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# Effectiveness of a New Service Delivery Model for Management of Knee Osteoarthritis in Primary Care: A Cluster Randomized Controlled Trial

David J. Hunter,<sup>1</sup> D Jocelyn L. Bowden,<sup>1</sup> Rana S. Hinman,<sup>2</sup> Thorlene Egerton,<sup>2</sup> Andrew M. Briggs,<sup>3</sup> Karen Schuck,<sup>2</sup> Simon D. French,<sup>4</sup> Marie Pirotta,<sup>2</sup> Rupendra Shrestha,<sup>4</sup> D Deborah J. Schofield,<sup>4</sup> Karen Schuck,<sup>1</sup> Nicholas A. Zwar,<sup>5</sup> S. Sandun M. Silva,<sup>6</sup> Gillian Z. Heller,<sup>6</sup> Kim L. Bennell,<sup>2</sup> Andrew M. Briggs,<sup>3</sup> Rupendra Shrestha,<sup>4</sup> Rupendra Shrestha,<sup>4</sup> Rupendra Shrestha,<sup>4</sup> Nicholas A. Zwar,<sup>5</sup> S. Sandun M. Silva,<sup>6</sup> Kim C. Bennell,<sup>2</sup> Rupendra Shrestha,<sup>4</sup> Rupendra Shrestha,<sup>4</sup> Simon Schuck,<sup>1</sup> Nicholas A. Zwar,<sup>5</sup> S. Sandun M. Silva,<sup>6</sup> N Gillian Z. Heller,<sup>6</sup> Kim L. Bennell,<sup>2</sup> Rupendra Shrestha,<sup>4</sup> N Kim L. Bennell,<sup>2</sup> N Kim L. Bennell,<sup>2</sup> Simon Schuck,<sup>4</sup> N Kim Study Team

**Objective.** To evaluate the effectiveness and health costs of a new primary care service delivery model (the Optimising Primary Care Management of Knee Osteoarthritis [PARTNER] model) to improve health outcomes for patients with knee osteoarthritis (OA) compared to usual care.

**Methods.** This study was a 2-arm, cluster, superiority, randomized controlled trial with randomization at the general practice level, undertaken in Victoria and New South Wales, Australia. We aimed to recruit 44 practices and 572 patients age  $\geq$ 45 years with knee pain for >3 months. Professional development opportunities on best practice OA care were provided to intervention group general practitioners (GPs). All recruited patients had an initial GP visit to confirm knee OA diagnosis. Control patients continued usual GP care, and intervention patients were referred to a centralized care support team (CST) for 12-months. Via telehealth, the CST provided OA education and an agreed OA action plan focused on muscle strengthening, physical activity, and weight management. Primary outcomes were patient self-reported change in knee pain (Numerical Rating Scale [range 0–10; higher score = worse]) and physical function (Knee Injury and Osteoarthritis Outcome Score activities of daily living subscale [range 0–100; higher score = better] at 12 months. Health care cost outcomes included costs of medical visits and prescription medications over the 12-month period.

**Results.** Recruitment targets were not reached. A total of 38 practices and 217 patients were recruited. The intervention improved pain by 0.8 of 10 points (95% confidence interval [95% CI] 0.2, 1.4) and function by 6.5 of 100 points (95% CI 2.3, 10.7), more than usual care at 12 months. Total costs of medical visits and prescriptions were \$3,940 (Australian) for the intervention group versus \$4,161 for usual care. This difference was not statistically significant.

**Conclusion.** The PARTNER model improved knee pain and function more than usual GP care. The magnitude of improvement is unlikely to be clinically meaningful for pain but is uncertain for function.

# INTRODUCTION

**Arthritis Care & Research** 

Osteoarthritis (OA) is a leading cause of lower limb pain and disability, affecting >500 million people worldwide (1). OA has a considerable detrimental effect on individual well-being, and the

overreliance on health care services such as surgery and painrelieving medications contributes to rising personal, societal, and socioeconomic costs and reduced work productivity (2). In many countries, OA management is coordinated in primary care (3), including Australia, where 75% of patients with knee OA visit a

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<sup>&</sup>lt;sup>1</sup>David J. Hunter, MBBS, PhD, FRACP, Jocelyn L. Bowden, BHMSc, BSc (Hons), PhD, Karen Schuck, BPhty: Kolling Institute, The University of Sydney and Royal North Shore Hospital, Sydney, New South Wales, Australia; <sup>2</sup>Rana S. Hinman, BPhysio (Hons), PhD, Thorlene Egerton, BPhty, MPhil, PhD, Stephen J. Bunker, RN, PhD, Marie Pirotta, MBBS, MMed, PhD, FRACGP, Kim L. Bennell, BPhysio (Hons), PhD: The University of Melbourne, Melbourne, Victoria, Australia; <sup>3</sup>Andrew M. Briggs, BSc (Hons), PhD, FACP: Curtin University, Perth, Western Australia, Australia; <sup>4</sup>Simon D. French, BAppSc, MPH, PhD, Rupendra Shrestha, BSc, MSc, PhD, Deborah J. Schofield, BSpPath, PhD: Macquarie University, Sydney, New South Wales, Australia; <sup>5</sup>Nicholas A. Zwar, MBBS, MHP, PhD, FRACGP: University of New South Wales, Sydney, New South Wales, Australia; Australia;

#### **SIGNIFICANCE & INNOVATIONS**

- This study provides preliminary evidence for the effectiveness of a remotely delivered, integrated lifestyle and behavior change model on improving physical function for patients with osteoarthritis.
- It is difficult to unpack which components of the model are most important in achieving greater improvements, but patients reported being more satisfied with their care from the general practitioner (GP) and care support team than with usual GP care alone.

general practitioner (GP) (4). International clinical guidelines consistently recommend education and support for self-management, including muscle strengthening, physical activity, and weight loss, with judicious use of appropriate medications as first-line evidence-based treatments (5). However, the type and quality of OA care varies internationally, with many patients with OA either not being offered or not engaging with recommended care (6–8).

In response to international calls for novel models to improve uptake and engagement with OA care (9,10), we developed a new primary care-based service delivery model for knee OA. It was designed to address the multiple factors contributing to the evidence-to-practice gap, as highlighted by both GPs and patients with OA (11,12). System-level barriers include time constraints and financing models to effectively address OA (13) and a lack of services to support necessary lifestyle changes (14–16). Similarly, patients with OA have reported frustration with inconsistent and conflicting advice on how to manage their condition (6,17,18) and confusion around accessing the health care system and understanding the roles of different health care professionals (19). In addition, the costs of accessing treatments can be prohibitive (20,21). To date, only 2 studies have focused on general practice pathways, with 1 in the UK, involving practice nurses and GP care, finding no effect on patient-reported outcomes after 6 months (22), and 1 in Norway, which focused on uptake of clinical guideline recommendations rather than patientreported outcomes (23).

In addition to face-to-face service models, telehealth options are growing, with early effectiveness and feasibility trials showing promising, well-sustained improvements for OA pain and function (24). Telehealth offers an excellent opportunity to deliver coordinated evidence-based care and overcome barriers to accessing health services such as shortages of trained clinicians, large distances and geography, inconvenience, and more recently, COVID-19 considerations (25). These factors, and the known barriers to recommended knee OA care, informed the design of our new model of knee OA service delivery (12,14,26).

