Published in final edited form as:

Ann Intern Med. 2017 March 21; 166(6): 401–411. doi:10.7326/M16-1245.

Patient, Provider, and Combined Interventions for Managing Osteoarthritis in Primary Care:

A Cluster Randomized Trial

Kelli D. Allen, PhD, Eugene Z. Oddone, MD, MHSc, Cynthia J. Coffman, PhD, Amy S. Jeffreys, MStat, Hayden B. Bosworth, PhD, Raneer Chatterjee, MD, MPH, Jennifer McDuffie, PhD, Jennifer L. Strauss, William S. Yancy Jr., MD, MHS, Santanu K. Datta, PhD, MHS, Leonor Corsino, MD, MHS, Rowena J. Dolor, MD, MHS

Durham Veterans Affairs Medical Center, Duke University, and Duke University Medical Center, Durham, and University of North Carolina, Chapel Hill, North Carolina.

Abstract

Background: A single-site study showed that a combined patient and provider intervention improved outcomes for patients with knee osteoarthritis, but it did not assess separate effects of the interventions.

Objective: To examine whether patient-based, provider-based, and patient-provider interventions improve osteoarthritis outcomes.

Design: Cluster randomized trial with assignment to patient, provider, and patient-provider interventions or usual care. (ClinicalTrials.gov:)

Requests for Single Reprints: Kelli D. Allen, PhD, Thurston Arthritis Research Center, University of North Carolina at Chapel Hill, 3300 Thurston Building, CB# 7280, Chapel Hill, NC 27599; kdallen@email.unc.edu.

Current author addresses and author contributions are available at www.annals.org.

Current Author Addresses: Dr. Allen: Thurston Arthritis Research Center, University of North Carolina at Chapel Hill, 3300 Thurston Building, CB# 7280, Chapel Hill, NC 27599. Drs. Oddone, Coffman, Jeffreys, Bosworth, and McDuffie: Health Services Research and Development (152), Durham Veterans Affairs Medical Center, 508 Fulton Street, Durham, NC 27705. Drs. Chatterjee, Datta, and Dolor: Duke Division of General Internal Medicine, 411 West Chapel Hill Street, Box 104427, Durham, NC 27710.

Ms. Strauss: Building 6, Durham Veterans Affairs Medical Center, 508 Fulton Street, Durham, NC 27705.

Dr. Yancy: Duke Diet and Fitness Center, 501 Douglas Street, Durham, NC 27705.

Dr. Corsino: Duke Department of Medicine, Box 3451, Durham, NC 27710.

Author Contributions: Conception and design: K.D. Allen, E.Z. Oddone, C.J. Coffman, A.S. Jeffreys, H.B. Bosworth, J.L. Strauss, W.S. Yancy, S.K. Datta, R.J. Dolor.

Analysis and interpretation of the data: K.D. Allen, C.J. Coffman, A.S. Jeffreys, H.B. Bosworth, J. McDuffie, W.S. Yancy, S.K. Datta, R.J. Dolor.

Drafting of the article: K.D. Allen, C.J. Coffman, H.B. Bosworth, J. McDuffie, L. Corsino.

Critical revision for important intellectual content: K.D. Allen, E.Z. Oddone, C.J. Coffman, A.S. Jeffreys, H.B. Bosworth, R. Chatterjee, W.S. Yancy, L. Corsino, R.J. Dolor.

Final approval of the article: K.D. Allen, E.Z. Oddone, C.J. Coffman, A.S. Jeffreys, H.B. Bosworth, R. Chatterjee, J. McDuffie, J.L. Strauss, W.S. Yancy, S.K. Datta, L. Corsino, R.J. Dolor.

Provision of study materials or patients: R. Chatterjee, S.K. Datta, R.J. Dolor.

Statistical expertise: C.J. Coffman, A.S. Jeffreys.

Obtaining of funding: K.D. Allen, C.J. Coffman, S.K. Datta. Administrative, technical, or logistic support: K.D. Allen, E.Z. Oddone, A.S. Jeffreys, J. McDuffie, R.J. Dolor.

Collection and assembly of data: K.D. Allen, C.J. Coffman, A.S. Jeffreys, J. McDuffie, S.K. Datta, R.J. Dolor.

Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health (NIH).

Reproducible Research Statement: *Study protocol:* Available from Dr. Allen (e-mail, kdallen@email.unc.edu). *Statistical code and data set:* Available to approved persons through agreement with the authors (e-mail, kdallen@email.unc.edu).

Setting: 10 Duke University Health System community-based primary care clinics.

Participants: 537 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 electronic delivery of patient-specific osteoarthritis treatment recommendations to providers.

Measurements: The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score at 12 months. Secondary outcomes were objective physical function (Short Physical Performance Battery) and depressive symptoms (Patient Health Questionnaire). Linear mixed models assessed the difference in improvement among groups.

Results: No difference was observed in WOMAC score changes from baseline to 12 months in the patient (−1.5 [95% CI, −5.1 to 2.0]; $P=0.40$), provider (2.5 [CI, −0.9 to 5.9]; $P=0.152$), or patient-provider (−0.7 [CI, −4.2 to 2.8]; $P=0.69$) intervention groups compared with usual care. All groups had improvements in WOMAC scores at 12 months (range, −3.7 to −7.7). In addition, no differences were seen in objective physical function or depressive symptoms at 12 months in any of the intervention groups compared with usual care.

Limitations: The study involved 1 health care network. Data on provider referrals were not collected.

Conclusion: Contrary to a previous study of a combined patient and provider intervention for osteoarthritis in a Department of Veterans Affairs medical center, this study found no statistically significant improvements in the osteoarthritis intervention groups compared with usual care.

