Trials

STUDY PROTOCOL

Open Access

Evaluating the effect of incentives on recruiting people with low back pain with limited English proficiency as part of the COMFORT cluster randomised controlled trial: a study protocol for a study within a trial (SWAT)

Lisa Vizza[1,2], Christopher G. Maher[1,2], Rowena Ivers[3], Andrew J. McLachlan[4], Patrick J. Kelly[1], Fiona Blyth[1], Philip James Clare[1,5,6], Rachel Thompson[7], Thomas Lung[1,8], Louisa Degenhardt[6], Sharon Reid[9], Bradley C. Martin[10], Michael Wright[11], Rawa Osman[12], Simon D. French[13], Kirsten J. McCaffery[1,14], Gabrielle Campbell[15], Hazel J. Jenkins[13], Stephanie Mathieson[1,4], Monika Boogs[16], Jarrod McMaugh[17], Carol Bennett[18,19,20], Fiona Stanaway[1†] and Christina Abdel Shaheed[1,2*†]

Abstract

Background Previous research has reported that Australians with limited English proficiency are less likely to be included in clinical trials due to language, literacy, and cultural factors. In the pain field, participants with limited English proficiency are three times more likely to be excluded from research, whereas in low back pain trials, 1 in 5 participants are excluded. This low representation can limit the generalisability of research findings to Australia's diverse population, and strategies are required to facilitate the inclusion of participants with limited English proficiency in clinical trials. This study within a trial (SWAT) embedded within a registered cluster randomised trial (ACTRN12622001505796) will evaluate a strategy to improve recruitment of participants with limited English proficiency who speak Arabic, Cantonese, Mandarin or Italian. These were chosen as they are the top non-English languages spoken at home in Australia.

Methods This SWAT will evaluate the effect of per-participant monetary incentive to facilitate the recruitment of participants with limited English proficiency (in Arabic, Chinese and Italian communities) from participating general practices enrolled in the COMFORT trial. In brief, the COMFORT trial will randomise general practices in a 1:1 ratio to either (i) intervention (educational outreach visits to support GPs to provide opioid stewardship for their patients with low back pain with non-drug strategies including heat wraps and patient education about judicious opioid use) or (ii) control (usual care). In this embedded SWAT, the randomisation schedule will also randomly allocate general

†Fiona Stanaway and Christina Abdel Shaheed are co-senior authors.

*Correspondence:
Christina Abdel Shaheed
Christina.abdelshaheed@sydney.edu.au
Full list of author information is available at the end of the article

practices 1:1 to either (a) SWAT intervention (monetary incentive aimed at enhancing recruitment of individuals with limited English proficiency) or (b) SWAT control (no additional incentive). The SWAT primary outcome will be the proportion of participants with limited English proficiency enrolled into the COMFORT trial in the SWAT intervention versus SWAT control. Data collection, analyses and general study procedures will follow the COMFORT protocol.

Discussion This SWAT will determine whether a per-participant monetary incentive facilitates greater recruitment of people with limited English proficiency who speak Arabic, Cantonese, Mandarin or Italian by participating GPs.

Trial registration The trial has been registered via SWAT222 Christina Abdel Shaheed (2023 NOV 14 1147).pdf.

Keywords Study within a trial (SWAT), Limited English proficiency, Financial incentive, Randomised trial, Low back pain, General practice

Administrative information

Title {1}	Evaluating the effect of incentives on recruiting people with low back pain with limited English proficiency as part of the COMFORT cluster randomised controlled trial: a study within a trial (SWAT) protocol
Trial registration {2a and 2b}	The trial has been registered via SWAT222 Christina Abdel Shaheed (2023 NOV 14 1147).pdf
Protocol version {3}	1.1 Dated 3 June 2024
Funding {4}	The SWAT is embedded within the COMFORT trial which is supported by the National Health and Medical Research Council (NHMRC) of Australia (APP2000989)
Author details {5a}	Lisa Vizza[1,2], Chris G Maher[1,2], Rowena Ivers[3], Andrew J McLachlan[4], Patrick J Kelly[1], Fiona Blyth[1], Philip James Clare[1,5,6], Rachel Thompson[7], Thomas Lung[1,8], Louisa Degenhardt[6], Sharon Reid[9], Bradley C Martin[10], Michael Wright[11], Rawa Osman[12], Simon D French[13], Kirsten McCaffery[1,14], Gabrielle Campbell[15], Hazel J Jenkins[13], Stephanie Mathieson[1,4], Monika Boogs[16], Jarrod McMaugh[17], Carol Bennet[18–20], Fiona Stanaway[1]*, Christina Abdel Shaheed[1,2]* *co-senior authors 1. Sydney School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia 2. Institute for Musculoskeletal Health, Sydney Local Health District, Sydney, New South Wales, Australia 3. Graduate School of Medicine, University of Wollongong, Sydney, New South Wales, Australia 4. Sydney Pharmacy School, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia 5. Prevention Research Collaboration, University of Sydney, Sydney, New South Wales, Australia 6. National Drug and Alcohol Research Centre (NDARC), Faculty of Medicine, University of New South Wales, Sydney, New South Wales, Australia 7. Sydney School of Health Sciences, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia 8. The George Institute for Global Health, University of New South Wales, Sydney, New South Wales, Australia 9. Specialty of Addiction Medicine, Central Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia 10. Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy, Arkansas, Arkansas, USA 11. Centre for Health Economics Research Evaluation, University of Technology Sydney, Sydney, New South Wales, Australia 12. Quality Use of Medicines (QUM) Connect, Sydney, New South Wales, Australia 13. Department of Chiropractic, Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, New South Wales, Australia 14. Sydney Health Literacy Lab, School of Public Health, University of Sydney, Sydney, New South Wales, Australia 15. School of Psychology, University of Queensland, Queensland, Queensland, Australia 16. Painaustralia Consumer Advisory Group, Canberra, ACT, Australia 17. Pharmaceutical Society of Australia, Canberra, ACT, Australia 18. College of Arts and Social Sciences, The Australian National University, Canberra, ACT, Australia 19. Department of Health, Therapeutic Goods Administration National Medicines Scheduling Advisory Committee, Canberra, ACT, Australia 20. Faculty of Health Science, University of Canberra, Canberra, ACT, Australia
Name and contact information for the trial sponsor {5b}	SPIRIT guidance: Name and contact information for the trial sponsor Sponsor: University of Sydney Contact: clinical-trials.research@sydney.edu.au
Role of sponsor {5c}	This study is embedded within the COMFORT trial. The COMFORT trial is funded by a National Health and Medical Research Council grant. The funder has no role in the design, conduct, analyses and intereptation of this study and the larger randomised trial