We aimed to determine the effectiveness and health costs of the Optimising Primary Care Management of Knee Osteoarthritis (PARTNER) model of service delivery compared to usual primary care in Australia (27,28). We hypothesized that the PARTNER model would be superior to usual GP care in improving knee pain and function at 12 months. Here, we report primary and secondary patient-level outcomes and health costs. The process and feasibility evaluation and other secondary analyses will be reported separately.

#### PATIENTS AND METHODS

**Trial design.** We undertook a pragmatic 2-arm, cluster randomized controlled trial (CRCT) (September 2018 to December 2020). The protocol was prospectively registered (ACTRN: 12617001595303) and published (27,28). Ethics approval was received from the University of Sydney Human Research Ethics Committee (2016/959). Services Australia (MI7185) approved linkages to the Medical and Pharmaceutical Benefits Schemes (MBS/PBS). Written informed consent was obtained from the general practices, GPs, and patient participants. The trial has been reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for CRCTs.

**Study setting.** The study was undertaken in general practices in New South Wales (NSW) and Victoria, Australia. Most Australian GPs work in private practice, either solo or in small group practices, with the majority operating as small local businesses (29). GPs are paid a fee for service, with the MBS, a publicly funded universal health insurance scheme, the main funding mechanism. Medicare provides full (bulk billing) or subsidized access to eligible treatments and services. Any gap between the GP fee charged and the Medicare payment is typically covered by the patient (29).

**General practices and GPs.** General practices and GPs were recruited by GP coordinators embedded in general practice research networks. General practices were eligible if they had at least 2 GPs willing to participate, if they agreed to use the Inca electronic desktop information technology (IT) support tool (Precedence Health Care) (30), and if they were not involved in

<sup>&</sup>lt;sup>6</sup>S. Sandun M. Silva, BSc, PhD, Gillian Z. Heller, BSc (Hons), MSc, PhD: The University of Sydney, Sydney, New South Wales, Australia.

Drs. Hunter and Bowden contributed equally to this work.

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Address correspondence via email to David Hunter, MBBS, PhD, FRACP, at david.hunter@sydney.edu.au.

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the pilot trial. GPs were eligible if they worked in a consenting practice and managed patients with knee OA. We did not specify a minimum number of knee OA patients to be seen. Due to slow GP recruitment, inclusion criteria were amended and approved in February 2019 to only require 1 GP per practice and optional use of Inca (see Supplementary Table 1, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/ 10.1002/acr.25037).

**Patient participants.** Administration staff within each general practice not involved with the study prepared a list from the practice's database of randomly selected patients age  $\geq$ 45 years who had previously seen a trial GP. An invitation letter was sent via the practice to these patients, as appropriate to practice size (range 88–1,241 invitations/per practice). Interested patients with self-reported activity-related knee pain for >3 months completed initial online/phone screening. Eligible patients were (e)mailed forms for completing consent and the baseline survey. Patients' inclusion and exclusion criteria are outlined in see Supplementary Table 2, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037.

**Randomization, allocation concealment, and blinding.** Randomization was at the level of general practice. Practices were randomly allocated to either PARTNER (intervention) or usual care (control) using a 1:1 ratio in random permuted blocks stratified by location (metropolitan, regional/rural) (31) and practice size (<4 GPs,  $\geq$ 4 GPs). The randomization schedule was computer generated offsite by a study statistician and remained concealed in opaque, sealed envelopes. Allocation occurred after all GPs at the practice had completed baseline assessment and the patient list had been prepared. Envelopes were opened by research staff not involved in the trial, and the GP/trial coordinators informed practices of their allocation.

Patients were unaware of their practice's allocation. GPs were unblinded but were requested not to discuss practice allocation with their patients. The GP coordinators were unblinded but not involved in patient screening. Research staff involved in screening patients remained blinded until screening was complete. The chief investigators (RSH, TE, AMB, SJB, SDF, MP, RS, DJS, NAZ, GZH, and KLB) remained blinded throughout except for the trial coordinator (JLB) and, if necessary, the allocated medical officer (DJH). Statistical analyses were performed by a blinded statistician (SSMS).

**Trial procedures.** Figure 1 outlines participant flow through the study. All enrolled participants had an initial visit to their GP for a knee-focused consultation and confirmation of an OA diagnosis (32). Over the remainder of the 12 months, patients from the PARTNER practices received the PARTNER model, while the control group continued usual care as directed by their GP.

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Intervention (PARTNER model). Detailed descriptions of the PARTNER model, its development, and implementation plan have been described previously (12,14,26-28). Briefly, PARTNER was underpinned by evidence-based clinical practice guidelines (32), the Chronic Care model (33), and extensive stakeholder input from health professionals and managers, policy makers, health insurers, behavior change experts, peak consumer bodies, and consumers. The implementation plan was designed using the Behaviour Change Wheel and informed by the Theoretical Domains Framework (34). A nonrandomized pilot feasibility study was undertaken with 2 general practices (8 GPs, 12 patients) in Victoria (May to December 2017) to test the recruitment strategy, key intervention components, and trial operational aspects, and to train the care support team (CST) (35). Changes to the protocol and study materials arising from semistructured interviews with the GPs, patients, and the CST were approved before the trial commenced, unless otherwise noted (see Supplementary Table 1, available at http://onlinelibrary.wiley.com/doi/10.1002/ acr.25037).

The intervention aimed to improve GPs' and patients' knowledge and management of OA (see Supplementary Figure 1, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037). GPs were offered a suite of online professional development opportunities to update knowledge of current evidence-based OA management and access to the online integrated care (Inca) desktop support platform. Patients were supported by a centralized, remotely delivered multidisciplinary CST whose role was to provide additional support to help patients effectively self-manage their knee OA using a behavior change methodology.

**GP professional development.** Intervention-allocated GPs were asked to undertake the professional development activities prior to seeing study patients. These included the following: 1) self-audit and feedback activity to reflect on their management of recent patients with OA and self-identify areas for improvement (part 1 recommended, 2–3 hours to complete; part 2 optional); 2) knee OA in general practice online learning module (36) delivered through the Royal Australian College of General Practitioners (RACGP; 1 hour, recommended); and 3) PARTNER study website (Wix web development company, 2018), which included a PARTNER study introductory video (recommended), skills building modules, and reading resources (optional).

**GP desktop IT decision support platform.** All general practices and GPs in the intervention group were offered free use of, and training in, the Inca platform (30), designed to help health care providers manage chronic disease and preventive care. The system was customized for the study to include OA decision support features to prompt GPs to discuss exercise and weight management and review medications during their consultations. An



**Figure 1.** Participant flow through the cluster randomized controlled trial. Online screening was considered incomplete if patients did not include their contact details in the online screening tool. GP = general practitioner; ITT = intent-to-treat; NSW = New South Wales; OA = osteoarthritis; PARTNER = Optimising Primary Care Management of Knee Osteoarthritis (model); TKR = total knee replacement. \* = did not complete 6-month survey, but did complete 12-month survey.

OA chronic disease management plan template, a mechanism for direct CST referral, and 2 printable PARTNER patient education resources were also embedded.

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Patients and the CST. Each intervention group GP was asked to prepare an OA chronic disease management plan for their patients and refer them to the CST. The CST comprised 6 health professionals (5 physical therapists, 1 occupational therapist). All CST members were provided with training in best practice OA management, health coaching, and behavior change (HealthChange Australia) (37) prior to commencing the study. To maintain continuity of care, 1 CST member was assigned to each patient on referral and typically remained their primary contact through until the end of the patient's involvement (i.e., the patient opted out or 12 months). A CST member was allocated based on availability, and if possible, state of residence. Comprehensive handovers were provided if a change to the consulting CST member was required during the trial. There was no maximum number of permitted contacts between the patient and the CST. Consultations were delivered remotely according to patient preference

(e.g., phone, email, mail, short message service [SMS]) and in 2 phases.

