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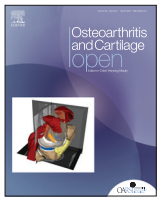

Optimizing osteoarthritis care through clinical and community partnership: Results of an exploratory trial

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ABSTRACT

Background/Purpose: To conduct an exploratory trial of a clinic-community care model (OA CARE) for managing osteoarthritis (OA).
Design: Participants (n = 60) with symptomatic knee or hip OA and overweight/obesity were randomized to OA CARE or a usual care control group (UC). Participants in the OA CARE group received a 12-month medical membership to a local YMCA, which included a 12-week weight loss program and access to exercise programming, as well as referrals to rehabilitation, nutrition, sleep-related and psychological services. Participants' primary care clinicians were given a video-based summary of OA treatment guidelines. Feasibility metrics included engagement with the weight loss program and exercise resources. Outcomes were assessed at baseline, 6-months and 12-months. The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Outcomes were analyzed between groups across time points using general linear mixed models.
Results: Eighty-seven percent of the OA CARE group participated in the weight loss program, with a mean attendance of 9.2 sessions; 57 % participated in an exercise class. At 6-months, there was a statistically significant between-group difference in change in WOMAC total scores, with the OA CARE group showing greater improvement (−11.0, 95 % Confidence Interval −20.1, −1.9). At 12-months, the between-group change in WOMAC score was not statistically significant, though there was a small difference in favor of OA CARE Group (−4.9, 95 % Confidence Interval −14.1, 4.3).
Conclusion: Feasibility metrics were positive, but effects of OA CARE were modest, and a more intensive approach may be needed to enhance impacts.

1. Introduction

Management of knee and hip osteoarthritis (OA) requires a combination of pharmacological and non-pharmacological therapies [1–4]. In particular, high quality guidelines consistently recommend the use of exercise, education, and weight management, as well as consideration of non-steroidal anti-inflammatory drugs and intra-articular corticosteroid injections [5]. However, many studies have documented deficiencies in quality of care, particularly with respect to recommended behavioral components (e.g.,weight management, physical activity) [6–10]. For example, in a national US survey only 57 % of patients with arthritis (including OA) report that a health care provider ever recommended

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physical activity, and only 46 % of those with arthritis and overweight report that weight loss was recommended [9,10]; this is concerning because the majority of individuals with OA have overweight/obesity and do not meet physical activity recommendations [11,12]. While factors underlying these deficiencies are multifactorial, potential drivers include a lack of standardized models for comprehensive OA management and limited time to address non-pharmacological aspects of OA care during clinic visits. These challenges may be particularly salient in the context of primary care, where OA is treated for the majority of the disease course.

In response to the persistent shortcomings in OA management, there has been growing interest in the development of systematic OA care models [13–15]. However, research is limited on OA care models in the U.S. [16,17]; this is important because models developed in one health care context may not fit the organizational or payment structures of health systems in other countries. To address this gap, we developed the OA Clinic-Community CARE Model (OA CARE) based on the following core principles: 1) alignment with OA treatment guidelines through a multifactorial and standardized approach that includes both pharmacological and non-pharmacological components; 2) emphasis on delivery of behavioral interventions, which are considered first-line treatments, appropriate for all patients with hip and knee OA [1–4]; 3) incorporation of a stepped care approach [18], in which all patients begin with first-line interventions (weight management and physical activity) and then consider additional therapies based on needs and preferences; and 4) a clinic-community partnership in which the YMCA delivers weight management and exercise programming, which addressed scalability since it is challenging to deliver these components adequately in clinical settings, and YMCAs exist throughout the U.S. The Centers for Disease Control and Prevention, Institute of Medicine and other organizations have recommended and prioritized clinic-community partnerships based on evidence for effectiveness [19]. However, previously studied OA care models have largely been clinically-based or remotely delivered [13–15], including self-directed and clinician-directed exercise programs [20–22]; they have not formally incorporated established community-based organizations as key partners in delivering components of OA management. We conducted an exploratory trial to evaluate the feasibility and acceptability of OA CARE and to collect preliminary data on the efficacy of this care model.

2. Methods

2.1. Study design

This was an exploratory trial with 60 patients randomized to OA CARE or a usual care (UC) control group. Assessments were conducted at baseline, 6-months and 12-months. Participants randomized to the UC group were offered a 12-month YMCA Medical Membership (described below) once they completed follow-up assessments. This study was reviewed and approved by the Institutional Review Board of the University of North Carolina at Chapel Hill. The study was registered on Clinicaltrials.gov (NCT05349500) on April 21, 2022, and recruitment began on May 24, 2022.