Primary Funding Source: National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Osteoarthritis is a leading cause of pain and disability (1–3). Already a leading chronic health condition in primary care settings (4), osteoarthritis will become increasingly prevalent (5–8). Treatment involves a combination of behavioral, pharmacologic, and other clinical therapies (9–11); therefore, both patients and health care providers play key roles in effective management. However, studies have identified gaps in the use of key behavioral strategies, including physical activity and weight management (12–14), as well as low use of some recommended clinical therapies (15–20). These studies emphasize the need to improve the use of evidence-based osteoarthritis therapies.

It is not known whether interventions focused on health care providers or patients may be more effective for improving osteoarthritis management and outcomes. Most previous osteoarthritis interventions occurred at the patient level, with little attempt to effect provider- or system-level changes. We previously reported that among a group of patients with osteoarthritis receiving care at a single Veterans Affairs medical center (VAMC), a combined patient and provider intervention resulted in statistically significant, modest improvements in physical function (21). This study extends this research area by separately examining patient-level, health care provider-level, and combined osteoarthritis interventions in several primary care clinics.

METHODS

The Institutional Review Board of Duke University Medical Center approved this study. Methods were published previously (22). Owing to our lack of awareness, the study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) 15 days after the first participant was enrolled, which met institutional requirements but not the International Committee of Medical Journal Editors' requirement of registration before participant enrollment. Only 1 participant was enrolled, and no analyses were done before registration.

Study Setting and Design

This study was conducted within the Duke Primary Care Research Consortium. Ten primary care clinics were randomly assigned to provider intervention or control conditions, and patients within those clinics were assigned to patient intervention or control, resulting in 4 study groups: patient intervention, provider intervention, patient-provider intervention, and usual care. Randomization schedules for clinics and patients were computer generated by the statistician. Clinic randomizations were paired on the basis of type (family or internal medicine) as well as similarities in practice size (numbers of patients and providers) and rural versus urban location; 1 clinic in each pair was assigned to the provider intervention and 1 to the provider control group. Patient randomizations were stratified by race (white vs. nonwhite) and sex. All participants continued with usual care for osteoarthritis as recommended by their providers, with no restrictions.

Participants and Recruitment

All primary care providers (PCPs) at the study clinics were invited to participate; only 2 declined. Patients were eligible if they had osteoarthritis of the hip (based on radiographic evidence in the electronic medical record [EMR]) or knee (based on radiographic evidence in the EMR or satisfaction of American College of Rheumatology clinical criteria [23]), along with self-reported joint symptoms (pain, aching, stiffness, or swelling in or around a hip or knee joint with arthritis that was present or for which the patient used pain medications on most days during the past month) (24). Participants had to be overweight (body mass index [BMI] ≥ 25 kg/m²) and not currently meeting U.S. Department of Health and Human Services physical activity recommendations (≥ 150 minutes of aerobic activity and 2 sessions of muscle strengthening activity weekly) (25). Exclusion criteria are summarized in Appendix Table 1 (available at www.annals.org). Potential participants were identified from the EMR, were mailed an introductory letter, and were called for screening. Eligible patients gave consent, completed baseline assessments, and were informed of their randomization assignment by the study coordinator via telephone.

Interventions

Patient Behavioral Intervention for Osteoarthritis—The intervention took place over 12 months and focused on physical activity, weight management, and cognitive behavioral strategies for managing pain (22). Telephone calls were scheduled twice per month for the first 6 months, then 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 intervention components. Motivational interviewing strategies were used throughout the

intervention (22, 26, 27). Participants were given written educational materials, an exercise video, and an audio CD of relaxation exercises.

Provider Intervention—The study team delivered the following patient-specific osteoarthritis treatment recommendations to PCPs, based on treatment guidelines (11, 28, 29): refer to physical therapist, refer for evaluation for knee brace, refer to weight management program, refer to physical activity program, perform or refer for intra-articular injection, recommend topical nonsteroidal anti-inflammatory drug or capsaicin, add gastroprotective agent or remove nonsteroidal anti-inflammatory drug in patients at high risk for peptic ulcer disease, discuss new or alternate pain medication, and refer to orthopedic evaluation for joint replacement surgery. We developed algorithms based on patient data (Appendix Table 2, available at www.annals.org) regarding when each treatment option would be reasonable for a PCP to consider for a patient (22). However, decisions regarding whether to recommend these treatments to patients were at the discretion of the PCPs. The study team monitored upcoming visits for provider intervention participants, and recommendations were delivered only once per participant, before the first routine visit after enrollment. Most recommendations were delivered via the Duke EMR, but 22 were delivered via secure e-mail during an EMR transition.

Outcome Measures

The primary and secondary analyses include measures at baseline through 12 months. Analyses of maintenance effects (18 and 24 months) will be presented separately. All outcomes (including osteoarthritis treatment use) were assessed in person at baseline and 12 months, except for 48 participants who could not return at 12 months but completed some measures via telephone. The primary outcome also was assessed via telephone at 6 months. Outcomes assessors were blind to randomization. Participants were reimbursed \$25 and \$10 for in-person and phone assessments, respectively.

Primary Outcomes—The primary outcome was the 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 past 2 weeks (30–32). All items are rated on a 5-point Likert scale ranging from “none” to “extreme” (total range, 0 to 96; higher scores indicate worse symptoms and function).

Secondary Outcomes—We examined WOMAC pain and function sub-scales separately. We also administered the Short Physical Performance Battery (33), which 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 8-item Patient Health Questionnaire (PHQ-8) (34), with scores ranging from 0 to 24.

