfully adapted to be effective in real world clinical and community settings and also be cost effective.

Participants (age $\geq$ 50 years; BMI $\geq$ 25 kg/m^2) will be randomized to one of 2 groups: diet-induced weight loss and exercise or an attention control group. The sample will consist of 30 ambulatory, community-dwelling persons that meet the ACR clinical criteria for knee osteoarthritis.

Primary Hypothesis and Aim
Hypothesis 1. The study will demonstrate the feasibility of conducting a trial similar to WE-CAN in Cherokee, NC that will recruit American Indian participants. It will leverage the organizational structure and expertise of the parent WE-CAN pragmatic, community-based trial.

Aim 1. To conduct a trial in Cherokee, NC that will be comprised of (a) 90% participants who self-identify as American Indian,, including but not limited to the Eastern Band Cherokee Indian Tribe, and who are older, overweight or obese with symptomatic knee OA; (b) the executive clinical director of Cherokee Indian Hospital to act as site PI and co-investigator of the parent

trial; (c) local community based American Indian staff trained by our coordinating center to deliver the intervention; and (d) an American Indian Community Advisory Board.

Secondary Hypothesis and Aim

Hypothesis 2. A subgroup analysis of the American Indian participants will provide pilot data of whether a pragmatic, diet-induced weight-loss and exercise intervention implemented by local American Indian personnel will reduce knee pain and improve self-reported function, mobility, and health-related quality of life compared to an attention control group.

Aim 2. To determine whether a pragmatic, community-based 3-month, diet-induced weight-loss and exercise intervention reduces knee pain, measured by the Western Ontario McMasters Universities Osteoarthritis Index (WOMAC), and improves WOMAC self-reported function, health-related quality of life as measured by the physical subscale of the SF-36 questionnaire, and 6-minute walk distance (an accepted measure of mobility) in overweight and obese American Indian older adults with knee OA compared to an attention control group.

Study Design

We will randomize 30 overweight and obese (BMI 25 ≥ kg/m^2), adults age ≥50 yrs knee OA into one of 2 groups: an intensive dietary restriction-plus-exercise (D+E) group or an attention control (nutrition and health) group. Our minimum weight-loss goal for the weight-loss group will be 5% of body weight. The exercise intervention will meet 3 days/wk at the clinical site. The intervention will be comprised of both aerobic and strength training exercises. The nutrition and health group will meet 2 times over a 3 month period and will also receive a combination of text messages, emails (via personal email or Facebook), phone calls, and mailings for the remaining months. Participants will be allowed to choose their preferred method.

Measures

Western Ontario McMasters Universities Osteoarthritis Index (WOMAC). We will measure self-reported physical function and pain using the WOMAC (scores will be pulled from the KOOS Questionnaire in which the WOMAC is embedded). The LK version asks participants to indicate on a scale from 0 (none) to 4 (extreme) the degree of difficulty experienced in the last week due to knee OA. Individual scores for the 17 items are totaled to generate a summary score that could range from 0-68, with higher scores indicating poorer function. The pain index assesses participants' pain on the same scale, ranging from 0 (none) to 4 (extreme). The pain subscale consists of 5 items and total scores can range from 0-20, with larger scores indicating greater dysfunction. This instrument has been validated and recommended by the Osteoarthritis Research Society as the health status measure of choice in older adults with knee OA. In order to measure the minimal clinically improvement difference (MCID) participants will be asked to compare their knee pain to how it was at the beginning of the study.

Mobility. Our primary mobility measure will be 6-minute walk distance. Participants are told to walk as far as possible in 6 minutes on an established course. No personal timing devices are permitted, and participants are not provided feedback during the test. Results are significantly correlated to treadmill time and symptom-limited maximal oxygen consumption ($r = 0.52$ and $r = 0.53$, respectively) and have a 3-month test-retest reliability of 0.86 (Pennix et al). The Short Physical Performance Battery (SPPB) will also be used to measure mobility (Guralnik et al).