2.2. Participants, recruitment and randomization

Participants were patients with clinician-diagnosed knee or hip OA, self-reported knee or hip pain of $\geq$3 (scale of 0–10) on most days of the week, body mass index (BMI) $\geq$27 kg/m^2, and not currently meeting physical activity recommendations [23]. We chose a minimum BMI of 27 kgm [2] because of the association with earlier mortality and the precedence of this threshold in other OA trials [24–26]. Exclusion criteria were: major surgery of hip, knee or ankle in the past 6 months; planning a total joint replacement in the next 6 months; 3 or more falls in the last 6 months; significant cognitive impairment; hospitalization for a cardiovascular condition in the last 6 months; psychosis; substance abuse disorder; other health conditions determined by the study team to be contraindications to a home exercise program; participation in another interventional study related to knee or hip OA, weight loss or physical activity. Participants were recruited from Internal Medicine and Family Medicine clinics in an academic medical center. Patients with knee or hip OA were identified by the study team via the electronic health record (EHR; ICD-10 codes M15 (0.0-0.9), M16 (0.0-0.9), M17(0.0-0.9), M19 (0.9-0.93) or referred to the study team by their primary care provider. A study team member then contacted potential participants to assess interest and administer a brief screening questionnaire. All eligible patients were asked to attend a baseline visit and then wear an accelerometer at home to assess physical activity. Following return of the accelerometer, participants were informed of their randomization assignment via telephone. Participants were randomized with equal allocation to OA CARE and UC groups, with block sizes of 20. The rationale for block size was that 10 participants were needed in the intervention group to start a new weight loss class. The randomization code was generated in SAS (Cary, NC), using the PROC PLAN procedure.

2.3. OA CARE content and administration

2.3.1. Overview

OA CARE was designed to address all aspects of knee and hip OA treatment recommendations [1–4] (Fig. 1). This was accomplished through three complementary components. First, all participants were provided with access to weight management and exercise programs through the YMCA. Second, participants were assessed for needs and interests in additional, more specialized services with an evidence base for improving OA outcomes: physical therapy, psychological interventions, additional weight/nutrition-related services and sleep-related services [1–4,27,28]. Third, primary care providers of participants were provided with education related to OA treatment guidelines and engaged in referrals to clinical therapies, as appropriate. Details for each component are as follows.

2.3.2. Weight loss & exercise interventions

Weight loss and exercise programs were delivered by the YMCA of the Triangle, within the structure of a Medical Membership. This membership provides access to group exercise programs, exercise facilities, exercise classes (in person and online) and a health coach. All patients in OA CARE began with participation in the YMCA's Weight Loss Program. This program involves 12 weekly sessions that include goal-setting, food and activity tracking, introduction to physical activity offerings, and self-reported weigh-ins. Topics for the 12 sessions are as follows: 1: Get to Know One Another, Get to Know Yourself, 2: Get to Know Your Environment, 3: Goal Setting, 4: Putting It All Together, 5: Understanding Food Choices,6: Physical Activity, 7: Mindfulness, 8: Positive Psychology, 9: Stress and Sleep, 10: All Foods Fit, 11: Sustaining Your Progress, 12: Celebrating Your achievements. The Weight Loss Program was delivered to OA CARE members via a videoconferencing platform (to accommodate participants living in different geographical areas) in groups of 10. Participants were also mailed a handout with information on physical activity and osteoarthritis (Supplement 1).

2.3.3. Additional tailored services

At 6-month follow-up an OA CARE Navigator with training in health coaching engaged participants in a screening and shared decision-making process regarding additional interventions (Fig. 1, Table 1). Prior to this call, participants were mailed an information sheet describing potential referrals and additional resources, including additional weight management and physical activity interventions (Supplement 2). The shared decision-making process focused on therapies and services for which participants met criteria for potential need, shown in Table 1, but participants could be referred or guided to resources for any additional interventions. All referrals for medical services (e.g., physical therapy, sleep testing) were coordinated with the primary care provider.

