

I. Background

The “Knee osteoarthritis Exercise and Education Program-Active” (KEEP-Active) for individuals with knee osteoarthritis (OA) will include combined aerobic and strength exercise (CASE) and self-management education (SME) guided by the framework of the social cognitive theory (SCT). The participants of the program will complete both patient-reported and performance-based outcome measures to measure their progress.

A seminal study demonstrated that aerobic or strengthening exercise regimens were superior to health education alone logging improvements in 6-minute walk distance (6MWD) and timed functional measures such as stair climbing and lift-and-carry tasks,¹ showing that either mode of exercise can result in improved fitness. Recent research has demonstrated that CASE is beneficial for patients with knee OA on multiple outcomes.²⁻⁴ A 2016 RCT found clinically meaningful improvements of 33% and 15% in the Western Ontario and McMaster Universities Osteoarthritis Index-physical function (WOMAC-pf) and 6MWD, respectively². There were also significant reductions in pain, get-up-and-go times, and trends toward significant improvements in daily physical activity (PA) levels.² The aerobic portion, which consisted primarily of walking, began with bouts as short as 10 minutes² and progressed up to 30 minutes total at intensities of 50-70%HRR.¹ Stationary cycling was offered for those who could not achieve the appropriate intensity with walking as a result of pain or comorbidities.² Evidence suggests that CASE is further enhanced when delivered in a group setting using constructs from the SCT.³ One study found moderate-vigorous PA levels in the treatment group were double that of the exercise-only group and were sustained 9 months after the study ended, suggesting both immediate and long-term effects on

exercise self-efficacy.³ Both aerobic and strength training are considered core management strategies in the treatment of knee OA⁵ and are important for the preventing development of other chronic conditions.⁶ Furthermore, offering both interventions in a group-based community setting can help build social support, improve motivation, and develop exercise skills that may influence activity levels.⁷ In many studies, the strengthening portions of the program took approximately 20-30 minutes and included exercises for the upper and lower extremities, with a greater emphasis on the latter.²⁻⁴ They utilized a variety of free weight and machine exercises to accommodate individual needs and abilities.¹⁻³ Research has shown that 2-4 sets of 8-12 repetitions at 60-80% 1RM has resulted in the previously described benefits.^{1,2} Where 1RM testing isn't feasible, the Borg RPE scale can be used to measure subjective intensity of both aerobic and strengthening exercise with participants being encouraged to stay between 11-15 on the 6-20 scale.^{3,8} Using a subjective intensity scale could give the participants a skill that allows them to reproduce similar intensities while exercising independently. The CASE interventions will be delivered in a group fashion but will be tailored to account for different fitness levels and comorbidities.² A brief group-mediated activity counseling (GMAC) session delivered after exercise has been shown to improve self-motivation and self-regulation skills.³ The discussion topics were guided by the SCT and included goal setting and action planning targeted towards improving exercise adherence and habitual PA.³ This small group design allows for social support and uses group dynamics to identify barriers and facilitators—these socioenvironmental factors are key constructs of the SCT that may promote healthy behavior change.¹⁰ When CASE and GMAC are used in this fashion both exercise self-

efficacy and satisfaction with function trend upward, which may mediate changes in PA levels.³

The second part of the program will be SME—another core component of knee OA management.⁵ One study found sustained long-term improvements of 19%, 30%, and 32.5% for timed up and down stairs, timed-up-and-go (TUG), and five-times-sit-to-stand (FTSST), respectively.⁸ These improvements along with significant increases in PA were observed after only one day of education delivered by a multidisciplinary team.⁸ Another SME program delivered in a community setting resulted in 23% improvement for WOMAC-pf as well as 30% reduction in pain.⁹ The results from both of these studies^{8,9} indicate that education can have a meaningful effect on both patient-reported and functional outcomes and should be a part of community program for patients with knee OA. Educational sessions will be delivered on a regular basis in a small group setting and will cover topics pertinent knee OA including: anatomy and pathophysiology, treatment options, benefits of exercise, medications, techniques to alleviate pain, coping strategies, activity modification, and nutrition counseling for weight management.^{8,9} The small group setting encourages interactive discussion and social support.⁹ Research has indicated that compliance and adherence are improved when patients receive non-conflicting information and support from multiple health care professionals.^{7,8} Patient's with knee OA commonly believe exercise results in joint destruction and some have been given advice that exercise is harmful.^{7,9} The SCT involves an interplay between socioenvironmental, cognitive, and behavioral factors.¹⁰ If a patient has been told that exercise is harmful then they may expect poor outcomes and as a result not engage in PA.⁹ Therefore, the SME component delivered by multiple