Introduction

Background and rationale {6a}

Australia has a culturally and linguistically diverse population, where 3 in 10 (30%) Australians are born overseas [1], and approximately 1 in 5 (21%) speak a language other than English at home, according to the 2021 National Census [2]. Previous research has reported that Australians from a Culturally and Linguistically Diverse (CALD) background (including those with limited English proficiency) are at greater risk of health conditions, such as cardiovascular disease, diabetes, and musculoskeletal pain in comparison to those from non-CALD communities [3–5]. In addition, these individuals may

also experience reduced access to health care services [6, 7], as a result of cultural and language barriers, lower health literacy and experiences of discrimination [6, 7].

Despite this evidence of health disparities and barriers to accessing health care services, Australians with limited English proficiency are less likely to be included in clinical trials due to language, literacy, and cultural factors [8]. In addition, a study showed that the odds of a trial reporting English language exclusions has increased since 1995 by 8% (OR 1.08, 95% CI 1.04–1.12) [9]. However, it is unclear if this result is potentially confounded by earlier trials failing to report exclusion due to English language proficiency. In the low back pain field, approximately 1 in 5 trials report excluding individuals with limited English proficiency [10], and in pain trials more broadly, participants with limited English proficiency were three times more likely to be excluded [11]. Exclusions of those with limited English proficiency from research can affect the generalisability of findings to Australia's diverse population, and limited guidance is available as to the most effective methods to recruit participants with limited English proficiency in clinical trials.

One suggested method to enhance research evidence to guide future recruitment of participants with limited English proficiency is using a study within a trial (SWAT) methodology [12]. SWATs are a new concept within research [13]. The general concept of the SWAT is that they are incorporated into a main trial to evaluate ways to improve or deliver a trial process [12, 13]. For example, strategies can be included to address time barriers often noted in recruiting participants with limited English proficiency, particularly those requiring translation [14, 15]. A possible strategy to overcome the limitation of time barriers may involve providing additional funding within a healthcare setting to reimburse study general practitioners (GPs) for the additional time spent recruiting patients with limited English proficiency.

Financial incentives have been explored in a few trials, with improvements in consent and response rates for participants across six randomised controlled trials [15]. The clinical settings for these trials were in smoking cessation and ambulation among hospitalised patients [15]. To the best of our knowledge, limited trials are available that have evaluated the effect of financial incentives in patients with low back pain or have evaluated the effect of these financial incentives by using a SWAT. This SWAT will assess whether a monetary incentive to GPs will improve the recruitment of patient-participants with low back pain and limited English proficiency into the COMFORT opioid stewardship trial.

Objectives {7}

Aims

This study aims to determine whether providing additional monetary incentive to study GPs as part of a study within a trial (SWAT) increases recruitment of patient-participants with limited English proficiency who speak Arabic, Chinese (Cantonese, Mandarin) or Italian into the COMFORT opioid stewardship trial.

Hypothesis

Providing an incentive to study GPs for the additional time to recruit each patient-participant with limited English proficiency will facilitate greater recruitment of these patient-participants into the COMFORT trial compared to no incentive.

Trial design {8}

The COMFORT trial [16] (ACTRN12622001505796) is a cluster randomised trial that will evaluate an opioid stewardship intervention in patients with low back pain in general practice. Interested general practices are recruited (consented) following a site visit by study investigators to discuss the trial. Recruited general practices are then randomised to receive either (i) intervention (educational outreach to provide opioid stewardship for patients with low back pain in combination with other strategies such as heat wraps and patient education about judicious opioid use) or (ii) control (GPs deliver usual care). Patient outcomes, such as pain, function, quality of life, medicines use and co-interventions (i.e. professional and self-care) will be collected over 1 year.