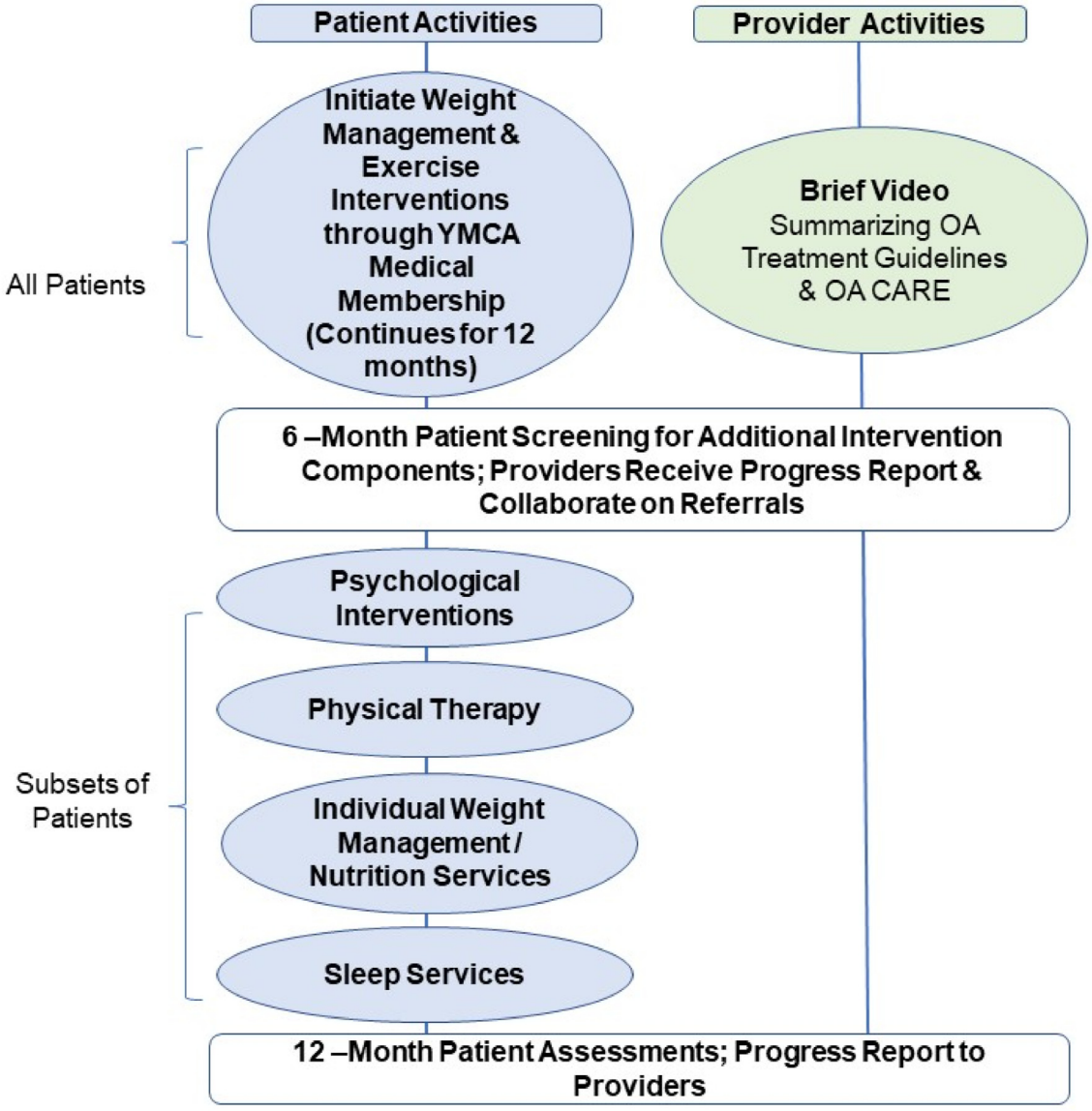

Fig. 1. OA care intervention.

2.3.4. Provider intervention

The three-component primary care provider intervention was designed to be brief to maximize feasibility and engagement. First was a brief video summarizing current OA treatment guidelines, developed by our study team, with a focus on practical application and the role of the primary care provider (https://youtu.be/idk0c35mW6A). Second, providers received progress reports for their enrolled patients through the EHR; this included changes in symptoms and engagement in weight loss and physical activity programs. Third, providers were involved with referrals to additional services, as noted above.

2.4. Outcomes

Assessments were conducted at baseline (in person), 6-months (phone) and 12-months (in-person) by a trained study team member blinded to participants' randomization assignment.

2.4.1. Feasibility and acceptability metrics

We computed the proportion of eligible patients who consented to participate in the study, proportions of participants who completed follow-up assessments, and patient engagement in YMCA classes and OA CARE Navigator calls. We report the frequencies and proportions of participants who met criteria for and were interested in each type of additional service (at 6-month follow-up), along with participants' self-reported use of these services during the study period. We also asked participants in the OA CARE group to complete a series of satisfaction ratings regarding the program overall, interactions with the OA CARE Navigator, and the YMCA programs; all items were rated on a scale of 0 (not helpful at all) to 10 (very helpful).

2.4.2. Primary patient outcome: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The primary outcome for this study was the WOMAC, a measure of lower extremity pain (5 items), stiffness (2 items), and function (17 items) [29]. All items were rated on a Likert scale of 0 (no symptoms) to 4 (extreme symptoms). The WOMAC has well established psychometric properties including reliability, construct validity and internal consistency [30]. We also separately examined WOMAC pain and function subscales.

Table 1
Criteria, referrals and use of additional therapies in OA CARE group.

