

# A Combined Patient and Provider Intervention for Management of Osteoarthritis in Veterans

## A Randomized Clinical Trial

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**Background:** Management of osteoarthritis requires both medical and behavioral strategies, but some recommended therapies are underused.

**Objective:** To examine the effectiveness of a combined patient and provider intervention for improving osteoarthritis outcomes.

**Design:** Cluster randomized clinical trial with assignment to osteoarthritis intervention and usual care groups. (ClinicalTrials.gov: NCT01130740)

**Setting:** Department of Veterans Affairs Medical Center in Durham, North Carolina.

**Participants:** 30 providers (clusters) and 300 outpatients with symptomatic hip or knee osteoarthritis.

**Intervention:** The telephone-based patient intervention focused on weight management, physical activity, and cognitive behavioral pain management. The provider intervention involved delivery of patient-specific osteoarthritis treatment recommendations to primary care providers through the electronic medical record.

**Measurements:** The primary outcome was total score on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 12 months. Secondary outcomes were WOMAC function and pain subscale scores, physical performance (Short Physical Performance Battery), and depressive symptoms (Pa-

tient Health Questionnaire-8). Linear mixed models that were adjusted for clustering of providers assessed between-group differences in improvement in outcomes.

**Results:** At 12 months, WOMAC scores were 4.1 points lower (indicating improvement) in the osteoarthritis intervention group versus usual care (95% CI,  $-7.2$  to  $-1.1$  points;  $P = 0.009$ ). WOMAC function subscale scores were 3.3 points lower in the intervention group (CI,  $-5.7$  to  $-1.0$  points;  $P = 0.005$ ). WOMAC pain subscale scores ( $P = 0.126$ ), physical performance, and depressive symptoms did not differ between groups. Although more patients in the osteoarthritis intervention group received provider referral for recommended osteoarthritis treatments, the numbers who received them did not differ.

**Limitation:** The study was conducted in a single Veterans Affairs medical center.

**Conclusion:** The combined patient and provider intervention resulted in modest improvement in self-reported physical function in patients with hip and knee osteoarthritis.

**Primary Funding Source:** Department of Veterans Affairs, Health Services Research and Development Service.

*Ann Intern Med.* 2016;164:73-83. doi:10.7326/M15-0378 [www.annals.org](http://www.annals.org)

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This article was published at [www.annals.org](http://www.annals.org) on 22 December 2015.

Osteoarthritis is one of the most common chronic health conditions and a leading cause of pain and disability (1-5). Its prevalence is increasing, and this trend is expected to continue (6, 7). In addition to the substantial toll at the individual level (8), osteoarthritis is placing an increasing burden on health care systems (9, 10).

Evidence-based guidelines indicate that adequate management of hip and knee osteoarthritis requires both behavioral and clinical strategies (11-14). Physical activity and weight management are key behavioral strategies for managing hip and knee osteoarthritis, but most adults with osteoarthritis are physically inactive or overweight (15, 16). Similarly, despite strong evidence supporting several clinical strategies, such as joint injections, physical therapy, and pain medications, some of these treatments are underused, and studies have shown low rates of adherence to osteoarthritis quality indicators (17-20). Improvement in osteoarthritis management is needed at both the patient and provider levels. The purpose of our study was to examine a combined patient and provider intervention for management of osteoarthritis in primary care.

## METHODS

The Institutional Review Board of the Department of Veterans Affairs (VA) Medical Center in Durham, North Carolina, approved this study. Detailed methods have been published previously (21).

### Study Design

This was a cluster randomized, controlled trial, with primary care providers (PCPs) assigned to an osteoarthritis intervention group or a usual care control group. Randomization was computer-generated, maintained by the study statistician, and stratified on the basis of the providers' volume of female patients ( $<15\%$  vs.  $\geq 15\%$ ). We aimed to enroll 10 patient participants (5 white and 5 nonwhite) from each of 30 PCPs. Providers assigned to the osteoarthritis intervention group received the provider intervention, and their enrolled pa-

### See also:

Web-Only  
Supplement

**EDITORS' NOTES****Context**

Despite their established benefit in patients with osteoarthritis, many treatment strategies are underused.

**Contribution**

In this randomized trial, providing treatment recommendations to physicians in addition to telephone-based support to patients with knee or hip osteoarthritis resulted in modest improvements in physical function.

**Caution**

The relative contributions of the physician- and patient-based interventions to the observed improvement could not be assessed.

**Implication**

A combined physician and patient intervention may be beneficial in patients with knee or hip osteoarthritis.

tient participants received the patient intervention. Patient participants in both groups continued with any usual medical care recommended by their providers. Because all patient participants were enrolled at the Durham VA Medical Center, usual care could include any of the standard treatments for osteoarthritis given by a PCP as well as referral to other providers or specialists. Provider and patient participants in the usual care group received no additional intervention during the study.

**Participants and Recruitment**

Primary care providers in the Ambulatory Care Service of the Durham VA Medical Center, with patient panels large enough to be likely to enroll 10 participants, were invited to participate. Patients were eligible if they had hip osteoarthritis (based on radiographic evidence in the electronic medical record [EMR]), knee osteoarthritis (based on radiographic evidence in the EMR or clinical criteria from the American College of Rheumatology [22]), or both, along with self-reported joint symptoms ("pain, aching, stiffness or swelling in or around a hip or knee joint with arthritis") that were present on most days during the past month or for which the patient had used pain medications on most days during the past month (23). Participants also had to be overweight (body mass index [BMI]  $\geq 25$  kg/m<sup>2</sup>) and not currently adhering to physical activity recommendations from the U.S. Department of Health and Human Services (24). Exclusion criteria are summarized in the **Appendix Table** (available at [www.annals.org](http://www.annals.org)). Potential participants were identified from the Durham VA Medical Center EMR, mailed an introductory letter, and called for a screening interview. Eligible patients completed consent and baseline assessments at the Durham VA Medical Center and were subsequently informed of their group assignment by telephone. Study team members involved in screening and consent were

blinded to randomization. Potential patient participants were blinded to their PCP's group assignment until after the baseline assessments.