This SWAT, embedded within the COMFORT trial [16], will aim to evaluate the impact of providing monetary incentive versus no monetary incentive to enhance the recruitment of patient-participants with limited English proficiency from participating general practices. Patient outcomes collected in the COMFORT trial will also be collected for SWAT patient-participants over 1 year.

Methods: participants, interventions and outcomes

Study setting {9}

General practitioners in practices in New South Wales, Australia. Recruitment of patient-participants will occur via participating general practitioners in those practices.

Eligibility criteria {10}

Eligibility of patient-participants will be determined as per the COMFORT protocol as the SWAT is embedded into the COMFORT trial [16]. Patient-participants will be invited to participate when they present to the recruited study GP with low back pain and the study GP considers it appropriate to prescribe an opioid. General

practitioners at participating practices randomised to the SWAT arm will determine the patient's level of English proficiency and indicate on the trial screening form whether the enrolled patient-participant has requested that they require an interpreter into one of three languages: Chinese (traditional, simplified), Arabic or Italian. Patient-participants with limited English proficiency (self-rated as 'not well' or 'not well at all' at the baseline questionnaire) will be recruited using the same criteria and follow-up methods as for the main trial (week 1, 4, 12, 26 and 52 timepoints), with interpretation facilitated by GPs or members of the study team who are bilingual and can communicate in the participant's language spoken at home. All GPs, regardless of allocation to the SWAT intervention or control, will be encouraged to recruit participants with limited English proficiency for the trial and will have access to translated study materials.

Translations

Both the parent COMFORT trial and the SWAT study will use certified translations of study documents (in Arabic, simplified and traditional Chinese and Italian) that have been linguistically validated. The linguistic validation process involved two translators independently performing forward translation of materials from English to the target language. The materials were then provided to the bilingual native speakers of the target language along with the English language version to assess for cultural appropriateness [17]. The materials were then backward translated by independent translators. Translated materials include the participant information statement, consent form, and other relevant trial documents. Materials were translated into the most spoken languages other than English in Australia, including Arabic, Chinese (traditional, simplified) and Italian, which were identified among the top six languages spoken at home in the latest Australian census [18]. Furthermore, previous studies have reported that the burden of back pain is high in the communities which speak these languages [19–21]. The translated materials will be offered to all patient-participants with limited English proficiency. Translations to other languages other than those specified will not be available through the trial.

All participants (including those with limited English proficiency) will also be provided with an English copy of the Consumer Medicines Information (CMI) leaflet for the opioid medicine(s) prescribed at the enrolment visit. We will provide only the English language CMI to patients requiring translation as there are currently no approved non-English translations of CMI leaflets in Australia. Although not ideal, this approach emulates what would typically happen in real-life clinical practice where it is expected that a family member or friend may help translate key messages from this information.

Who will take informed consent? {26a}

Enrollment procedure

As per the COMFORT trial protocol, the study GP will notify the study team once a patient-participant has been enrolled into the trial (e.g. by forwarding/faxing study documents including the screening and consent forms). The study team will then review the screening form that was completed by the study GP to determine whether the patient-participant requires a translated version of the study documents (based on a yes/no response). If required, the study team will circulate a copy of the translated material (i.e. study questionnaire) for the patient-participant to complete on their own (e.g. via email), or alternatively, the study questionnaire can be completed together with a study team member over the phone who is bilingual and able to communicate in the preferred language. The baseline questionnaire for patient-participants will also record information regarding self-reported English proficiency with responses ranging from very well, well, not well or not well at all [22].

Additional consent provisions for collection and use of participant data and biological specimens {26b}

In accordance with procedures for patient-participants in the COMFORT trial [16], all participants in the SWAT will be asked to complete a consent form for the release of information about dispensed medicines and healthcare services provided to them.

Interventions

Explanation for the choice of comparators {6b}

The comparator for this SWAT will be no additional financial incentive. Previous trials that investigated the use of financial incentives compared to no financial incentive have reported improvements in consent and response rates among participants [15]. However, there is limited evidence evaluating these financial incentives in patients with low back pain with limited English proficiency. One of the outcomes that will be evaluated in the SWAT is to determine whether financial incentives within general practice compared to no financial incentive may result in improved recruitment of patient participants with limited English proficiency requiring translation.

Intervention description {11a}

SWAT intervention

General practitioners from practices randomised to the SWAT intervention will receive a financial incentive of AUD $150 for each patient participant with limited

English proficiency recruited into the trial, upon receipt of completed study materials. This is in addition to the remuneration GPs receive for enrolling any individual into the main COMFORT trial. The financial incentive for participating practices randomised to the SWAT intervention will be mailed or emailed immediately after the recruitment of the patient-participants with limited English proficiency (AUD $150 for each participant), as previous literature suggests that an immediate reward can reinforce the behavior [23]. Where feasible, a bilingual study team member may also facilitate the consent process on behalf of the general practice.