Type of Service	Criteria for Potential Need	Example Interventions & Resources	# Patients Meeting Criteria	# Referral sent to Primary Care Providers	# Patients Reporting Use of Service at 12-month Assessment
Psychological interventions	Subgroups for targeted treatment (STarT back) tool [48–50]: 4 or more psychosocial risk factors (pain bothersomeness, fear, worry, catastrophizing, depression) [51]	Free, evidence-based pain coping skills training programs, referral to local mental health providers who specialize in pain management	1	1	1 (self-directed resource)
Physical therapy	Persistent self-reported difficulty with walking or stair-climbing, balance difficulties, recent falls or pain as a limitation to engaging in regular exercise	Referrals based on based on patients' preferences for location, geography, and health insurance coverage	18	6	8
Weight Management & Nutrition Services	< 5 % weight loss from baseline [46]	Referrals to registered dieticians and other credentialled clinicians who specialize in weight loss support	13	5	Not assessed[a]
Sleep Services	Sleep apnea: "High risk" based on the STOP questionnaire, score ≥2 [52]. Insomnia: Score ≥11 on the insomnia Severity index [53].	Referrals for sleep testing, recommendations for free, evidence-based cognitive behavioral therapy for insomnia programs, and referrals to local providers or group programs focusing on sleep-related therapies.	Sleep apnea: 7, insomnia: 4	3	2 (1 self-directed, 1 clinical service)

[a] Participants were not asked specifically about weight management & nutrition services beyond the YMCA class.

2.4.3. Secondary patient outcomes

2.4.3.1. Body weight. We assessed body weight using the clinic scale at baseline and 12-months. Since the 6-month follow-up assessment was conducted via telephone, weight was collected via self-report at that time point. We also measured participants' height at baseline to calculate BMI.

2.4.3.2. Physical Activity. All participants were asked to wear an Actigraph GT3X+ (Pensacola, FL) [31] at the hip during waking hours for 7 days. Data were cleaned and processed using standard methods which have been used successfully in our prior studies [32]. Physical activity metrics included minutes of any intensity activity, minutes of moderate to vigorous intensity physical activity (MVPA), step counts and sedentary minutes. We also asked participants to complete a modified version of the Community Health Activities Model Program for Seniors Physical Activity Measure (CHAMPS) [33], which provides information on the types of activities in which participants engaged. The CHAMPS has been shown to effectively measure high-light activity, total activity and MVPA in older adults [34]. From this measure, we computed self-reported minutes of MVPA per week.

2.4.3.3. Physical function. At 12-month follow-up, we administered a 30-s chair stand test, Timed Up-and-Go test, and 2-min march test in accordance with established protocols [35,36]. Based on strong psychometric properties, feasibility to administer, and expert consensus, the 30-s chair stand and Timed Up-and-Go tests are among the core set of performance-based measures recommended by the Osteoarthritis Research Society International to assess physical function in knee and hip OA [36,37]. The 2-min march test has also been shown to have sufficient validity and excellent reliability in assessing function in individuals with knee OA [38].

2.4.4. Participant characteristics

We collected the following additional information to characterize the study sample: age, race/ethnicity, sex, education level, work status, marital status, comorbid illnesses [39], and duration of knee/hip OA symptoms.

2.5. Sample size & statistical analysis

The sample size of n = 30 per arm would allow for detection of a large effect size of at least 1.7 standard deviation (SD)s with 80 % power and a two-sided 0.05 significance level. Due to the exploratory nature of this trial, the objective was to inform estimates for a larger RCT, as well as drop-out and loss-to-follow-up rates; hence, the study was not fully powered for statistical significance. Descriptive statistics are provided for participant demographic and clinical characteristics, as well as participants' ratings of satisfaction with OA CARE. An intent-to-treat approach was followed in these analyses. The primary patient outcome of the total WOMAC score was analyzed using a general linear mixed effects model with changes from baseline as the dependent variable. The SAS MIXED procedure (Cary, NC) was used to fit this model. Transformations were considered for the dependent variable when model diagnostics suggested violation of the normality assumption. An unstructured within-person error covariance matrix was specified using a REPEATED statement. Fixed effects included indicators for the OA CARE group, the follow-up time point, their interaction (group by time), and baseline total WOMAC score. Random effects were included for blocks within the OA CARE arm (e.g. 10-participant Weight Management Program groups) to account for clustering. Customized statistical linear contrasts were constructed to estimate the effect size via the difference in means for OA CARE versus usual care, along with the corresponding 95 % confidence limits, separately at 6- and 12- months. Within-group changes were also estimated. Corresponding analytic strategies were used for secondary outcomes. In case of model non-convergence, the block variable was included as an additional fixed effect rather than as random effects or a compound symmetric covariance matrix was used.

3. Results

3.1. Feasibility & acceptability metrics

Among 558 patients who were mailed a recruitment letter for the study, 109 were ineligible, 196 could not be reached by phone, 178 declined to participate and 75 were eligible (Fig. 2). Of those eligible, 61