**Interventions****Patient Intervention**

This was a 12-month intervention focusing on physical activity, weight management, and cognitive behavioral pain management strategies (21). Telephone calls were scheduled twice per month for the first 6 months and monthly for the last 6 months and were delivered by a counselor with training in osteoarthritis and behavior change. Goal setting and action planning were major components of the intervention. The counselor used motivational interviewing strategies throughout the intervention (21, 25, 26). Patient participants were given written educational materials corresponding to intervention topics, an exercise video for patients with osteoarthritis, and an audio CD of relaxation exercises.

**Provider Intervention**

This intervention involved delivery of the following patient-specific osteoarthritis treatment recommendations to PCPs, based on published treatment guidelines (13, 14, 27): refer to a physical therapist, refer for an evaluation for a knee brace, refer to MOVE! (the VA system's weight management program that includes physical activity counseling [28]), perform or refer for an intra-articular injection, recommend a topical nonsteroidal anti-inflammatory drug (NSAID) or capsaicin, add a gastroprotective agent or remove an NSAID, discuss the possibility of a new or alternate pain medication, or refer to an orthopedic evaluation for joint replacement surgery. We developed algorithms (**Appendix**, available at [www.annals.org](http://www.annals.org)) to determine when each treatment option might be reasonable for a PCP to consider for a patient (21). Study team members collected all information needed to complete the algorithm for each patient participant during baseline assessments. Patient-specific recommendations were delivered to PCPs via the EMR as a progress note requiring an electronic signature. The study team monitored upcoming visits for participants in the osteoarthritis intervention group, and recommendations were delivered to PCPs about 1 week before the participants' first routine visit after enrollment. The recommendations remained available to PCPs within the EMR, but no further communications were transmitted to osteoarthritis intervention providers.

**Outcome Measures**

Baseline and 12-month follow-up measures were completed in person, except for 36 participants who could not return to the Durham VA Medical Center at 12 months but completed some measures via telephone. The primary outcome was also assessed via telephone at 6 months. Outcomes assessors were blinded to randomization. Participants were reimbursed \$25 and \$10 for completing in-person and telephone assessments, respectively.

### Primary Outcome

The primary outcome measure was total score on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a self-reported measure of lower extremity pain (5 items), stiffness (2 items), and function (17 items) in the previous 2 weeks (29–31). All items are rated on a 5-point Likert scale ranging from “none” to “extreme”; total scores range from 0 to 96, with higher scores indicating worse symptoms and function.

### Secondary Outcomes

We examined the WOMAC pain and function subscales separately. We also administered the Short Physical Performance Battery (SPPB) (32), a commonly used performance measure in older adults that includes 3 tests of balance, a timed 8-foot walk, and 5 chair stands. The total score ranges from 0 (worst performance) to 12 (best performance). Depressive symptoms were assessed with the Patient Health Questionnaire-8 (33), with scores ranging from 0 to 24.

### Process Measures

We collected additional “process measures” related to behaviors or outcomes intermediate to changes in symptoms or function. Self-reported physical activity was measured with the Community Healthy Activities Model Program for Seniors (CHAMPS) (34, 35), which assesses the frequency and duration of light to vigorous activities in the previous 4 weeks; we report the weekly frequency and duration of all exercise as well as moderate- or higher-intensity exercise. CHAMPS has established test-retest reliability and association with accelerometer-based physical activity among older adults (36). Body mass index was calculated using measured height and weight; when 12-month follow-up measures were administered via telephone, weight was self-reported.

For all patient participants, we used the Durham VA Medical Center EMR to examine osteoarthritis-related referrals from PCPs and participants' actual visits for physical therapy, evaluations for knee braces, joint injections, MOVE!, and orthopedic consultation during the study. We assessed changes in oral and topical pain medication by participant self-reports. For oral pain medications, we defined new use during the study as either no pain medication use at baseline but some use at follow-up or use of a different pain medication at follow-up than at baseline. For topical creams, we defined new users as those who reported using any type at follow-up but not at baseline. We acknowledge that use of new oral or topical pain medications may not necessarily have led to better pain control. We also report proportions of osteoarthritis intervention participants whose PCP received each treatment recommendation from the study team and, among those, proportions who had referrals and visits for those treatments.

### Participant Characteristics

We collected patient-reported information on age, sex, race/ethnicity (white vs. nonwhite), household financial situation (participants with “inadequate income” were defined as those who reported that they “just meet basic expenses” or “don't even have enough to meet basic expenses”), education level, marital status, work status (employed or student vs. other), disability (positive response to “disabled” in the work status question, regardless of other responses), self-rated health (excellent, very good, or good vs. fair or poor), and duration of osteoarthritis symptoms. We also report presence of osteoarthritis in the knee only, the hip only, or both based on the enrollment data described earlier. For provider participants, we collected information on clinician category (physician, nurse, nurse practitioner, or physician assistant), sex, and whether the patient panel was less than 15% or at least 15% female.

### Adverse Events

Per protocol, we inquired at each study encounter about hip and knee injuries or surgeries. Information about other adverse events was noted when participants informed the study team of them during a regular contact or when an event was discovered during study-related review of medical records.

### Sample Size

We based our sample size of 300 patient participants on detection of a moderate effect size of approximately 0.30 for the difference in mean WOMAC scores between groups, with 80% power and a type I error rate of 0.05. This translates to a 4.2-point difference at 12 months, which is equivalent to an improvement of approximately 11% from the anticipated mean baseline score; this allowed sufficient power to detect a clinically relevant difference (12% to 18%, based on prior relevant literature) (37–39). We used a 2-sample *t* test sample size calculation for the between-group difference at 12 months multiplied by a factor of  $1 - \rho^2$ , where  $\rho$  represents the Pearson correlation between baseline and follow-up outcome measures (0.60) (40). This sample size was then adjusted to reflect provider clustering using an intraclass correlation coefficient of 0.02 (41) and was inflated to compensate for potential attrition (12%). On the basis of our pilot work, we assumed a mean baseline WOMAC score of 38 (SD, 14).