SWAT control

General practices randomised to the SWAT control will be encouraged to discuss and recruit patient-participants with low English proficiency during the training visit as per the COMFORT protocol but will not receive the additional financial incentive of AUD $150. The study will also provide translated materials for the SWAT (Arabic, Chinese (traditional, simplified) and Italian) to participating practices randomised in the SWAT control. Similarly, a bilingual member of the study team may also facilitate the consent process on behalf of sites where appropriate.

Criteria for discontinuing or modifying allocated interventions {11b}

There are no planned modifications to the intervention. Any modifications deemed necessary will occur after ethics approval from the sponsor. Participation in the trial is voluntary, and patient-participants or study GPs may withdraw consent at any time.

Strategies to improve adherence to interventions {11c}

General practices randomised to either the SWAT intervention or SWAT control will be encouraged to discuss and recruit participants with low English proficiency. General practice sites will be followed up monthly (via phone) and every 3 months (via site visit). During these follow-ups, GPs will be encouraged to actively consider recruiting patient participants with low English proficiency into the trial.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants will not be restricted from seeking concomitant treatment(s) during the study.

Provisions for post-trial care {30}

Patient-participants in the SWAT and randomised to the COMFORT intervention [16] will be provided with heat wraps by the study team at no cost to the participant. Any costs or treatments outside of the SWAT will not be covered by the study.

Outcomes {12}

Primary outcome

The primary outcome will be the proportion of patient-participants with limited English proficiency (English understanding self-reported as 'not well' or 'not well at all') who speak Arabic, Chinese (Cantonese (traditional Chinese), Mandarin (simplified Chinese)) or Italian, enrolled into the COMFORT trial via study GPs receiving the additional financial incentive versus those who are not (expressed as a percentage of the total number recruited to either the SWAT intervention or SWAT control).

Secondary outcomes

Secondary outcomes for the SWAT will include:

- The proportion of patient-participants with limited English proficiency recruited by study GPs from a culturally and linguistically diverse background who speak a language other than English versus by GPs who do not speak a language other than English in the SWAT intervention versus control.
- The proportion of patient-participants with self-reported limited English proficiency recruited from participating general practices (e.g. by location).
- The number of patient-participants requiring translation as a proportion of the total number of patient-participants from a culturally diverse background recruited in each study arm (recognising that not all such participants will require translation). This will be measured by comparing the proportion of study questionnaires completed in another language (Arabic, Chinese (Cantonese (traditional Chinese), Mandarin (simplified Chinese), and Italian) versus English.
- The proportion of patient-participants with limited self-reported English proficiency from a CALD background (from participant self-report of country of birth, primary language spoken at home, ancestry, or English proficiency [6]) who complete study questionnaires versus participants with good English proficiency from a CALD background versus participants who do not identify as being culturally or linguistically diverse in each study arm.
- Comparison of adverse events. All the harms information [24] will be collected in the main (COMFORT) study [16], and we will compare the preva-

lence of harms in the SWAT incentive vs SWAT no-incentive group.

Demographic information

In addition to demographic measures to be collected as part of the COMFORT trial, culture and language diversity measures for study GPs and patient-participants (self-reported country of birth, primary language spoken at home, ancestry or English proficiency [6]) will also be collected as part of the baseline data of the COMFORT trial for the SWAT.

Participant timeline {13}

The participant timeline is show in Fig. 1.

Sample size {14}

No formal power calculation has been conducted for the SWAT as it has been embedded within the parent COMFORT trial, which has a sample size of 410 patient participants [16].

Recruitment {15}

There is no isolated strategy to increase recruitment rates for the SWAT as the SWAT is embedded into the COMFORT trial. Strategies used to facilitate recruitment for COMFORT will also occur for the SWAT.

Assignment of interventions: allocation

Sequence generation {16a}

Randomisation and allocation for the SWAT groups is embedded into the COMFORT randomisation procedure [16]. The randomisation procedure and stratification by Socio-Economic Indexes for Areas (SEIFA) and remoteness [25, 26] are fully detailed in the COMFORT trial protocol [16]. To summarise, the allocation schedule will use random permuted blocks of size 2 and 4, and the SWAT randomisation is embedded within the COMFORT randomisation schedule. There will be two strata variables, one with two levels (remoteness) and one with three levels (SEIFA), giving a total of six strata. Randomisation will occur at the general practice level, and general practices will be allocated a 1:1:1:1 chance to either:

- COMFORT intervention and SWAT financial incentive
- COMFORT intervention and no SWAT financial incentive
- COMFORT control and SWAT financial incentive
- COMFORT control and no SWAT financial incentive

A summary of the flow chart is provided in Fig. 2.

Concealment mechanism {16b}

The randomisation schedule has been developed by the blinded trial statistician. The randomisation schedule is embedded into REDCap with allocation concealment built in. General practices are randomised following consent and advised about which group they are allocated to by an unblinded member of the study team at the time of site training of the study procedures.

