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Protocol Title:

ConnecTBack Trial – Creating Team-Based care for a new primary care model for low back pain: A cluster randomised trial

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Signature: _____

Date: _____

Ethics Statement:

The study will be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007), the CPMP/ICH Note for Guidance on Good Clinical Practice and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety, and well-being of trial participants are respected.

1. SUMMARY

Study title: ConnecTBack Trial – Creating Team-Based care for a new primary care model for low back pain: A cluster randomised trial

Protocol version: 2024/1.8

Objectives:

Overarching objective
To evaluate whether integrating a musculoskeletal (MSK) clinician (physiotherapist/chiropractor) within primary care teams for people with low back pain (LBP) and making this clinician available to LBP patients as an early point of contact, will improve outcomes.

Specific objectives
The specific aims are to determine whether a new model of care for people presenting to primary care with LBP, incorporating a team-based approach, is more effective than usual general practitioner (GP)-led care, evaluated over a one-year period, for:

1) disability (primary outcome at 3 months), pain intensity, quality of life, global rating of change, patient satisfaction, and adverse events.

2) health system and societal outcomes, including healthcare access, GP workload, emergency department visits, diagnostic imaging, opioid medications used, and missed work.

3) cost-effectiveness.

Further, a process evaluation will assess the implementation of the model of care and the perspectives of patients and primary care providers towards the model.

Study design:

The trial is a parallel arm cluster randomised trial (CRT) with 20 primary care practices randomised 1:1 to either an innovative primary care model of care incorporating a team-based approach, or to usual GP-led care for low back pain (LBP).

Planned sample size:

Twenty GP practice sites will recruit a total of 1,560 participants.

Selection criteria:

Practice inclusion criteria: At least 2 GPs from the practice are willing to participate; and the practice can accommodate a trial MSK clinician to coordinate patient treatment.

Practice exclusion criteria: The practice already has an integrated MSK clinician (physiotherapist or chiropractor) onsite.

GP inclusion criteria: GP works in an eligible practice, and the GP is willing for their practice to be randomised to the intervention or usual care arm.

GP exclusion criteria: working in a practice that already has a physiotherapist/chiropractor integrated into the team.

Patient inclusion criteria: adults (≥18 years) with LBP of any duration (with or without associated leg pain), who can read, write, and speak in English.

Patient exclusion criteria: known or suspected serious pathology as the cause of LBP (e.g. cancer, infection or fracture). or neurodegenerative disease, or inability to complete the scheduled follow-ups over 1-year.

Intervention:

The trial intervention is an organisational-level intervention that will involve integrating an Australian Health Practitioner Regulation Agency (AHPRA) registered MSK clinician (physiotherapist/chiropractor) within the primary care team for people with LBP.

Control:

Usual GP-led management of LBP

Duration of the Study:

4 years total.

2. BACKGROUND

Low back pain (LBP) imposes an immense burden on individuals and society in Australia and around the world. In Australia, LBP is the leading cause of years lived with disability [1], costs the Australian healthcare system AUD$4.8 billion annually [2], and is the one of most common reasons for visiting a general practitioner (GP) [3]. Further, 70-90% of people will suffer from LBP at some point in their lives, with back problems affecting approximately 16% of the Australian population at any point in time, and LBP is the number one cause of early retirement and income poverty [4]. Many people with an acute episode of LBP recover quickly (within six weeks); however, ~50% of people have disability after three months and, of these, almost 30% are not fully recovered by 12 months [5]. LBP often leads to poorer quality of life, psychological distress, and disability [4].

Better patient outcomes and more efficient use of resources could be achieved by involving other healthcare providers within the primary care team using a share care model. The use of musculoskeletal (MSK) clinicians such as physiotherapists and chiropractors have been shown to improve patient outcomes for low back pain in primary care settings. However, in Australia, physiotherapist and chiropractors more commonly work in solo practices, not co-located within GP medical practices.

We propose that the use of physiotherapists or chiropractors early in LBP care will assist in the delivery of evidence-based treatments, reduce the burden on GPs, decrease costs for the healthcare system, and lead to better outcomes for patients. We will undertake a cluster randomised trial (CRT) to assess if a novel team-based care approach for people with MSK conditions improves patient outcomes and reduces costs for LBP in the Australian setting.

