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Title: 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)

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Abstract

Introduction: This protocol outlines the rationale, design and methods for the process and feasibility evaluations of the PARTNER study. PARTNER is a randomised controlled trial to evaluate a new model of service delivery (the PARTNER model) against 'usual care'. PARTNER is designed to encourage greater uptake of key evidence-based non-surgical treatments for knee osteoarthritis (OA) in primary care. The intervention supports general practitioners (GPs) to gain an understanding of the best management options available through online professional development. Their patients receive telephone advice and support for OA management by a centralised, multidisciplinary 'Care Support Team'. We will conduct concurrent process and feasibility evaluations to understand the implementation of this new complex health intervention, identify issues for consideration when interpreting the effectiveness outcomes, and develop recommendations for future implementation, cost effectiveness and scalability.

Methods and analysis: The UK Medical Research Council Framework for undertaking a process evaluation of complex interventions and the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) frameworks inform the design of these evaluations. We utilise a mixed methods approach including analysis of survey data, administrative records, consultation records, and semi-structured interviews with general practitioners and their enrolled patients. The analysis will examine fidelity and dose of the intervention, observations of trial setup and implementation, and the quality of the care provided. We will also examine details of "usual care". The semi-structured interviews will be analysed using thematic and content analysis to draw out themes around implementation and acceptability of the model.

Ethics and dissemination: The primary study protocol (2016/959) and sub-study protocol (2019/503) have been approved by the Human Research Ethics Committee of the University of Sydney. This evaluation is crucial to explaining the PARTNER study results, and will be used to determine the feasibility of rolling out the intervention in an Australian healthcare context. ACTRN12617001595303, 1/12/2017.

ARTICLE SUMMARY

Strengths and limitations of this study

- A comprehensive, pre-planned, process and feasibility evaluation of a complex model of service delivery
- Mixed methods approach, underpinned by theoretical frameworks for design and evaluation of complex health interventions and chronic disease management
- Co-designed by a broad range of stakeholders including general practitioners, people with OA, physiotherapists, rheumatologists, industry groups and policy makers.
- Outcomes from this study will directly contribute to the implementation priorities of the Australian "National Osteoarthritis Strategy".

INTRODUCTION

Osteoarthritis (OA) is a leading cause of lower limb pain and disability, affecting more than 2 million Australians.[1] Although there is no cure, there are effective non-surgical treatments for the long-term management of symptomatic OA.[2] In particular, education and advice on OA, exercise and physical activity, and weight management are the core interventions recommended by current clinical guidelines.[3-5] These treatments are, however, often underutilised in primary care, and day-to-day management of Australians with knee OA is inconsistent with these recommendations.[6] We designed the *Effectiveness of a new model of primary care management on knee pain and function in patients with knee osteoarthritis study* (PARTNER), to address this issue.[7] The aim of the PARTNER study is to test a new model of service delivery (the PARTNER model), designed to encourage greater uptake of these key non-surgical treatments in primary care pathways, in comparison to usual care.

The PARTNER model is a complex health intervention (Fig. 1) employing multiple interacting components that target different organisational levels of healthcare delivery.[8] The intervention will target both general practitioners (GPs) and their patients with OA. General practitioners will be provided with online professional development opportunities to gain an understanding of the effective conservative, non-surgical management options available for treatment of patients with OA and endorsed by the Royal Australian College of General Practitioners (RACGP). Their patients will receive tailored advice and support on issues related to the management of OA including physical activity and exercise, weight loss, pain management and other effective self-management behaviours. This support will be delivered remotely for 12-months by a centralised, multidisciplinary 'Care Support Team' (CST) of health professionals trained in best-practice management of OA and health behaviour change.

The effectiveness and cost-effectiveness of this new model is being tested through a two-arm, cluster randomised controlled trial (RCT), and the process and feasibility evaluations described here will be conducted concurrently with the RCT. These evaluations will help us to understand the factors influencing the implementation of the intervention, identify issues for consideration when interpreting the effectiveness results, and enable us to develop recommendations for future implementation of the new model into Australian general practice. This process evaluation and feasibility protocol has two aims, namely:

1. To explain the PARTNER study results in terms of fidelity and engagement with the intervention, and determine:
   - 1.1. whether the intervention and control arms were delivered as intended for both the GPs and patients enrolled in the study,
   - 1.2. what "usual care" entailed, including types and rate of uptake of other services recommended for the patient,
   - 1.3. the types of issues typically identified or actioned during the consultations between the participants and the healthcare professionals in the study (i.e the GPs and CST), and determine the nature of the support and advice provided for each issue,

1.4. participants' (GPs and patients) and the CST personnel's perspectives on how, why and for whom the intervention did or did not work, and
1.5. if the primary and secondary outcome effects were due to the nature of the implementation, or to the intervention.[9]

2. To determine the feasibility of having the model adopted broadly in an Australian healthcare context (if the study is found to be effective), specifically:
   2.1. are there potential barriers and enablers to rolling the model out in the Australian primary care setting that have not been identified previously? We will look at barriers and enablers at the patient level; professional, organisational and service level (meso); and health systems level (macro)[10]
   2.2. do people with OA, and GPs, value the intervention as it was delivered?
   2.3. are the results generalisable to other people with OA, healthcare service providers and to different Australian health care contexts (e.g. public or private hospitals).
   2.4. Is the intervention cost effective compared to usual care?

METHODS AND ANALYSIS

The PARTNER Cluster Randomised Controlled Trial:

The PARTNER study is an investigator-initiated pragmatic RCT. A detailed explanation of the background, theoretical development and protocol for the broader PARTNER study (2016/959) has been described previously[7 11], and the trial prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12617001595303). The process and feasibility evaluations will be reported in accordance with the Standards for Reporting Implementation Studies (STaRI), and the Consolidated Criteria for Reporting Qualitative Research (COREQ 32) guidelines.[12 13]

Briefly, the RCT is comparing the new PARTNER model of service delivery to usual care.[7] We will recruit 44 general practices and 572 patients with knee OA in urban and regional practices in Victoria and New South Wales, Australia. The patients will be 45 years of age or older, and have had knee pain (≥4/10) for a minimum of three months. The model has interventions for both the person with OA, and their general practitioner (GP). The GP intervention will provide professional development and training opportunities on the most current conservative, non-surgical management options available for OA, as recommended by national and international clinical guidelines[3-5]. This will include audit/feedback activities, online learning modules, and the Integrated Care (INCA) electronic desktop IT support tool (previously named cdmNET). All GPs in the study regardless of group allocation will be asked to provide an initial evidence-based consultation for their participating patients. If allocated to the intervention arm, patients will be referred to the PARTNER Care Support Team (CST). The CST is a centralised, multidisciplinary team of health professionals trained in best-practice OA management, and with skills in health behaviour change. The CST will support patient participants to manage their knee OA for a period of 12 months. The CST will provide the patients with education, advice and ongoing support for behaviour change on the key OA treatments, including leg strengthening exercises, general physical activity, weight loss, and appropriate use of pain medications as agreed with the patient. Patients with a BMI ≥27 will have the option of

completing the Commonwealth Scientific and Industrial Research Organisation's (CSIRO) online "Total Wellbeing Diet" (TWD) program[14 15]. The TWD program based on an evidence-based, structured, nutritionally balanced eating plan designed to be delivered as part of a balanced lifestyle programme.[16] Patient participants may also be directed to one or more secondary interventions or additional health care services if they meet the referral criteria and/or have identified it as a personal priority. These treatment options may include online cognitive behavioural therapy (CBT) programs for mood, pain coping and sleep, or referrals to health care professionals (e.g. physiotherapists or dieticians) for face-to-face sessions. The primary outcomes of the PARTNER study are change in self-reported pain and function at 12-months. We will also assess a range of secondary patient-level outcomes at 6 and 12 months, and including the cost-effectiveness of the model (see[7]).