disciplines is necessary to dispel misguided “normative beliefs” and improve self-efficacy.¹⁰ Lastly, groups that receive printed materials in addition to face-to-face education, are more likely to improve their knowledge and skills which may translate into an improved ability to perform certain healthy behaviors.^{9,10}

The WOMAC is a patient-reported health status measure designed for use in patients with knee OA.² The WOMAC has been shown to be valid, reliable, and responsive to change² making it an ideal choice for measuring progress. The WOMAC has 3 subscales (pain, stiffness, function),^{2,9} however, this program will primarily focus on the results of the physical function subscale as decreased function has been shown to be a risk factor for decreased PA levels.² The WOMAC-pf subscale MCID is -9.1 points or 26% change from baseline.⁹ Participants who exceed the minimal clinically important difference (MCID) may be encouraged by their improvement and motivated to continue being active.¹⁰ Since the program is hinged on improving PA levels and self-management of knee OA symptoms, it’s important to use a measure such as the WOMAC to track the effectiveness of the program components on achieving this goal.

Aerobic capacity is directly targeted in this program and is highly correlated with higher levels of PA.⁶ The 6MWT is a well-established measure of exercise capacity and has been shown to be valid and reliable when used with patients that have knee OA.^{2,11} While OA-specific norms values are not available, there are norms for healthy community dwelling adults aged 60-89¹² which can be useful for goal setting and monitoring progress over time. A clear MCID has not been established with values ranging from 20-50 meters in community-dwelling elderly.¹¹ While this range is wide, participants in this range or exceeding it could be motivated by their progress.

The 30-second chair stand test (30CST) is a valid and reliable measure of lower extremity strength in older patients with knee OA and reduces the ceiling effects of other repetition-based sit-to-stand tests.¹¹ Normative values are available from community dwelling adults based on age (60-94), sex, and PA level¹³ which can be helpful for goal setting and measuring progress. While there are no established MCIDs for patients with knee OA, the MCID for patients with hip OA ranges from 2-2.6,¹¹ which could be used for participants in this program. Patients with knee OA often have decreased lower extremity strength secondary to decreased levels of activity.^{6,9} Administering the 30CST before and after the program can help evaluate the effectiveness of the strengthening interventions and provide evidence to patients on their progress. Showing the patient objective progress may improve self-efficacy and reinforce healthy behaviors.¹⁰

The Longitudinal Aging Study Amsterdam Physical Activity Questionnaire (LAPAQ) is a valid and reliable measure of minutes of PA in older adults.^{2,14} The LAPAQ assess both frequency and duration of activities such as walking, gardening, household activities, and sporting activities performed over the previous 2 weeks.^{2,14} Tracking weekly minutes of PA can be useful for goal setting and activity planning if administered on a regular basis. Additionally, the LAPAQ can be used to see if PA levels are maintained after the program has ended.² Since regular PA is paramount to nonoperative knee OA management and prevention of chronic conditions,⁶ it's important to use a metric such as the LAPAQ to track changes in habitual PA. By delivering the aforementioned evidence-based interventions based on the constructs of the SCT, KEEP-Active can help individuals with knee OA improve disease self-management, physical function, and long-term adherence to PA.

II. Program Goals

The overall program goals of KEEP-Active are to provide education on disease self-management, improve physical function, and promote long-term adherence to PA in patients with knee OA. The following goals are what KEEP-Active hopes to achieve at the end of the 12-week community-based program.