### Statistical Analysis

Our primary hypothesis was that osteoarthritis intervention participants would have significantly greater improvement in WOMAC scores than usual care participants. Analyses involved all randomly assigned participants and used all collected data (42). Observations were not deleted if follow-up data were missing (43). The estimation procedure for our analytic technique (linear mixed models) implicitly accommodates missingness that is related to the prior outcome or to other baseline covariates in the model (that is, missing at random). To assess the robustness of the primary model to

missing observations, we multiply imputed missing WOMAC follow-up scores using a Markov-chain Monte Carlo algorithm incorporating additional variables beyond those in the linear mixed-effects models to strengthen the missing-at-random assumption (Supplement, available at [www.annals.org](http://www.annals.org)).

For primary and secondary outcomes and continuous process measures, linear mixed models were fit using the PROC MIXED procedure in SAS, version 9.4 (SAS Institute) (44). A random effect to account for clustering of PCPs and an unstructured covariance structure for the repeated measures over time were used. For CHAMPS outcomes, the change from baseline to 12 months was used due to normality assumptions.

Predictors in all models included dummy-coded follow-up time effects and an indicator variable for the interaction between the intervention and follow-up time effects (45). This model assumed that study groups had equal baseline means, which is appropriate for a randomized, controlled trial and is equivalent in efficiency to an analysis-of-covariance model (46). The final models also included patient participant race and the provider stratification based on the proportion of female patients. Our primary inference was on the interaction between the intervention group and follow-up time because this was the estimated difference between groups at the end of the study. For the change in CHAMPS scores between baseline and 12 months, fixed-effect terms in the model included baseline CHAMPS score and an indicator variable for study group. For the BMI analysis, in-person weight at the 12-month follow-up visit was the outcome; sensitivity analyses included self-reported weight from participants without an in-person 12-month visit.

In a post hoc analysis that examined clinically meaningful change in WOMAC scores (based on prior studies of behavioral and rehabilitative interventions) (37, 39, 47), we categorized patients as either improved or not improved at 12 months using a 12% improvement (5.8-point reduction) and an 18% improvement (8.7-point reduction) in the total score from baseline, which corresponded with the upper and lower range of previously reported estimates of clinically meaningful change. We used generalized estimating equation models (48) with a logit link function and an unstructured correlation structure and used empirical SEs for inference.

### Role of the Funding Source

The funding source approved the project and monitored progress but had no direct role in the design or conduct of the study, data analyses, or the decision to submit the manuscript for publication.

## RESULTS

### Participant Enrollment and Retention

Forty-three PCPs were approached, and 30 were enrolled (Figure and Table 1). We identified 5094 potential patient participants from the EMR. Of 1053 patients screened by telephone, 356 were eligible and 300 were enrolled and randomly assigned (Table 1).

There were 151 and 149 patient participants in the osteoarthritis intervention and usual care groups, respectively. One patient was assigned to a usual care provider at the beginning of the recruitment process but switched to an osteoarthritis intervention provider before being notified of his study group assignment. We decided to include the participant in the assigned group of his provider at the time of notification of random assignment (osteoarthritis intervention).

Among enrolled participants, 88% completed 6-month measures and 91% completed 12-month measures (Figure). Seventeen participants were withdrawn by the study team (10 [3 in the osteoarthritis intervention group and 7 in the usual care group] underwent hip or knee replacement or another significant hip or knee surgery; 3 [1 in the osteoarthritis intervention group and 2 in the usual care group] developed a serious health condition that would have made generalized exercise or diet advice risky; 2 [1 in each group] became ineligible after giving consent; 1 in the osteoarthritis intervention group moved out of the area, making it impossible for treatment recommendations to be issued; and 1 switched from an osteoarthritis intervention provider to a usual care provider before treatment recommendations were issued). In addition, 5 patients withdrew from the study and 5 were lost to follow-up.

### Intervention Delivery

The average number of patient participants enrolled was 10.0 (SD, 2.1; range, 3 to 12) per provider. Osteoarthritis intervention participants completed an average of 11.5 (SD, 4.9) of 18 planned telephone calls, and the average length of the calls was 16.6 minutes (SD, 12.4). The study team was able to deliver treatment recommendations to the PCP within the intervention period for all but 8 patient participants. Of these, 2 were withdrawn by the study team, 1 withdrew, 1 was reassigned to a nonstudy PCP who had not yet seen the patient, 2 transferred to another VA medical center, and 2 were inadvertently missed by the study team. For 26 participants, nonacute visits were scheduled with PCPs not enrolled in the study; in all but 1 case, the covering PCP agreed to receive the recommendations. The mean number of recommendations issued was 4.6 (SD, 1.8) per patient participant.