Intensive phase (18 weeks) and maintenance phase (6 months). Patients were contacted once per fortnight (~9 contacts) or as agreed with the patient. At the first consultation, the CST member undertook a biopsychosocially informed interview, provided OA education, and discussed potential management options focused on weight management, home-based leg muscle strengthening, and physical activity. A tailored care plan was codeveloped to align with the patient's goals, priorities, and preferences and revised at subsequent consultations. Eligible patients (body mass index [BMI]  $\geq 27$  kg/m<sup>2</sup>) were offered the Commonwealth Scientific and Industrial Research Organisation (CSIRO) online Total Well Being Diet program (38,39) delivered by Digital Wellness (www.digitalwellness.com). Online evidencebased cognitive behavioral therapy (CBT) options for mood (This Way Up Depression and Anxiety) and sleep (This Way Up Insomnia) (40) and pain coping (painTRAINER) (41) were optional interventions for eligible patients (27). Patients were recommended to see additional health care professionals (e.g., physical

therapists, dieticians, psychologists) in a private setting (potentially at their own cost) or via GP referral to a publicly funded service if they presented with more complex issues or required face-to-face assistance. Patients were contacted monthly (~6 contacts), or as agreed, and supported to continue their OA self-management, including addressing any new issues.

**Usual care.** GPs allocated to usual care did not receive any OA training during the trial. After the initial GP consultation, usual care patients continued under their GP's care until the end of the 12 months. There were no restrictions on the number of visits to or type of care provided by their GP or other health care professionals. Data on GP usual care will be presented in the PARTNER process evaluation.

**Data collection.** Descriptive and demographic information was collected from patients, general practices, and GPs at baseline. Patients completed self-reported surveys at baseline, 6 months, and 12 months either electronically (REDCap) or in hardcopy. Patients were provided with a \$50 gift voucher after completing the final survey.

**Primary outcome measures.** Coprimary outcomes were changes from baseline in self-reported pain and activities of daily living (ADL) function of the knee at 12 months. Both primary outcomes were also measured at 6 months (secondary). Average knee pain (previous week) was measured on an 11-point Numerical Rating Scale (NRS) (range 0–10; higher score = worse pain). Function (last 7 days) was measured using the function in daily living subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS) ADL scale (range 0–100; higher score = better function) (42).

**Secondary outcome measures.** Self-reported secondary outcome measures collected at 6 and 12 months included all KOOS subscales, weight (kg), calculated BMI (kg/m<sup>2</sup>), healthrelated quality of life, mood (depression), sleep and fatigue, satisfaction with overall change in the knee and knee symptoms, and overall satisfaction with treatment. Work productivity measures noted in the protocol will be reported separately. Supplementary Table 3, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037, summarizes all the secondary outcomes, measurement tool details, and time points.

**Health care costs.** Health care costs included total costs of medical visits and procedures and the costs of prescription medicines filled at pharmacies from baseline to the 12-month completion date. With patient consent, participants' data from the MBS and the PBS were obtained through record linkage with patient administration data from Services Australia. The MBS data included information on medical visits, procedures, and associated costs; the PBS data included information on prescription medicines and their costs. Results are presented in Australian dollars.

Trial fidelity. The RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework and the UK Medical Research Council framework for the development and evaluation of complex interventions were used to guide the process evaluations and are described elsewhere (43). The full results of the process and feasibility evaluations will be reported in a future study. Here, we report trial fidelity outcomes that potentially impact the primary and secondary outcomes, specifically: 1) completion of GP professional development activities; 2) delivery of the main PARTNER components by the GPs and the CST; 3) patient interaction with the CST and participation with the PARTNER components; and 4) protocol deviations and changes. Fidelity data were collected in parallel with the effectiveness data from study administration records, patient and GP electronic surveys, CST electronic consultation records, and service provider records (e.g., weight loss intervention, CBT programs, RACGP).

**Sample size.** Our a priori sample size accounted for clustering effects of patients treated within the same GP practice. We estimated that 44 general practices and 572 patients were needed at baseline to detect an effect size of 0.30 (small to moderate) (44) in the primary outcomes at 12 months with 80% power (5% two-sided significance), allowing for 20% dropout of both GPs and patients. We assumed a minimum of 2 GPs and 13 patients per practice, a coefficient of variation in practice size of 0.5, and an intracluster correlation of 0.05.

Adverse events and changes in response to COVID-19. Data on self-reported adverse events and serious adverse events (SAEs) were collected at 6 and 12 months if they were reported during CST consultations or the research team became aware of them through another mechanism (e.g., phone call/email). COVID-19 had minimal impact on the study methods, including the trial design, interventions, outcomes, and the CST's delivery of care (45). As participant recruitment ceased in December 2019, there was no impact on recruitment, randomization, or baseline data collection. However, any additional face-to-face or external health care that the patient may have been receiving, or planned to receive, would have been impacted by NSW and Victorian lockdowns and health service restrictions between March and December 2020. The trial coordinator (JLB) and medical officer (DJH) provided additional training to the CST in March 2020 for reported cases of COVID-19 and recommendations for continuing OA care in accordance with local COVID-19 public health orders.

**Statistical analysis.** Outcome data were analyzed by a blinded statistician (SSMS) using R, version 4.0.3 (46). Analyses were conducted at the patient level using intent-to-treat (ITT) with

all available data from all randomized patients and using their randomized group allocation. The multilevel missing data in the outcome measures were imputed using multiple imputation method with 10 imputed data sets while allowing random effects for GP practices. It was applied to missing patient-level data from GP practices that did not withdraw before data collection and that recruited at least 1 patient. It is assumed that missingness in data is missing at random where it may be related to the observed values but not related to the missing observations itself (47). Therefore, utilization of multiple imputation in this case is appropriate and justifiable to reduce any bias caused by complete data (47).

Missing values for difference in mean change (baseline minus follow-up) at 6 months and 12 months were imputed using the "panImpute" function in R package mitml (48), adjusting for baseline values of the outcome variable and stratification variables (i.e., location of the practice [metropolitan, regional/rural]), while specifying random effects for GP practices. It should be noted that 5,000 number of burns in iterations were used before any imputations were drawn, with 500 iterations between imputations. These steps help to ensure imputation integrity (49). For continuous outcomes, differences in mean change (baseline minus follow-up) were compared between groups using generalized estimating equations (GEEs) (49) to account for withinpractice correlation with exchangeable correlation, robust SEs, and adjusting for the baseline value of the outcome variable and stratification variables. Analyses were also repeated using complete-case data.

Self-perceived overall change in the study knee and satisfaction with treatment and any change in symptoms at 12 months were dichotomized with scores of 6 or 7 on the 1-7 scale (moderately to extremely better/satisfied) classified as "improved," and scores 1-5 as "not improved," after multiple imputation. The multiple imputation was performed on the original scale of these outcome variables, and differences between groups were compared in a similar imputation procedure as for the continuous outcomes. Data were compared between groups using logistic regression models, with results presented as risk ratios obtained using marginal standardization. Post hoc responder analyses were also undertaken to determine the proportion of participants with improvements that met or exceeded the minimum clinically important difference (MCID) for pain (≥1.8 NRS points), function (less than or equal to -8 points) (42), and weight loss (≥5% of body weight) at 12 months. For these binary outcomes, logistic regression GEEs were fitted using a logit link function assuming an exchangeable correlation structure and robust variance estimation, adjusting for stratification variables, with results presented as odds ratios.