1. Participants will improve their WOMAC-physical function score -9.1 points (0-100) or 26% from their baseline score to meet the MCID by the end of the 12-week KEEP-Active program to demonstrate improved patient-reported physical function and disease self-management.^{2,9}
2. Participants will improve their WOMAC-pain score -10 points (0-100) or 20% from their baseline score to meet the responder criteria by the end of the 12-week KEEP-Active program to demonstrate improved self-management of symptoms.^{2,15}
3. Participants will improve their 6MWT an average of 50 meters to exceed the MCID by the end of the 12-week KEEP-Active community-based program to demonstrate improvement in aerobic capacity.¹¹
4. Participants will improve their 30CST by an average of 3 repetitions to exceed the MCID by the end of the 12-week KEEP-Active community-based program to demonstrate improved lower extremity strength.¹¹
5. Participants will improve-to, maintain, or exceed at least 150 minutes per week of moderate-intensity activity as measured on the LAPAQ by the end of the 12-week program and at 24-week follow-up in order to meet the minimum guidelines for PA.^{2,14,16}

III. **Methods**

1. **Personnel**

- a. There will be two primary physical therapists leading the program assessments, exercise sessions, and the self-management education sessions. One therapist will lead the exercise sessions and post-exercise group activity counseling session. The other therapist will coordinate and lead the education sessions.
 - i. Both therapists will be present on the 4 planned assessment days. Both therapists will work with other providers to plan education topics and develop handouts. Local physical therapists will be recruited to volunteer their time on regular program meeting days and assessment days. A goal of 4 therapists will be set for assessment days to help them run efficiently.
- b. For the self-management education sessions, a multidisciplinary team will be assembled consisting of an orthopedic surgeon, physician, pharmacist, certified exercise physiologist, clinical psychologist, social worker, and dietician.^{8,9} The physical therapist will share the purpose of the program with each clinician so that their presentations are in line with the goals of the program.
- c. Volunteers with (i.e. certified personal trainers) experience guiding exercise will be recruited from the program location and surrounding local gyms. These volunteers will assist the physical therapists during each exercise session by monitoring participants and making exercise modifications. These volunteers will be educated about the knee OA population prior to the first session.

2. **Location**

- a. Nautilus Family Fitness Center – All program events will be held at Nautilus Family Fitness Center in Asheboro, NC. The gym requires a small monthly membership fee of \$20, or, \$35 per couple. Membership includes unlimited access to gym equipment and group fitness classes. Nautilus is equipped with machines, free weights, elastic bands, and a large private multipurpose room where most of the program components will take place. Chairs and a projector are available for the education sessions.

3. Enrollment and Program Schedule

- a. Participants will learn about the program through flyers posted in local physician practices, physical therapy clinics, grocery stores, and senior centers. Local clinicians will be encouraged to recommend patients for participation.
- b. A cohort of 20 participants will enroll by calling the program director where they will be told the location and time of the initial assessments.
- c. The first day of the program will be held on a Saturday morning at Nautilus. Participants will arrive between 9 and 10 a.m. to fill out a preparticipation health screening form and complete baseline program outcome measures (i.e. WOMAC-pf). After completing the self-report measures, the participants will be given a brief 10-minute overview of the program with a printed summary and schedule provided. Initial performance measures will be administered by the 4 physical therapists after the overview. The first day of the exercise portion of the program will begin on Tuesday of the following week.
- d. The schedule will consist of two CASE training sessions and one self-management education session per week. There will be one GMAC session

per week. There will be an abbreviated optional CASE training session offered before the self-management education session. The program meetings are intentionally spread throughout the week to allow time for recovery between sessions. The weekly meeting days and times will be consistent throughout the program and are depicted in the calendar below.

JUL2020 **KEEP-ACTIVE PROGRAM SCHEDULE**

SUN	MON	TUE	WED	THU	FRI	SAT
CASE = combined aerobic and strengthening exercise GMAC = group-mediated activity counseling SME = self-management education *All activities held at Nautilus Family Fitness Center in Asheboro, NC				01	02	03 9am: Enrollment, initial assessment & program overview
05	06 6-715am: CASE 730-750am: GMAC	07	08 6-715am: CASE	09	10 815-845am: Optional CASE 9-11am: SME topic: Knee anatomy and pathophysiology	11
12	13 6-715am: CASE 730-750am: GMAC	14	15 6-715am: CASE	16	17 815-845am: Optional CASE 9-11am: SME topic: Treatment options and benefits of exercise	18
19	20 6-715am: CASE 730-750am: GMAC	21	22 6-715am: CASE	23	24 815-845am: Optional CASE 9-11am: SME topic: Diet and nutrition	25
26	27 6-715am: CASE 730-750am: GMAC	28	29 6-715am: CASE	30	31 9am: Assessment day	August 1