Implementation {16c}

The randomisation schedule as per the COMFORT trial [16] has been developed by the blinded trial statistician and will randomise general practices in a 1:1:1:1 chance to either COMFORT intervention and SWAT financial incentive; COMFORT intervention and no SWAT financial incentive; COMFORT control and SWAT financial incentive; or COMFORT control and no SWAT financial incentive. After GPs have received training in the trial procedures by a member of the study team, consented GPs will enrol patient participants for both the COMFORT trial and SWAT.

Assignment of interventions: blinding

Who will be blinded {17a}

Blinded members include the trial statisticians, members of the study team involved in patient follow-up (outcome assessment) and data analysts. Study GPs will not be blinded to the SWAT allocation. Patient-participants will not know which arm of the SWAT the GP was randomised to. Only the members of the study team delivering the training on trial procedures to the study GPs will be aware of the treatment allocation.

Procedure for unblinding if needed {17b}

Procedures for unblinding will follow those for the COMFORT trial, upon advice by the Data Safety Monitoring Board. Instances where this may be required include the assessment of harms as part of the main COMFORT trial.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Patient-participants and study GP

Data collected for the SWAT includes patient demographics, study questionnaire (for example, outcomes including health related quality of life, medication use) and adverse events. This is summarised in Fig. 1. Data will be collected at weeks 1, 4, 12, 26 and 52. Data collected from the study GPs will include patient demographics and study questionnaires.

	STUDY PERIOD								
	Allocation	Enrolment	Post-allocation						Close-out
TIMEPOINT	*GP Training completion & site activation*	*GP/patient consultation*	*Baseline*	*Week 1*	*Week 4*	*Week 12*	*Week 26*	*Week 52*	*Month 12-18*
Allocation	X*								
ENROLMENT									
Eligibility screen		X							
Informed consent		X							
INTERVENTIONS									
SWAT intervention + COMFORT intervention			X	X	X	X	X	X	
SWAT intervention + COMFORT control			X	X	X	X	X	X	
SWAT control + COMFORT intervention			X	X	X	X	X	X	
SWAT control + COMFORT control			X	X	X	X	X	X	
ASSESSMENTS									
Participant demographics&			X						
SWAT outcome data^				X	X	X	X	X	
Adverse events#				X	X	X	X	X	
Site Close-out and Data Analysis									X

Fig. 1 SPIRIT figure describing schedule of events. Footnotes: * Randomisation allocation takes place at the general practice level. & Participant demographics including country of birth, primary language spoken at home, ancestry, English proficiency (rated from very well, well, not well or not well at all). Collected for both patient-participants and study GP participants. ^SWAT outcomes will be collected from baseline through to week 52 and analysed at the end of the study. # Includes self-reported serious adverse events and adverse events

Plans to promote participant retention and complete follow-up {18b}

Patient-participant data collection will be via online collection means using the secure platform REDCap or phone calls from study researchers to complete study questionnaires. The REDCap database will include the study questionnaires that have been translated into Arabic, Italian, Chinese (traditional or simplified) and patient-participants will be able to nominate their preferred spoken language prior to completion of the study questionnaire. Alternatively, patient-participants will be able to complete the study questionnaires over the phone with a bilingual study team member.

Patient-participants will be sent an electronic notification to advise that their questionnaire is due per each follow-up time point. For patient participants who complete the study questionnaires electronically or over the phone, three reminders will be provided for each timepoint (i.e. weeks 1, 4, 12, 26 and 52).

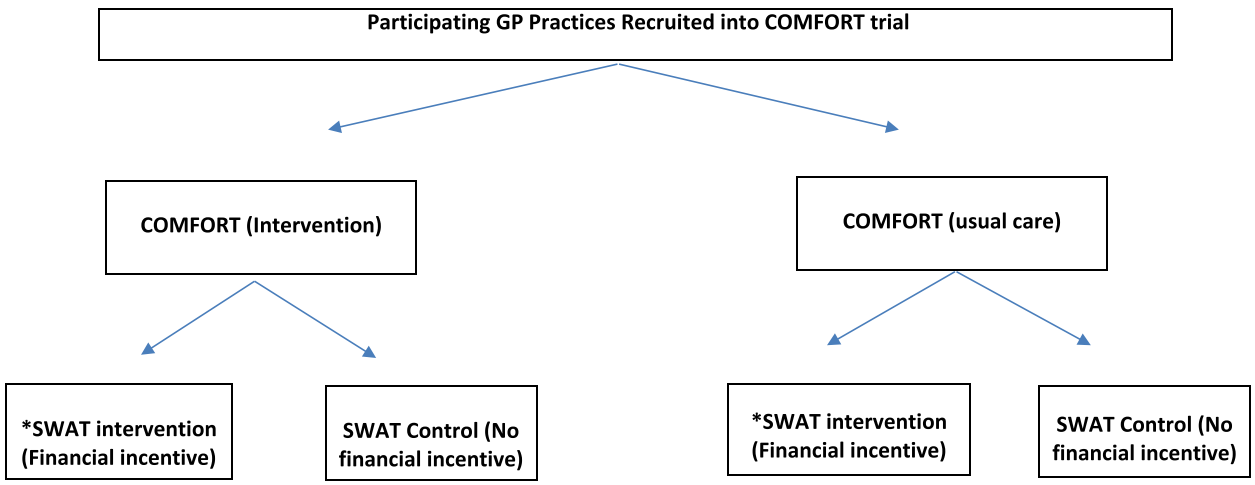

Fig. 2 Schematic of the study within a trial (SWAT) embedded within the COMFORT trial. *Reimbursement AUD $150: recruitment of CALD patient-participants requiring translation

The SWAT will not provide translating services and/or translate study materials into languages other than those listed.