## RESULTS

Participant flow through the trial is summarized in Figure 1, and patient characteristics in Table 1. Comorbidities and general

Table 1.         Baseline characteristics of particular	atients by group	)*
Characteristic	Usual care (n = 105)	PARTNER (n = 112)
Age, median (range) years	66 (46–85)	63 (45–95)
Sex Female Male BMI ≥27 kg/m <sup>2</sup>	60 (57) 45 (43) 69 (66)	71 (63) 41 (37) 53 (47)
Knee affected Left knee Right knee Dominant knee	51 (49) 54 (51) 54 (51)	58 (52) 54 (48) 55 (49)
Pain duration <1 year 1–2 years 3–5 years 5–10 years >10 years	11 (10) 20 (19) 28 (27) 28 (27) 18 (17)	9 (8.0) 16 (14) 35 (31) 25 (22) 27 (24)
State of residence New South Wales Victoria	78 (74) 27 (26)	61 (54) 51 (46)
Aboriginal or Torres Strait Islander Yes No	0 (0) 105 (100)	2 (1.8) 110 (98)
Race Asian Black or African American Hispanic or Latino Native Hawaiian or other Pacific Islander	8 (8) 0 (0) 0 (0) 1 (1)	6 (5) 1 (1) 2 (1.8) 0 (0)
White Unknown/not reported	86 (82) 9 (9)	88 (79) 12 (11)
Living arrangements Living with others Living alone	78 (74) 27 (26)	88 (79) 24 (21)
<ul> <li>≤3 years of high school</li> <li>≥3 years of high school</li> <li>Some tertiary training, but did not</li> </ul>	2 (2) 26 (25) 11 (10)	7 (6) 35 (31) 12 (11)
Graduate from university or polytechnic	36 (34)	25 (22)
Postgraduate study (e.g., graduate diploma, master's, PhD)	30 (29)	33 (29)
Current or previous occupation Manager or professional Tradesperson or clerical worker Transport, sales, service worker or laborer	50 (48) 27 (26) 8 (8)	50 (45) 32 (29) 6 (5)
No paid job	5 (5)	4 (4)
Current employment status Works full time Works part time Unable to work (knee problems) Unable to work (other health	30 (29) 16 (15) 6 (6) 7 (7)	29 (26) 26 (23) 2 (2) 3 (3)
Retired (not due to health)	45 (43)	51 (46)

\* Values are the number (%) unless indicated otherwise. BMI = body mass index; PARTNER = Optimising Primary Care Management of Knee Osteoarthritis (model).

1(1)

1(1)

Unemployed/seeking work

practice and GP characteristics are shown in Supplementary Tables 4-6, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037. The trial was stopped before the target number of practices or patients was recruited. This was due to a delayed start, slow initial practice recruitment, and our funder's timeframe.

**General practices (clusters) and GPs.** We recruited 38 general practices (86% a priori sample) and 71 GPs. Most practices were in metropolitan areas (84%), had  $\geq$ 4 GPs (71%), and were privately owned (92%). Four practices did not recruit any patients.

**Patients.** Of the 672 patients screened, 217 (38% a priori sample) were enrolled. Eighty-four (13%) patients declined to participate, and 371 were excluded (55%) (Figure 1). Of those enrolled, 193 patients (89%) returned a 6-month survey, and 191 (88%) a 12-month survey.

**Baseline characteristics.** The baseline characteristics of GPs were similar between groups, except PARTNER GPs were younger, less experienced, and had less specialty interests in musculoskeletal conditions. Baseline patient characteristics were comparable between groups (<10% variation), except for the number with a BMI of  $\geq$ 27 kg/m<sup>2</sup>, low back pain, and select joint pain. Overall, 122 patients (56%) had a baseline BMI of  $\geq$ 27 kg/m<sup>2</sup> (usual care 66%, PARTNER 47%), and 84 (39%) reported back pain (usual care 30%, PARTNER 46%). Supplementary Table 7, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037, includes the number of missing participants for each variable and compares the means and SDs of complete data along with missing participants at baseline, 6 months, and 12 months on the self-reported outcomes.

Trial fidelity outcomes. *GP professional development*. A total of 18 of 34 (53%) PARTNER GPs completed the audit and feedback activity (part 1), 18 (53%) accessed the PARTNER website and study introduction video, and 10 (29%) completed the gplearning module. Ten general practices (56%) installed the Inca desktop support system, but only 2 (11%) elected to use it (see Supplementary Table 8, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037). The low uptake of Inca impacted our ability to collect data on the preparation of GP OA management plans.

Patient interaction with the CST. A total of 110 patients were eligible for CST referral, with 101 (92%) referred. Nine patients were not referred (single GP, no reason provided). Ninety-six referred patients (95%) completed the first consultation with the CST (average 54 minutes), 2 declined for medical/family reasons, and 3 opted out. Overall, the CST completed 927 consultations, all via telephone, with an average of 9 (range 2–15) consultations per patient. The average duration of follow-up consultations in the intensive phase (calls 2–8) was 24 minutes, and the maintenance phase (calls 10–15) was 29 minutes. Sixty-three patients (62%) discussed the negative impacts that COVID-19 had on their life. PARTNER components and protocol deviations. Fidelity of the main trial components delivered to patients is outlined in Supplementary Table 9, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037. The numbers of patients in both arms who self-reported trying to lose weight (at 6 and 12 months, respectively, PARTNER 55% and 48%, usual care 49% and 44%), undertake physical activity (82%/79%, 76%/72%), or a muscle strengthening program (80%/79%, 72%/70%) are summarized in Supplementary Table 10, available on the Arthritis Care & Research website at http://onlinelibrary. wiley.com/doi/10.1002/acr.25037. Three protocol deviations were reported during the trial (see Supplementary Table 1, available at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037).

*Cointervention/adverse events.* Four total knee replacements (1 PARTNER, 3 usual care) and 9 knee arthroscopies (3 PARTNER, 6 usual care) were self-reported. There were no SAEs directly related to the trial intervention (see Supplementary Table 11, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037).

**Primary outcomes.** At 12 months, PARTNER improved pain by 0.8 of 10 points (95% confidence interval [95% CI] 0.2, 1.4) (Table 2) and function by 6.5 of 100 points (95% CI 2.3, 10.7) more than usual care. Pain improvements overall did not reach the MCID (≥1.8 NRS points); however, the 95% CI for ADL function spanned the MCID range of less than or equal to -8 points. Analyses of complete case data produced similar results (see Supplementary Table 12, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037).

Secondary outcomes. ITT results are provided in Tables 3-4 and Figure 2, and complete case results are provided in Supplementary Table 12, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/10.1002/ acr.25037. In summary, these are as follows: 1) KOOS subscales (mean between-group differences favored PARTNER for the other KOOS subscales at both time points); 2) weight and BMI (at 6 months, but not 12 months, the between-group differences for weight favored PARTNER by -1.4 kg [95% CI -2.4, -0.3] and -0.5 BMI units [95% CI -0.9, -0.1]; compared to usual care, more patients reached 5% weight loss in the PARTNER group at 6 months [see Supplementary Table 13, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/ 10.1002/acr.25037]); 3) other secondary outcomes (betweengroup differences favored PARTNER for sleep at 12 months [Tables 3 and 4], but not 6 months; there was no evidence of between-group differences at either time point for health-related quality of life, depression, or fatigue); and 4) MCIDs (more patients in the PARTNER group reached the MCIDs in pain and function at 12 months than in usual care [see Supplementary Table 13, available at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037]).