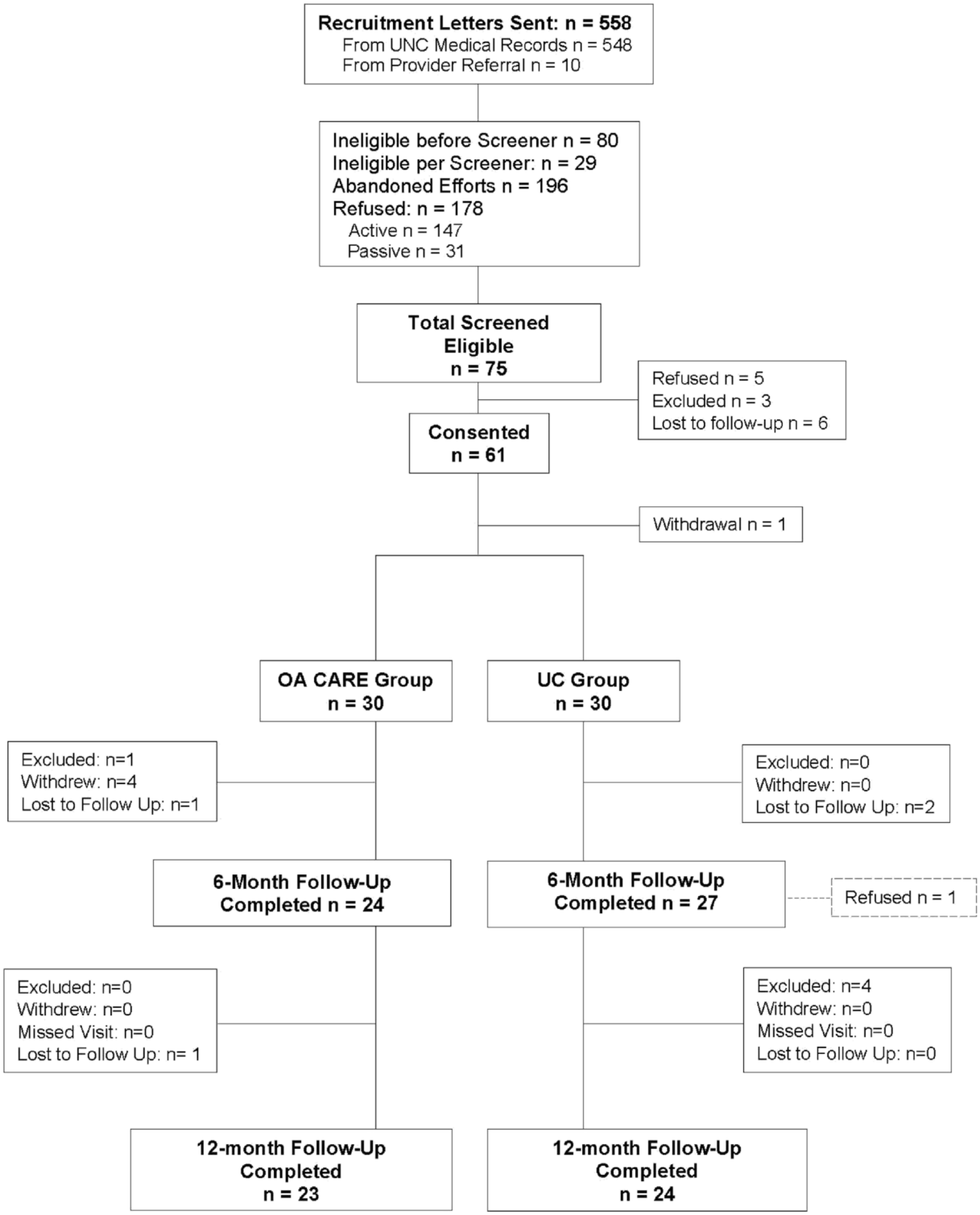

Fig. 2. CONSORT diagram.

(81 %) consented to participate; one individual withdrew from the study before randomization, so an additional participant was enrolled to reach the goal of 60 randomized participants. Characteristics of study participants are shown in Table 2. Among enrolled participants, 51 (85 %) completed 6-month assessments and 47 (78 %) completed 12-month follow-up assessments. No study-related adverse events occurred. There were 17 attending physicians and 5 resident physicians whose patients were involved in the study and who received the intervention components described above.

In the OA CARE group, 26 (86.7 %) participated in the YMCA weight loss program, with an average attendance of 9.2 (SD = 3.1, range = 1–12) sessions, and 17 (56.7 %) accessed YMCA exercise resources, including use of the exercise facilities and/or participation in online or in-person exercise classes. The average number of times participants accessed exercise resources (e.g., visited the exercise facility, participated in a class) over the 1-year period was 21.1, with a range of 2–81. Twenty-four OA CARE group participants (80 %) completed the 6-month call with the OA CARE Navigator. Table 1 shows frequencies of participants who screened

Table 2
Participant characteristics (n = 60).