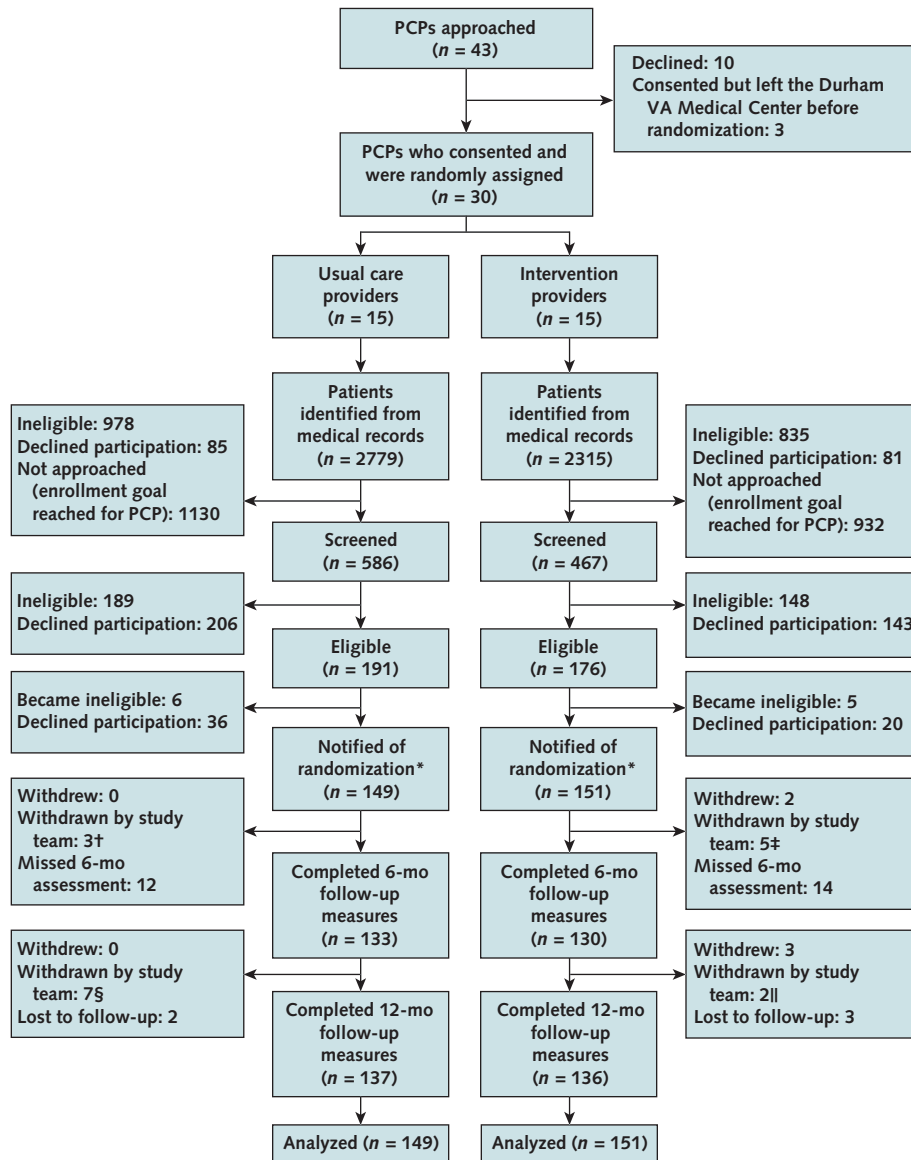
### Adverse Events

Four adverse events occurred, but none was associated with the osteoarthritis intervention.

### Primary Outcome

At 12 months, the estimated mean change in total WOMAC score was  $-4.0$  points (95% CI,  $-6.2$  to  $-1.8$  points) in the osteoarthritis intervention group and  $0.1$  point (CI,  $-2.1$  to  $2.3$  points) in the usual care group, with an estimated mean difference of  $-4.1$  points (CI,  $-7.2$  to  $-1.1$  points;  $P = 0.009$ ) between groups (Table 2). Both groups showed improvement at 6 months compared with baseline, with the mean score for the usual care group returning to baseline levels by 12 months. WOMAC scores also increased between 6 and 12 months for participants in the osteoarthritis interven-

Figure. Study flow diagram.



PCP = primary care provider; VA = Department of Veterans Affairs.

\* 1 patient switched from a usual care provider to an osteoarthritis intervention provider before being notified of randomization and was analyzed with the osteoarthritis intervention group.

† 1 became ineligible after giving consent, 1 had hip or knee surgery, and 1 developed a serious health condition.

‡ 1 became ineligible after giving consent, 2 had hip or knee surgery, 1 moved out of the area, and 1 changed health care providers before treatment recommendations were issued.

§ 6 had hip or knee surgery and 1 developed a serious health condition.

|| 1 had hip or knee surgery and 1 developed a serious health condition.

tion group but remained below baseline scores. We observed a clustering effect for WOMAC scores within provider, with an estimated intraclass correlation coefficient of 0.02. We found similar results when we used the multiply imputed data sets (mean difference,  $-4.2$  points [CI,  $-7.3$  to  $-1.2$  points];  $P = 0.007$ ). In post hoc analyses examining improvements in WOMAC scores from baseline to 12 months, an estimated 42.0% of participants improved by at least 12% in the osteoarthritis intervention group compared with 32.2% in the usual

care group (odds ratio, 1.3 [CI, 0.9 to 1.8];  $P = 0.118$ ); 29.7% improved by at least 18% in the osteoarthritis intervention group compared with 22.2% in the usual care group (odds ratio, 1.3 [CI, 0.8 to 2.1];  $P = 0.22$ ).

### Secondary Outcomes

We found no difference between groups in the WOMAC pain subscale score ( $P = 0.59$  at 6 months and 0.126 at 12 months) (Table 2). However, at 12 months, the estimated mean WOMAC physical function score in