	Estimate	SE	T value	df	P(> t )	95% CI
Pain†						
Intercept	-1.3	0.6	-2.3	13,041.6	0.033	-2.5, 0.1
Practice location: regional/rural	-0.5	0.7	-0.7	32,619.0	0.430	-1.7, 0.7
Allocated treatment: PARTNER	0.8‡	0.3	2.6	13,003.2	0.008 <mark>5</mark>	0.2, 1.4
Baseline pain (NRS)	0.4	0.1	4.0	6,675.3	<0.001 <mark>9</mark>	0.2, 0.6
KOOS (ADL)						
Intercept	-19.7	5.0	-4.0	203,263.6	<0.001 <mark>§</mark>	-29.4, -9.9
Practice location: regional/rural	1.8	3.3	0.5	143,628.9	0.587	-4.7, 8.4
Allocated treatment: PARTNER	-6.5 <mark>9</mark>	2.1	-3.0	15,870.6	0.002 <mark>§</mark>	-10.7, -2.3
Baseline KOOS (ADL)	0.2	0.1	3.5	251,777.1	<0.001	0.1, 0.4

Table 2.	Model output fo	r change in j	pain (NRS)	and Knee	Injury and	Osteoarthritis	Outcome	Score	(ADL)	at
12-month	follow-up (imputed	d data)*								

\* 95% CI = 95% confidence interval; ADL = activities of daily living; NRS = Numerical Rating Scale; PARTNER = Optimising Primary Care Management of Knee Osteoarthritis (model).

<sup>†</sup> The model output for pain (NRS) when regressed with practice location, allocated treatment, and baseline pain (NRS).

<sup>‡</sup> The positive number indicates an improvement compared to usual care.

§ Significant (P < 0.05).

¶ The negative number indicates an improvement compared to usual care.

Table 3.	Scores or	primary	and secondar	outcome measures	across time by gr	roup*

	Base	eline	Follow-up	(6 months)	Follow-up (	12 months)
Outcome measure	Usual care	PARTNER	Usual care	PARTNER	Usual care	PARTNER
Primary outcomes						
Pain NRS score (of 10)	5.5 ± 1.6	5.7 ± 1.6	4.7 ± 2.3	4.3 ± 2.6	4.7 ± 2.3	4.0 ± 2.5
	(n = 105)	(n = 112)	(n = 95)	(n = 98)	(n = 93)†	(n = 96)†
KOOS ADL function score	65.9 ± 17.8	63.0 ± 16.9	70.5 ± 18.0	73.0 ± 18.9	70.0 ± 20.1	75.1 ± 17.8
	(n = 105)	(n = 112)	(n = 94)	(n = 98)	(n = 92)†	(n = 96)†
Secondary outcomes						
KOOS pain score	62.5 ± 14.4	58.3 ± 15.2	65.6 ± 16.8	66.4 ± 19.00	66.1 ± 18.8	68.5 ± 18.2
	(n = 105)	(n = 112)	(n = 95)	(n = 98)	(n = 92)	(n = 97)
KOOS symptoms score	65.1 ± 17.6	57.7 ± 16.7	65.3 ± 18.1	64.1 ± 20.3	66.2 ± 19.0	64.8 ± 19.1
	(n = 105)	(n = 112)	(n = 92)	(n = 97)	(n = 88)	(n = 94)
KOOS knee-related QoL score	44.4 ± 17.9	39.2 ± 19.9	48.5 ± 21.3	50.2 ± 23.2	51.0 ± 21.6	53.1 ± 25.0
	(n = 105)	(n = 112)	(n = 91)	(n = 96)	(n = 87)	(n = 93)
KOOS sport and recreation score	42.3 ± 25.6	32.6 ± 22.0	44.0 ± 26.3	41.8 ± 26.2	44.0 ± 26.4	46.4 ± 27.5
	(n = 105)	(n = 112)	(n = 94)	(n = 97)	(n = 89)	(n = 95)
Weight, kg	81.7 ± 16.0	80.4 ± 17.9	80.8 ± 16.0	80.1 ± 16.4	81.3 ± 15.8	79.1 ± 16.7
	(n = 105)	(n = 112)	(n = 93)	(n = 96)	(n = 87)	(n = 94)
BMI, kg/m <sup>2</sup>	28.8 ± 5.1	28.5 ± 5.9	28.4 ± 4.8	28.4 ± 5.3	28.6 ± 4.7)	28.0 ± 5.1
	(n = 105)	(n = 112)	(n = 93)	(n = 96)	(n = 87	(n = 94)
Health-related QoL score (AQoL-8D)	74.0 ± 11.8	74.3 ± 11.7	74.6 ± 12.0	75.8 ± 14.6	75.1 ± 12.2	77.7 ± 13.0
	(n = 105)	(n = 112)	(n = 90)	(n = 95)	(n = 89)	(n = 94)
Depression score (PHQ-9)	$4.0 \pm 4.1$	$4.0 \pm 3.9$	4.1 ± 3.8	4.2 ± 5.3	3.6 ± 3.7	$3.5 \pm 3.9$
	(n = 105)	(n = 112)	(n = 90)	(n = 95)	(n = 88)	(n = 92)
Sleep T score (PROMIS 8a)	$48.7 \pm 9.2$	49.8 ± 9.3	$48.2 \pm 9.7$	$47.4 \pm 11.0$	$48.0 \pm 9.3$	46.8 ± 9.3
	(n = 105)	(n = 112)	(n = 90)	(n = 95)	(n = 87)	(n = 93)
Fatigue T score (PROMIS 8a)	$49.9 \pm 8.3$	$50.5 \pm 9.5$	$47.6 \pm 9.4$	$48.0 \pm 11.2$	$47.9 \pm 9.4$	$47.3 \pm 9.8$
	(n = 105)	(n = 112)	(n = 90)	(n = 94)	(n = 87)	(n = 93)
Global rating of change (of 7)‡	NA	NA	$4.09 \pm 1.12$ (n = 91)	$4.92 \pm 1.37$ (n = 96)	$4.05 \pm 1.47$ (n = 87)	$5.02 \pm 1.49$ (n = 93)
Satisfaction with treatment (of 7)‡	NA	NA	$4.24 \pm 1.55$	$5.64 \pm 1.61$	$4.35 \pm 1.59$	$5.56 \pm 1.68$
Satisfaction with symptoms (of 7)‡	NA	NA	4.15 ± 1.34 (n = 89)	5.30 ± 1.41 (n = 96)	4.07 ± 1.53 (n = 86)	5.24 ± 1.65 (n = 93)

\* Values are the mean ± SD; the number of complete responses received for each variable is noted in brackets. ADL = activities of daily living; AQoL-8D = Assessment of Quality of Life 8-domain instrument (range 35–176, higher = worse QoL); BMI = body mass index; KOOS = Knee Injury and Osteoarthritis Outcome Score (range 0–100, higher = better outcome); NA = not applicable; NRS = Numerical Rating Scale (range 0–10, higher = worse pain); PARTNER = Optimising Primary Care Management of Knee Osteoarthritis (model); PHQ-9 = Patient Health Questionnaire 9 (range 0–27, higher = more depressive symptoms); PROMIS 8a = Patient-Reported Outcomes Measurement Information System 8-item short form (sleep [range 30–81] and fatigue [range 33.0–77.8], higher = more symptoms); QoL = quality of life. † Primary outcomes.