	Total Sample	Usual Care	OA CARE
	Mean (Standard Deviation) or n (%)		
Age (years)	64.4 (9.8)	65.6 (9.1)	63.2 (10.5)
Body Mass index (kg/m^2)	36.6 (7.0)	35.4 (6.8)	37.8 (7.1)
Body Weight (kg)	101.6 (22.4)	97.1 (22.4)	106.3 (22.2)
Duration of arthritis symptoms (years)	10.4 (8.0)	10.3 (7.8)	10.5 (8.5)
Total # of self-reported comorbid health conditions	6.7 (3.4)	7.1 (3.7)	6.3 (3.1)
Female Sex	49 (81.7 %)	25 (83.3 %)	24 (80.0 %)
Married or Living with Partner as Married	34 (56.7 %)	17 (56.7 %)	17 (56.7 %)
Low Education: High school or less	6 (10.0 %)	5 (16.7 %)	1 (3.3 %)
Currently Working	25 (41.7 %)	11 (36.7 %)	14 (46.7 %)
Self-reported Race			
White	37 (61.7 %)	20 (66.7 %)	17 (56.7 %)
Black	21 (35.0 %)	9 (30.0 %)	12 (40.0 %)
>1 Race	2 (3.3 %)	1 (3.3 %)	1 (3.3 %)
Hispanic Ethnicity	2 (3.3 %)	1 (3.3 %)	1 (3.3 %)
WOMAC total	39.3 (15.8)	37.9 (17.3)	40.7 (14.4)
WOMAC Pain	8.2 (3.3)	8.0 (3.7)	8.4 (3.0)
WOMAC Function	26.8 (11.9)	25.9 (13.2)	27.6 (10.7)
Minutes of MVPA per week	56.4 (55.2)	64.8 (66.1)	48.0 (40.9)
Steps per day	4652.7 (2429.1)	4862.7 (2312.0)	4442.7 (2562.7)
Minutes Sedentary Per Day	673.7 (93.3)	678.9 (81.8)	668.4 (104.8)
Self-Report Minutes of MVPA Per Week (CHAMPS)	37.7 (81.5)	45.0 (89.7)	30.3 (73.3)
Minutes total Per Day	286.3 (93.3)	281.1 (81.8)	291.6 (104.8)
30-Second Chair Stand test	10.3 (3.7)	10.2 (3.3)	10.5 (4.1)
2-Minute March test	50.8 (25.0)	53.6 (26.9)	47.4 (22.8)
Timed Up and Go test (seconds)	9.1 (3.1)	8.7 (2.6)	9.4 (3.6)

Table 3
Within- and between-group mean changes in outcomes and 95 % confidence intervals (CI).

Outcome	Baseline to 6-Month Difference (95 % CI)	Difference in Baseline to 6-Month, OA CARE vs. Usual Care (95 % CI), p-value	Baseline to 12-Month Difference (95 % CI)	Difference in Baseline to 12-Month, OA CARE vs. Usual Care (95 % CI), p-value
WOMAC total				
Usual Care (N = 27)	3.2 (−4.8, 11.2)		−3.3 (−11.3, 4.6)	
OA CARE (N = 24)	−7.8 (−16.04, 0.4)	−11.0 (−20.1, −1.9), 0.019	−8.3 (−16.4, −0.2)	−4.9 (−14.1, 4.3), 0.286
WOMAC Pain				
Usual Care (N = 27)	0.5 (−1.6, 2.5)		−0.4 (−2.5, 1.6)	
OA CARE (N = 24)	−1.5 (−3.6, 0.5)	−2.0 (−4.0, −0.0), 0.046	−2.1 (−4.1, −0.0)	−1.6 (−3.8, 0.5), 0.128
WOMAC Function				
Usual Care (N = 27)	2.6 (−2.8, 8.0)		−2.6 (−7.9, 2.8)	
OA CARE (N = 24)	−4.9 (−10.6, 0.7)	−7.5 (−14.3, −0.7), 0.031	−4.5 (−10.1, 1.0)	−2.0 (−8.8, 4.9), 0.564
Body Weight (kg)				
Usual Care (N = 27)	−4.2 (−9.9, 1.6)		−5.4 (−13.0, 2.3)	
OA CARE (N = 24)	−9.9 (−16.1, −3.8)	−5.8 (−14.4, 2.8), 0.181	−7.6 (−15.5, 0.4)	−2.2 (−13.4, 8.9), 0.688
Minutes of MVPA per week[a]				
Usual Care (N = 25)	−0.0 (−0.3, 0.3)		−0.1 (−0.4, 0.3)	
OA CARE (N = 22)	0.2 (−0.2, 0.5)	0.2 (−0.2, 0.6), 0.349	−0.3 (−0.6, 0.1)	−0.2 (−0.6, 0.2), 0.303
Steps per day[ca]				
Usual Care (N = 25)	−0.0 (−0.3, 0.2)		−0.1 (−0.4, 0.1)	
OA CARE (N = 22)	0.00 (−0.2, 0.3)	0.04 (−0.1, 0.2), 0.507	−0.1 (−0.3, 0.2)	0.0 (−0.2, 0.2), 0.729
Minutes Sedentary Per Day[c]				
Usual Care (N = 25)	−2.9 (−26.4, 20.6)		9.3 (−18.6, 37.2)	
OA CARE (N = 22)	10.5 (−15.1, 36.1)	13.4 (−21.5, 48.2), 0.444	18.6 (−9.6, 46.9)	9.3 (−30.6, 49.2), 0.638
Self-Report Minutes of MVPA Per Week (CHAMPS)[b]				
Usual Care (N = 27)	1.2 (−0.9, 3.3)		2.2 (−0.7, 5.1)	
OA CARE (N = 24)	4.6 (2.3, 6.9)	3.4 (0.3, 6.5), 0.034	4.3 (1.3, 7.3)	2.1 (−2.1, 6.3), 0.315
Minutes total Per Day[c]				
Usual Care (N = 25)	0.0 (−0.1, 0.1)		−0.1 (−0.2, 0.1)	
OA CARE (N = 22)	−0.0 (−0.1, 0.1)	−0.1 (−0.2, 0.1), 0.4214	−0.1 (−0.2, 0.0)	−0.0 (−0.2, 0.1), 0.6475
30-Second Chair Stand test				
Usual Care (N = 21)			−0.6 (−1.8, 0.7)	
OA CARE (N = 14)	NA	NA	−0.9 (−2.5, 0.7)	−0.4 (−2.5, 1.7), 0.709