Patient and public involvement: One of the strengths of this process and feasibility evaluation is that it has been incorporated into the overall study design from conception. Both the main protocol and this evaluation and feasibility sub-protocol are underpinned by existing theoretical frameworks.[17-21] It has built upon considerable background work undertaken by our team, and with input from a broad range of stakeholders, general practitioners and consumers who participated in our five working groups: i) scientific methods, ii) data, iii) GP model of service delivery, iv) consumer engagement and, v) policy and marketing. Each working group was chaired by an appropriate representative from either an industry partner, consumer group, or other stakeholder organisation. This process and feasibility evaluation protocol has had further input from colleagues with expertise in implementing and assessing health interventions, and its content has evolved after findings from our pilot work. We send 6 monthly updates on the study's progress to our stakeholders and participants via an online newsletter.

Theoretical frameworks for the process evaluation: Figure 1 outlines the PARTNER logic model, which summarises the key questions, target behaviours, interventions, mediators and outcomes for both GPs and patients recruited to the study. The development of the model used Wagner's theoretical framework for the management of chronic disease[17], the Behaviour Change Wheel and the Theoretical Domains Framework[18] to identify key intervention components and propose a causal pathway between the study intervention and the main outcomes.

Our methods for the process and feasibility evaluations are based on the recommendations from the UK Medical Research Council framework for undertaking a process evaluation of complex interventions.[19] The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) has further guided the development of our evaluation questions[20 21]. RE-AIM is recommended by the Osteoarthritis Research Society International (OARSI) for conducting implementation trials on OA.[9] RE-AIM emphases the need to look into the proportion and representativeness of the participants' involved in the trial, the impact of the intervention, the fidelity and dose of the implementation, and identify issues impacting on long-term scaling of the model. It covers 5 domains, briefly:

- *Reach:* did the intervention reach who we intended?
- *Effectiveness:* was the intervention effective and cost-effective? (this question is primarily addressed by the RCT)[7]

- *Adoption:* who do we need to target to develop institutional support for the intervention? Did the practices recruited to our study adopt the changes at an organisational level, how representative were these sites compared to other Australian settings, and what needs to be undertaken to have it adopted more widely? Will actual change in the way OA is managed in primary care be achievable with our model, and how well do the end-users (clinicians, patients and other service providers) accept the intervention and processes? [9]
- *Implementation:* was the intervention delivered correctly and consistently (fidelity) as intended at the trial outset?
- *Maintenance:* can the intervention be delivered sustainably in different health care contexts and more broadly?

Data sources for the PARTNER study

We will use a mixed methods approach that utilises both quantitative and qualitative methods to capture process data for analysis (Table 1, Fig. 1), all of which involve informed consent and have been approved by an ethics committee. Detailed descriptions of the quantitative data collection instruments and analysis have been described previously in the main protocol[7], with details relevant to this protocol outlined below. The type and timing of data collected to address each aim of the process evaluation, including the details of the qualitative data collection are described in the following sections. Figure 2 illustrates the integration of the process and feasibility evaluations with the main RCT. Briefly, the data collection methods and time points relevant to these evaluations include:

a. Study administration records: include participant tracking, screening, training, withdrawal and serious adverse event logs; and training logs for the GPs, CST and other trial staff. Data are collected for the duration of the trial.
b. Electronic survey data from patients and GP surveys. GP complete surveys at baseline and after the study team has confirmed all their patients have attended their first GP consultation. Patients complete surveys at baseline, post GP visit, 3, 6 and 12 months.
c. Electronic consultation detailed records of each of the CSTs' consultations with the intervention patients over the 12-month period.
d. Service provider records will be collected from external providers delivering the weight-loss intervention, and the online CBT programs offered to the intervention group (i.e. *painTrainer* and *ThisWayUp)*.
e. Recorded consultation phone calls between the patient and the CST: all patient consultations for the duration of the patient's involvement with the CST will be audio recorded. For the first 18-weeks patients will be contacted once a fortnight on average (9 calls), and then monthly for the next 6 months (6 calls). The actual number and timing of these calls will be agreed between the patient and the CST.
f. Semi-structured qualitative interviews: these will be undertaken with a selection of GPs, patients and the CST personnel. GP interviews will be undertaken after all their enrolled patients have had their initial GP visit. Patient interviews will be undertaken after they have completed their 12-

month survey. The CST interviews will be undertaken after all patients have finished their last consultation.

Quantitative data analysis to address the aims of the process evaluation:

We will use a wide selection of the quantitative data to explain the study's effectiveness results in terms of fidelity and engagement with the intervention, particularly around the consistency of the study's implementation as per the primary protocol (Fig. 1) and the trial procedures manuals (Aim 1.1). This will include the study administration records, the electronic survey data collected from both patients and GPs, the electronic consultation records from the CST, and any changes required to the protocol over the duration of the study. For the GPs in the intervention group we will also examine how many completed the required professional development training modules, the optional capacity building training modules, and the number of intervention patients who were ultimately referred to the CST with OA (i.e. if there were any patients who were not diagnosed with OA). We will further examine if patients have reported receiving information on, or discussed with, their GP any of the four key topics (OA education, physical activity, muscle strengthening and weight-loss), and whether OA management plans were prepared for each patient. To determine what usual care entailed for our control cohort (Aim 1.2), we will analyse the electronic survey data from both the GPs and patients, including if there were any unanticipated treatments prescribed or activities undertaken that may need to be addressed in a future roll out of the model.

Table 1: Data collection methods used to address each aim and question of the process evaluation.

	Data collection method					
Aims	**i**	**ii**	**iii**	**iv**	**v**	**vi**
Aim 1: Explain the trial results in terms of fidelity and engagement:						
1.1 Were the intervention and control arms delivered as intended:						
GPs	X	X			X	X
Patients	X	X	X	X	X	X
CST			X	X		
1.2 What did "usual care" entail?						
GPs		X			X	
Patients		X			X	
1.3 What types of issues were discussed or actioned during the interactions between the CST /GPs and the patients?						
GPs		X			X	
CST		X	X	X	X	
1.4 Participants and healthcare professionals' perspectives on how, why, and for whom the interactions did or did not work? (semi-structured qualitative interviews)						
GPs					X	
CST					X	
Patients					X	
1.5 Were the primary and secondary outcome effects due to the nature of the implementation or to the intervention?						
GPs		X			X	
Patients		X	X	X	X	
Aim 2: Feasibility of scaling the intervention in Australia						
2.1 What are the possible barriers and enablers to rolling out the model in Australian primary care?						
GPs			X		X	
Patients			X		X	
2.2 Do patients and GPs value the intervention as delivered?					X	
GPs					X	
Patients					X	
2.3 Are the results generalisable to other patients with OA, healthcare service providers and across states?						
	X				X	
2.4 Is the intervention cost-effective compared to usual care?						