‡ Global rating and satisfaction scores (range 0–7, higher = improved score).

	Change within g to 6 m	groups, baseline nonths	Change within g to 12 r	groups baseline nonths	Difference in change between groups,		Difference in change between groups,	
Outcome measure	Usual care	PARTNER	Usual care	PARTNER	baseline to 6 months, mean (95% Cl)	Р	baseline to 12 months, mean (95% Cl)	Ρ
Primary outcomes Pain score (NRS) (of 10)† KOOS ADL function score	0.9 ± 2.1 -4.3 ± 11.70	1.4 ± 2.2 -8.5 ± 12.0	0.9 ± 2.3 - 3.9 ± 14.3	1.7 ± 2.3 −10.8 ± 14.2	-0.5 (-1.1, 0.1) 4.2 (0.8, 7.6)	0.122 0.015 <mark>8</mark>	-0.8 (-1.5, -0.2)‡ 6.9 (2.9, 11.0)‡	0.021 <mark>5</mark> 0.001 <u>5</u>
Secondary outcomes KOOS pain score¶	-2.6 ± 12.2	-7.2 ± 13.8	-3.3 ± 14.8	-10.0 ± 14.8	4.6 (0.9, 8.3)	0.015 <mark>8</mark>	6.6 (2.4, 10.9)	0.0025
KOOS symptoms score	$0.1 \pm 11.4$	-6.1 ± 13.3	-1.6 ± 14.0	-6.3 ± 14.7	6.2 (2.7, 9.7)	0.001 <mark>5</mark>	4.7 (0.6, 8.8)	0.025 <mark>8</mark>
KOOS knee-related QoL score	-3.5 ± 15.6	$-10.0 \pm 17.3$	-5.8 ± 17.3	$-12.6 \pm 20.5$	6.5 (1.8, 11.1)	0.007 <mark>5</mark>	6.8 (1.5, 12.1)	0.013 <mark>5</mark>
KOOS sport and recreation score	-1.0 ± 21.2	-8.4 ± 18.5	-0.6 ± 21.6	-11.9 ± 22.8	7.4 (1.7, 13.0	0.011 <mark>8</mark>	11.3 (4.9, 17.7)	0.001 <mark>5</mark>
Weight, kgt	$0.3 \pm 3.6$	$1.7 \pm 4.0$	$0.6 \pm 4.4$	$1.6 \pm 4.8$	-1.4 (-2.4, -0.3)	0.013 <mark>5</mark>	-1.0 (-2.3, 0.3)	0.129
BMI, kg/m <sup>2</sup> †	$0.1 \pm 1.3$	$0.6 \pm 1.4$	$0.2 \pm 1.7$	$0.6 \pm 1.8$	-0.5 (-0.9, -0.1)	0.011 <mark>8</mark>	-0.4 (-0.9, 0.1)	0.113
Health-related QoL score (AQoL-8D)†	$0.4 \pm 6.5$	$-0.6 \pm 6.8$	0.2 ± 7.7	-2.0 ± 7.1	1.0 (-0.8, 2.9)	0.280	2.1 (0.0, 4.2)	0.048 <mark>5</mark>
Depression score (PHQ-9)†	-0.7 ± 3.4	-0.5 ± 3.1	-0.2 ± 2.9	$0.1 \pm 2.8$	-0.2 (-1.1, 0.7)	0.654	-0.3 (-1.2, 0.5)	0.400
Sleep T score (PROMIS 8a)†	-0.1 ± 8.1	2.2 ± 7.5	-0.1 ± 7.2	2.3 ± 7.6	-2.1 (-4.3, 0.1)	0.060	-2.3 (-4.4, -0.2)	0.029 <mark>5</mark>
Fatigue T score (PROMIS 8a)†	1.9 ± 7.7	2.3 ± 6.8	1.3 ± 7.6	2.4 ± 7.6	-0.4 (-2.5, 1.7)	0.696	-1.1 (-3.3, 1.1)	0.324
* Values are the mean ± SD unless indica (range 35–176, higher = worse QoL); BMI = (range 0–10, higher = worse pain); PARTNI depressive symptoms); PROMIS & = Patie symptoms); QoL = quality of life. † Positive (+) within-group change repress # Primary outcomes.	ted otherwise. 95 body mass index ER = Optimising P int-Reported Outt ints an improverr	% Cl = 95% confid. ;; KOOS = Knee Inju rimary Care Mana comes Measureme tent from baseline	ence interval; ADI ury and Osteoarth gement of Knee C ent Information S , and negative be	L = activities of da iritis Outcome Sco Dsteoarthritis (moi ystem 8-item shor tween-group char	ily living: AQoL-8D = Assee tre (range 0-100, higher = 1 del); PHQ-9 = Patient Heal t form (sleep [range 30-81 tge favors intervention.	ssment of better out th Questic ] and fatij	Quality of Life 8-domain i come); NRS = Numerical R annaire 9 (range 0–27, hig <sup>1</sup> gue [range 33.0–77.8], hig <sup>1</sup>	nstrument ating Scale ner = more ner = more
§ Significant (P < 0.05). ¶ Negative (-) within-group score represe	nts an improvem	ent from baseline.	and nositive het	אפהח-פרטווח רhans	re favors the intervention	PARTNE		

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**Table 4.** Change within groups and between groups for continuous variables (imputed)\*

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**Figure 2.** Between-group differences for pain Numerical Rating Scale (**A**) and Knee Injury and Osteoarthritis Outcome Score (KOOS) (**B**) subscales at 6 and 12 months using imputed data. Shading indicates the clinical worthwhile difference assumed for pain (greater than or equal to -1.8 points) and the KOOS subscales ( $\geq$ 8 points). Circles represent the mean (open = 6 months, solid = 12 months); bars indicate the 95% confidence interval. ADL = activities of daily living. \* = *P* < 0.05.

At 12 months, more patients in the PARTNER group reported overall improvement in their knee OA than in usual care (see Supplementary Table 14, available on the *Arthritis Care & Research* website at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037). More patients in the PARTNER group also reported greater satisfaction with their treatment and knee symptoms.

**Health care costs outcomes.** Based on those who completed 12-month follow-up and consented to access of their data on health care costs (PARTNER, n = 101; usual care, n = 95), the total medical and prescription costs were slightly lower, at \$3,940 for the PARTNER group, than for usual care, at \$4,161, over the 12-month period. The average health care costs related to medical visits and procedures over 12 months was lower for PARTNER, at \$2,757, compared to \$3,276 for usual care. However, costs related to prescription medicine were higher for PARTNER, with an average 12-month cost of \$990, compared to \$659 for usual care. There was no evidence of between-group difference in health care costs for medical and prescription costs combined or for either the costs related to medical visits or prescription medicine.

# DISCUSSION

Our results showed that a new primary care model of service delivery (PARTNER) for knee OA led to a modest improvement in function and a small improvement in pain at 12 months compared with usual care. Although the magnitude of the mean betweengroup differences for the primary outcomes was below the specified MCIDs, the 95% CI for function included the difference within the plausible range (Figure 2) (50). However, as our trial was underpowered, findings should be considered preliminary and interpreted cautiously.