**Table 1.** Provider and Patient Participant Characteristics at Baseline\*

Characteristic	Overall	Usual Care	Osteoarthritis Intervention
<b>Provider participants, n</b>	30	15	15
Mean patient participants (SD), n	10.0 (2.1)	9.9 (1.7)	10.1 (2.5)
Patient panel <15% female, n (%)	25 (83.3)	13 (86.7)	12 (80.0)
Men, n (%)	12 (40.0)	5 (33.3)	7 (46.7)
Provider type, n (%)			
Physician	19 (63.3)	9 (60.0)	10 (66.7)
Nurse practitioner	3 (10.0)	0 (0)	3 (20.0)
Physician assistant	7 (23.3)	6 (40.0)	1 (6.7)
Registered nurse	1 (3.3)	0 (0)	1 (6.7)
<b>Patient participants, n</b>	300	149	151
Mean age (SD), y	61.1 (9.2)	61.7 (9.0)	60.4 (9.4)
Men, n (%)	272 (90.7)	141 (94.6)	131 (86.8)
Nonwhite race, n (%)	150 (50.0)	75 (50.3)	75 (49.7)
Married or living with partner, n (%)	199 (66.3)	106 (71.1)	93 (61.6)
High school education or less, n (%)	81 (27.0)	44 (29.5)	37 (24.5)
Inadequate income, n (%)	103 (34.3)	48 (32.2)	55 (36.4)
Employed or student, n (%)†	127 (42.8)	60 (40.5)	67 (45.0)
Disabled, n (%)†	98 (33.0)	53 (35.8)	45 (30.2)
Fair or poor health, n (%)	115 (38.3)	57 (38.3)	58 (38.4)
Mean BMI (SD), kg/m <sup>2</sup>	33.8 (5.8)	33.4 (5.7)	34.3 (6.0)
Joints with osteoarthritis, n (%)			
Knee only	238 (79.3)	124 (83.2)	114 (75.5)
Hip only	32 (10.7)	14 (9.4)	18 (11.9)
Knee and hip	30 (10.0)	11 (7.4)	19 (12.6)
Mean duration of arthritis symptoms (SD), y†	14.2 (11.6)	14.6 (12.1)	13.8 (11.1)
Mean WOMAC score (SD)†	48.4 (17.5)	47.8 (17.4)	48.9 (17.6)
Mean SPPB score (SD)‡	8.0 (2.6)	8.1 (2.5)	8.0 (2.6)
Mean PHQ-8 score (SD)†	6.8 (5.4)	6.4 (5.1)	7.2 (5.6)
All exercise assessed by CHAMPS†			
Median frequency per week (IQR)	14.0 (8.0-23.0)	14.0 (8.0-23.5)	14.0 (9.0-22.0)
Median duration (IQR), h/wk	10.0 (4.8-17.3)	10.8 (5.0-17.9)	9.8 (4.8-16.8)
Moderate- or higher-intensity exercise assessed by CHAMPS			
Median frequency per week (IQR)†	5.0 (2.0-10.0)	5.0 (2.0-10.0)	5.0 (2.0-9.0)
Median duration (IQR), h/wk†	3.5 (0.5-8.3)	3.5 (0.5-9.5)	2.8 (0.5-7.8)

BMI = body mass index; CHAMPS = Community Healthy Activities Model Program for Seniors; IQR = interquartile range; PHQ-8 = Patient Health Questionnaire-8; SPPB = Short Physical Performance Battery; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

\* Percentages may not sum to 100 due to rounding.

† Data missing for ≤4 participants.

‡ Data missing for 16 participants (11 in the osteoarthritis intervention group and 5 in the usual care group).

the osteoarthritis intervention group was 3.3 points lower (CI, −5.7 to −1.0 points;  $P = 0.005$ ) than in the usual care group. For objective physical function and depressive symptoms, we found no differences between groups (Table 2). Because some patient participants completed 12-month follow-up assessments by telephone, SPPB scores were missing more often at this time point than the self-reported measures (see Table 2 for details).

### Process Measures

Patient participants in the osteoarthritis intervention group had greater improvement in both the frequency (3.3 more times per week [ $P = 0.009$ ]) and duration (3.6 more hours per week [ $P = 0.003$ ]) of all physical activity at 12 months than those in the usual care group (Table 2). Results were similar for change in physical activity of moderate or greater intensity, with increases of 1.6 times and 1.6 hours per week in the osteoarthritis intervention group compared with the usual care group ( $P = 0.042$  and  $0.017$ , respectively). We found no difference between groups for BMI. Results were similar in sensitivity analyses that included

patient participants with self-reported weight at 12 months.

### Osteoarthritis Treatment Recommendations and Use

Table 3 shows proportions of all patient participants (by study group) who received specific osteoarthritis-related referrals and treatments or visits during the study. Referrals to several rehabilitative and behavioral therapies were higher in the osteoarthritis intervention group than in the usual care group, including physical therapy (12% vs. 7%), knee braces (19% vs. 11%), and MOVE! (20% vs. 3%). However, the numbers of patients who actually received these therapies at the Durham VA Medical Center during the study were low in both groups. Referrals for and receipt of joint injections were similar between groups, as were orthopedic visits. Referrals were not needed for topical pain medications, NSAIDs, or alternative pain medications. Similar proportions of patient participants in the osteoarthritis intervention and usual care groups reported new use of topical creams (NSAIDs or capsaicin) at 12 months (9% and 7%, respectively). The proportions of

those who reported using a new or different pain medication at follow-up were also similar (36% and 35%, respectively).

Table 4 shows proportions of osteoarthritis intervention participants whose PCP received specific treatment recommendations from the study team and, among these, proportions who had PCP referrals and visits for those treatments. The most commonly issued treatment recommendations were MOVE! (87%) and discussion of new pain medication (83%). Primary care providers of 16 participants received a recommendation to add a gastroprotective agent or remove an NSAID (data not shown). The proportions of participants who received referrals from PCPs ranged from 11% to 43% of those with a study-issued recommendation. However, the numbers of participants who received each treatment were low.