Patients		X		X	X	

Table 1: Legend

i. Analysis of inclusion / exclusion criteria, screening logs and withdrawal logs.
ii. Analysis of the quantitative data collected in electronic surveys for both the GPs and patients with OA.
iii. Analysis of a sample of recorded telephone interactions between the CST responsible for providing the intervention and the patients with OA.
iv. Audit of data collected over the trial (the electronic consultation notes) that captures the number, length and nature of the interactions between the CST and patients with OA.
v. Semi-structured interviews with patient participants and the GPs and CST involved in the study.
vi. Audit of training logs and other activity logs for GPs in the interventions group. This includes analysis of web usage statistics.

For the CST we will analyse the study records and survey data to determine the amount of time spent with each patient, and if the key interventions or secondary interventions (mood, pain and sleep management), were discussed in the consultations. Electronic patient survey data, the CST electronic consultation records and a selection of the recorded patient consultations will be further examined to establish what issues or topics were typically discussed during the consultations (Aim 1.3), including any additional issues that may need to be incorporated into the intervention long-term (also see *Qualitative data collection methods* below). We will examine the nature of the support and advice provided to patients by both the GPs and the CST, map the frequency and accuracy of each treatment component to the international care standards for OA (OA Quality Indicators)[22 23], and identify any conflicting advice that may need to be address when designing future training or educational materials.

We will also use the quantitative data sets to determine the feasibility of having the model adopted broadly in an Australian healthcare context by exploring health care providers' and patients' experience of the intervention and its perceived impact (Aim 2.3). We will undertake an audit of the inclusion and exclusion criteria, and the screening logs for general practices, GPs and patients to identify any reasons for not choosing not to participate and for any loss to follow-up. These data will be compared to the general population to give an indication of the representativeness and generalisability of the results to other patients, healthcare service providers and other Australian states/territories. Collectively, these data will provide some insight into the generalisability of the efficacy results, and any amendments that may need to be incorporated into the current model. This information will also be used to determine the cost effectiveness of the PARTNER model compared to usual care[7].

Qualitative data collection:

In addition to the quantitative datasets, we will collect and analyse qualitative data that will address many of the process and feasibility aims of this study (see Table 1). Firstly, we will analyse a sample of the telephone interactions between the patients in the intervention group and the CST. A selection of 20 purposively selected telephone consultations between the patients and the CST will be chosen after the final patient is recruited. We aim to ensure maximum heterogeneity of sampling, based on clinical and demographic characteristics, and gain the perspectives of patients and GPs in both urban and regional / rural general practices, and smaller versus larger practices. To capture the change in the perspectives over the 12 months, three phone calls will be analysed per person, covering the initial consultation, one randomly selected call from the first 18 months of the intervention (intensive phase), and one randomly selected call from the last 6 months of the CST intervention (maintenance phase). The phone recordings will be transcribed and analysed using a pre-designed checklist to determine how much time is spent on the key priority topics and the targeted secondary interventions (mood, pain coping and sleep)(Fig. 1). A tally will be made of the different types of issues discussed during the calls and the type of information given (Aim 1.1, 1.3, 1.5). We will also assess if the components of care delivered by the CST are accompanied by the appropriate behaviour change methods to support self-management as per the PARTNER protocol. This analysis will be undertaken by a member of the study team involved with the intervention, and an independent person not involved with running the trial. Data will be compiled and compared, and if required adjudicated by a third party.

Secondly, we will undertake semi-structured qualitative interviews with a selection of patients, GPs and the CST. These results will also address a range of the aims of these process and feasibility evaluations (Table 1), and a primary focus on contextual factors affecting delivery and implementation, and thus those that influence rolling out and long-term sustainability of the PARTNER model (Aims 2.1, 2.2, and 2.3). The interviews will be conducted over the telephone or face-to-face, by dedicated researcher/s not involved with delivering the RCT and with experience in qualitative data collection. Our multidisciplinary research team will develop the semi-structured interviews to explore issues around patients', GPs' and CST personnel's perspectives on how, why and for whom the interventions did or did not work, positive and negative (unintentional) outcomes, possible barriers and facilitators to rolling out the intervention, including any adoption considerations at the setting or organisational (meso) level, if the new model of care is valued by the users, and if they found any aspects burdensome (i.e. the number of appointments for patients or the amount of training for GPs).

Similar to the selection of recorded CST phone consultations, we will use purposive sampling to gain perspectives from patients and GPs from different regional and practice-related contexts. This will include around 30 patients (15 control and 15 intervention) and 14 GPs (7 from each group), or until redundancy is observed. We will also interview all willing members of the CST. Patients will be different from those used in the examination of the telephone consultations with the CST and will have finished their involvement with the trial. The interviews will be conducted one-to-one and will take approximately 1 hour each. Participants will be consented by the interviewer over the phone. The interviews will follow an interview guide which outlines the broad discussion topics. The draft interview schedule will be tested with patients and health care professional volunteers prior to use.

Qualitative data analysis plan: The semi-structured interview data and content data will be thematically analysed and interpreted. Interviews will be audio-recorded and transcribed verbatim. Transcripts will be coded and analysed thematically, using methods of constant comparison derived from grounded theory[24]. Contextual information derived from other process data will be used to triangulate the identified themes. The logic model (Figure 1) and process evaluation framework (Table 1) will aid the analysis by triangulating the quantitative data with the relevant qualitative data under each sub-heading. Qualitative data analysis software 'NVivo' will be used (QSR International, Melbourne, Australia). Identified themes will be explored, looking for shared or disparate views among the patients, GPs and CST about their experiences of participation, implementation and operationalisation of the study at their practice (if relevant). The collection and analysis of the qualitative data will be conducted iteratively so that themes identified in early interviews can be explored in more depth later.[19]

ETHICS AND DISSEMINATION

The primary study protocol (2016/959), this sub-study protocol (2019/503), study documents, and all subsequent amendments have been approved by the Human Research Ethics Committee (HREC) of the University of Sydney. The study underwent peer review from the Australian National Health and Medical Research Council (NHMRC) before receiving funding, and the protocol was prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12617001595303).

This protocol outlines the rationale, design and methods for process and feasibility evaluations of the PARTNER study, a randomised controlled trial designed to test the new PARTNER model of service delivery. This evaluation of a complex intervention is crucial to explaining the PARTNER study results, and to determine the feasibility of scaling the intervention in an Australian healthcare context. The data and results will be used to identify and address issues in the intervention and improve the delivery of the model long term, with a focus on effectiveness, quality and safety, and scalability.