3. PROJECT AIMS

The overarching goal of this CRT is to evaluate whether integrating a MSK clinician (physiotherapist/chiropractor) within primary care teams for people with LBP and making this clinician available to LBP patients as an early point of contact, will improve outcomes. The specific aims are to determine whether a new model of care for people presenting to primary care with LBP, incorporating a team-based approach, is more effective than usual GP-led care, evaluated over a one-year period, for:

1) disability (primary outcome at 3 months), pain intensity, quality of life, global rating of change, patient satisfaction, and adverse events.
2) health system and societal outcomes, including healthcare access, GP workload, emergency department visits, diagnostic imaging, opioid medications used, and missed work.
3) cost-effectiveness.

Further, a process evaluation will assess the implementation of the model of care and the perspectives of patients and primary care providers towards the model. This current ethics application does not include the process evaluation; we will submit the ethics application for the process evaluation at a later date.

4. PROJECT DESIGN

4.1. Research project setting and participants

The project setting will be primary care sites in Australia. We will allocate sites to either incorporating a team-based approach or to usual GP-led care. Two levels of participants requiring consent include:

(1) GPs located within primary care sites in Australia

(2) Patients under the care of GPs within these primary care sites.

See Appendix–PICFs for all Participant Information and Consent Forms.

4.1.1. General practitioner participant recruitment

Planned recruitment is 20 primary care sites across Australia, with at least 2 GPs from each site who are willing to participate . We will recruit GPs within these primary care sites by the following methods:

1) **Advertising:** we will place advertisements in primary health network (PHN) newsletters across Australia. We will use the internet to advertise on websites such as the Royal Australian College of General Practitioners (RACGP) or similar, and on social media platforms such Facebook in order to target GPs who may be interested in participating in the research (Appendix–ADV). We will also run information sessions face to face or online where we will discuss the trial for GPs who are potentially interested in the study.
2) **Direct contact:** If one of the research team or our PHN collaborators has a professional contact within a GP practice they will make initial direct contact (phone, email or face to face) to inform the practice about the potential study, provide the PICF, and determine their interest in participating in the study. We may also contact other GP practices where we do not have professional contacts, via email or phone call.

After initial contact, GPs who are interested in finding out more will be provided with a PICF and any questions they have will be answered by the research team before GPs consent to take part in the project. GPs will be screened by an RA for inclusion/exclusion criteria.

A flow chart outlining the precise method of communication and informed consent procedure is outlined in the appendix section, primary care site Consent Flow chart (Appendix–FLOW).

4.1.2. Patient participant recruitment

Twenty GP practice sites will recruit a total of 1,560 participants.

Consecutive patients consulting their GP with LBP and meeting the inclusion criteria for the study will be invited to participate in the trial. Patients will be given a brief description of the

study by their GP and a hardcopy of the Patient Information and Consent Form (PICF) to read and take away and for their consideration.

If patients are interested in knowing more about the study, the GP will ask for patient verbal consent to release contact details, including patient name, mobile number, and email, to a study research assistant (RA). The RA will then contact the patient by telephone within 24 hours of the patient receiving the PICF to discuss the research project and to seek their voluntary participation.

All potential participants interested in participating after being screened by the RA will be provided with an electronic link to the baseline questionnaire and consent form in REDCap. The first page of the questionnaire will state that by completing this questionnaire the patient is giving consent for their baseline data to be used for the purposes of this research. The baseline questionnaire will be immediately followed by the patient information sheet, the trial consent form and the Medicare consent form. Once the trial consent form is completed, the patient is officially enrolled as a participant in the trial. For any participants who do not have access to the internet or would prefer to do the baseline questionnaire on paper or over-the-phone, this can be completed with a RA who will then enter responses into the database. These participants can then choose to either complete the consent form online like other participants or have the PICF mailed to them with the consent form. On returning the signed consent form patients will then be considered participants in the trial.

As this trial utilises a cluster randomised trial design, the primary care sites which the patient attends will have already been randomly allocated to either the comparator or the intervention arm. As such the GP will be encouraged to use one of the following scripts to inform their patient about the trial and the method of treatment and care they will receive if they choose to participate.

A flow chart outlining the precise method of communication and informed consent procedure is outlined in the appendix section, Patient Consent Flow chart (Appendix–FLOW).

