SWAT 222: Evaluating the effect of incentives on recruitment of people with low back pain with limited English proficiency as part of the COMFORT cluster randomized trial

Objective of this SWAT
The SWAT will assess whether additional monetary reimbursement to general practitioners (GPs) will improve recruitment of patient-participants with limited English proficiency into the Clinical Observation, Management and Function Of low back pain Relief Therapies (COMFORT) trial.

Study area: Recruitment, Outcomes
Sample type: Healthcare Professionals, Participants
Estimated funding level needed: Unknown

Background
The CALD (culturally and linguistically diverse) community, constituting 30% of Australia's population [1], faces health disparities, including higher risks of cardiovascular disease and diabetes [2,3]. Limited English proficiency leads to underrepresentation in clinical trials, with an 8% increase in English language exclusions since 1995 [4,5]. In low back pain trials, 1 in 5 patients with limited English proficiency are excluded [6].

To address this gap, this Study Within A Trial (SWAT) [7] will assess the impact of additional monetary reimbursement to GPs on recruiting patient-participants with limited English proficiency (English understanding: 'not well' or 'not well at all') into the COMFORT trial for low back pain (ACTRN12622001505796) [8]. The SWAT will target three language groups: people with limited English proficiency who speak Arabic, Chinese (Cantonese, Mandarin) or Italian. We opted to provide additional monetary compensation to account for the extra time that GPs may need when enrolling individuals with limited English proficiency. The GPs in the intervention group will receive extra reimbursement, while those in the control group do not. The study will compare the enrolment proportions of participants with limited English proficiency between the two SWAT groups.

Interventions and comparators
Intervention 1: An additional $150 to the GP for each eligible patient-participant requiring translation.
Intervention 2: No supplementary reimbursement.

Index Type: Incentive

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Proportion of patient-participants with limited English proficiency enrolled in each SWAT group.
Secondary: 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 into each SWAT group; proportion of patient-participants with limited English proficiency recruited from different types of participating general practices (e.g., by location); patient-participants requiring translation as a proportion of the total number of patient-participants from a culturally or linguistically diverse background recruited in each SWAT group (recognising that not all such participants will require translation); completion of study questionnaires by patient-participants with limited English proficiency from a CALD background versus participants with good English proficiency from a CALD background versus participants who do not identify as being culturally or linguistically diverse in each SWAT group (presented as a percentage); prevalence of harms in each SWAT group (using harms information collected in the host trial).

Analysis plans
<u>Primary analysis</u>

This SWAT is embedded within the COMFORT trial [8]. Primary analyses will follow the intention-to-treat principle with the statistician blinded to the SWAT group. The primary outcome 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 descriptively (as percentages and frequencies).

Secondary analysis
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. We will use inferential statistics e.g. Chi square test to evaluate secondary outcomes. In addition, subgroup analyses will be performed to compare harms, and adjusted by English proficiency.

Statistical analysis plan
The statistical analysis plan for the SWAT will be included in the COMFORT trial protocol, and will detail methods for methods of analysing data, and handling missing data.

Possible problems in implementing this SWAT
General practices may be reluctant to adopt additional responsibilities related to recruiting individuals with limited English proficiency. The extra effort required for outreach and recruitment may be met with resistance from busy healthcare providers. Despite support, the engagement level of GPs in recruiting patient-participants within the CALD community could vary. Some GPs may be more proactive, while others may not prioritize or actively participate in the recruitment process, potentially affecting balanced representation across practices.

References
1. Australian Bureau of Statistics (ABS) Estimated Resident Population, Country of Birth, State/Territory, Age and Sex—As at 30 June 1996 to 2016. Australian Bureau of Statistics; Canberra, Australia: 2016.
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3. Green CR, Anderson KO, Baker TA, et al. The unequal burden of pain: confronting racial and ethnic disparities in pain. Pain Medicine 2003;4(3):277–94.
4. 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):667.
5. Egleston BL, Pedraza O, Wong YN, et al. Characteristics of clinical trials that require participants to be fluent in English. Clinical Trials. 2015;12(6):618-26.
6. 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. Journal of Clinical Epidemiology 2022;152:13-22.
7. Treweek S, Bevan S, Bower P, et al. Trial forge guidance 1: what is a study within a trial (SWAT)? Trials 2018;19:139.
8. 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.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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