Outcomes from this study, regardless of the effectiveness of the RCT, will directly contribute to the implementation priorities of the Australian "National Osteoarthritis Strategy"[25], the aligned jurisdictional Models of Care in WA[26], NSW[27] and Victoria[28], and other associated national strategies[4 29]. The National OA Strategy has multi-partisan support from peak and professional bodies, governments, private health insurers and consumers to improve access to evidence-based, non-surgical OA interventions that deliver high-value care to all Australians with OA. It specifically calls for the prioritisation of testing and implementation of new models of service delivery to support referral to allied health and community-based services, assist primary care practitioners to deliver essential lifestyle-based interventions, and ultimately reduce the over-reliance on medications and joint replacement surgery. Our findings will be disseminated to all partners and stakeholders involved with both the study's initial design, and those with an interest in its long-term implementation. The National OA Strategy Leadership Group and Implementation Advisory Committee will help drive dissemination of our results across all levels of healthcare to address the local, meso and macro needs identified. At an international level our results will contribute to the work of the Osteoarthritis Research Society International's "Joint Effort Initiative" who are currently developing broadscale guidelines and recommendations to assist with the global

implementation of OA management programs[30]. Specific research findings will be disseminated via peer-review journals and conferences, and we anticipate delivering training workshops for interested health care professionals.

In conclusion, this paper reports of the design of the mixed methods process and feasibility evaluations for the PARTNER study. The results will help us gain a better understanding of the implementation of the intervention and identify issues for consideration when interpreting its effectiveness. However, these evaluations will also allow us to identify any broader issues or considerations that will need to be addressed for a wider rollout of this new model of service delivery in Australian primary care.

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AUTHOR STATEMENT

KLB, RSH and DJH conceived the initial project and procured the project funding, and DJH is leading the trial. KLB, RSH, DJH and TE developed the primary study protocol, and JLB led the further development of the process evaluation and feasibility protocol. AMB, SJB, ABF, SDF, JK, MP, DJS, and NAZ assisted with both protocol designs. JLB wrote the first and final draft of this manuscript. All authors participated in the trial design, provided feedback on drafts, and read and approved the final manuscript.

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COMPETING INTERESTS

DJH provides consulting advice to Pfizer, Lilly, Merck Serono and TLC bio. SB is an employee of Medibank.

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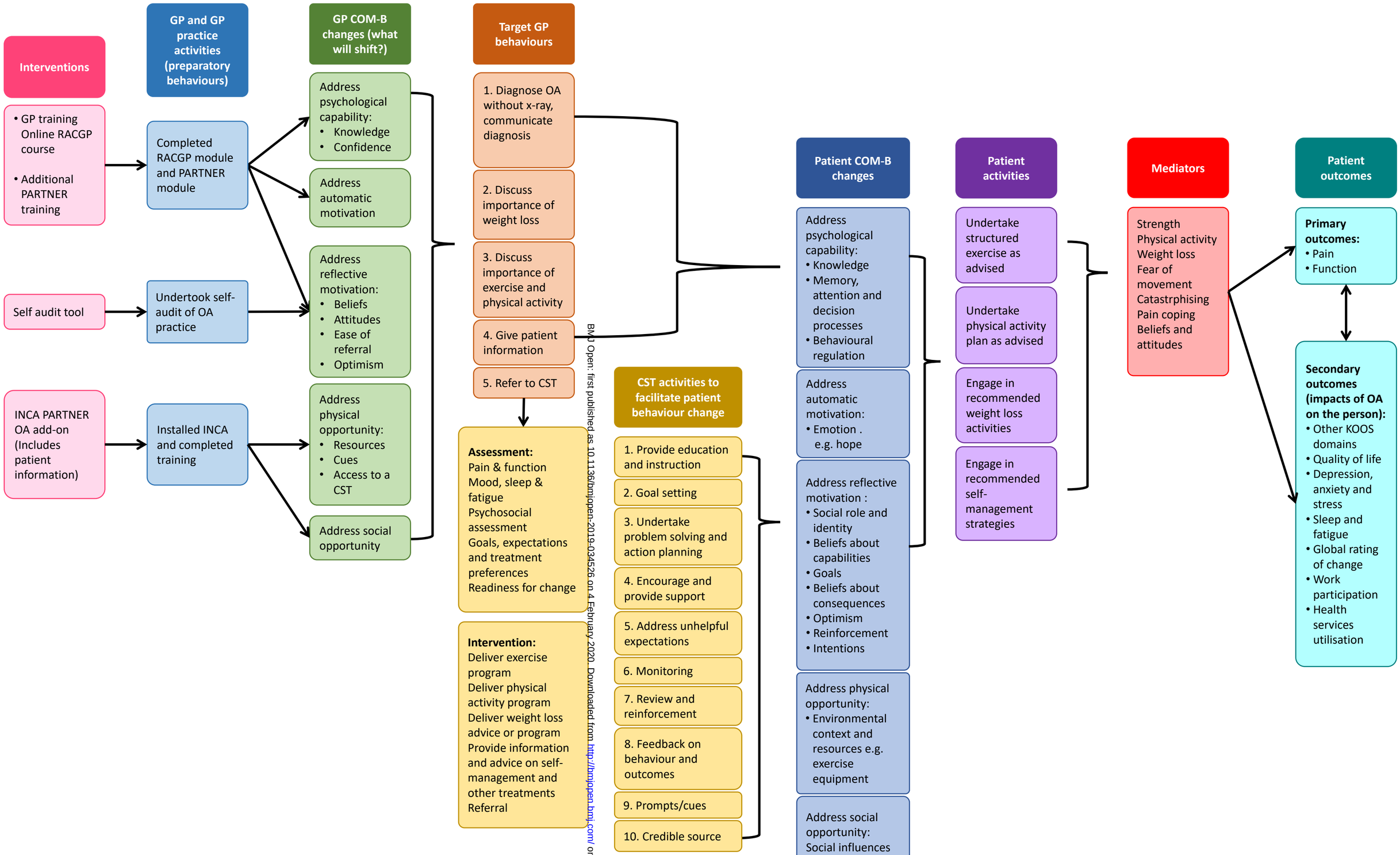
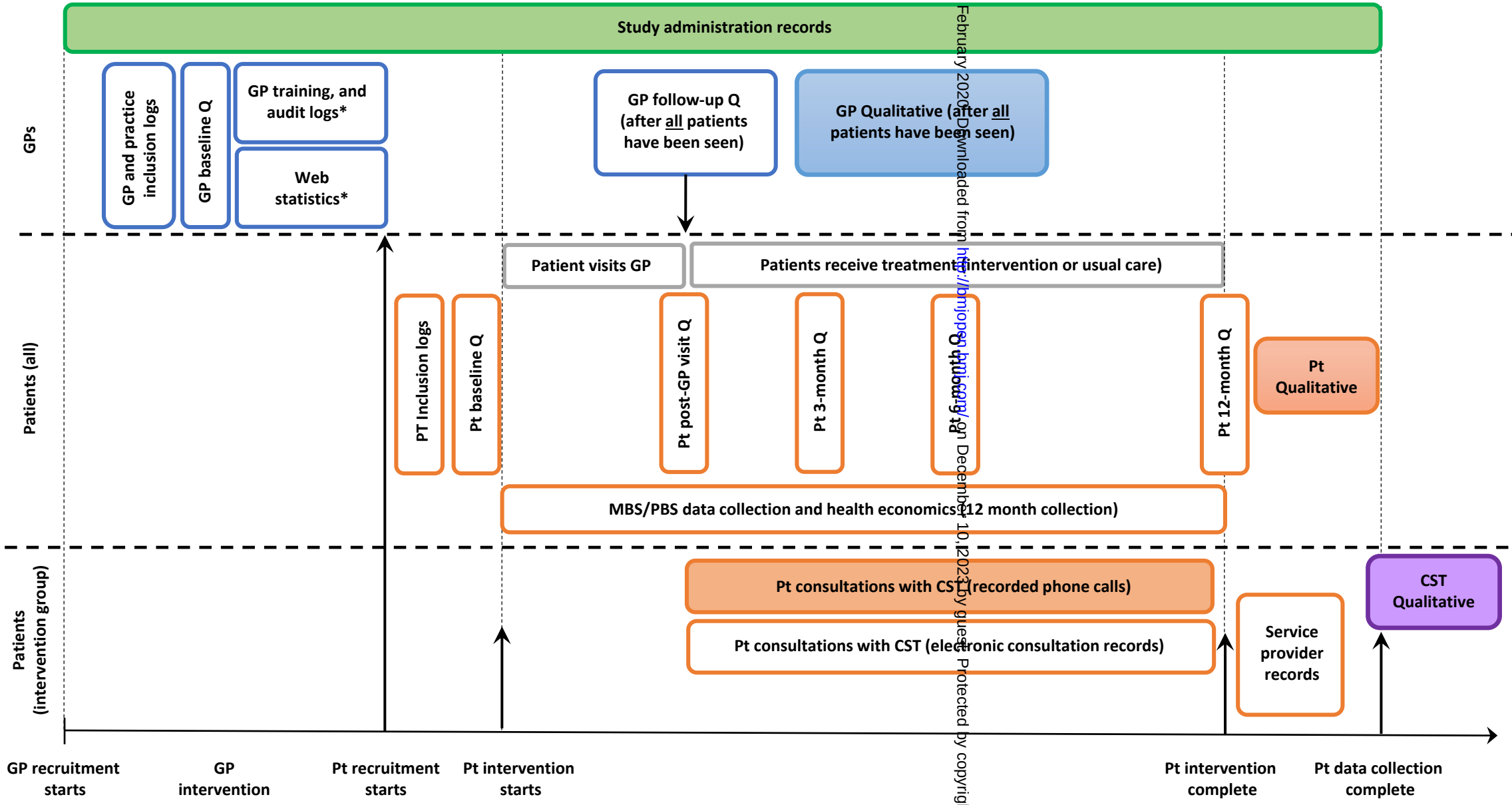
- The PARTNER Study Team: Karen Shuck, Charlotte Marshall, Stephanie Hawkins, Michelle King, Rebecca Doyle, Janet Cook, Carin Pratt, Iqbal Hasan, and Anna Wood.