(*continued on next page*)

Table 3 (*continued*)

Outcome	Baseline to 6-Month Difference (95 % CI)	Difference in Baseline to 6-Month, OA CARE vs. Usual Care (95 % CI), p-value	Baseline to 12-Month Difference (95 % CI)	Difference in Baseline to 12-Month, OA CARE vs. Usual Care (95 % CI), p-value
2-min March test				
Usual Care (N = 21)			14.8 (4.9, 24.7)	
OA CARE (N = 14)	NA	NA	29.7 (17.4, 42.0)	14.9 (−1.0, 30.8), 0.066
Timed Up and Go test (seconds)				
Usual Care (N = 21)			2.0 (0.9, 3.1)	
OA CARE (N = 15)	NA	NA	0.5 (−0.9, 1.8)	−1.5 (−3.3, 0.2), 0.089

[a] A log transformation was applied; transformed values are presented here.
[b] A square root transformation was applied; transformed values are presented here.
[c] Standardized to a 16-h day.

eligible for potential need for additional services, referrals to primary care providers, and self-reported use of services. Eight participants in the OA CARE group received physical therapy during the study period, with few (≤2) accessing other services described in Table 1. The mean rating of helpfulness of the OA CARE program (0 (not helpful at all) to 10 (very helpful)) was 8.52 (SD = 1.68). The mean ratings of helpfulness for the OA Navigator call and YMCA programs were 9.00 (SD = 1.48) and 8.13 (SD = 3.47), respectively.

3.2. Patient outcomes

Within- and between-group mean changes in outcomes are shown in Table 3. At 6-month follow-up, there was a statistically significant between group difference in change in WOMAC total score, with the OA CARE group showing greater improvement (−11.0, 95 % Confidence Interval (CI) (−20.1, −1.9), p = 0.019, Cohen's d = 0.64, 95 % CI 0.28, 1.01). At 12-months, the between-group change in WOMAC total score was not statistically significant, though there was a small difference in favor of the OA CARE Group (−4.9, 95 % CI -14.1,4.3, p = 0.286, Cohen's d = 0.30, 95 % CI -0.26, 0.86). For both WOMAC pain and function subscales, there were statistically significant between-group differences at 6-months, favoring the OA CARE group, but these were attenuated at 12-months and not statistically significant.

Both OA CARE and UC groups lost weight during the intervention period. At 6-month follow-up, mean weight loss in the OA CARE group was 9.4 % of baseline; the UC group lost 4.3 % of baseline weight. At 12-month follow-up, the OA CARE group had lost 7.1 % of baseline body weight and the UC group 5.5 %. Physical activity metrics measured via accelerometer did not change appreciably for either the OA CARE or UC group, and there were no significant between-group differences at either 6-months or 12-months. At 6-month follow-up, there was a significant between-group difference in self-reported weekly minutes of MVPA (CHAMPS), favoring the OA CARE group, but this was attenuated and not statistically significant at 12-month follow-up.

Both groups had a small decrease in number chair stands completed in of 30-s at 12-months, with no significant between-group difference. For the 2-min march test, the OA CARE group improved by about 15 steps more than the UC group, a change that was close to statistical significance (p = 0.066). For the Timed Up-and-Go test, the OA CARE group had a greater reduction in time to completion compared with the UC group (approximately 1.5 s difference), but this between-group difference was not statistically significant (p = 0.089).