The SPPB is comprised of the following tests (balance, walking speed, and chair rise). A test of ascending and descending stair activity measured by the time (in seconds) it takes to ascend and descend a flight of 8 steps with 20cm (8 inch) step height and handrail will also be performed.

Cost Effectiveness Resource utilization will be collected by questionnaire, with domains including visits to clinicians (physicians, nurses, physical therapists, others), tests, medications, injections, surgery, alternative therapies. The Work Productivity and Activity Impairment index (WPAI) will be used to assess absenteeism and reduced productivity while at work (presenteeism).

Body weight, height, hip/waist circumference, BMI. Body weight and height will be obtained using standard techniques. Only persons with a BMI ≥ 25 kg/m^2 will be eligible. Circumference measurements will be collected using standard techniques.

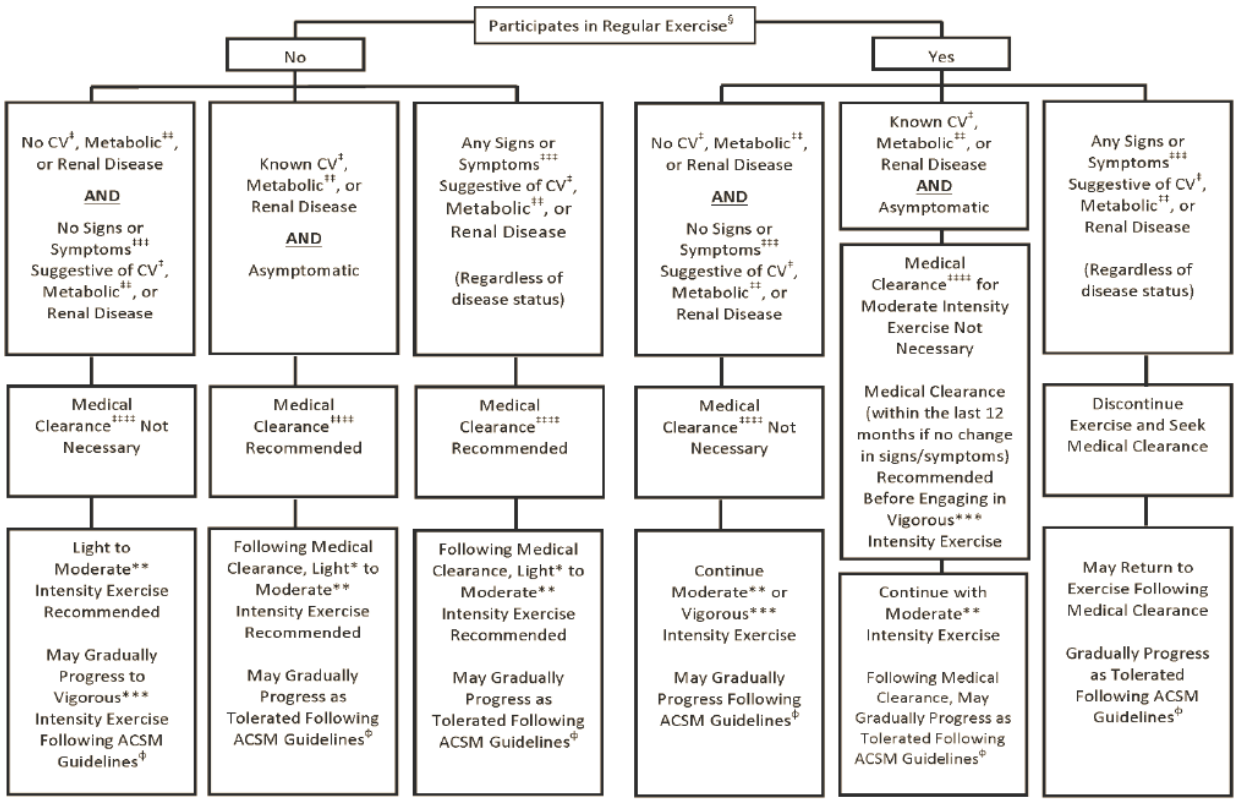
Medical History, Medications, and Blood Pressure. Participants will be given forms to assess medical history and presence of comorbidities. Participants will also be asked questions about their medical history during the phone screen so as to reduce participant burden by identifying potential exclusion criteria. Participants will be administered a medication questionnaire adapted from the ARIC study and widely used in field research and in our prior studies at each testing visit (ARIC).