4.1.2.1. Usual care group GP script

Our practice is involved in a low back pain research project being run by Macquarie University. Our practice is part of the GP-led model of care for managing people with low back pain, and if you take part your progress with your back pain will be tracked over a 12-month period by filling out a set of questionnaires throughout the year. If you are interested in finding out more, I will have a research assistant give you a call to discuss the details of the study. I will give you a copy of the Patient Information and Consent Form now to take home and read before the research assistant telephones you later today. Do you have any questions? Are you happy for me to pass on your contact details to the research assistant?

4.1.2.2. Intervention group GP script

Our practice is involved in a low back pain research project being run by Macquarie University. Our practice is part of the team-based model of care for low back pain, and if you take part your progress with your back pain will be tracked over a 12-month period by filling out a set of questionnaires throughout the year. As part of the team-based model I will refer you to see our partner musculoskeletal clinician (physiotherapist or chiropractor) who has

been trained by the research team and has expertise in the management of low back pain. I have a good working relationship with her/him and we will be in regular communication about your progress. Your first appointment with the musculoskeletal clinician will be organised for you. The cost of the first two (2) visits will be free of charge as the research project will cover these costs. If you need further treatment, these visits will be at your own expense (or if relevant we might be able to organise a Chronic Disease Management plan). If you are interested in finding out more, I will have a research assistant give you a call later today to discuss the details of the study. I will give you a copy of the Patient Information and Consent Form now to take home and read before the research assistant telephones you later today. Do you have any questions? Are you happy for me to pass your contact details to the research assistant?

4.1.3. Participant selection criteria

4.1.3.1 Practice selection criteria

Practice inclusion criteria: At least 2 GPs from the practice are willing to participate; and the practice can accommodate a trial MSK clinician to coordinate patient treatment."

Practice exclusion criteria: The practice already has an integrated MSK clinician (physiotherapist or chiropractor) onsite.

4.1.3.2. GP participant selection criteria

GP inclusion criteria: GP works in an eligible practice, and the GP is willing for their practice to be randomised to the intervention or usual care arm.

GP exclusion criteria: working in a practice that already has a physiotherapist/chiropractor integrated into the team.

4.1.3.3 Patient participant selection criteria

Patient inclusion criteria: adults (≥18 years) with LBP (with or without associated leg pain) of any duration, who can read, write, and speak in English. We have excluded non-English speaking patients due to the cost burden of employing interpreters at each of the 20 primary care sites. LBP is defined as pain between the 12th rib and the buttock crease.

Patient exclusion criteria: known or suspected serious pathology as the cause of LBP (e.g. cancer, infection or fracture) or neurodegenerative disease, or inability to complete the scheduled follow-ups over 1-year.

4.2. Randomisation

The trial is a parallel arm cluster randomised trial (CRT) with 20 primary care sites randomised 1:1 to either a new primary care model for LBP incorporating a team-based approach, or to usual GP-led care for low back pain. Randomisation of practices, rather than patients, allows MSK clinicians to fully integrate within the primary care team at primary care sites and reduces potential contamination from therapists concurrently managing intervention and control patients. A logic flow model of the trial is included in the appendix (Appendix–LOGIC FLOW).

Practices meeting the inclusion criteria will be sequentially randomised to receive either the intervention of team-based care or the control of GP led care. Stratified randomisation will be used to reduce the probability of baseline imbalance. Practices will be allocated to the intervention and control groups (1:1 ratio using randomly permuted blocks of variable lengths).

Two strata will be defined by whether the practice is in an urban, or regional/rural-remote location. Clusters will be stratified by geographic region using Modified Monash Model (MMM) classification (urban, regional/rural-remote: MMM1, MMM2-5) [7]. A statistician independent of the trial team will computer-generate the allocation sequence. The statistician will be provided with practice identification codes and stratification information.

4.3. Blinding and unblinding

GPs, MSK clinicians and patients will not be blinded due to the nature of the interventions being compared. However, to achieve a level of equipoise rather than blinding, GPs in each intervention arm will be encouraged to use the same amount of enthusiasm when describing the study to patients, and emphasise we do not know which model of care is superior. The GP at the comparator primary care site will explain that the patient will receive a GP-led care model, while at the intervention sites, GPs will explain that the patients will receive a team-based model of care involving a referral to an MSK clinician.