FIGURE LEGENDS

Figure 1: The PARTNER logic model. Theoretical basis for the development of the PARTNER model of service delivery, and the mechanisms underpinning the process evaluation. GP = General Practitioner; RACGP = Royal Australian College of General Practitioners; INCA = Integrated Care management software (formally cdmNET); COM-B = Capability, Opportunity, Motivation and Behaviour.

Figure 2: Indicative timing of the data collection processes for GPs and patients. This schematic illustrates the integration of the process and feasibility evaluations with the main RCT. Open boxes are quantitative data collection, filled boxes are qualitative data (interviews or phone call recordings). The patient intervention is for 12-months. Pt = patients, CST = Care Support Team, GPs = General practitioners, Q = online survey questionnaires. * data are collected for GPs in the intervention group only.





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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

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Title: 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

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Abstract

Introduction: This protocol outlines the rationale, design and methods for the process and feasibility evaluations of the PARTNER study. PARTNER is a randomised controlled trial to evaluate a new model of service delivery (the PARTNER model) against 'usual care'. PARTNER is designed to encourage greater uptake of key evidence-based non-surgical treatments for knee osteoarthritis (OA) in primary care. The intervention supports general practitioners (GPs) to gain an understanding of the best management options available through online professional development. Their patients receive telephone advice and support for OA management by a centralised, multidisciplinary 'Care Support Team'. We will conduct concurrent process and feasibility evaluations to understand the implementation of this new complex health intervention, identify issues for consideration when interpreting the effectiveness outcomes, and develop recommendations for future implementation, cost effectiveness and scalability.

Methods and analysis: The UK Medical Research Council Framework for undertaking a process evaluation of complex interventions and the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) frameworks inform the design of these evaluations. We utilise a mixed methods approach including analysis of survey data, administrative records, consultation records, and semi-structured interviews with general practitioners and their enrolled patients. The analysis will examine fidelity and dose of the intervention, observations of trial setup and implementation, and the quality of the care provided. We will also examine details of "usual care". The semi-structured interviews will be analysed using thematic and content analysis to draw out themes around implementation and acceptability of the model.

Ethics and dissemination: The primary and sub-study protocols have been approved by the Human Research Ethics Committee of The University of Sydney (2016/959 and 2019/503). Our findings will be disseminated to national and international partners and stakeholders, who will also assist with wider dissemination of our results across all levels of healthcare. Specific findings will be disseminated via peer-review journals and conferences, and via training for health care professionals delivering osteoarthritis management programs. This evaluation is crucial to explaining the PARTNER study results, and will be used to determine the feasibility of rolling out the intervention in an Australian healthcare context. ACTRN12617001595303, 1/12/2017.

ARTICLE SUMMARY

Strengths and limitations of this study

- A comprehensive, pre-planned, process and feasibility evaluation of a complex model of service delivery
- Mixed methods approach, underpinned by theoretical frameworks for design and evaluation of complex health interventions and chronic disease management
- Co-designed by a broad range of stakeholders including general practitioners, people with OA, physiotherapists, rheumatologists, industry groups and policy makers.
- Outcomes from this study will directly contribute to the implementation priorities of the Australian "National Osteoarthritis Strategy".

INTRODUCTION

Osteoarthritis (OA) is a leading cause of lower limb pain and disability, affecting more than 2 million Australians.[1] Although there is no cure, there are effective non-surgical treatments for the long-term management of symptomatic OA.[2] In particular, education and advice on OA, exercise and physical activity, and weight management are the core interventions recommended by current clinical guidelines.[3-5] These treatments are, however, often underutilised in primary care, and day-to-day management of Australians with knee OA is inconsistent with these recommendations.[6] We designed the *Effectiveness of a new model of primary care management on knee pain and function in patients with knee osteoarthritis study* (PARTNER), to address this issue.[7] The aim of the PARTNER study is to test a new model of service delivery (the PARTNER model), designed to encourage greater uptake of these key non-surgical treatments in primary care pathways, in comparison to usual care.