It is designed to obtain information about all prescription and over-the-counter medicines and supplements used during the 2 weeks prior to the interview (home or clinic). The participants will be mailed the medication form to fill out at home and will return the form to the interviewer. Participants may also be asked to provide the interviewer with all medicine containers so that the interviewer can transcribe the information. In addition participants will be encouraged to notify the study staff of any medication changes during the course of the study.

In addition to the medical history and medication questionnaires, participants will also be given a risk stratification questionnaire at the first screening visit. The purpose of this questionnaire is to determine if participants will need medical clearance prior to enrolling into an exercise program. The determination is based on the presence/absence of cardiovascular/pulmonary/metabolic disease risk factors, sign and symptoms, and known medical history. The following schematic demonstrates how medical clearance will be determined (Figure 1). The American College of Sports Medicine recommends that all patients are first screened to determine if they are participate in regular exercise (defined as performing planned, structured physical activity at least 30 min at moderate intensity on at least 3 days per week for at least the last 3 months). If the participant responds with no medical clearance will be not be needed for those who have not been diagnosed with any CV, Metabolic, or renal disease and are showing no signs/symptoms. If the response is yes those who have not been diagnosed as well as those with a diagnosis and are asymptomatic will not need physician clearance [6]. Like the previous recommendations this is only for moderate intensity exercise. Our exercise protocol falls within this moderate intensity range. The original protocol called for participants to exercise in the range of 50-75% of their maximal heart rate reserve (i.e., moderate to high intensity). The range was previously modified

to 40-60% of maximal heart rate reserve (i.e., moderate intensity). Hence, participants that have no diagnosis of CV, Metabolic, or renal disease or those that have been diagnosed but are asymptomatic will be enrolled without the need for physician clearance. *Those who have signs and symptoms or who have been diagnosed but do not meet the exercise criteria will require medical clearance from their physician.* Final approval and acceptance into the program for patients will be provided by our study physician. It's worth noting the risk of serious adverse events occurring during properly supervised exercise is extremely low (< 1 per 100,000 hours of exercise) even in older adults, with cardiovascular disease. Blood pressure will also be measured.

Figure 1: Exercise preparticipation health screening logic model for aerobic exercise participation [6]



Measures of Quality of Life and Self-Efficacy. The SF-36 is the most widely used and carefully validated measure of health related quality of life and will be used to yield 2 broad summary scores: physical health and mental health [7–9]. The Eurqol Quality of Life will also be used to measure quality of life and health state [10]. The walking efficacy for duration scale measures one's ability to walk/jog at a moderately fast pace for various durations [11]. The Positive and Negative Affect (PANAS) measures both positive and negative affect, leading to more insightful outlooks regarding participants' feeling states. This scale consists of 20 items that reflect the intensity of how the participant "feels" right now [12]. The gait efficacy/environmental efficacy

scale will ask the participants' confidence in performing certain activities [13]. Among the various components of subjective well-being, the Satisfaction with life scale is focused to assess global life satisfaction [14]. The Weight Efficacy Lifestyle Questionnaire (WEL) is a 20-item measure employed to assess self-efficacy for weight management [15]. The Perceived Stress Scale (PSS) will measure the degree to which people perceive their lives as stressful [16]. The adherence self-efficacy questionnaire is designed to assess beliefs in one's ability (confidence) to continue exercising at various intensities and frequencies [11].