4.4. Interventions

4.4.1. Intervention group

The trial intervention is an organisational-level team-based intervention that will involve integrating an Australian Health Practitioner Regulation Agency (AHPRA) registered MSK clinician (physiotherapist/chiropractor) within a primary care team for people with LBP (see Appendix section for all Patient flow, GP flow, MSK clinician flow charts (Appendix–FLOW)).

Patients with LBP will first see the GP as usual and will then be provided with a rapid referral to see the practice MSK clinician for 2 visits (paid for by the study) as soon as is convenient for the patient, aiming for within 48 hours. The MSK clinicians will either be co-located (onsite at primary care site) or located nearby (depending on the preference of the GP and needs of the patient). While the MSK clinician is providing care, they will keep the referring GP informed about the patient's progress and refer back to the GP as appropriate.

Led by the MSK clinician, the intervention will have four components:
1) Assessment; 2) Individualised self-management intervention; 3) Health services navigation and team collaboration; 4) Providing additional MSK care to specific people as needed.

1. **Assessment:** the MSK clinician will: take a thorough history; screen for pathology (e.g. cauda equina syndrome, traumatic fracture, cancer); physical and neurological exam; apply evidence-based tools to identify comorbid health conditions (e.g. depression, anxiety) potentially requiring additional care; and use a validated tool (The STarT Back Tool [7]) that

has been shown to identify risk factors, and overall risk, associated with persistent LBP and disability [8].

2. **Individualised self-management intervention**: Over the two visits, the MSK clinician will provide an individualised intervention based on guidelines for LBP. The intervention will comprise effective communication to validate the patient's experiences and allow the patient to disclose the impact of their LBP on their lives [9], cognitive reassurance [10], advice/strategies to stay active, individually tailored exercises (if indicated) [11], and strategies to manage recurrences or flares ups. The recommendations will be supported with written information provided to the patient.

3. **Health services navigation and team collaboration**: The MSK clinician will act as the 'case manager' for individuals with LBP, triaging and linking other team members as needed, and regularly communicating with the referring GP. First, the MSK clinician will further screen and identify pathology requiring referral (e.g., malignancy, fracture), and refer appropriately, including back to their GP if necessary. Next, they will identify comorbid conditions that require collaboration with other primary care team members, e.g., people who screen positive for depression or anxiety that appears to be contributing to their pain and disability may be referred to their GP or to a member of a mental healthcare team. The MSK clinician will collaborate with the GP and other team members and identify the appropriate health services (within the team or community) based on assessment findings.

4. **Providing additional MSK care to specific people according to their need:** The MSK clinician will provide or organise additional care, beyond the two initial sessions, for patients who require ongoing treatment. Care will include evidence-based, guideline consistent management, such as individualised education, exercise [11], and cognitive behavioural approaches [12]. The MSK clinician will determine if the patient requires ongoing care informed by their overall assessment, progress over the 2 sessions and by the patient's score on the STarT Back tool. The STarT Back tool categorises patients with LBP into low, medium, or high risk of persistent pain and disability based on physical and psychosocial risk factors. The recommended matched treatment for low-risk patients is to provide self-management advice and to avoid referral and investigations where possible. This intervention is brief and can take place over two visits. The recommended matched treatment for medium-risk patients is referral for standard community MSK treatment, such as physical therapy or exercise, and the matched treatment for high risk patients is treatment from a MSK clinician with specific training aimed at reducing physical and psychosocial risk factors for chronic pain and disability [12]; the training sessions for the MSK clinicians will include how to appropriately use the StarT back tool. This stratified approach to care has demonstrated improved function, quality of life, and cost-effectiveness in comparison to usual care in a UK based clinical trial [13]. The MSK clinician will provide this care, and help patients navigate the available resources.

4.4.2. Intervention group MSK clinician training

We will use our existing networks to identify physiotherapists and chiropractors who are appropriately qualified and interested in delivering the intervention. Clinicians will undergo a training program organised by the research team. This training will cover the intervention

details, requirements for team-base care procedures within a GP primary care model. This training will be conducted face-to-face at Macquarie University campus prior to the commencement of the trial.

4.4.3. Comparison group: usual GP-led care

Usual GP-led care will be provided in the comparison primary care sites. GPs in the comparison group are free to provide the care they would normally provide, including referral to clinicians such as physiotherapists or chiropractors. Interventions provided or recommended by the GP will be recorded and monitored.