Physical Activity and BMI—Several exploratory measures were collected (22); here, we focus on physical activity and BMI, because they assess core patient intervention components. Self-reported physical activity was measured with the Community Healthy Activities Model Program for Seniors (CHAMPS) (35, 36); we report the weekly frequency and duration of all exercise, as well as moderate- or higher-intensity exercise, during the past

4 weeks. Height and weight were measured to calculate BMI; when 12-month follow-up measures were administered via telephone, weight was self-reported.

Osteoarthritis Treatment Use and Recommendations—We describe the proportions of participants who reported receiving the following treatments during the study period: physical therapy for knee or hip osteoarthritis, new knee brace use, joint injections, a change in oral pain medications, new use of topical creams, and joint replacement surgery. We assessed osteoarthritis treatment use via self-report, because the EMR would not capture care received outside the Duke system. For the provider intervention groups, we also report the proportions of participants for whom each treatment recommendation was given to the PCP by the study team. Data regarding recommendations or referrals given to patients by PCPs were not collected.

Participant Characteristics—We collected patient-reported characteristics, including age, sex, race/ethnicity (white vs. nonwhite), household financial situation (with “inadequate income” meaning just enough or not enough to meet basic expenses), education level, marital status, work status (employed or student vs. other), disabled (positive response to “disabled” in the work status question), general self-rated health (excellent, very good, or good vs. fair or poor), and duration of osteoarthritis symptoms.

Adverse Events—At each study encounter, we inquired about hip and knee injuries or surgeries. We noted other adverse events that participants reported to the study team during regular contact or that were discovered during study-related EMR review.

Sample Size

The estimated sample size of 140 participants per group (56 per clinic) was based on detecting a 15% improvement in WOMAC scores at 12 months for either of 2 primary hypotheses, with 80% power and a type I error rate of 0.05. Sample size calculations were based on methods for appropriate analysis of covariance-type methods (37, 38) and were adjusted for clinic clustering (intraclass correlation coefficient, 0.03) (39). A correlation of 0.60 between time points was assumed, as were an SD of 14 and a 15% attrition rate at 12 months. We had 2 primary hypotheses but did not adjust our type I error, because the purpose of this trial was to demonstrate effects in both (40).

Data Analysis

Our primary hypotheses were that at 12 months, compared with usual care, participants who received the patient-provider intervention would have greater improvement in mean WOMAC score than those who received either the patient or provider intervention (H_1), and compared with usual care, participants who received either the patient or provider intervention would have greater improvement in mean WOMAC score (H_2). Analyses involved all randomly assigned participants and used all data collected for each participant (40, 41). The estimation procedure for our analytic technique (linear mixed models) accommodates missingness when related to previous outcome or other baseline covariates (missing at random). To assess the model’s robustness to missing observations, we multiply imputed missing WOMAC follow-up scores by using a Markov chain Monte Carlo

algorithm incorporating additional variables to strengthen the missing-at-random assumption (Supplement, available at www.annals.org).

For continuous variables, hierarchical linear mixed models were fit by using SAS (version 9.4) PROC MIXED (SAS Institute) (42). A random effect accounting for clustering of clinics and an unstructured covariance structure accounting for repeated measures were used. Because the number of clinic pairs was small, we performed unmatched analyses (43, 44). For all outcomes except CHAMPS, the assessed values at 0, 6 (WOMAC), and 12 months were included as outcomes in models, and contrasts of model parameters were used to compare changes from baseline to 12 months between groups. For CHAMPS, change from baseline to 12 months was modeled as the result of normality assumptions; similarly, contrasts were used to compare change between groups. Predictors in all models included intervention indicator variables, dummy-coded follow-up time effects, and indicator variables for interventions interacting with follow-up time (45). We originally assumed equal baseline means across groups (45, 46). However, because this was a cluster randomized trial and baseline mean WOMAC scores differed across groups, we dropped this assumption. Final models also included the stratification variables race and sex. For the CHAMPS 12-month change from baseline, model fixed-effect terms included baseline CHAMPS score and an indicator variable for study group. For BMI, primary analyses included only in-person weight collected at 12 months; sensitivity analyses included self-reported weight from participants without an in-person visit at 12 months.

In a post hoc analysis to examine clinically meaningful change in WOMAC scores (47–49), we categorized participants as either improved or not at 12 months based on 12% (4.3- to 4.9-point reduction) and 18% (6.4- to 7.4-point reduction) improvement. For these dichotomous outcomes, we used generalized estimating equation models (50) with a logit link and an unstructured correlation structure fit with PROC GENMOD.

Role of the Funding Source

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) had no role in the study design, collection, analysis or interpretation of data, writing of the manuscript, or decision to submit for publication.

RESULTS

Participants

We identified 16 393 potential participants from the EMR (Figure 1). Of 2315 patients who met medical record criteria and underwent screening, 537 (56 at each of 5 provider intervention clinics and 1 provider control clinic, 57 at each of 2 provider control clinics, 40 at 1 provider control clinic, and 47 at 1 provider control clinic) were eligible, enrolled, and randomly assigned to one of the groups; 87% and 81% of participants completed 6- and 12-month measures, respectively. Participants who completed 12-month outcomes were older (aged 64 vs. 61 years; $P = 0.007$) and had lower baseline WOMAC (37.2 vs. 44.7; $P < 0.001$) and PHQ-8 (4.3 vs. 5.7; $P = 0.013$) scores than noncompleters; they also were less likely to be employed or students (77.9% vs. 86.8%; $P = 0.008$).

Clinic characteristics are shown in Table 1 and participant characteristics in Table 2.

Adverse Events

No study-related adverse events occurred.