4. Detail of Interventions

Each CASE training session will begin with a 5-minute warm-up and period consisting of low intensity walking or cycling. The aerobic portion of the session will consist of 20-30 minutes of walking or cycling at a moderate intensity of 11-15 RPE or 50-70% HRR. After the aerobic portion, participants will begin the strength training portion, which will be set-up in a station-based format to maximize the 20-30 minutes of allotted time. Participants will complete 2-4 sets of 8-12 repetitions at intensities between 11-15 RPE. The focus will be on lower extremity exercises; however, upper extremity exercises are also incorporated into the program. The physical therapist and

volunteers will be present throughout the CASE training session to answer questions, offer support, make modifications, and educate the participants about the relevance of the chosen exercises. The intensity and volume of exercise will increase each week using the principle of progressive overload. The participants will record specific exercises and parameters used during each session. After a 5-10-minute cool-down, participants will grab chairs and form a circle in the multipurpose room for GMAC. The chart below provides additional details about the program.

CASE & GMAC	SME		
<p>5-minute active warm-up</p> <p>Aerobic exercise</p> <ul style="list-style-type: none"> • 20-30 minutes of aerobic exercise <ul style="list-style-type: none"> ○ Walking will occur in the multipurpose room or outside in the large parking lot if weather permits. ○ Moderate intensity: RPE 11-15 or 50-70% HRR <p>Strength exercise</p> <ul style="list-style-type: none"> • 20-30 minutes of strength exercise <ul style="list-style-type: none"> ○ 2-4 sets, 8-12 repetitions or the number needed to induce fatigue, 1-2 min rest intervals ○ Moderate intensity RPE 11-15 ○ Leg press, leg extension, leg curl, step-ups, calf raises, squats, glute bridge, and forward lunges ○ Upper extremity exercises using machines, bands, and free weights <p>5-10-minute active cool-down</p> <p>GMAC</p> <ul style="list-style-type: none"> • 15-20 minutes • Topics: symptom self-monitoring, group and individual goal setting, identifying barriers to meeting goals, and a written action plan 	Topic	Personnel	
	1	Knee anatomy and pathophysiology	Orthopedic surgeon, physical therapist
	2	Treatment options and benefits of exercise for Knee OA	Orthopedic surgeon, exercise physiologist, physical therapist
	3	Diet, nutrition, and weight management	Registered Dietician
	4	Review: group discussion of topics	Physical therapist
	5	Coping Strategies and mental health	Clinical Psychologist
	6	Medications and pain management strategies	Physician, pharmacist, and physical therapist
	7	Importance of leisure, sports, and social gatherings	Social worker and physical therapist
	8	Exercise workshop: Different options for exercise, measuring intensity, activity modification, long-term PA planning	Physical therapist, personal trainer
9	Review: tying all the topics together	Physical therapist	

The GMAC sessions will be facilitated by the physical therapist but led by the group. The participants will discuss group and individual goals, barriers and facilitators to PA, problem-solving, as well as pain-management and relaxation strategies. Participants will work together to develop written action plans for improving weekly moderate-vigorous PA and managing symptoms of knee OA. These action plans will be reviewed, discussed, and modified each week.

The SME portion of the program will be held on Saturday mornings and will be preceded by an optional 30-minute CASE workout. This short session is designed to show participants that benefits can be achieved with shorter bouts of exercise. Each SME session will cover a topic presented by a member of the multidisciplinary team and is designed to build on itself every week. There will be a total of 9 sessions: 7 unique topics and 2 review sessions to help consolidate the information. At a minimum, each presenter will have a PowerPoint presentation and a printed handout summary. The sessions will last 1 to 2 hours with one hour of presentation and plenty of time for questions and interactive group discussion.