Results for secondary outcomes were mixed. Differences in improvements favored PARTNER for the knee-specific KOOS subscales at all time points, weight/BMI at 6 months, and sleep

at 12 months. The remaining secondary outcomes showed no between-group differences, although mean scores for these outcomes were low at baseline for both groups, giving little scope for change (Table 1). Similarly, as many of the secondary outcomes were not knee specific, results may have been impacted by pain from other comorbidities, although the proportions with comorbidities are similar in both groups (see Supplementary Table 4, available at http://onlinelibrary.wiley.com/doi/10.1002/ acr.25037). Total health care costs related to medical visits and prescriptions over 12 months were slightly lower for the PARTNER group, but this was not significant. Collectively, findings suggest that the PARTNER model may provide some benefits for knee OA over usual general practice care.

Our pragmatic CRCT was codesigned with a range of stakeholders (26), and the feasibility of the main components was tested in a pilot study prior to commencement (35). Patient care was tailored, with the main CST components delivered to >85% of patients referred. Overall, >70% of patients self-reported undertaking leg strengthening or physical activity. The trial used valid and reliable OA outcomes, patient blinding to group allocation, independent blinded statistical analysis, and patient recruitment independent of the treating GPs. Our CST remotely supported patients with their behavior change and selfmanagement journey over 12 months, longer than similar interventions to date (22,23,51). The primary limitation was our inability to recruit the required sample size. Time constraints and competing priorities were 2 major reasons cited by GPs for not participating. Similar reasons explained the low rates of installing and/or undertaking training in the IT desktop decision support system and our suboptimal engagement with GPs for the knowledge and skills building components. The low uptake of the GPtargeted interventions necessitated changes to the GP inclusion criteria (see Supplementary Table 1, available at http:// onlinelibrary.wiley.com/doi/10.1002/acr.25037). These fidelity issues may have reduced the potential for better outcomes in

the PARTNER group; however, it was a pragmatic design, and difficulties engaging GPs are not unique to our study (22). Our results may also have been influenced by a higher number of usual care GPs having a prior special interest in musculoskeletal care and who may have provided higher quality OA care compared to the PARTNER group (see Supplementary Table 6, available at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037). However, recent data evaluating usual care for knee OA among Australian GPs showed that rates of recommended first-line nonpharmacologic treatments are low and that imaging, medications, and surgical referral rates are high (8). Our planned process evaluations will explore these issues in further detail. We suggest that our inclusion of a dedicated CST, external to the general practice care, was the main contributor to the functional benefits gained. The centralized delivery of the CST may also explain our better outcomes compared with the in-house, general practice nurse model trialed in the UK (22).

Given our complex intervention, it is unclear as to which parts of the model are most important to improving care. Patients were more satisfied with the PARTNER model than with usual GP care alone, although the overall number of patients reporting moderate-to-extreme satisfaction with the PARTNER model was only 30%. Partial patient blinding may have contributed to this finding, as patients were unsure of the treatments offered at recruitment and were unprepared for the type of intervention delivered. The onset of the COVID-19 pandemic halfway through our trial also presented unforeseeable challenges. Only 35 patients had completed 6-month surveys by March 2020, when Australia commenced COVID-19-related lockdowns. The CST noted that patients reported increased anxiety, decreased opportunity to exercise, and difficulties buying fresh food, potentially impacting adherence to the agreed care plan and influencing their survey responses. Ultimately, however, we had 88% patient retention at 12 months, with only 2 patients citing COVID-19 as their reason for withdrawal.

Between 44% and 55% of all patients reported trying to lose weight across the 12 months (see Supplementary Table 9, available at http://onlinelibrary.wiley.com/doi/10.1002/acr.25037). Twenty-two patients with a baseline BMI of  $\geq$ 27 kg/m<sup>2</sup> self-reported successfully losing >5% of their baseline weight at 12 months (n = 15 [7%] PARTNER, n = 15 7 [3%] usual care). However, although our weight measures showed small but significant between-group differences at 6 months, this was not statistically significant at 12 months. Our findings may reflect our sample weight heterogeneity (52), the self-reported nature of our data, or the challenge of maintaining weight loss over time. Future exploration of these findings will be undertaken in future studies. Finally, there are limitations to the generalizability of our findings because we recruited few people from culturally and racially diverse backgrounds or outside metropolitan areas.

In conclusion, our findings suggest that the PARTNER model improved knee pain and function more than usual GP care,

although, as the trial was underpowered, our findings around the magnitude of change lack precision and should be interpreted with caution. Further rollout of the telehealth-delivered CST component of the PARTNER model is promising; however, strategies to better engage with GPs and to reach more communities require further work to ensure delivery of best practice OA care nationally.

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### **AUTHOR CONTRIBUTIONS**

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Hunter had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Hunter, Bowden, Hinman, Egerton, Briggs, Bunker, French, Pirotta, Shrestha, Schofield, Zwar, Bennell. Acquisition of data. Bowden, Schuck.

Analysis and interpretation of data. Hunter, Bowden, Hinman, Egerton, Briggs, Bunker, French, Pirotta, Shrestha, Schofield, Schuck, Zwar, Silva, Heller, Bennell.

#### **ROLE OF THE STUDY SPONSOR**

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# REFERENCES

- Institute for Health Metrics and Evaluation. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) results. 2020. URL: https://ghdx.healthdata.org/record/ihmedata/global-burden-disease-study-2019-gbd-2019-reference-lifetable.
- 2. Callander EJ, Schofield DJ. Arthritis and the risk of falling into poverty: a survival analysis using Australian data. Arthritis Rheumatol 2016;68: 255–62.
- Finley CR, Chan DS, Garrison S, et al. What are the most common conditions in primary care? Systematic review. Can Fam Physician 2018;64:832–40.
- Nicolson PJ, Hinman RS, French SD, et al. Improving adherence to exercise: do people with knee osteoarthritis and physical therapists agree on the behavioral approaches likely to succeed? Arthritis Care Res (Hoboken) 2018;70:388–97.
- Bowden JL, Hunter DJ, Deveza LA, et al. Core and adjunctive interventions for osteoarthritis: efficacy and models for implementation. Nat Rev Rheumatol 2020;16:434–47.
- Basedow M, Esterman A. Assessing appropriateness of osteoarthritis care using quality indicators: a systematic review. J Eval Clin Pract 2015;21:782–9.
- Healey EL, Afolabi EK, Lewis M, et al. Uptake of the NICE osteoarthritis guidelines in primary care: a survey of older adults with joint pain. BMC Musculoskelet Disord 2018;19:295.
- Bennell KL, Bayram C, Harrison C, et al. Trends in management of hip and knee osteoarthritis in general practice in Australia over an 11-year window: a nationwide cross-sectional survey. Lancet Reg Health West Pac 2021;12:100187.
- National Osteoarthritis Strategy Project Group. National Osteoarthritis Strategy: Institute of Bone and Joint Research, University of Sydney; 2018.
- Eyles JP, Hunter DJ, Bennell KL, et al. Priorities for the effective implementation of osteoarthritis management programs: an OARSI international consensus exercise. Osteoarthritis Cartilage 2019;27:1270–9.
- Briggs AM, Hinman RS, Darlow B, et al. Confidence and attitudes toward osteoarthritis care among the current and emerging health workforce: a multinational interprofessional study. ACR Open Rheumatol 2019;1:219–35.
- Egerton T, Nelligan RK, Setchell J, et al. General practitioners' views on managing knee osteoarthritis: a thematic analysis of factors influencing clinical practice guideline implementation in primary care. BMC Rheumatol 2018;2:30.
- Briggs AM, Houlding E, Hinman RS, et al. Health professionals and students encounter multi-level barriers to implementing high-value osteoarthritis care: a multi-national study. Osteoarthritis Cartilage 2019;27:788–804.
- Egerton T, Diamond LE, Buchbinder R, et al. A systematic review and evidence synthesis of qualitative studies to identify primary care clinicians' barriers and enablers to the management of osteoarthritis. Osteoarthritis Cartilage 2017;25:625–38.