Intervention Delivery

Participants in the patient and patient-provider interventions completed an average of 7.8 (SD, 4.6) and 8.4 (SD, 4.3) telephone calls, respectively, of a possible 18. Treatment recommendations were delivered successfully to PCPs for 261 (of 280) participants; the remaining participants could not be contacted for notification of randomization assignment ($n = 2$), withdrew or were excluded from the study before recommendations could be delivered ($n = 14$), or were inadvertently missed by the study team ($n = 3$).

Primary Outcome

Compared with usual care, participants in the patient-provider intervention did not have greater improvement in mean WOMAC scores between baseline and 12 months than those in the patient or provider interventions (estimated difference, -1.6 [95% CI, -6.6 to 3.3]; $P = 0.52$) (Figure 2). Also, no improvement was observed in any of the intervention groups compared with usual care (Table 3). Improvements in mean WOMAC score were seen at 12 months in all 4 groups, with the largest estimated mean improvement (-7.7 and -6.8 points) for the patient and patient — provider interventions, respectively, although substantial improvement (-6.1 points) also was noted in the usual care group. The intraclass correlation from this model was 0.02, indicating similar patient outcomes within clinics. Box plots of observed changes in total WOMAC score between baseline and 12 months by clinic are shown in Supplement Figure 1 (available at www.annals.org), and smoothing curves fit to longitudinal scores by group within clinics are shown in Supplement Figure 2 (available at www.annals.org). Results were similar in multiply imputed data sets (Supplement).

The proportions of participants with a 12% or greater improvement in WOMAC score were 56%, 63%, 41%, and 50% for the usual care, patient, provider, and patient-provider groups, respectively (see the Supplement Table [available at www.annals.org] for 95% CIs for these estimates); only the provider group differed from usual care (odds ratio, 0.7 [CI, 0.6 to 0.9]; $P = 0.002$). Proportions showing an 18% or more improvement in WOMAC score were 49%, 49%, 35%, and 33% for the usual care, patient, provider, and patient-provider groups, respectively (see the Supplement for 95% CIs for these estimates); only the provider group differed from usual care (odds ratio, 0.7 [CI, 0.4 to 0.9]; $P = 0.016$).

Secondary Outcomes

On the WOMAC pain and physical function sub-scales, compared with usual care, participants receiving the patient-provider intervention did not have greater improvement than those in the patient or provider intervention groups (-0.1 [CI, -1.5 to 1.2 ; $P = 0.83$] and -1.5 [CI, -5.1 to 2.1 ; $P = 0.41$], respectively). Also, no differences in improvement compared with usual care were observed in any of the treatment groups (Table 3). Regarding objective physical function and depressive symptoms, we likewise found no differences compared with usual care among participants receiving the patient-provider intervention and

those receiving either the provider or patient intervention (0.5 [CI, -0.3 to 1.2; $P = 0.23$] and -0.8 [CI, -2.1 to 0.4; $P = 0.185$], respectively). No other group differences were found for these outcomes compared with usual care (Table 3).

Physical Activity and BMI

Compared with participants receiving usual care, those receiving the patient-provider intervention did not have greater improvement at 12 months in frequency or duration of physical activity than those receiving the patient or provider intervention (1.6 [CI, -0.8 to 4.1; $P = 0.188$] and 0.6 [CI, -2.0 to 3.1; $P = 0.65$], respectively). No group differences were seen in mean change from baseline compared with usual care (Table 3). For BMI, we also found no differences compared with usual care between participants receiving the patient-provider intervention and those receiving the patient or provider intervention (0.7 [CI, -0.2 to 1.5]; $P = 0.120$). Mean change in BMI between baseline and 12 months differed between the provider intervention and usual care groups ($P = 0.022$) (Table 3). Sensitivity analyses for BMI that included participants who self-reported their weight at 12 months were similar to results obtained by using only data from participants who had their weight measured, except that mean change in BMI between baseline and 12 months no longer differed between the provider and usual care groups (-0.5 [CI, -1.0 to 0.09]; $P = 0.098$).

Osteoarthritis Treatment Recommendations and Use

Table 4 shows the proportions of participants who reported having specific osteoarthritis-related treatments during the study period. For most treatments, use was lower in the usual care group than in the intervention groups, but the differences were very small. The most common treatment change during the study period involved pain medications (29% to 39% of participants). Use of physical therapy, knee braces, and topical creams was low (<10% of participants). Table 5 shows the proportions of participants in the provider intervention groups for whom specific treatment recommendations were issued and, among those, the proportions who reported receiving those treatments.

DISCUSSION

In this study, none of the osteoarthritis intervention groups showed greater improvements in outcomes than usual care. These results differ from our recent 2-group study, in which the same combined patient and provider intervention improved WOMAC total and function scores, as well as physical activity, among VAMC patients with osteoarthritis (21). In the VAMC study, WOMAC scores improved 8.5% in the osteoarthritis intervention group, whereas the usual care group did not improve. Interestingly, although percentage improvement in WOMAC scores was greater for all intervention groups in this study compared with the VAMC investigation (patient, 18.7%; provider, 9.8%; patient-provider, 17.3%), the usual care group also improved 17.0%.

Several reasons may explain the improved WOMAC scores in the usual care group. First, a Hawthorne effect may have occurred, with usual care participants reporting improvements in response to being observed in the study (51). However, the degree of improvement in the usual care group was greater than expected on the basis of previous clinical trials of

behavioral interventions for osteoarthritis (21, 52, 53). Second, because the study recruited from primary care clinics, usual care participants may have received osteoarthritis treatments that resulted in improved outcomes. On the basis of self-report, about 20% of usual care participants received a joint injection and about 30% tried a new pain medication during the study; treatment use overall was similar to that in the intervention groups. Third, studies indicate that in some patients, osteoarthritis symptoms improve over time, and this pattern is more common among individuals with less severe symptoms at baseline evaluation (54–58). Baseline WOMAC scores were somewhat lower in the usual care group than the other groups.