Data management {19}

Questionnaire data will be entered directly into an electronic data capturing system, e.g. REDCap [27] to minimise errors in data capture and recording. Data collected by the bilingual study team will be entered directly into the database, while surveys completed online will be automatically transcribed into the database. Any information initially completed on a paper-based questionnaire will be cross-checked by two study members when entered into the REDCap database. Data will be cross-checked for any errors in accordance with data management procedures outlined in the COMFORT trial [16].

Confidentiality {27}

General practices will provide a copy of the patient-participant consent forms to the study team via fax or via the study email. Patient-participant consent forms will be stored using approved The University of Sydney databases, such as the highly protected SharePoint, and de-identified information will be entered using electronic databases such as REDCap. Patient-participant information will only be accessed by approved study members.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/a.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Primary analysis

Primary analyses will follow the intention-to-treat principle with the statistician blinded to the treatment group. The primary outcome for the SWAT will be analysed using a mixed-effects regression model, with a random intercept for recruitment strata to control for any within-strata clustering. Findings will be presented as between-group differences in proportions along with inferential statistics (e.g. confidence intervals).

Secondary analyses

The balance of baseline patient-participant characteristics will be assessed, and any characteristics not well balanced will be included in the model, as a secondary analysis.

Further analyses details, such as how trial results will be reported, are detailed in the COMFORT protocol [16], and a statistical analyses plan will be completed and approved by trial investigators before the completion of the last follow-up data collection.

Interim analyses {21b}

N/a.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Subgroup analyses will be performed to compare harms per treatment allocation based upon self-reported English proficiency at baseline.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Handling of missing data will follow the same process as the main COMFORT trial [16] and will be detailed in the statistical analysis plan for the COMFORT trial [16].

Plans to give access to the full protocol, participant level data and statistical code {31c}

Data sharing requests will be considered by the Principal Investigator (CAS) on a case-by-case basis.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5 d}

The central trial operations coordinating team will be responsible for the conduct of the trial, including recruitment of general practitioners, providing training to general practitioners to screen and enrol patient-participants, and conducting quarterly on-site monitoring visits. Overall trial conduct will be overseen by the steering committee, led by the Principal Investigator. Quarterly meetings will be scheduled with the steering committee and the operations team to discuss trial progress. Trial progress will be reported to trial investigators via monthly newsletters and to the trial Sponsor annually.

Composition of the data monitoring committee, its role and reporting structure {21a}

The Data Safety Monitoring Board (DSMB) that has been formed for the COMFORT trial will assess and review serious adverse events (SAE) for SWAT patient-participants and assess causality of the serious adverse events (SAEs), review trial data, and provide recommendations

where appropriate. An initial meeting has been held with the DSMB board, and meetings will be arranged as agreed by the DSMB and study team to review events.

Adverse event reporting and harms {22}

Safety outcomes, such as adverse events and serious adverse events, will be collected at weeks 1, 4, 12, 26 and 52 weeks. Definitions of these safety outcomes are provided in the main COMFORT protocol [16].

Frequency and plans for auditing trial conduct {23}

An initial audit has been formally conducted for the COMFORT trial [16].

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Protocol amendments will be submitted to The University of Sydney Human Ethics Committee and only implemented upon approval.

Dissemination plans {31a}

Results from the study will be published in a peer-reviewed journal, communicated to patients that provided consent to be notified of the study findings, and further disseminated via conference presentations, media (to name a few).

Discussion

The findings of the SWAT will evaluate if financial incentives provided to general practitioners can improve recruitment of patient-participants with limited English proficiency requiring translation. Key potential barriers to patient-participant follow-up have been considered in our risk assessment, and appropriate mitigation strategies have been developed and adapted in the protocol. For example, the involvement of bilingual team members to conduct the follow-up of patient-participants has been considered during the set-up for the SWAT. The Steering Committee will oversee future operational issues that may occur during the trial.

Trial status

Protocol Version 1.0 Dated 7th August 2023 (original). Protocol version 1.1 Dated 3rd June 2024 (current). Recruiting clinician and patient-participants. SWAT recruitment start date 14 th November 2023. Anticipated recruitment end date 31 st December 2026.

Abbreviations

SWAT	Study within a trial
COMFORT	Clinical Observation, Management and Function Of low back pain Relief Therapies
CALD	Culturally and linguistically diverse
GP	General practitioner
CMI	Consumer medicines information
SAE	Serious adverse events

Acknowledgements

We would like to thank the following people for their contribution: Sarah Diprose, Chantay Lenord.