4. Discussion

In this study, we found preliminary evidence that OA CARE, which combined clinical care with behavioral therapies delivered by the YMCA, was feasible to deliver, was perceived as very helpful by patients, and may improve some OA outcomes. With respect to feasibility, we found that rates of enrollment and follow-up were similar to other clinical trials of behavioral interventions for OA [40,41]. A majority of the OA CARE group (~87 %) participated in the YMCA Weight Loss Program, with good attendance (average 75 % of sessions). This supports the feasibility of engaging a community-based partner in delivering behavioral aspects of OA management. However, a small proportion of participants (57 %) used YMCA exercise resources, with fairly low frequency of use even among those who did access these resources; this was a limitation of our intervention approach. The high level of participation in the YMCA Weight Management Program was likely facilitated by videoconference-based delivery. The YMCA of the Triangle offered in person and online exercise classes during our study period; however, YMCA data on use of exercise resources did not differentiate between in-person and online participation. Some participants lived further from the nearest YMCA facility, which may have been a barrier to in-person exercise participation. And, it is possible that study participants were less comfortable with virtually delivered general exercise classes that were not tailored to older adults with knee OA. Evidence-based, self--directed exercise programs specifically for individuals with knee OA have been developed [21,22,42]; Further, recent work has illustrated the effectiveness of telehealth delivery of established instructor-led programs like GLA:D [43], and increased availability of these remotely delivered classes would benefit individuals with OA.

The incorporation of an OA CARE Navigator was another novel aspect of our care model. Previously studied OA Management Programs have utilized physical therapists or other clinical personnel in a central or first-line delivery role [16,20,44]. An advantage of the OA CARE Navigator is that it can be filled by individuals with different types of training backgrounds (e.g., health education or coaching, care management, nursing, rehabilitation). This flexibility is beneficial for embedding a care pathway into primary care clinics. Helpfulness ratings for the Navigator calls were very high, though a fairly low proportion of patients engaged in additional treatments discussed during these calls. This suggests patients may have benefitted from overall guidance regarding strategies available to them for managing OA. The most common additional service received by participants was physical therapy (Table 1). Given the relatively low use of physical therapy for OA, it is notable that ~25 % of OA CARE participants engaged in this treatment during the study period. However, since outcomes at 12-months indicated persistence of functional limitations, even more participants may have benefited from physical therapy. More work is needed to understand how to best facilitate patients' engagement with other non-pharmacological treatment options when appropriate.

Although this exploratory trial was not intended to be fully powered to detect statistically significant between-group differences, our data provide preliminary evidence regarding the efficacy of OA CARE. There was a statistically significant and clinically meaningful between-group difference in WOMAC total scores (primary outcome) at 6-month follow-up. Specifically, prior research suggests that in the context of behavioral/rehabilitation interventions for OA, a change or 12 % from baseline represents a minimal clinically important difference [45]. In this case, a 12 % change from the common baseline WOMAC mean would be 4.7 points, and at 6-months there was a between-group difference of 11.0. This difference was attenuated by 12-months (between group difference of 4.9 points), though the mean WOMAC total score in the OA CARE group was lower (better) at 12-months than at 6-months. The OA

CARE group lost a clinically meaningful amount of weight, (≥5 %) [46], though there was some regain between 6 and 12 months; this could also be due to the greater accuracy of weight measurement at 12 months, as weight was self-reported at 6 months. There were no statistically signifiacnt between-group differences in accelerometer-measured or self-reported physical activity at 12 months, which aligns with the fairly limited use of YMCA exercise programming. While there are no established clinically meaningful differences in physical activity metrics with respect to OA outcomes, based on the small magnitude of these between-group differences, they are likely not of clinical relevance. With respect to function tests, there were no statistically significant between-group differences. The between-group differences for the 2-min march test and Timed Up-and-Go test may be clinically relevant based on prior research [36,47]. However, the between-group difference for the 30-s chair stand and Timed Up-and-Go did not meet the threshold for clinical relevance [36].

There are several limitations to this study.The study was conducted within one health system, which limits generalizability. The study sample included primarily Black and non-Hispanic White individuals, and there is a need to examine this care model in a more racially and ethnically diverse group of patients. The study time period coincided with increased prescribing of newly approved anti-obesity medications (e.g., glucagon-like peptide-1 agonists), and it is possible that some patients began taking these medications during the study period. While this could have contributed to weight loss, we do not expect there was differential use of these medications between study arms. There was a slight imbalance in baseline BMI between study arms. We conducted sensitivity analyses in which his variable was included as a covariate in statsitcal models, and results did not change meaningfully. Study eligibility criteria were related to ability to engage safely in exercise and other study activities and may limit external generalizability. Because physical therapy was provided outside of the study team and at different clinics, we do not have data on specific care provided. Finally, we did not assess co-interventions (e.g., joint injections) that may have impacted study outcomes.

In conclusion, this study provided support for the feasibility of the OA CARE model, patient ratings of helpfulness were high, and a meaningful proportion of participants received physical therapy during the intervention period. Preliminary data regarding the efficacy of OA CARE were mixed but suggest this approach may hold promise with some adaptations, particularly enhancing engagement with weight loss and exercise programs, whether in-person or remote, and more intensive strategies for connecting patients with other non-pharmacological treatment options.

Author's contribution

All authors contributed to the conception and design of the study. KH and DH contributed to acquisition of data. All authors contributed to interpretation of data. All authors contributed to drafting of the article or revising it for important intellectual content and approved of the final version to be submitted.

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Declaration of competing interest

The authors have no competing interests to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ocarto.2025.100588.

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