4.5. Outcome Measures

Self-reported patient outcome measures will be collected at baseline, 2-weeks, 6 weeks, 3-, 6-, 9-, and 12-months from the initial visit with a primary comparison at 3-months. See the Table for the timing of each of the outcomes. All these outcomes will be collected using REDCap and will be completed by participating patients. If they are unable to enter their information directly, a study RA will assist them to do this over the telephone/Zoom.

See Appendix – Data collection forms for all outcomes that will used for this study and the data collection time points.

Table: Patient participant outcome measures and timing

Outcome measure	**Baseline**	**2 weeks**	**6 weeks**	**3 months (primary comparison)**	**6 months**	**9 months**	**12 months**
Individual health outcomes							
Pain intensity questions based on Brief Pain Inventory	X	X	X	X	X	X	X
Roland Morris Questionnaire (RMQ)	X	X	X	X	X	X	X
EQ-5D-5L	X	X	X	X	X	X	X
PSEQ	X	X	X	X	X	X	X
TSK	X	X	X	X	X	X	X
GROC		X	X	X	X	X	X
Patient satisfaction		X	X	X	X	X	X
Adverse events		X	X	X	X	X	X
Health system, societal and cost outcomes							
Healthcare utilisation	X			X	X	X	X
Absenteeism/Presenteeism (iPCQ)	X			X	X	X	X

NB: EQ-5D-5L = European Quality of Life five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression questionnaire. PSEQ = Patient Self-Efficacy Questionnaire; TSK = Tampa Scale for Kinesiophobia; GROC = global rating of change. iPCQ =Productivity Cost Questionnaire

4.5.1. Primary Outcome Measure:

Self-reported LBP disability using the Roland Morris Questionnaire (RMQ) [14] measured at 3 months. Disability and function are considered the most important outcomes for people with LBP [15].

4.5.2. Secondary Outcome Measures:

4.5.2.1. Individual health outcomes:

LBP intensity using the Brief Pain Inventory (BPI) severity index [16]. Health-related quality of life: using the European Quality of life questionnaire EQ-5D-5L [17], which demonstrates good reliability and validity, and is suitable for economic evaluation in LBP [18]. The utility score will be used to calculate quality-adjusted life years (QALY) for our outcome in the economic evaluation. Global rating of change: using an 11-point global rating of change scale (GROC) (-5 to +5) as has been recommended for self-reported rating of change [19]. The Pain Self-Efficacy Questionnaire (PSEQ) will measure psychosocial factors associated with LBP related disability [20] and The Tampa Scale for Kinesiophobia will quantify fear of movement and reinjury [21]. Patient satisfaction and experience: using an 11-point scale, extremely dissatisfied (-5) to extremely satisfied (+5). Adverse events: using a self-reported adverse events questionnaire consistent with reporting guidelines (Appendix–AE REPORTING) [22].

4.5.2.2. Health system, societal and cost outcomes

These secondary outcomes will all be self-reported with patients completing the questionnaires using the study REDCap database, measured over 12 months.
GP workload: number of repeat GP visits for LBP.
Healthcare utilisation: using a patient self-reported questionnaire, with total count over 15 months for all types of visits combined, focused on: consultations with health professionals outside the trial (e.g., physiotherapists, chiropractors, massage therapists, specialists), emergency department visits, diagnostic imaging, medications, and other treatment.
Absenteeism/Presenteeism: self-reported time (days) lost from normal activities related to LBP using a modified iPCQ [23].
Costs: Sources of direct healthcare cost data: Intervention costs will include the MSK clinician salary, training, space, and resources and equipment needed to carry out the intervention. Self-reported costs will be used for private healthcare services and other costs incurred by the participant. MBS/PBS data will be collected to determine medications taken and the healthcare services that are used. This will allow us to complete an economic analysis to determine the cost of health care related to the trial intervention.

Indirect costs: non-healthcare costs will be limited to loss of productivity (LOP) using a human capital approach. The mean Australian wage reported by Australian Bureau of Statistics will be used to assign a monetary value to time lost from paid employment by both patients and caregivers. For retirees, we will determine time lost from volunteer, homemaking, or usual activities, and apply the minimum wage value in New South Wales.