## DISCUSSION

In this study, a combined patient and provider osteoarthritis intervention improved the primary outcome (total WOMAC score) at 12 months. WOMAC function subscale scores also improved at 12 months, which is important because osteoarthritis is one of the primary contributors to functional limitations in adults (4), leading to loss of ability to perform daily activities if it is not mitigated. The WOMAC function score makes up a large portion of the total score (68 of 96 possible points), and this probably drove changes in the primary outcome. The intervention also improved physical activity levels. Only about 10% of patients with osteoarthritis adhere to physical activity recommendations (49), and increasing activity levels in these patients is a high public health priority (50). We found no statisti-

**Table 2.** Estimated Mean Differences Between Usual Care and Intervention Groups in Patient Outcomes\*

Time Point, by Outcome	Usual Care (n = 149)	Osteoarthritis Intervention (n = 151)	Difference (Osteoarthritis Intervention – Usual Care) (95% CI)†	P Value
<b>WOMAC total score</b>				
Baseline	48.4	48.4	NA	NA
6 mo	43.5	41.2	-2.3 (-5.6 to 0.9)	0.162
12 mo	48.5	44.4	-4.1 (-7.2 to -1.1)	0.009
<b>WOMAC pain subscale score</b>				
Baseline	10.2	10.2	NA	NA
6 mo	8.7	8.5	-0.2 (-0.9 to 0.5)	0.59
12 mo	9.9	9.4	-0.5 (-1.2 to 0.2)	0.126
<b>WOMAC function subscale score</b>				
Baseline	33.8	33.8	NA	NA
6 mo	30.7	28.7	-1.9 (-4.4 to 0.6)	0.127
12 mo	34.3	31.0	-3.3 (-5.7 to -1.0)	0.005
<b>Physical function (SPPB score)</b>				
Baseline	8.0	8.0	NA	NA
12 mo	7.6	7.8	0.3 (-0.3 to 0.9)	0.38
<b>Depressive symptoms (PHQ-8 score)</b>				
Baseline	6.8	6.8	NA	NA
12 mo	6.8	6.2	-0.6 (-1.5 to 0.3)	0.160
<b>Change from baseline in all exercise assessed by CHAMPS at 12 mo</b>				
Frequency per week	-0.3	3.0	3.3 (0.8 to 5.8)	0.009
Duration, h/wk	0.2	3.9	3.6 (1.3 to 5.9)	0.003
<b>Change from baseline in moderate- or higher-intensity exercise assessed by CHAMPS at 12 mo</b>				
Frequency per week	-1.1	0.5	1.6 (0.1 to 3.1)	0.042
Duration, h/wk	-0.5	1.2	1.6 (0.3 to 2.9)	0.017
<b>BMI, kg/m<sup>2</sup></b>				
Baseline	33.8	33.8	NA	NA
12 mo	33.6	33.5	-0.1 (-0.5 to 0.2)	0.47

BMI = body mass index; CHAMPS = Community Healthy Activities Model Program for Seniors; NA = not applicable; PHQ-8 = Patient Health Questionnaire-8; SPPB = Short Physical Performance Battery; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

\* Linear mixed model results. 37 (21 in the osteoarthritis intervention group and 16 in the usual care group) and 27 (15 in the osteoarthritis intervention group and 12 in the usual care group) participants had no follow-up data at 6 and 12 mo, respectively. In addition, WOMAC scores were missing in 6 participants (1 at baseline, 2 in the osteoarthritis intervention group and 1 in the usual care group at 6 mo, and 1 in the osteoarthritis intervention group and 1 in the usual care group at 12 mo), SPPB scores were missing in 55 participants (16 at baseline and 21 in the osteoarthritis intervention group and 18 in the usual care group at 12 mo), PHQ-8 scores were missing in 19 participants (4 at baseline and 5 in the osteoarthritis intervention group and 10 in the usual care group at 12 mo), data on frequency and duration of exercise were missing in 11 participants (1 at baseline and 4 in the osteoarthritis intervention group and 6 in the usual care group at 12 mo), and measured BMI was missing in 4 participants (3 in the osteoarthritis intervention group and 1 in the usual care group). Additional data were missing across all time points because of scoring algorithms and persons who declined to participate.

† May not match estimated difference in means because of rounding.

**Table 3.** Provider Referrals and Treatment Receipt\*

Treatment/Visit	Usual Care (n = 149), n (%)		Osteoarthritis Intervention (n = 151), n (%)	
	Received Referral From Provider	Received Treatment†	Received Referral From Provider	Received Treatment†
Physical therapy‡	10 (6.7)	2 (20.0)	18 (11.9)	1 (5.6)
Knee osteoarthritis	-	1 (10.0)	-	0 (0)
Hip osteoarthritis	-	1 (10.0)	-	1 (5.6)
Knee brace	17 (11.4)	3 (17.6)	29 (19.2)	5 (17.2)
MOVE!§	5 (3.4)	2 (40.0)	30 (19.9)	8 (26.7)
Orthopedic visit‡	9 (6.0)	6 (66.7)	8 (5.3)	4 (50.0)
Knee osteoarthritis	-	5 (55.6)	-	3 (37.5)
Hip osteoarthritis	-	1 (11.1)	-	1 (12.5)
Joint injection	16 (10.7)	7 (4.7)	14 (9.3)	8 (5.3)

\* Data were missing on receipt of topical creams in 16 participants in the usual care group and 16 in the osteoarthritis intervention group and receipt of oral pain medication in 12 participants in the usual care group and 15 in the osteoarthritis intervention group.

† For physical therapy, knee braces, MOVE!, and orthopedic visits, proportions were calculated using participants with referrals during the study as the denominator. For joint injections (which can be done by a primary care provider without a specialty consultation), proportions were calculated using all participants in the study group as the denominator.

‡ Referrals did not differentiate between hip and knee osteoarthritis.

cally significant or clinically relevant differences between groups for other secondary outcomes and process measures, including WOMAC pain subscale score, depressive symptoms, and BMI (51, 52).

Effects of this osteoarthritis intervention on WOMAC total and function subscale scores were modest. In the context of behavioral and rehabilitative interventions for osteoarthritis, thresholds for clinically meaningful improvements in WOMAC score have typically ranged from 12% to 18% (37–39). In this study, we observed an 8.5% improvement in WOMAC total scores and a 9.8% improvement in WOMAC function scores in the osteoarthritis intervention group, both of

which are below these thresholds. We found that 42% and 30% of patient participants in the osteoarthritis intervention group achieved at least 12% and 18% improvement in WOMAC total scores, respectively. Future analyses will examine whether specific participant characteristics were associated with differential improvement.