Pain Catastrophizing Scale (PCS). The PCS questionnaire will be used to assess catastrophizing (rumination, magnification, and helplessness) [17].

Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS questionnaire will be used to assess the patient's opinion about their knee and associated problems. The KOOS evaluates both short-term and long-term consequences of knee injury and also consequences of primary osteoarthritis (OA) [18]

Intermittent and Constant Osteoarthritis Pain (ICOAP). The ICOAP assesses pain in individuals with knee osteoarthritis taking into account both constant and intermittent pain experiences [19].

Dietary Intake. National Cancer Institute Modified Health Habits and History Questionnaire (HHHQ) provides nutrient assessment of dietary intake and has been shown to be reliable in American Indians [20]. The National Cancer Institute has developed a more recent questionnaire that is now being used DHQ (Dietary History Questionnaire).

Health Literacy. Behavioral Risk Factor Surveillance System measures health literacy [21].

Physical Activity. The Physical Activity Scale for the Elderly (PASE) has proven reliable in many of our clinical trials, including a group of 254 men and women aged ≥65 yrs [22].

Cognitive Functioning/Depression. The Mini Mental State Exam (MMSE) will be used to measure cognitive function and has been measured in older American Indians [23]. Depression will be measured using the Center for Epidemiologic Studies Depression Scale [24]. This measure has previously been validated with older American Indians in the Great Lakes region [25].

Inclusion/Exclusion Criteria

Inclusion Criteria:

(1) Age ≥ 50 years

(2) Knee Pain plus ACR Criteria for Knee Osteoarthritis

(3) BMI = 25 ≥ kg/m^2

Exclusion Criteria:

1. Significant co-morbid disease that would threaten safety or impair ability to participate in interventions or testing (Method: Medical history; medications; physical exam; telephone pre-screen; risk stratification)
    a. Blindness
    b. Type 1 diabetes
    c. History or symptoms of coronary artery disease or pulmonary disease with no medical clearance (symptoms include angina, unreasonable breathlessness, dizziness/fainting/blackouts)
    d. Unable to walk without a device
    e. Lower extremity fracture (within previous 3 months)
    f. Joint Replacement (excluded if double KR or within previous 6 months)
    g. Knee injection or surgery (within previous month)
    h. Lower extremity injury that affects activities of daily living
2. Not sufficiently overweight or obese, BMI < 25 kg/m^2 (Method: Ht/Wt)
3. Not having knee pain: (Method: < 1 on the pain scale, WOMAC and Telephone Screen)
4. Inability to finish pilot study or unlikely to be compliant (Method: Telephone Screen, Screening Interviews)
    a. Planning to leave area > 1 month during the next 3 months
    b. Unwilling to change eating or physical activity habits
    c. Unwilling to attend exercise/diet sessions
    d. Participating in another intervention study (only if the other study has requested they not be enrolled)
    e. Living > 30 minutes from the intervention site
5. Age, age < 50 (Method: Telephone Screen & Demographics Forms)
6. Other conditions that may prohibit the effective delivery of the intervention (Method: Telephone Screen)
    a. Unable to provide own transportation to exercise center
    b. Unable to read or write, cannot speak or read English

Community Advisory Board

We created an American Indian Community Advisory Board as a part of the revision that was submitted to NIH. The investigators plan to involve the community advisory board with the pilot study. The board includes Dr. Ronny Bell, Chair of the North Carolina American Indian Health Board, Dr. Francis Owl-Smith, a pathologist and native Eastern Band Cherokee Indian and former board member of Cherokee Indian Health, and Sheena Kanott Lambert, program director of Cherokee Choices. We also will be working with Turner Goins, professor at Western Carolina University, as a consultant for the study.