4.6. Adverse event reporting

Adverse events will be self-reported by patients during the standard online follow-up.
Adverse events (AEs) will be monitored and defined as any new medical condition or exacerbation of an existing condition as reported by the participants during the study.

Questioning of AEs will occur at all follow ups. Serious AEs will also be monitored and are defined as any untoward medical occurrence that results in death, is life threatening, requires hospitalisation or results in significant disability. We will comply with relevant Australian guidelines and requirements for reporting AEs [24].

4.7. Data management

The data for the current study will primarily be collected and stored in REDCap software. This includes the patient baseline questionnaire (including online consent) and follow up data collected at 2-weeks, 6 weeks, 3-, 6-, 9-, and 12-months. These data will remain secure in REDCap during the period of the study. All participants will be allocated a de-identification code at the time of study enrolment. This will be a sequential enrolment number and contain no identification information. However, the identifiable data (e.g email and address) will be in the REDCap data base with non-identifiable data. The Primary investigator will control access to different data within REDCap for study investigators with different roles, ensuring only essential data are accessed by each investigator. At the completion of the study the non-identifiable data will be exported as an excel file including the de-identifiable code (Participant ID). A separate coding file will also be exported which would enable re-identification if required. These 2 files will be stored on SharePoint under different directories and only the data custodians (Simon French and Mark Hancock) will have access to the coding file enabling re-identification.

We will also collect a small amount of hard copy data (e.g. GP hard copy consent forms). The data will be stored in a locked filing cabinet in the primary investigator's locked office, or entered into a spreadsheet that is saved on a secure SharePoint folder. If a participant withdraws from the study all previously collected and de-identified data will remain in the study.

At the completion of the study, all data will be stored securely in perpetuity. The data collected in this study may be made available to other research groups, in a de-identified form, for future Human Research Ethics Committee approved research projects which are an extension of, or closely related to, this proposed study. A data sharing agreement will be required for any research team wishing to access the data. The data-sharing agreement will require a commitment to using the data only for specified research purposes, to securing the data appropriately and to destroying the data after a nominated period. A full data management plan will be lodged at Macquarie University.

4.8. Data analysis

4.8.1. Sample size calculation

We used the Teerenstra et al [25] method to calculate the required number of clusters based on an ANCOVA analysis for the primary outcome (RMQ) at 3 months with the baseline measurement of RMQ as a covariate. A total of 18 clusters (9 per arm) with an average of 62 participants per practice (i.e. total 1,116 participants) achieves 90% power to detect a minimum clinically important mean difference (MCID) of 2.5 points [26] (Cohen's d=0.4) using a two-sided α=0.05 and assuming a standard deviation (SD) of 5.7 points based on pilot study data [27], a conservative intra-cluster correlation coefficient of 0.1, a cluster

autocorrelation coefficient (correlation between cluster means at baseline and follow-up) of 0.5, and an individual autocorrelation coefficient (correlation between participant scores at baseline and follow-up) of 0.6 informed by our Canadian pilot study. To allow for 20% patient attrition at 12 months and the possibility of attrition of 2 sites, we will aim to recruit 20 clusters and an average of 78 participants per cluster (i.e., a total of 1,560 participants). In our Canadian pilot study, we achieved 11% patient attrition after 12 months, and lost no sites. We will also have 85% power to detect a MCID of 0.1 points on the EQ-5D-5L [28] (Cohen's d=0.42) assuming a SD of 0.24 points (informed by our pilot study) after accounting for attrition.

4.8.2. Health outcome data analysis

All analyses will be by intention-to-treat. Our primary outcome (RMQ) with repeated measures at 0, 2-week, 6-weeks, 3-, 6-, 9-, and 12-months will be analysed using linear mixed-effects regression, estimated using restricted maximum likelihood (REML). The model will include fixed effects for time, group by time interaction (omitting the group main effect to ensure baseline differences are constrained to 0), factors used in the covariate constrained allocation procedure, and other prespecified covariates associated with LBP-related disability. The correlation in repeated measures on the same participant will be modelled using a suitable covariance structure, identified using information criteria (AIC/BIC) and likelihood ratio tests. To account for clustering within practices, site will be modelled as a random effect. The intervention effect will be obtained as the adjusted least square mean difference between arms at 12-months together with 95% confidence intervals. Secondary comparisons will be obtained using least square mean differences at intermediate time points. The use of REML estimation under an assumption of missing at random allows the use of all available data without the need for multiple imputation. To examine the risk of bias due to missing data, we will compare characteristics of those remaining and those lost to follow-up to identify factors associated with attrition and adjust for any such factors as covariates. Secondary outcomes (remaining individual health outcomes, healthcare access, GP workload, healthcare utilisation, and lost work) that are continuous will be analysed as described for the primary outcome, while secondary outcomes that are categorical will be analysed using generalised linear mixed effects modelling with binomial, Poisson, or negative binomial distribution. We will analyse results after completion of 12-month follow-up with no planned interim analyses.