The PARTNER model is a complex health intervention (Fig. 1) employing multiple interacting components that target different organisational levels of healthcare delivery.[8] The intervention will target both general practitioners (GPs) and their patients with OA. General practitioners will be provided with online professional development opportunities to gain an understanding of the effective conservative, non-surgical management options available for treatment of patients with OA and endorsed by the Royal Australian College of General Practitioners (RACGP). Their patients will receive tailored advice and support on issues related to the management of OA including physical activity and exercise, weight loss, pain management and other effective self-management behaviours. This support will be delivered remotely for 12-months by a centralised, multidisciplinary 'Care Support Team' (CST) of health professionals trained in best-practice management of OA and health behaviour change.

The effectiveness and cost-effectiveness of this new model is being tested through a two-arm, cluster randomised controlled trial (RCT), and the process and feasibility evaluations described here will be conducted concurrently with the RCT. These evaluations will help us to understand the factors influencing the implementation of the intervention, identify issues for consideration when interpreting the effectiveness results, and enable us to develop recommendations for future implementation of the new model into Australian general practice. This process evaluation and feasibility protocol has two aims, namely:

1. To explain the PARTNER study results in terms of fidelity and engagement with the intervention, and determine:
   - 1.1. whether the intervention and control arms were delivered as intended for both the GPs and patients enrolled in the study,
   - 1.2. what "usual care" entailed, including types and rate of uptake of other services recommended for the patient,
   - 1.3. the types of issues typically identified or actioned during the consultations between the participants and the healthcare professionals in the study (i.e the GPs and CST), and determine the nature of the support and advice provided for each issue,

1.4. participants' (GPs and patients) and the CST personnel's perspectives on how, why and for whom the intervention did or did not work, and
1.5. if the primary and secondary outcome effects were due to the nature of the implementation, or to the intervention.[9]

2. To determine the feasibility and acceptability of having the model adopted broadly in an Australian healthcare context (if the study is found to be effective), specifically:
   2.1. are there potential barriers and enablers to rolling the model out in the Australian primary care setting that have not been identified previously? We will look at barriers and enablers at the patient level; professional, organisational and service level (meso); and health systems level (macro)[10]
   2.2. do people with OA, and GPs, value the intervention as it was delivered?
   2.3. are the results generalisable to other people with OA, healthcare service providers and to different Australian health care contexts (e.g. public or private hospitals).
   2.4. Is the intervention cost effective compared to usual care?

METHODS AND ANALYSIS

The PARTNER Cluster Randomised Controlled Trial:

The PARTNER study is an investigator-initiated pragmatic RCT. A detailed explanation of the background, theoretical development and protocol for the broader PARTNER study (2016/959) has been described previously[7 11], and the trial prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12617001595303). The process and feasibility evaluations will be reported in accordance with the Standards for Reporting Implementation Studies (STaRI), and the Consolidated Criteria for Reporting Qualitative Research (COREQ 32) guidelines.[12 13]

Briefly, the RCT is comparing the new PARTNER model of service delivery to usual care.[7] We will recruit 44 general practices and 572 patients with knee OA in urban and regional practices in Victoria and New South Wales, Australia. The patients will be 45 years of age or older, and have had knee pain (≥4/10) for a minimum of three months. The model has interventions for both the person with OA, and their general practitioner (GP). The GP intervention will provide professional development and training opportunities on the most current conservative, non-surgical management options available for OA, as recommended by national and international clinical guidelines[3-5]. This will include audit/feedback activities, online learning modules, and the Integrated Care (INCA) electronic desktop IT support tool (previously named cdmNET). All GPs in the study regardless of group allocation will be asked to provide an initial evidence-based consultation for their participating patients. If allocated to the intervention arm, patients will be referred to the PARTNER Care Support Team (CST). The CST is a centralised, multidisciplinary team of health professionals trained in best-practice OA management, and with skills in health behaviour change. The CST will support patient participants to manage their knee OA for a period of 12 months. The CST will provide the patients with education, advice and ongoing support for behaviour change on the key OA treatments, including leg strengthening exercises, general physical activity, weight loss, and appropriate use of pain medications as agreed with the patient. Patients with a BMI ≥27 will have the option of

completing the Commonwealth Scientific and Industrial Research Organisation's (CSIRO) online "Total Wellbeing Diet" (TWD) program[14 15]. The TWD program based on an evidence-based, structured, nutritionally balanced eating plan designed to be delivered as part of a balanced lifestyle programme.[16] Patient participants may also be directed to one or more secondary interventions or additional health care services if they meet the referral criteria and/or have identified it as a personal priority. These treatment options may include online cognitive behavioural therapy (CBT) programs for mood, pain coping and sleep, or referrals to health care professionals (e.g. physiotherapists or dieticians) for face-to-face sessions. The primary outcomes of the PARTNER study are change in self-reported pain and function at 12-months. We will also assess a range of secondary patient-level outcomes at 6 and 12 months, and including the cost-effectiveness of the model (see[7]).

Patient and public involvement: One of the strengths of this process and feasibility evaluation is that it has been incorporated into the overall study design from conception. Both the main protocol and this evaluation and feasibility sub-protocol are underpinned by existing theoretical frameworks.[17-21] It has built upon considerable background work undertaken by our team, and with input from a broad range of stakeholders, general practitioners and consumers who participated in our five working groups: i) scientific methods, ii) data, iii) GP model of service delivery, iv) consumer engagement and, v) policy and marketing. Each working group was chaired by an appropriate representative from either an industry partner, consumer group, or other stakeholder organisation. This process and feasibility evaluation protocol has had further input from colleagues with expertise in implementing and assessing health interventions, and its content has evolved after findings from our pilot work. We send 6 monthly updates on the study's progress to our stakeholders and participants via an online newsletter.

Theoretical frameworks for the process evaluation: Figure 1 outlines the PARTNER logic model, which summarises the key questions, target behaviours, interventions, mediators and outcomes for both GPs and patients recruited to the study. The development of the model used Wagner's theoretical framework for the management of chronic disease[17], the Behaviour Change Wheel and the Theoretical Domains Framework[18] to identify key intervention components and propose a causal pathway between the study intervention and the main outcomes.

Our methods for the process and feasibility evaluations are based on the recommendations from the UK Medical Research Council framework for undertaking a process evaluation of complex interventions.[19] The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) has further guided the development of our evaluation questions[20 21]. RE-AIM is recommended by the Osteoarthritis Research Society International (OARSI) for conducting implementation trials on OA.[9] RE-AIM emphases the need to look into the proportion and representativeness of the participants' involved in the trial, the impact of the intervention, the fidelity and dose of the implementation, and identify issues impacting on long-term scaling of the model. It covers 5 domains, briefly:

- *Reach:* did the intervention reach who we intended?
- *Effectiveness:* was the intervention effective and cost-effective? (this question is primarily addressed by the RCT)[7]

- *Adoption:* who do we need to target to develop institutional support for the intervention? Did the practices recruited to our study adopt the changes at an organisational level, how representative were these sites compared to other Australian settings, and what needs to be undertaken to have it adopted more widely? Will actual change in the way OA is managed in primary care be achievable with our model, and how well do the end-users (clinicians, patients and other service providers) accept the intervention and processes? [9]
- *Implementation:* was the intervention delivered correctly and consistently (fidelity) as intended at the trial outset?
- *Maintenance:* can the intervention be delivered sustainably in different health care contexts and more broadly?