We did not observe between-group differences in self-reported osteoarthritis treatments during the study period, which may partly explain the lack of effect in the provider intervention groups. Even when the study team recommended a treatment to PCPs, patient use was low. Possible reasons for this outcome include lack of patient or provider confidence in osteoarthritis therapies, patients' inability to afford copayments for such services as physical therapy, and limited time to address osteoarthritis during visits to primary care clinics (59, 60). Because we could not capture actual provider recommendations or referrals, we could not assess whether low use of osteoarthritis treatments was the result of a lack of provider action or of patient choice regarding follow-up. In our VAMC study, we found that providers in the intervention group were more likely to refer patients for osteoarthritis treatments, but patients' use of these treatments did not differ between groups (21). Taken together, these studies suggest that more comprehensive strategies are needed to enhance use of evidence-based osteoarthritis treatments. Decision aids may enhance patients' engagement in treatment discussions, and option grids used by clinicians also have improved shared decision making in osteoarthritis (61–63). Embedding these types of tools in the EMR and the routine process of care may improve osteoarthritis management, but larger effectiveness studies are needed to evaluate specific approaches.

This study had several limitations. First, although we attempted to match provider intervention and provider control sites based on clinical characteristics, some differences in baseline WOMAC scores existed across groups. Second, the study was conducted within 1 health care system. Third, the accuracy of self-reported physical activity and osteoarthritis treatment use is limited, although we do not suspect that it differed among study groups. Fourth, we did not obtain radiographs to verify osteoarthritis. We assumed there was a low risk for including patients without osteoarthritis, because all participants had documentation of a physician diagnosis based on radiographic evidence (or met American College of Rheumatology clinical criteria for knee osteoarthritis). Fifth, previous radiographs were not read with respect to a specific scoring system, so we could not characterize participants' radiographic osteoarthritis severity.

In conclusion, patient and provider osteoarthritis interventions did not improve outcomes beyond usual care in this study conducted in community-based clinics, in contrast to the results of our VAMC study (21). These interventions may have variable added benefit for different patient groups and health care environments. However, the overall effects in the VAMC study also were modest, suggesting that for at least some patients, more intensive interventions may be needed to produce meaningful, sustained changes in osteoarthritis

management and outcomes (64–68). Automated e-health interventions are a potential strategy for increasing intervention intensity in a scalable manner (69, 70).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgment:

The authors thank study team members Catherine Stanwyck, Carrie Bumgarner, Dorothea Brock, and Stephanie Smith, as well as the clinics of the Duke Primary Care (DPC) Research Consortium that participated in this study: DPC Butner-Creedmoor, DPC Henderson, DPC Hills-borough, DPC Pickett Road, DPC Harps Mill, DPC Timberlyne, Durham Medical Center, Oxford Family Physicians, Sutton Station Internal Medicine, and Triangle Family Practice. The authors also are deeply grateful to all the patients who participated in this study.

Financial Support: By the NIAMS of the NIH under award 1R01AR059673–01 and contributions from the Department of Veterans Affairs Health Services Research and Development Service (CIN 13–410).

Disclosures: Drs. Allen, Coffman, Dolor, and Datta report grants from the NIH during the conduct of the study. Dr. Bosworth reports grants and personal fees from Sanofi; grants from Johnson and Johnson, Takeda, and Improved Patient Outcomes; and personal fees from Genentech, outside the submitted work. Dr. Yancy reports grants from NIH/NIAMS during the conduct of the study; personal fees from University of Pennsylvania/Weight Watchers International; and grants from the NIH and Department of Veterans Affairs, outside the submitted work. Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M16-1245.

Appendix

Appendix Table 1.

Exclusion Criteria

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 Duke in the past 18 mo
Other health condition that would prohibit safe or appropriate participation in the study

Appendix Table 2.

Provider Intervention Recommendations and Algorithms

Criteria to refer to physical therapy for evaluation and/or therapeutic exercises

Patient may be interested in being referred for physical therapy for OA if his or her provider recommends, and

Patient is not doing lower-extremity strengthening exercises 2 times per week, and

Patient indicates being dissatisfied with his or her ability to perform one or more activities on the Satisfaction with Physical Function Scale (walking, lifting/carrying, stair climbing, and housework), and

Patient has not seen a physical therapist for his or her OA in the past year.

Criteria to refer for evaluation for knee brace*

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 his or her provider recommends.

Criteria to refer to weight management program

Patient has a BMI ≥ 25 kg/m², and

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

Criteria to refer to physical activity program

Patient is not doing at least 2 h and 30 min of aerobic activity per week and strengthening exercises 2 times per week, and

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

Criteria to perform or refer for intra-articular knee injection

Patient has moderate to severe knee pain (≥ 6 on a 10-cm visual analog scale), and

Patient has radiographic evidence of OA in that knee, and

Patient is already taking oral pain medications, and

Patient has not received a joint injection in the past 6 mo, and

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

Criteria to perform or refer for intra-articular hip injection

Patient has moderate to severe hip pain (≥ 6 on a 10-cm visual analog scale), and

Patient has radiographic evidence of OA in that hip, and

Patient is already taking oral pain medications, and

Patient has not received a hip joint injection in the past 6 mo, and

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

Criteria to recommend or prescribe topical NSAID or capsaicin

Patient is not currently using topical creams for OA, 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 bleeding. Criteria to consider addition of gastroprotective agent or switch to other pain medication

Patient is currently using an NSAID without gastroprotective agent, and

Patient has ≥ 1 risk factor for gastrointestinal bleeding: age ≥ 75 y, history of peptic ulcer disease or gastrointestinal bleeding, and current glucocorticoid use.