Authors' contributions {31b}

All authors contributed to the conception and design of the SWAT, reviewed the protocol and provided critical input. LV, CAS and FS drafted the initial manuscript. All authors read and approved the final manuscript.

Funding {4}

This SWAT has not received specific external funding; however, it is embedded within the COMFORT trial, which is supported by the National Health and Medical Research Council (NHMRC) of Australia (APP2000989).

Data availability {29}

The trial database will be accessed by the study team. A copy of the dataset will be provided to the trial statistician to perform the study analyses (which will be blinded to the treatment allocation). Data sharing requests will be considered by the Principal Investigator (CAS) on a case-by-case basis.

Declarations

Ethics approval and consent to participate {24}

Ethics approval has been received by The University of Sydney (2023/632).

Consent for publication {32}

No separate consent for publication is required. The results for the SWAT will be de-identified.

Competing interests {28}

The Sydney Pharmacy School receives funding for a postgraduate scholarship from GlaxoSmithKline for a student under the supervision of AM. JM is an employee of the Pharmaceutical Society of Australia. BM receives royalties for the development of an opioid risk prediction tool which is unrelated to the current study protocol. CAS hold grants from Australia's National Health and Medical Research Council, and Medical Research Future Fund. CM holds several research grants and a research fellowship from the National Health and Medical Research Council (NHMRC); and several grants from the Medical Research Future Fund (MRFF). Both the NHMRC and MRFF are Australian Government medical research funding agencies. He has received research grants from New South Wales Health, Ramsay Hospital Research Foundation, HCF Research Foundation, Arthritis Australia, Australian Rheumatology Association, and Royal Prince Alfred Hospital. His travel expenses have been covered when he has been an invited speaker at a scientific conference.

Author details

[1]Sydney School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia. [2]Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District, Sydney, NSW, Australia. [3]Graduate School of Medicine, University of Wollongong, Sydney, NSW, Australia. [4]Sydney Pharmacy School, Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia. [5]Prevention Research Collaboration, University of Sydney, Sydney, NSW, Australia. [6]National Drug and Alcohol Research Centre (NDARC), Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia. [7]Sydney School of Health Sciences, Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia. [8]The George Institute for Global Health, University of New South Wales, Sydney, NSW, Australia. [9]Specialty of Addiction Medicine, Central Clinical School, Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia. [10]Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR, USA. [11]Centre for Health Economics Research Evaluation, University of Technology Sydney, Sydney, NSW, Australia. [12]Quality Use of Medicines (QUM) Connect, Sydney, NSW, Australia. [13]Department of Chiropractic, Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, NSW, Australia. [14]Sydney Health Literacy Lab, School of Public Health, University of Sydney, Sydney,

NSW, Australia. [15]School of Psychology, University of Queensland, Queensland, QLD, Australia. [16]Painaustralia Consumer Advisory Group, Canberra, ACT, Australia. [17]Pharmaceutical Society of Australia, Canberra, ACT, Australia. [18]College of Arts and Social Sciences, The Australian National University, Canberra, ACT, Australia. [19]Department of Health, Therapeutic Goods Administration National Medicines Scheduling Advisory Committee, Canberra, ACT, Australia. [20]Faculty of Health Science, University of Canberra, Canberra, ACT, Australia.

Received: 19 December 2024 Accepted: 19 April 2025
Published online: 17 June 2025