Interventions

Diet-induced weight loss plus exercise

Month 1

There will be two individual sessions per month and 2 group sessions per month. The behavioral sessions will focus on awareness of changing eating habits to lower caloric intake. Educational content information regarding what food changes to make, how to make them, and why they are important will be clearly explained and discussed with participants and significant others. Each group session will include problem solving, review of a specific food topic, and tasting of several well-balanced, low-fat, nutritious foods prepared with widely available ingredients. During the individual sessions, the counselor will review individual progress, solve problems, answer questions, and set goals. During the initial individual session, the nutrition counselor will give the participant a weight history background questionnaire. The major emphasis for Period 1 is to enhance participant awareness of the importance and the need to change eating habits, i.e. lower caloric intake for weight loss. Each participant should be given the opportunity to practice skills using goal setting in a stepwise approach. Participants will follow a weekly menu plan which will incorporate meal replacements into their diet plan. Lean Shakes, a General Nutrition Center (GNC), product will be the meal replacement used. Participants may replace the Lean Shakes with a healthy, low-calorie meal of their choice, such as Lean Cuisine. Motivation and encouragement through the combined efforts of the nutrition counselor, the participant, significant others and the nutrition staff will enhance adherence.

Month 2

In period 2 participants will focus on continued weight loss to reach the study weight loss goal of 5% of baseline weight. Participants will follow a weekly menu plan with recipes using traditional foods and the option to incorporate meal replacements. The traditional meals will contain 400-600 kcals, be low in fat and added sugars, and high in vegetables, fruits, and whole grains. Snacks may be a bar, fruit, or vegetable providing ~100-120 kcals. Daily caloric intake for each participant will be adjusted to his or her rate of weight change. Each group will be encouraged to take a daily multivitamin/mineral supplement containing no more than 100% of the Dietary Reference Intake for any particular nutrient.

Month 3

Period 3 will emphasize weight management over time. Participants will continue to follow a weekly menu plan with recipes using traditional foods and the option to incorporate meal replacements.

The exercise intervention will cover a 3-month period. The exercise program will consist of a 15-minute aerobic phase, a 20-minute strength-training phase, a second 15-minute aerobic phase, and a 10-minute cool-down phase. These sixty-minute exercise sessions will be conducted three days per week. Each participant will be prescribed an individual walking prescription by the exercise leader, which will be adjusted accordingly, as each

participant progresses throughout the 3 months. The exercise will be of moderate intensity. Alternate forms of aerobic exercise, such as but not limited to stationary bike, elliptical trainer, or treadmill walking, can be used in place of over-ground walking. This choice could be based on participant preference, the limitations of the exercise facility, or the participant's pain level.

Intervention Locations: The diet and exercise classes will be held at the Ginger Welch Complex.

All intervention staff in the WE-CAN study will be CPR certified. The exercise coordinator, who is part of the coordinating center and is responsible for maintaining exercise protocol congruity, will train and supervise the intervention staff. Intervention staff will meet monthly with the exercise coordinator to discuss any potential problems, risks, and concerns that have risen. AEDs will be available at each location. Emergency drills will be performed monthly in addition the AED will be checked monthly.

Nutrition & Health Intervention

The nutrition and health (attention control) intervention will cover a 3-month period. There will be two total face to face group meetings over the 3 months, with one meeting each at months 1 and 3; and during the other month (month 2) participants will receive a combination of text messages, emails, and phone calls. Participants will be able to select their preferred method. Each group meeting will last approximately one hour and will be held at the Ginger Welch Complex in Cherokee, NC. The sessions will be interactive and will provide useful information on nutrition and general health topics. The Community Advisory Board will give input on the class sessions.

Procedures-Screening and Follow-up Visits.