Criteria to discuss the possibility of trying a new/alternate pain medication with patient

Patient indicated he or she may like to talk with his or her health care provider about the possibility of trying a different pain medication for his or her arthritis.

Criteria for referral to orthopedics for evaluation for joint replacement surgery (if no contraindications to surgery)

Radiographic evidence of OA in that joint, and

Patient has tried each of the following: pain medications, joint injection, and physical therapy, and

Pain ≥ 6 (on a 10-cm visual analog scale) in that joint, and

Functional limitation due to OA ≥ 6 (on a 10-point visual numeric scale), and

Patient indicated he or she may be interested in being referred to a specialist for evaluation for potential joint replacement surgery.

BMI = body mass index; NSAID = nonsteroidal anti-inflammatory drug; OA = osteoarthritis.

*
For each knee with OA.

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Figure 1.
CONSORT diagram.

CONSORT = Consolidated Standards of Reporting Trials; DPC = Duke Primary Care; OA = osteoarthritis.

* Reasons for being dropped after randomization: total knee replacement ($n = 13$), total hip replacement ($n = 4$), change in primary care clinic ($n = 6$), primary care provider not in study ($n = 1$), enrollment in another OA intervention study ($n = 1$), serious medical event making

study intervention potentially unsafe ($n = 1$). For patients who withdrew or were dropped after randomization, all data collected up to that time point were used in analyses.

† Participants who could not be reached for 6-mo follow-up were still eligible for 12-mo assessments; participants who could not be reached at 12 mo are still being followed for subsequent time points.

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Figure 2.

Estimated mean WOMAC scores by study group and time point and 95% CI (error bars) from hierarchical linear mixed models. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

Table 1.

Baseline Clinic Characteristics

Characteristic	All Clinics (<i>n</i> = 10)	Usual Care Clinics (<i>n</i> = 5)	Intervention Clinics (<i>n</i> = 5)
Mean providers (SD), <i>n</i>	7.3 (1.6)	6.8 (1.8)	7.8 (1.3)
Mean medical physicians and osteopaths (SD), <i>n</i>	6.2 (1.6)	5.4 (1.5)	7.0 (1.4)
Mean nurse practitioners and physician assistants (SD), <i>n</i>	1.1 (1.2)	1.4 (1.7)	0.8 (0.4)
Practice type, <i>n</i> (%)			
Family medicine	6 (60.0)	3 (60.0)	3 (60.0)
Internal medicine	4 (40.0)	2 (40.0)	2 (40.0)
	All Providers (<i>n</i> = 73)	Usual Care Providers (<i>n</i> = 34)	Intervention Providers (<i>n</i> = 39)
Men, <i>n</i> (%)	28 (38.4)	13 (38.2)	15 (38.5)
Mean years since graduation (SD), <i>n</i>	18.9 (10.0)	17.7 (9.5)	19.9 (10.4)

Table 2.

Baseline Participant Characteristics^{*}

Characteristic	Total Sample (<i>n</i> = 537)	Usual Care (<i>n</i> = 129)	Patient Intervention (<i>n</i> = 128)	Provider Intervention (<i>n</i> = 140)	Patient-Provider Intervention (<i>n</i> = 140)
Mean age (SD), <i>y</i>	63.3 (9.6)	63.9 (10.2)	63.9 (9.3)	62.6 (9.6)	62.7 (9.3)
Men, <i>n</i> (%)	140 (26.1)	37 (28.7)	35 (27.3)	34 (24.3)	34 (24.3)
Nonwhite race, <i>n</i> (%)	217 (40.4)	49 (38.0)	51 (39.8)	58 (41.4)	59 (42.1)
Married or living with partner, <i>n</i> (%)	316 (58.9)	77 (59.7)	80 (62.5)	85 (60.7)	74 (52.9)
High school education or less, <i>n</i> (%)	127 (23.7)	40 (31.0)	37 (28.9)	25 (17.9)	25 (17.9)
Inadequate income, <i>n</i> (%)	95 (17.7)	29 (22.5)	22 (17.2)	22 (15.7)	22 (15.7)
Employed or student, <i>n</i> (%) [‡]	281 (53.0)	69 (53.9)	67 (54.0)	69 (49.3)	76 (55.1)
Disabled, <i>n</i> (%)	43 (8.1)	15 (11.7)	12 (9.7)	9 (6.4)	7 (5.1)
Fair or poor health, <i>n</i> (%)	107 (19.9)	27 (20.9)	29 (22.7)	26 (18.6)	25 (17.9)
Mean BMI (SD), <i>kg/m</i> ²	35.6 (7.4)	35.5 (8.1)	34.9 (6.9)	36.4 (7.8)	35.3 (6.6)
Joints with osteoarthritis, <i>n</i> (%)					
Knee only	455 (84.7)	110 (85.3)	106 (82.8)	120 (85.7)	119 (85.0)
Hip only	48 (8.9)	12 (9.3)	15 (11.7)	8 (5.7)	13 (9.3)
Knee and hip	34 (6.3)	7 (5.4)	7 (5.5)	12 (8.6)	8 (5.7)
Mean duration of arthritis symptoms (SD), <i>y</i> [‡]	10.4 (9.2)	9.9 (9.7)	9.3 (7.7)	10.4 (8.6)	11.8 (10.5)
Mean WOMAC score (SD) [§]	38.6 (17.0)	35.6 (18.0)	41.0 (15.9)	37.7 (17.9)	40.1 (15.8)
Mean SPPB score (SD) ^{//}	8.5 (1.9)	8.6 (2.1)	8.3 (1.8)	8.7 (1.8)	8.6 (1.9)
Mean PHQ-8 score (SD) [¶]	4.6 (4.3)	4.0 (3.7)	4.8 (4.3)	4.6 (4.2)	5.0 (4.9)

BMI = body mass index; PHQ-8 = 8-item Patient Health Questionnaire; SPPB = Short Physical Performance Battery; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

^{*} Percentages may not sum to 100 due to rounding.