Data sources for the PARTNER study

We will use a mixed methods approach that utilises both quantitative and qualitative methods to capture process data for analysis (Table 1, Fig. 1), all of which involve informed consent and have been approved by an ethics committee. Detailed descriptions of the quantitative data collection instruments and analysis have been described previously in the main protocol[7], with details relevant to this protocol outlined below. The type and timing of data collected to address each aim of the process evaluation, including the details of the qualitative data collection are described in the following sections. Figure 2 illustrates the integration of the process and feasibility evaluations with the main RCT. Briefly, the data collection methods and time points relevant to these evaluations include:

a. Study administration records: include participant tracking, screening, training, withdrawal and serious adverse event logs; and training logs for the GPs, CST and other trial staff. Data are collected for the duration of the trial.
b. Electronic survey data from patients and GP surveys. GP complete surveys at baseline and after the study team has confirmed all their patients have attended their first GP consultation. Patients complete surveys at baseline, post GP visit, 3, 6 and 12 months.
c. Electronic consultation detailed records of each of the CSTs' consultations with the intervention patients over the 12-month period.
d. Service provider records will be collected from external providers delivering the weight-loss intervention, and the online CBT programs offered to the intervention group (i.e. *painTrainer* and *ThisWayUp)*.
e. Recorded consultation phone calls between the patient and the CST: all patient consultations for the duration of the patient's involvement with the CST will be audio recorded. For the first 18-weeks patients will be contacted once a fortnight on average (9 calls), and then monthly for the next 6 months (6 calls). The actual number and timing of these calls will be agreed between the patient and the CST.
f. Semi-structured qualitative interviews: these will be undertaken with a selection of GPs, patients and the CST personnel. GP interviews will be undertaken after all their enrolled patients have had their initial GP visit. Patient interviews will be undertaken after they have completed their 12-

month survey. The CST interviews will be undertaken after all patients have finished their last consultation.

Quantitative data analysis to address the aims of the process evaluation:

We will use a wide selection of the quantitative data to explain the study's effectiveness results in terms of fidelity and engagement with the intervention, particularly around the consistency of the study's implementation as per the primary protocol (Fig. 1) and the trial procedures manuals (Aim 1.1). This will include the study administration records, the electronic survey data collected from both patients and GPs, the electronic consultation records from the CST, and any changes required to the protocol over the duration of the study. For the GPs in the intervention group we will also examine how many completed the required professional development training modules, the optional capacity building training modules, and the number of intervention patients who were ultimately referred to the CST with OA (i.e. if there were any patients who were not diagnosed with OA). We will further examine if patients have reported receiving information on, or discussed with, their GP any of the four key topics (OA education, physical activity, muscle strengthening and weight-loss), and whether OA management plans were prepared for each patient. To determine what usual care entailed for our control cohort (Aim 1.2), we will analyse the electronic survey data from both the GPs and patients, including if there were any unanticipated treatments prescribed or activities undertaken that may need to be addressed in a future roll out of the model.

Table 1: Data collection methods used to address each aim and question of the process evaluation.

	Data collection method					
Aims	**i**	**ii**	**iii**	**iv**	**v**	**vi**
Aim 1: Explain the trial results in terms of fidelity and engagement:						
1.1 Were the intervention and control arms delivered as intended:						
GPs	X	X			X	X
Patients	X	X	X	X	X	X
CST			X	X		
1.2 What did "usual care" entail?						
GPs		X			X	
Patients		X			X	
1.3 What types of issues were discussed or actioned during the interactions between the CST /GPs and the patients?						
GPs		X			X	
CST		X	X	X	X	
1.4 Participants and healthcare professionals' perspectives on how, why, and for whom the interactions did or did not work? (semi-structured qualitative interviews)						
GPs					X	
CST					X	
Patients					X	
1.5 Were the primary and secondary outcome effects due to the nature of the implementation or to the intervention?						
GPs		X			X	
Patients		X	X	X	X	
Aim 2: Feasibility and acceptability of scaling the intervention in Australia						
2.1 What are the possible barriers and enablers to rolling out the model in Australian primary care?						
GPs			X		X	
Patients			X		X	
2.2 Do patients and GPs value the intervention as delivered?					X	
GPs					X	
Patients					X	
2.3 Are the results generalisable to other patients with OA, healthcare service providers and across states?						
	X				X	

2.4 Is the intervention cost-effective compared to usual care?						
Patients		X		X	X	

Table 1: Legend

i. Analysis of inclusion / exclusion criteria, screening logs and withdrawal logs.
ii. Analysis of the quantitative data collected in electronic surveys for both the GPs and patients with OA.
iii. Analysis of a sample of recorded telephone interactions between the CST responsible for providing the intervention and the patients with OA.
iv. Audit of data collected over the trial (the electronic consultation notes) that captures the number, length and nature of the interactions between the CST and patients with OA.
v. Semi-structured interviews with patient participants and the GPs and CST involved in the study.
vi. Audit of training logs and other activity logs for GPs in the interventions group. This includes analysis of web usage statistics.

For the CST we will analyse the study records and survey data to determine the amount of time spent with each patient, and if the key interventions or secondary interventions (mood, pain and sleep management), were discussed in the consultations. Electronic patient survey data, the CST electronic consultation records and a selection of the recorded patient consultations will be further examined to establish what issues or topics were typically discussed during the consultations (Aim 1.3), including any additional issues that may need to be incorporated into the intervention long-term (also see *Qualitative data collection methods* below). We will examine the nature of the support and advice provided to patients by both the GPs and the CST, map the frequency and accuracy of each treatment component to the international care standards for OA (OA Quality Indicators)[2223], and identify any conflicting advice that may need to be address when designing future training or educational materials.

We will also use the quantitative data sets to determine the feasibility and acceptability of having the model adopted broadly in an Australian healthcare context. We will explore health care providers' and patients' experience of the intervention and its perceived impact (Aim 2.3) and examine any issues that arose during the trial that would affect broader implementation (Aim 2.1). We will undertake an audit of the inclusion and exclusion criteria, and the screening logs for general practices, GPs and patients to identify any reasons for not choosing not to participate and for any loss to follow-up. These data will be compared to the general population to give an indication of the representativeness and generalisability of the results to other patients, healthcare service providers and other Australian states/territories. Collectively, these data will provide some insight into the generalisability of the efficacy results, and any amendments that may need to be incorporated into the current model. This information will also be used to determine the cost effectiveness of the PARTNER model compared to usual care[7].