Participants are encouraged to attend all sessions for the duration of the 12-week program and will be encouraged to exercise independently on non-programmed days. All outcome measures will be assessed every 4 weeks by physical therapists. Printed copies of the WOMAC and LAPAQ will be provided by the program director. Standardized directions will be printed for the 6MWT and 30CST; both will be performed in the multipurpose room. A measuring wheel and stopwatch will be used to calculate 6MWT distance. The results of the assessments will be logged by the physical therapist and the participants will be able to keep their scores and keep track of their progress.

IV. Program Evaluation

The KEEP-Active program will conduct 4 assessments of its participants throughout the program—the initial assessment and 3 follow-up assessments which will occur once every 4 weeks. Scores will be logged and assessed by the two physical therapists. Average group scores for the 6MWT, 30CST, WOMAC-pf, WOMAC-pain, and LAPAQ will be calculated and compared to baseline scores. The results of the assessments will allow the program director to gauge the effectiveness of the program interventions at each time point. By the end of the 12-week program, participants should improve WOMAC-pf scores by -9.1 or 20%, WOMAC-pain scores by 10 points or 20%, 6MWT by 50 meters, and 30CST by 3 repetitions in order to meet clinically important change values.^{2,9,11,15} Participants will also improve their weekly moderate-intensity PA levels as measured by the LAPAQ, to at least 150 minutes per week by the end of the 12-week program and 12-weeks after the program has ended in order to meet national PA guidelines.^{2,14,16} The 24-week follow-up LAPAQ will be mailed to the participants with stamped return envelopes provided by the program director. The weekly PA levels will be compared to the results of the other assessments to identify trends and characteristics of patients with different PA levels. Regular assessments can inform the program director, participants, and other clinicians about the effectiveness of the program interventions.¹⁷ If a trend towards meeting the program goals is not observed, changes will be made to the interventions to improve the trajectory of outcomes.

Surveys will be utilized at 6 and 12-weeks to assess satisfaction of the program participants and personnel. Additionally, participants and presenters will complete an abbreviated survey about presentation delivery and whether or not their understanding

of the topic was improved after each SME session. These surveys will provide qualitative data about the program to inform the program director about the strengths, weaknesses, degree of perceived benefits, and overall implementation of the program.¹⁷ Questions about the program content, location, time of classes, frequency of classes and cost of the program will be included.¹⁷ The participant surveys will also include questions to determine the attribution of the program interventions towards meeting goals and the willingness of participants to plan and engage in PA. All of the questions will be analyzed to determine the effectiveness of the program. Attendance data will be collected with sign-in sheets at each meeting and will be analyzed with the results of outcome measures and qualitative data to identify trends in participation. This data will be valuable to ensure appropriate use of time and resources, improve program implementation, and demonstrate accountability for potential program funders.¹⁷

Program evaluation is paramount to the success of the KEEP-Active program for patients with Knee OA. Engaging all of the stakeholders in the evaluation process will ensure the program continues to improve and will result in meaningful outcomes for its participants.

V. Conclusion

KEEP-Active will be beneficial for individuals with knee OA in the Asheboro area by addressing self-management skills, and long-term adherence to exercise and PA through evidence-based interventions. Knee OA is characterized by pain, decreased function, and decreased quality of life. Despite PA being recommended as the first line of treatment, the majority of individuals with knee OA do not meet the recommended guidelines.³ By providing participants with the interventions and educational components in the KEEP-Active program, they could slow the progression of knee OA, improve their PA levels, and reduce the risk of developing other chronic diseases.³ By utilizing the SCT, KEEP-Active will help participants improve their self-efficacy, outcome expectations, and knowledge about exercise and disease self-management.¹⁰ The small group atmosphere offers additional benefits creating a social support network of participants with the same chronic disease.¹⁰ Lastly, KEEP-Active employs the expertise of a united, professional, multidisciplinary team to deliver education designed to improve the participant's perception of exercise and skills needed self-manage their knee OA, long-term. KEEP-Active and its components will improve physical function, disease self-management, and long-term adherence to PA. These outcomes will improve participant health-related quality of life, delay or prevent the need for TKA, and reduce the risk for developing other chronic diseases.

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