References

1. Australian Bureau of Statistics (ABS). Australia's Population by Country of Birth. Canberra: ABS;2021. Available from: https://www.abs.gov.au/statistics/people/population/australias-population-country-birth/2021. Cited 2024 Apr 9.
2. Australian Bureau of Statistics. Migration, Australia. Canberra: ABS; 2019–20 . Available from: https://www.abs.gov.au/statistics/people/population/migration-australia/latest-release. Cited 2023 Feb 10.
3. Gorman D, Brough M, Ramirez E. How young people from culturally and linguistically diverse backgrounds experience mental health: Some insights for mental health nurses. Int J Ment Health Nurs. 2003;12(3):194–202. https://doi.org/10.1046/j.1440-0979.2003.00289.x.
4. Green CR, Anderson KO, Baker TA, et al. The unequal burden of pain: confronting racial and ethnic disparities in pain. Pain Med. 2003;4(3):277–94. https://doi.org/10.1046/j.1526-4637.2003.03034.x.
5. Weerasinghe DP, Parr NJ, Yusuf F. Analysis using life tables of the major causes of death and the differences between country of birth groups in New South Wales. Australia Public Health. 2009;123(5):351–7. https://doi.org/10.1016/j.puhe.2009.03.006.
6. Australian Institute of Health and Welfare. Reporting on the health of culturally and linguistically diverse populations in Australia: An exploratory paper. Canberra: AIHW; 2022. Available from: https://doi.org/10.25816/fd8z-0b84. Cited 2024 Apr 9.
7. Henderson S, Kendall E. Culturally and linguistically diverse peoples' knowledge of accessibility and utilisation of health services: Exploring the need for improvement in health service delivery. Aust J Prim Health. 2011;17(2):195–201. https://doi.org/10.1071/PY10065.
8. Woodward-Kron R, Hughson JA, Parker A, et al. Culturally and linguistically diverse populations in medical research perceptions and experiences of older Italians their families, ethics administrators and researchers. Journal of Public Health Research 2016 ;5(1): jphr-2016. https://doi.org/10.4081/jphr.2016.667.
9. Egleston BL, Pedraza O, Wong YN, et al. Characteristics of clinical trials that require participants to be fluent in English. Clin Trials. 2015;12(6):618–26. https://doi.org/10.1177/1740774515592881.
10. Chen Q, Sánchez Medina CM, Maher CG, et al. Almost one in five physiotherapy trials excluded people due to lack of language proficiency: A meta-epidemiological study. J Clin Epidemiol. 2022;152:13–22. https://doi.org/10.1016/j.jclinepi.2022.09.007.
11. Stanaway F, Cumming RG, Blyth F. Exclusions from clinical trials in Australia based on proficiency in English. Med J Aust. 2017;207(1):36. https://doi.org/10.5694/mja16.01012.
12. Clarke M, Savage G, Maguire L, et al. The SWAT (study within a trial) programme; embedding trials to improve the methodological design and conduct of future research. Trials. 2015;16(Suppl 2):209.
13. Treweek S, Bevan S, Bower P, et al. Trial forge guidance 1: what is a study within a trial (SWAT)? Trials. 2018;19(139):1–5. https://doi.org/10.1186/s13063-018-2535-5.
14. Australian Clinical Trials Alliance. Clinical trial awareness and access amongst culturally and linguistic diverse (CALD) populations: environmental scan. 2020. Available from: https://clinicaltrialsalliance.org.au/wp-content/uploads/2020/06/ACTA-Clinical-trials-and-CALD-population_Environmental-Scan-V3_final.pdf. Cited 2023 Apr 14.
15. Abdelazeem B, Abbas KS, Amin MA, et al. The effectiveness of incentives for research participation: A systematic review and meta-analysis of randomized controlled trials. PLoS ONE. 2022;17(4): e0267534. https://doi.org/10.1371/journal.pone.0267534.PMID:35452488;PMCID:PMC9032371.
16. Shaheed CA, Ivers R, Vizza L, et al. Clinical observation, management and function of low back pain relief therapies (COMFORT): A cluster randomised controlled trial protocol. BMJ Open. 2023;13(11):e075286. https://doi.org/10.1136/bmjopen-2023-075286.
17. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). Spine (Phila Pa 1976). 2023;25((24)):3186–91. https://doi.org/10.1097/00007632-200012150-00014.
18. Australian Bureau of Statistics (ABS). *Language used at home (LANP)*. Canberra: ABS; 2021 . Available from: https://www.abs.gov.au/census/guide-census-data/census-dictionary/2021/variables-topic/cultural-diversity/language-used-home-lanp. Cited 2024 June 30.
19. Cecchi F, Debolini P, Lova RM, et al. Epidemiology of back pain in a representative cohort of Italian persons 65 years of age and older: the InCHIANTI study. Spine (Phila Pa 1976). 2006;31((10)):1149–55. https://doi.org/10.1097/01.brs.0000216606.24142.e1.
20. Alhowimel AS, Alodaibi F, Alshehri MM, et al. Prevalence and risk factors associated with low back pain in the Saudi adult community: A cross-sectional study. Int J Environ Res Public Health. 2021;18(24):13288. https://doi.org/10.3390/ijerph182413288.
21. Li Q, Peng L, Wang Y, et al. Risk factors for low back pain in the Chinese population: a systematic review and meta-analysis. BMC Public Health. 2024;24:1181. https://doi.org/10.1186/s12889-024-18510-0.
22. Australian Bureau of Statistics. Standards for Statistics on Cultural and Language Diversity. ABS. Available from: https://www.abs.gov.au/statistics/standards/standards-statistics-cultural-and-language-diversity/latest-release. Cited 2024 Apr 15.
23. Ladapo JA, Orstad SL, Wali S, et al. Effectiveness of goal-directed and outcome-based financial incentives for weight loss in primary care patients with obesity living in socioeconomically disadvantaged neighborhoods: A randomized clinical trial. JAMA Intern Med. 2023;183(1):61–9.
24. National Health and Medical Research Council. Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods. Canberra: National Health and Medical Research Council; 2016.
25. Australian Bureau of Statistics. Technical Paper: Socio-Economic Indexes for Areas (SEIFA). ABS; 2021. Available from https://www.abs.gov.au/statistics/people/people-and-communities/socio-economic-indexes-areas-seifa-australia/latest-release. Cited 2024 Apr.
26. Australian Bureau of Statistics. The Australian statistical geography standard (ASGS) remoteness structure. ABS. Available from: https://www.abs.gov.au/statistics/standards/australian-statistical-geography-standard-asgs-edition-3/jul2021-jun2026. Cited 2024 April 15.
27. Research Electronic Data Capture (REDCap). Available from: https://redcap.sydney.edu.au/. Accessed 4 June 2024.

Publisher's Note