4.8.3. Economic data analysis

We will perform our economic evaluation (cost utility analysis) from both societal (primary) and patient/consumer (secondary) perspectives to meet the needs of key stakeholders. The total costs will be determined by multiplying the quantity of resource use by the corresponding unit cost, summing the total cost over each follow up interval, and then calculating the mean cost at each follow-up time point, as well as an overall mean cost for the entire study period. Results will be presented as aggregated and disaggregated costs. To allow for the correlation between costs and outcomes, recognise clustering, and accommodate the hierarchical structure of the data, we will use bivariate multilevel modelling to estimate the incremental cost-per-QALY gained. We will present the uncertainty surrounding our estimate using bootstrap resampling to construct a cost effectiveness ellipse and cost-effectiveness acceptability curves.

4.9. Outcomes and Future Plans

At the conclusion of the study, patient participants and GP participants can request access to a plain language summary of the results of the study.

This study will serve as an important opportunity to engage target stakeholders (GPs, patients, MSK clinicians and policy makers) who will support effective knowledge translation after the trial. Findings from this study will be presented in multiple peer reviewed publications as well as conference presentations. If the new model of care for LBP in primary care sites is successful, we will create a package of resource and make them freely available to help GPs deliver the intervention in practice.

5. Appendices

1. Advertisement(s) (Appendix–ADV)
2. Trial Flow Chart (Appendix–LOGIC FLOW)
3. Participant Information and Consent Forms (Appendix–PICFs)
4. Participant Flow Charts (Appendix–FLOW)
5. Outcome questionnaires (Appendix–Data collection forms for patient participants and GP Participants.)

6. References

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Protocol Amendments to Ethics:

17 Nov 2022: Amendment to PICF for Medicare Approval: Added compulsory text regarding consent to MBS/PBS access (version 1.1) – approved 13/04/2023, **520231097048374 - ConnecTBack - ethics application** (v 1.1)

17 Nov 2022: Withdrawal of consent form created as per requirement for Medicare Application (version 1.0) – Approved 13/04/2023, **520231097048374-ConnecTBack - ethics application** (v1.1)

28/02/2023: Amend CRF to include a 6-month assessment timepoint. (v1.2)

28/02/2023: Health economics data asking about health care utilisation will be collected at Baseline – asking about the 3 months prior to consent/baseline, then again at 3,6,9, and 12 months. (v1.2)

Amendment 2 approved 14 April 2023.

16 May 2023: Amendment to outcome measures, table of outcomes and timings
Appendix: data collection forms for patient participants and GP participants.
Screening and consent document. (v1.3)

Amendment 3 approved 16 June 2023.

26/06/2023: Amendment to change the consent process for patient participants. (v1.4), addition of section 4.1.3.1 Practice selection criteria, Updating the appendices to reflect the changes in the consent process – practice and GP screening and consent document, patient baseline questionnaire instructions, Advertisement.

Amendment 4 approved 14 July 2023.

20/10/2023: Amendment to add advertising on websites and social media platforms for GP recruitment – using the approved advertisement document.
Adding trial personnel Kate Tong as Research Assistant. (v1.5)

Amendment 5 approved 17 November 2023.

19/02/2024: Amendment to protocol and outcome measures. Adding trial personnel.

Amendment 6 approved 1 March 2024.

20/5/2024 Amendment 7 to update the randomisation process for the clusters and to update the GP inclusion criteria from 3 GPs per clinic to 2. To update the number of active patients required per practice for the inclusion criteria. To update the area for recruitment from Sydney metro to Australia wide.

Amendment 7 approved 31 May 2024.

14/06/2024 Amendment to add to the project team, amend title for principal investigator, amendment to the Practice and GP participant data collection forms (v1.0).