- Rosemann T, Wensing M, Joest K, et al. Problems and needs for improving primary care of osteoarthritis patients: the views of patients, general practitioners and practice nurses. BMC Musculoskelet Disord 2006;7:48.
- Arthritis Australia. Whose problem is it anyway? The voice of GPs on arthritis: companion to the voice of arthritis consumer survey. 2012. URL: https://arthritisaustralia.com.au/wordpress/wp-content/ uploads/2017/09/the\_voice\_of\_gps\_final\_120321.pdf.
- 17. Dennis S, Watts I, Pan Y, et al. The likelihood of general practitioners referring patients to physiotherapists is low for some health problems: secondary analysis of the Bettering the Evaluation and Care of Health (BEACH) observational study. J Physiother 2018;64:178–82.
- Runciman WB, Hunt TD, Hannaford NA, et al. CareTrack: assessing the appropriateness of health care delivery in Australia. Med J Aust 2012;197:100–5.
- Papandony MC, Chou L, Seneviwickrama M, et al. Patients' perceived health service needs for osteoarthritis (OA) care: a scoping systematic review. Osteoarthritis Cartilage 2017;25:1010–25.
- Ackerman IN, Buchbinder R, Osborne RH. Factors limiting participation in arthritis self-management programmes: an exploration of barriers and patient preferences within a randomized controlled trial. Rheumatology (Oxford) 2013;52:472–9.
- Arthritis Australia. The ignored majority: the voice of arthritis 2011. A national survey to discover the impact of arthritis on Australians. 2011. URL: https://arthritisaustralia.com.au/wordpress/wp-content/ uploads/2017/09/the-voice-of-arthritis-2011.pdf.
- Dziedzic KS, Healey EL, Porcheret M, et al. Implementing core NICE guidelines for osteoarthritis in primary care with a model consultation (MOSAICS): a cluster randomised controlled trial. Osteoarthritis Cartilage 2018;26:43–53.
- Østerås N, Moseng T, van Bodegom-Vos L, et al. Implementing a structured model for osteoarthritis care in primary healthcare: a stepped-wedge cluster-randomised trial. PLoS Med 2019;16: e1002949.
- Safari R, Jackson J, Sheffield D. Digital self-management interventions for people with osteoarthritis: systematic review with meta-analysis. J Med Internet Res 2020;22:e15365.
- Bennell KL, Lawford BJ, Metcalf B, et al. Physiotherapists and patients report positive experiences overall with telehealth during the COVID-19 pandemic: a mixed-methods study. J Physiother 2021; 67:201–9.
- 26. Egerton T, Hinman RS, Hunter DJ, et al. PARTNER: a service delivery model to implement optimal primary care management of people with knee osteoarthritis: description of development. BMJ Open 2020;10: e040423.
- 27. Hunter DJ, Hinman RS, Bowden JL, et al. Effectiveness of a new model of primary care management on knee pain and function in patients with knee osteoarthritis: protocol for THE PARTNER STUDY. BMC Musculoskelet Disord 2018;19:132.
- Hunter DJ, Hinman RS, Bowden JL, et al. Correction to: Effectiveness of a new model of primary care management on knee pain and function in patients with knee osteoarthritis: protocol for THE PARTNER STUDY. BMC Musculoskelet Disord 2018;19:443.
- Swerissen H, Duckett S, Grattan Institute. Mapping primary care in Australia. 2018. URL: https://grattan.edu.au/wp-content/uploads/ 2018/07/906-Mapping-primary-care.pdf.
- Precedence Health Care. Inca: chronic disease management software. 2018. URL: https://precedencehealthcare.com/.
- Australian Bureau of Statistics. Report 1270.055.005 Australian Statistical Geography Standard (ASGS): volume 5 – remoteness structure. July 2016. URL: https://www.abs.gov.au/ausstats/abs@. nsf/mf/1270.0.55.005.

- National Institute for Health and Care Excellence (NICE). Osteoarthritis: care and management in adults. 2014. URL: https://www.nice. org.uk/guidance/cg177.
- Wagner EH, Bennett SM, Austin BT, et al. Finding common ground: patient-centeredness and evidence-based chronic illness care. J Altern Complement Med 2005;11 Suppl 1:S7–15.
- Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. 2nd ed. London: Silverback Publishing; 2014.
- Bowden JL, Schuck K, Marshall C, et al. Optimising primary care management of knee osteoarthritis (the PARTNER study): lessons from a non-randomised pilot study [abstract]. Osteoarthritis Cartilage 2019;27 Suppl 1:S297–8.
- Royal Australian College of General Practitioners (RACGP): gplearning tempo modules. Knee osteoarthritis in general practice. 2017. URL: https://gplearning.racgp.org.au/Content/Tempo/2020KneeOsteo. html.
- 37. HealthChange Associates. HealthChange Methodology. 2022 URL: https://www.healthchange.com/.
- Noakes M, Clifton PM. The CSIRO total wellbeing diet. Australia: Penguin; 2005.
- Noakes M, Keogh JB, Foster PR, et al. Effect of an energy-restricted, high-protein, low-fat diet relative to a conventional high-carbohydrate, low-fat diet on weight loss, body composition, nutritional status, and markers of cardiovascular health in obese women. Am J Clin Nutr 2005;81:1298–306.
- 40. St Vincent's Hospital Sydney. This way up: online courses. URL: https://thiswayup.org.au/.
- Rini C, Porter LS, Somers TJ, et al. Automated internet-based pain coping skills training to manage osteoarthritis pain: a randomized controlled trial. Pain 2015;156:837–48.
- Roos EM, Roos HP, Lohmander LS, et al. Knee Injury and Osteoarthritis Outcome Score (KOOS): development of a self-administered outcome measure. J Orthop Sports Phys Ther 1998;28:88–96.

- 43. Bowden JL, Egerton T, Hinman RS, et al. Protocol for the process and feasibility evaluations of a new model of primary care service delivery for managing pain and function in patients with knee osteoarthritis (PARTNER) using a mixed methods approach. BMJ Open 2020;10:e034526.
- 44. Ellis PD. The essential guide to effect sizes: statistical power, metaanalysis, and the interpretation of research results. Cambridge: Cambridge University Press; 2010.
- 45. Orkin AM, Gill PJ, Ghersi D, et al. Guidelines for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances: the CONSERVE 2021 statement. JAMA 2021;326:257–65.
- R Core Team. R project for statistical computing. 2020. URL: https:// www.r-project.org/index.html.
- Sterne JA, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. BMJ 2009;338:b2393.
- Grund S, Robitzsch A, Luedtke O. mitml: tools for multiple imputation in multilevel modeling. R package version 0.4–1. 2021. URL: https:// cran.r-project.org/web/packages/mitml/mitml.pdf.
- Mackinnon A. The use and reporting of multiple imputation in medical research: a review. J Intern Med 2010;268:586–93.
- Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes 2003;1:64.
- Allen KD, Choong PF, Davis AM, et al. Osteoarthritis: models for appropriate care across the disease continuum. Best Pract Res Clin Rheumatol 2016;30:503–35.
- 52. Hall M, Castelein B, Wittoek R, et al. Diet-induced weight loss alone or combined with exercise in overweight or obese people with knee osteoarthritis: a systematic review and meta-analysis. Semin Arthritis Rheum 2019;48:765–77.

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