Qualitative data collection:

In addition to the quantitative datasets, we will collect and analyse qualitative data that will address many of the process and feasibility aims of this study (see Table 1). Firstly, we will analyse a sample of the telephone interactions that have been recorded between the patients in the intervention group and the CST. After the final patient is recruited, we will purposively select 20 patients to conduct a detailed analysis of their telephone consultations. We aim to ensure maximum heterogeneity of sampling, based on clinical and demographic characteristics, and gain the perspectives of patients and GPs in both urban and regional / rural general practices, and smaller versus larger practices. To capture the change in the perspectives over the 12 months, three phone calls will be analysed per person, covering the initial consultation, one randomly selected call from the first 18 months of the intervention (intensive phase), and one randomly selected call from the last 6 months of the CST intervention (maintenance phase). The phone recordings will be transcribed and analysed using pre-designed checklists. The first checklist will be used to determine how much time is spent on the key priority topics and the targeted secondary interventions (mood, pain coping and sleep)(Fig. 1). A tally will be made of the different types of issues discussed during the calls and the type of information given (Aim 1.1, 1.3, 1.5). We will also assess if the components of care delivered by the CST are accompanied by the appropriate behaviour change methods to support self-management as per the PARTNER protocol. We will use a checklist based on the methodology developed by our partner "HealthChange Australia" to train the CST in behaviour change techniques to examine the fidelity of the delivery of the behaviour change component of the intervention. This analysis will be undertaken by a member of the study team involved with the intervention, and an independent person not involved with running the trial. Data will be compiled and compared, and if required adjudicated by a third party.

Secondly, we will undertake semi-structured qualitative interviews with a selection of patients, GPs and the CST. These results will also address a range of the aims of these process and feasibility evaluations (Table 1), and a primary focus on contextual factors affecting delivery and implementation, and thus those that influence rolling out and long-term sustainability of the PARTNER model (Aims 2.1, 2.2, and 2.3). The interviews will be conducted over the telephone or face-to-face, by dedicated researcher/s not involved with delivering the RCT and with experience in qualitative data collection. Our multidisciplinary research team will develop the semi-structured interviews to explore issues around patients', GPs' and CST personnel's perspectives on how, why and for whom the interventions did or did not work, positive and negative (unintentional) outcomes, possible barriers and facilitators to rolling out the intervention, including any adoption considerations at the setting or organisational (meso) level, if the new model of care is valued by the users, and if they found any aspects burdensome (i.e. the number of appointments for patients or the amount of training for GPs).

Similar to the selection of recorded CST phone consultations, we will use purposive sampling to gain perspectives from patients and GPs from different regional and practice-related contexts. This will include around 30 patients (15 control and 15 intervention) and 14 GPs (7 from each group), or until redundancy is observed. We will also interview all willing members of the CST. Patients will be different from those used in the examination of the telephone consultations with the CST and will have finished their

involvement with the trial. The interviews will be conducted one-to-one and will take approximately 1 hour each. Participants will be consented by the interviewer over the phone. The interviews will follow an interview guide which outlines the broad discussion topics. The draft interview schedule will be tested with patients and health care professional volunteers prior to use.

Qualitative data analysis plan: The semi-structured interview data and content data will be thematically analysed and interpreted. Interviews will be audio-recorded and transcribed verbatim. Transcripts will be coded and analysed thematically, using methods of constant comparison derived from grounded theory[24]. Contextual information derived from other process data will be used to triangulate the identified themes. The logic model (Figure 1) and process evaluation framework (Table 1) will aid the analysis by triangulating the quantitative data with the relevant qualitative data under each sub-heading. Qualitative data analysis software 'NVivo' will be used (QSR International, Melbourne, Australia). Identified themes will be explored, looking for shared or disparate views among the patients, GPs and CST about their experiences of participation, implementation and operationalisation of the study at their practice (if relevant). The collection and analysis of the qualitative data will be conducted iteratively so that themes identified in early interviews can be explored in more depth later.[19]

ETHICS AND DISSEMINATION

The primary study protocol (2016/959), this sub-study protocol (2019/503), study documents, and all subsequent amendments have been approved by the Human Research Ethics Committee (HREC) of the University of Sydney. The study underwent peer review from the Australian National Health and Medical Research Council (NHMRC) before receiving funding, and the protocol was prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12617001595303).

This protocol outlines the rationale, design and methods for process and feasibility evaluations of the PARTNER study, a randomised controlled trial designed to test the new PARTNER model of service delivery. This evaluation of a complex intervention is crucial to explaining the PARTNER study results, and to determine the feasibility of scaling the intervention in an Australian healthcare context. The data and results will be used to identify and address issues in the intervention and improve the delivery of the model long term, with a focus on effectiveness, quality and safety, and scalability.

Outcomes from this study, regardless of the effectiveness of the RCT, will directly contribute to the implementation priorities of the Australian "National Osteoarthritis Strategy"[25], the aligned jurisdictional Models of Care in WA[26], NSW[27] and Victoria[28], and other associated national strategies[4 29]. The National OA Strategy has multi-partisan support from peak and professional bodies, governments, private health insurers and consumers to improve access to evidence-based, non-surgical OA interventions that deliver high-value care to all Australians with OA. It specifically calls for the prioritisation of testing and implementation of new models of service delivery to support referral to allied health and community-based services, assist primary care practitioners to deliver essential lifestyle-based interventions, and ultimately reduce the over-reliance on medications and joint replacement surgery. Our findings will be disseminated to all partners and stakeholders involved with both the study's initial design, and those with

an interest in its long-term implementation. The National OA Strategy Leadership Group and Implementation Advisory Committee will help drive dissemination of our results across all levels of healthcare to address the local, meso and macro needs identified. At an international level our results will contribute to the work of the Osteoarthritis Research Society International's "Joint Effort Initiative" who are currently developing broadscale guidelines and recommendations to assist with the global implementation of OA management programs[30]. Specific research findings will be disseminated via peer-review journals and conferences, and we anticipate delivering training workshops for interested health care professionals.

In conclusion, this paper reports of the design of the mixed methods process and feasibility evaluations for the PARTNER study. The results will help us gain a better understanding of the implementation of the intervention and identify issues for consideration when interpreting its effectiveness. However, these evaluations will also allow us to identify any broader issues or considerations that will need to be addressed for a wider rollout of this new model of service delivery in Australian primary care.

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AUTHOR STATEMENT

KLB, RSH and DJH conceived the initial project and procured the project funding, and DJH is leading the trial. KLB, RSH, DJH and TE developed the primary study protocol, and JLB led the further development of the process evaluation and feasibility protocol. AMB, SJB, ABF, SDF, JK, MP, DJS, and NAZ assisted with both protocol designs. JLB wrote the first and final draft of this manuscript. All authors participated in the trial design, provided feedback on drafts, and read and approved the final manuscript.

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COMPETING INTERESTS

DJH provides consulting advice to Pfizer, Lilly, Merck Serono and TLC bio. SB is an employee of Medibank.

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FIGURE LEGENDS

Figure 1: The PARTNER logic model. Theoretical basis for the development of the PARTNER model of service delivery, and the mechanisms underpinning the process evaluation. GP = General Practitioner; RACGP = Royal Australian College of General Practitioners; INCA = Integrated Care management software (formally cdmNET); COM-B = Capability, Opportunity, Motivation and Behaviour.

Figure 2: Indicative timing of the data collection processes for GPs and patients. This schematic illustrates the integration of the process and feasibility evaluations with the main RCT. Open boxes are quantitative data collection, filled boxes are qualitative data (interviews or phone call recordings). The patient intervention is for 12-months. Pt = patients, CST = Care Support Team, GPs = General practitioners, Q = online survey questionnaires. * data are collected for GPs in the intervention group only.