In both study groups, WOMAC scores improved by the interim 6-month follow-up assessment, with greater improvement in the osteoarthritis intervention group. Scores then increased by 12 months (indicating relapse) in both groups and remained lower than at baseline in the osteoarthritis intervention group only. In this

**Table 4.** Treatment Recommendations, Referrals, and Treatment Receipt in the Osteoarthritis Intervention Group\*

Treatment/Visit	PCP Received Treatment Recommendation From Study Team, n (%)	Patient Received Treatment Recommendation and Referral From PCP, n (%)†	Patient Received Treatment Recommendation, Referral, and Treatment, n (%)‡
Physical therapy§	74 (49.0)	15 (20.3)	1 (6.7)
Knee osteoarthritis	-	-	0 (0)
Hip osteoarthritis	-	-	1 (6.7)
Knee brace	62 (41.1)	22 (35.5)	2 (9.1)
MOVE!	131 (86.8)	30 (22.9)	8 (26.7)
Weight and physical activity	110 (72.9)	25 (22.7)	7 (28.0)
Weight only	14 (9.3)	2 (14.3)	0 (0)
Physical activity only	7 (4.6)	3 (42.9)	1 (33.3)
Orthopedic visit§	18 (11.9)	2 (11.1)	0 (0)
Knee osteoarthritis	-	-	0 (0)
Hip osteoarthritis	-	-	0 (0)
Joint injection	33 (21.9)	NA	9 (27.3)
Topical NSAID or capsaicin	75 (49.7)	NA	11 (14.7)
Add gastroprotective agent or remove NSAID	16 (10.6)	NA	NA¶
Discuss new/alternative pain medication	125 (82.8)	NA	46 (36.8)

NA = not available; NSAID = nonsteroidal anti-inflammatory drug; PCP = primary care provider.

\* Data were missing on treatment recommendations in 8 participants (recommendations unable to be issued), receipt of topical creams in 16 participants in the usual care group and 16 in the osteoarthritis intervention group, and receipt of oral pain medication in 12 participants in the usual care group and 15 in the osteoarthritis intervention group.

† Number of participants who received treatment recommendations was used as denominator.

‡ For physical therapy, knee braces, MOVE!, and orthopedic visits, proportions were calculated using the number of participants who received treatment recommendations and referrals during the study as the denominator. For joint injections (which can be done by a PCP without a specialty consultation), topical creams, and oral pain medications, proportions were calculated using the number of participants who received treatment recommendations as the denominator.

§ Treatment recommendations and referrals did not differentiate between hip and knee osteoarthritis.

|| Participants could receive MOVE! recommendations for physical activity, weight management, or both. These recommendations are listed separately, but provider referrals and MOVE! visits did not differentiate.

¶ Could not be captured because use of NSAIDs could not be reliably assessed in medical records.

group, the decrease in response between 6 and 12 months may have been related to the decrease in frequency of intervention calls. There are several possible reasons that the effects of this intervention were smaller than those observed in other studies of behavioral interventions for osteoarthritis (53–57). First, the intervention was less intensive than those examined in most prior studies, involving no in-person visits and relatively brief telephone calls. Although a low-intensity intervention is appealing from a resource and dissemination perspective, more intensive interventions may be necessary to enable patients with osteoarthritis to achieve and sustain clinically relevant improvements. Second, participants in our study had greater pain and functional limitations than those in most prior studies of this type (53–55). Advanced osteoarthritis can be more difficult to alleviate with nonsurgical options, which may have limited treatment benefits for some of our participants. Third, participants had a high level of comorbid physical and psychological health conditions (58), which can contribute to such outcomes as pain, function, and depressive symptoms (59). Fourth, most similar studies have recruited patients predominantly by self-referral, which may primarily attract highly motivated persons. Our recruitment strategy of approaching patients proactively and inviting them to participate was designed to identify a sample that was comparable to a typical clinic population in terms of motivation to engage in a lifestyle-change intervention. Finally, tests included in the SPPB may not be highly sensitive to change in this type of patient sample, and recent recommendations indicate that other physical performance tests may be more appropriate in the context of knee and hip osteoarthritis (60).

This study was novel in its approach to a provider-based intervention for osteoarthritis, which resulted in greater referrals for some treatments, particularly physical therapy, knee braces, and MOVE!. However, participants' actual use of these therapies did not differ between study groups and was low overall. Some participants may have been unwilling or unable to return to the Durham VA Medical Center for additional treatment because they live relatively far from the facility. Others may have received these treatments after the study or outside the VA system and therefore were not captured in our data. Additional work is needed to understand the reasons patients may choose not to initiate key behavioral and rehabilitative therapies for osteoarthritis, particularly when they are referred by their PCP. For other clinical treatments addressed in the provider intervention (joint injections, medication use, and orthopedic referrals), we found no substantial differences between study groups. Primary care providers may already recommend these treatments regularly, as suggested by the relatively frequent use of joint injections in both study groups.

This study has several limitations. First, its design did not allow separate examination of the patient and provider interventions. Second, participants received care at a VA medical center and a high proportion of them were men, which may limit generalizability of the

findings. Third, the accuracy of self-reported physical activity data is limited; however, we do not believe that this differed between study groups. Finally, the algorithms used to generate treatment recommendations required more extensive data collection than would be feasible in clinical settings. However, simpler sets of criteria could be used to trigger these recommendations in clinical situations.

In conclusion, this combined patient and provider intervention resulted in modest improvements in self-reported physical function and physical activity for veterans with hip and knee osteoarthritis. The provider-based intervention seemed particularly useful for increasing referrals for behavioral and rehabilitative programs. However, changes in study outcomes were modest, which may indicate that higher-intensity interventions are needed to yield clinically meaningful changes in osteoarthritis-related outcomes.

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**Disclaimer:** The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Veterans Affairs.