[‡] Data are missing for 7 participants.

[§] Data are missing for 1 participant.

[¶] Data are missing for 1 participant.

^{//} Data are missing for 15 participants.

Data are missing for 2 participants.

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Table 3.

Estimated Baseline Means, Mean Changes From Baseline to 6 Months and Baseline to 12 Months, and Difference of Mean Changes Between Each Intervention Group and Usual Care and Associated 95% CIs^{*}

Outcome	Mean Baseline	Baseline to 6-Mo Difference (95% CI)	Baseline to 12-Mo Difference (95% CI)	Difference in Baseline to 12 Mo vs. Usual Care (95% CI)	P Value
WOMAC score[†]					
Total					
Usual care	35.8	-6.2 (-8.6 to -3.9)	-6.1 (-8.6 to -3.7)	-	
Patient	41.1	-7.3 (-9.8 to -4.8)	-7.7 (-10.3 to -5.1)	-1.5 (-5.1 to 2.0)	0.40
Provider	37.6	-5.0 (-7.3 to -2.8)	-3.7 (-6.0 to -1.3)	2.5 (-0.9 to 5.9)	0.152
Patient-provider	39.8	-8.9 (-11.3 to -6.6)	-6.8 (-9.4 to -4.3)	-0.7 (-4.2 to 2.8)	0.69
Pain subscale					
Usual care	7.6	-1.5 (-2.1 to -0.9)	-1.0 (-1.7 to -0.4)	-	
Patient	8.8	-1.9 (-2.5 to -1.2)	-1.5 (-2.2 to -0.8)	-0.4 (-1.4 to 0.5)	0.37
Provider	8.0	-1.3 (-1.9 to -0.7)	-0.8 (-1.4 to -0.1)	0.3 (-0.7 to 1.2)	0.60
Patient-provider	8.4	-2.2 (-2.8 to -1.5)	-1.4 (-2.1 to -0.7)	-0.3 (-1.3 to 0.6)	0.49
Function					
Usual care	24.7	-4.3 (-6.1 to -2.6)	-4.6 (-6.3 to -2.8)	-	
Patient	28.5	-5.0 (-6.8 to -3.1)	-5.6 (-7.4 to -3.7)	-1.0 (-3.5 to 1.6)	0.45
Provider	26.0	-3.3 (-5.0 to -1.6)	-2.3 (-4.0 to -0.6)	2.3 (-0.1 to 4.7)	0.065
Patient-provider	27.5	-6.1 (-7.9 to -4.3)	-4.8 (-6.6 to -3.0)	-0.2 (-2.7 to 2.3)	0.88
PHQ-8 score[‡]					
Usual care	4.0	NA	-0.7 (-1.3 to -0.1)	-	
Patient	4.8	NA	-0.4 (-1.0 to 0.2)	0.3 (-0.6 to 1.2)	0.55
Provider	4.5	NA	0 (-0.6 to 0.5)	0.6 (-0.2 to 1.5)	0.136
Patient-provider	4.9	NA	-0.6 (-1.2 to 0)	0.1 (-0.8 to 1.0)	0.86
Physical function (SPPB score)[§]					
Usual care	8.5	NA	0 (-0.4 to 0.3)	-	
Patient	8.3	NA	-0.3 (-0.7 to 0.1)	-0.3 (-0.8 to 0.3)	0.32
Provider	8.8	NA	-0.5 (-0.8 to -0.1)	-0.4 (-1.0 to 0.1)	0.092

Outcome	Mean Baseline	Baseline to 6-Mo Difference (95% CI)	Baseline to 12-Mo Difference (95% CI)	Difference in Baseline to 12 Mo vs. Usual Care (95% CI)	P Value
Patient-provider	8.5	NA	-0.3 (-0.7 to 0.1)	-0.3 (-0.8 to 0.3)	0.34
BMI, kg/m²					
Usual care	35.6	NA	-0.1 (-0.3 to 0.5)	-	
Patient	35.0	NA	-0.5 (-0.9 to 0)	-0.6 (-1.2 to 0.1)	0.073
Provider	36.3	NA	-0.6 (-1.0 to -0.2)	-0.7 (-1.2 to -0.1)	0.022
Patient-provider	35.3	NA	-0.4 (-0.9 to 0)	-0.6 (-1.1 to 0)	0.069
Change from baseline in weekly frequency of all exercise measured by mean CHAMPS scored^f					
Usual care	15.3	NA	-1.2 (-2.7 to 0.2)	-	
Patient	14.9	NA	-0.7 (-2.2 to 0.8)	0.5 (-1.3 to 2.3)	0.58
Provider	14.8	NA	-1.5 (-2.9 to -0.1)	-0.3 (-2.3 to 1.7)	0.73
Patient-provider	12.7	NA	0.6 (-0.9 to 2.1)	1.8 (-0.3 to 3.9)	0.087
Change from baseline in weekly duration of all exercise measured by mean CHAMPS score, h/wk^f					
Usual care	12.2	NA	-0.6 (-2.1 to 1.0)	-	
Patient	13.7	NA	-0.7 (-2 to 3 to 0.6)	-0.1 (-2.0 to 1.7)	0.76
Provider	12.4	NA	-0.9 (-2.4 to 0.6)	-0.3 (-2.5 to 1.9)	0.89
Patient-provider	10.8	NA	-0.4 (-2.0 to 1.2)	0.1 (-2.1 to 2.4)	0.90

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

* Calculated by hierarchical linear mixed models fit using PROC MIXED (SAS Institute). Follow-up data at 6 mo are missing for 69 participants (25 in the patient-provider group, 26 in the patient group, 11 in the provider group, and 7 in the usual care group) and at 12 mo for 102 participants (37 in the patient-provider group, 31 in the patient group, 16 in the provider group, and 18 in the usual care group).