Measurements	PSV	SV1	RV	FU3	Explanation
Informed Consent		x			
Questionnaires					
Eligibility Questionnaire	x				To determine eligibility
Medical History/Med History FU	xc	x		x	For eligibility and to document changes in health
Risk Stratification	xc	x			Used to screen cardiovascular risk
Comorbidities Questionnaire		x		x	
Randomization		x			
WOMAC		x		x	Pain is primary and function secondary outcomes. Will be taken from the KOOS
Knee Injury and Osteoarthritis Outcome Score (KOOS)		x		x	Assesses patient's opinion about their knee and associated problems
PASE scale		x		x	Physical Activity Scale for the Elderly
MOCA		x		x	Montreal Cognitive Assessment
EuroQol Quality of Life(EQ5D)		x		x	Quality of life measure
Resource Utilization		x		x	Visits to clinicians, tests, medications, injections, surgery, alternative therapies
Work Productivity and Activity Impairment Index		x		x	assesses absenteeism and presenteeism
DHQ II		x		x	NIH Diet History Questionnaire
SF-36		x		x	Health related quality of life (physical, mental)
Health Literacy		x		x	
Adherence Self Efficacy		x		x	Confidence in exercising at various intensities and frequencies
Adherence for Duration		x		x	Confidence in walking for different durations
Gait Efficacy		x		x	Confidence in completing tasks
Demographics		x			
Medication form		x		x	Atherosclerosis Risk in Communities form
Weight Efficacy Questionnaire		x		x	Self-Efficacy for Weight Management
PANAS		x		x	Positive and Negative Affect Scale
SWL		x		x	Satisfaction with Life
Perceived Stress		x		x	Stress
Pain Catastrophizing Scale		x		x	Catastrophizing
Intermittent and Constant Osteoarthritis Pain (ICOAP)		x		x	Intermittent and Constant Pain
CES-D		x		x	Depression
Transition Questionnaire				x	Knee pain
Adverse Events				x	Also collected as they occur
Physical Performance Tests/Knee Exam					
height	xc	x			To determine BMI
weight	xc	x		x	To determine BMI
Knee exam		x			To determine eligibility
6 minute walk		x		x	Measure of mobility
Expanded Short Physical Performance Battery (SPPB)		x		x	Gait speed, sit to stand, balance tests; predicts disability
Randomization		x	x	x	mobility measures

Procedures-Screening and Follow-up Visits.

Prescreening visit (PSV). Individuals who contact our recruitment office in response to advertising will be asked a series of brief questions that focus on major eligibility criteria. A screening visit appointment will be made for participants who meet major eligibility criteria. A medical history form and a medication form will be mailed to the participants for them to complete.

Screening Visit One (SV1) SV1 includes an explanation of the study and obtaining informed consent. Other assessments include medical history and medication use (previously mailed), cardiovascular risk, height and weight (to calculate BMI), hip/waist circumference

measurements, blood pressure, and a knee exam. The MOCA & CES-D will be administered. The following questionnaires will be given: demographics, cost effectiveness questionnaires, WOMAC, KOOS, Physical Activity Scale for the Elderly (PASE), Health-Related Quality of Life (HRQL), dietary intake questionnaires, health literacy, perceived stress, pain catastrophizing, and efficacy measures. Physical performance measures include the SPPB, 6 minute walk, GaitRite, and stair climb. This screening visit will last approximately 3 - 4 hours.

Randomization Visit (RV) At the RV an orientation to the group will be done.

3-month Follow-up Data Collection Visit (FU3): Participants will return to repeat all measures collected at baseline (minus the knee exam and demographics). The testing session will last approximately 2.5 – 3.5 hours. At the end of 3 months the participants will have a mini session on what the other group received.

Safety Monitoring Plan

An internal safety committee has been established to monitor participant safety and to evaluate the progress of the study.

Statistical Considerations

Data Management
The Data Management Group, part of the Coordinating Center, has primary responsibility for randomization and analyzing data generated by the clinical centers. Data will be collected on hard-copy forms at each site and transformed to an electronic database. Our web-based management system will assure integrity and validity. Dynamic reports and periodic statistical analyses will monitor quality. A participant-based inventory system will track recruitment, retention, adherence, and missing data from entry through exit, close-out, and lock-down of final datasets. Our team developed a similar database for the IDEA and START studies.

Statistical Analyses
Statistical analyses will be conducted according to intention-to-treat principles using SAS.

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