**Acknowledgment:** The authors thank the Ambulatory Care Service of the Durham VA Medical Center for participation in the study; study team members Jennifer Chapman, Karen Juntilla, and Laurie Marbrey; and all of the veterans who participated in this study.

**Financial Support:** This project was supported by the Department of Veterans Affairs, Health Services Research and Development Service (IIR 10-126). Dr. Bosworth is funded by a Career Scientist award (08-027).

**Disclosures:** Dr. Allen reports grants from the Department of Veterans Affairs Health Services Research and Development Service during the conduct of the study. Dr. Yancy reports grants from the Department of Veterans Affairs during the conduct of the study and personal fees from Nutrisystem and University of Pennsylvania/Weight Watchers International outside the submitted work. Dr. Bosworth reports grants from the National Institutes of Health during the conduct of the study; grants from Sanofi, Johnson & Johnson, Takeda Pharmaceutical Company, and the PhRMA Foundation outside the submitted work; and personal fees from CVS and Walgreens outside the submitted work. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-0378](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-0378).

**Reproducible Research Statement:** *Study protocol:* Available from Dr. Allen (e-mail, [Kelli.allen@va.gov](mailto:Kelli.allen@va.gov)). *Statistical code and data set:* Available to approved persons through agreement with the authors (e-mail, [Kelli.allen@va.gov](mailto:Kelli.allen@va.gov)).

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# IMPROVING PATIENT CARE

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## APPENDIX: PROVIDER INTERVENTION RECOMMENDATIONS AND ALGORITHMS

### Refer to Physical Therapy for Evaluation and/or Therapeutic Exercises

Criteria:

- Patient may be interested in being referred for physical therapy for osteoarthritis if their provider recommends, AND

- Patient is not doing lower extremity strengthening exercises  $\geq 2$  times per week, AND

- Patient indicates being dissatisfied with their ability to perform  $\geq 1$  activity on the Satisfaction with Physical Function Scale (walking, lifting/carrying, stair climbing, housework), AND

- Patient has not seen a physical therapist for their osteoarthritis in the past year.

### Refer for Evaluation for Knee Brace

Criteria for each knee with osteoarthritis:

- Patient is not currently using a knee brace, AND

- Patient may be interested in trying a knee brace (or different kind of knee brace) if their provider recommends.

Criteria for specific brace consults (VA-based study only)

- Knee sleeve: knee pain rating of 1 to 3 (on a 10-cm visual analogue scale) AND varus/valgus alignment  $< 10^\circ$  AND does not indicate knee “buckling”.

- Hinged brace: knee pain rating  $> 3$  (on a 10-cm visual analogue scale) OR indicates knee “buckling,” AND varus/valgus alignment  $\leq 15^\circ$ .

- Unloader brace: knee pain rating  $> 3$  (on a 10-cm visual analogue scale) OR indicates knee “buckling,” AND varus/valgus alignment  $> 15^\circ$ .

### Refer to Weight Management Program (MOVE!)

Criteria:

- Patient has BMI  $\geq 25$  kg/m<sup>2</sup>, AND

- Patient may be interested in being referred to a weight management program if his or her provider recommends.

### Refer to Physical Activity Program (MOVE!)

Criteria:

- Patient is not doing at least 2 hours and 30 minutes of aerobic activity per week and strengthening exercises  $\geq 2$  times per week, AND

- Patient may be interested in being referred to a physical activity program if his or her provider recommends.

### Perform or Refer for Intra-articular Injection

Criteria:

- Patient has moderate to severe knee pain ( $\geq 6$  on a 10-cm visual analogue scale), AND

- Patient has radiographic evidence of osteoarthritis in that knee, AND

- Patient is already taking oral pain medications, AND

- Patient has not received a joint injection in the past 6 months, AND

- Patient may be interested in having a knee joint injection if his or her provider recommends.

### Recommend or Prescribe Topical NSAID or Capsaicin

Criteria:

- Patient is not currently using topical creams for osteoarthritis, AND

- Patient may be interested in trying a topical cream (or different type of topical cream) if his or her provider recommends.

### Patient Reports Taking an NSAID (Prescription or Over-the-Counter) but Has Risk Factors for Gastrointestinal (GI) Bleeding; Consider Addition of Gastroprotective Agent or Switch to Other Pain Medication

Criteria:

- Patient is currently using an NSAID without gastroprotective agent, AND

- Patient has  $\geq 1$  risk factor for GI bleeding: age  $\geq 75$  years, history of peptic ulcer disease or GI bleeding, current glucocorticoid use.

### **Discuss the Possibility of Trying a New/Alternate Pain Medication With Patient**

Criterion:

- Patient indicates a desire to talk with his or her health care provider about the possibility of trying a different pain medication for their arthritis.

### **Referral to Orthopedics for Evaluation for Joint Replacement Surgery (If No Contraindications to Surgery)**

Criteria:

- Radiographic evidence of osteoarthritis in that joint, AND
- Patient has tried each of the following: pain medications, joint injection, and physical therapy, AND
- Pain  $\geq 6$  (on a 10-cm visual analogue scale) in that joint, AND
- Functional limitation due to osteoarthritis  $\geq 6$  (on a 10-point visual numeric scale), AND
- Patient indicates an interest in being referred to a specialist for evaluation for potential joint replacement surgery.

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### **Appendix Table. Exclusion Criteria**

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Other rheumatologic conditions  
Recent hip or knee surgery or injury  
On waiting list for arthroplasty  
Recent hospitalization for cardiovascular or cerebrovascular events  
Severe neurologic or psychiatric conditions  
Severe memory loss  
Terminal illness  
Nursing home residence  
Severe hearing or speech impairment  
Blindness  
Current participation in another osteoarthritis intervention or other lifestyle-change study  
Current pregnancy or plans to become pregnant  
No primary care visits at the Durham VA Medical Center in the past 12 mo

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VA = Department of Veterans Affairs.