^f Data for the total and physical function scores are missing for 3 participants (1 at baseline, 1 in the patient group at 6 mo, and 1 in the provider group at 12 mo).

^g Data are missing for 13 participants (2 at baseline, 3 in the patient-provider group, 3 in the patient group, 2 in the provider group, and 3 in the usual care group at 12 mo).

^h Data are missing for 65 participants (15 at baseline, 11 in the patient-provider group, 11 in the patient group, 17 in the provider group, and 11 in the usual care group at 12 mo).

ⁱ Data are missing for 48 participants (11 in the patient-provider group, 10 in the patient group, 16 in the provider group, and 11 in the usual care group at 12 mo).

^j Data for frequency and duration of exercise are missing for 10 participants (2 in the patient-provider group, 3 in the patient group, 2 in the provider group, and 3 in the usual care group at 12 mo). Mean baseline CHAMPS scores are observed, because outcome in models was changed from baseline to 12 mo. Only patients with nonmissing change scores were included in the observed baseline CHAMPS score means.

Table 4.

Self-reported Osteoarthritis Treatments Initiated During the Study Period*

Treatment	Usual Care (n = 129)	Patient Intervention (n = 128)	Provider Intervention (n = 140)	Patient-Provider Intervention (n = 140)
Physical therapy	9 (8.4)	12 (12.5)	16 (13.1)	9 (9.1)
Knee osteoarthritis [‡]	7 (7.1)	12 (14.0)	13 (11.3)	7 (7.6)
Hip osteoarthritis [‡]	2 (10.5)	0 (0)	3 (21.4)	2 (12.5)
Knee brace				
Any [§]	6 (5.8)	8 (8.6)	7 (6.0)	8 (8.0)
Metal	0 (0)	1 (1.2)	2 (1.8)	0 (0)
Joint injection [¶]	19 (18.5)	22 (23.7)	27 (22.9)	17 (16.7)
Topical NSAID or capsaicin [¶]	7 (5.7)	8 (7.1)	10 (7.6)	8 (6.6)
New pain medication ^{**}	32 (28.8)	27 (27.8)	41 (33.1)	40 (38.8)
Joint replacement surgery	4 (3.1)	5 (3.9)	3 (2.1)	5 (3.6)

NSAID = nonsteroidal anti-inflammatory drug.

* Values are numbers (percentages). Treatments specific to knee or hip osteoarthritis were calculated only among patients diagnosed with either of these conditions at the medical chart review. All osteoarthritis treatment data from the 12-mo visit are missing for 102 patients (18 in the usual care group, 31 in the patient group, 16 in the provider group, and 37 in the patient-provider group).

[‡] Data are missing for 18 patients.

[§] Data are missing for 1 patient.

^{||} Data are missing for 12 patients.

[¶] Data are missing for 19 patients.

[¶] Defined as self-report of using a topical NSAID or capsaicin at 12-mo follow-up but not at baseline. Data on new use of topical therapy are missing for 47 patients.

^{**} Change in pain medication was defined as self-report of using a pain medication for osteoarthritis at 12-mo follow-up but not at baseline or self-report of using a different pain medication at 12-mo follow-up than at baseline.

Table 5. Treatment Recommendations and Self-reported Use of Osteoarthritis Treatment in Provider Intervention Groups*

Treatment	Provider Intervention (n = 140)		Patient-Provider Intervention (n = 140)	
	Treatment Recommended	Received Recommended Treatment	Treatment Recommended	Received Recommended Treatment
Physical therapy [†]	85 (60.7)	10 (11.8)	76 (54.3)	8 (10.5)
Any knee brace [‡]	102 (72.9)	7 (6.9)	99 (70.7)	7 (7.1)
Weight management program [§]	127 (90.7)	-	117 (83.6)	-
Physical activity program [§]	78 (55.7)	-	67 (47.9)	-
Joint injection	26 (18.6)	6 (23.1)	31 (22.1)	8 (25.8)
Orthopedic visit ^{†§}	5 (3.6)	-	2 (1.4)	-
Topical NSAID or capsaicin	104 (74.3)	9 (8.7)	92 (65.7)	7 (7.6)
Add gastroprotective agent or remove NSAID [§]	5 (3.6)	-	7 (5.0)	-
Discuss new/alternative pain medication [¶]	107 (76.4)	33 (30.8)	101 (72.1)	34 (33.7)

NSAID = nonsteroidal anti-inflammatory drug.

* Values are numbers (percentages). Nineteen treatment recommendations were not issued (16 in the patient-provider group and 3 in the provider group).

[†] Treatment recommendations did not differentiate between hip and knee osteoarthritis; numbers are combined for hip and knee osteoarthritis.

[‡] Recommendations did not specify the type of brace (e.g., elastic or metal).

[§] Self-reported data on treatment use did not include initiating a new weight management program, physical activity program, orthopedic visit, or use of a gastroprotective medication.

^{||} Defined as self-report of using a topical NSAID or capsaicin at 12-mo follow-up but not at baseline.

[¶] Defined as self-report of using a pain medication for osteoarthritis at 12-mo follow-up but not at baseline or self-report of using a different pain medication at 12-mo follow-up than at baseline.