

# Clinical Observation, Management, and Function Of low back pain Relief Therapies (COMFORT)

ACTRN12622001505796

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Status	RECRUITING
Sponsor	The University of Sydney
Enrollment	410 participants

## Plain Language Summary

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Back pain is one of the most common reasons Australians visit their GP, but opioid pain medicines — despite being frequently prescribed — often do not work well for long-term back pain and carry real risks of dependence, overdose, and other harms. The COMFORT study is testing whether a structured approach to reducing opioid prescribing for low back pain, led by GP practice education visits and supported with alternative tools like heat wraps and patient information about opioid risks, leads to fewer opioid prescriptions and better outcomes.

GP practices will be randomly assigned to receive the full opioid stewardship intervention or to continue with usual care. Patients enrolled in the study will complete questionnaires at regular intervals tracking their pain levels, disability, mental health, quality of life, and any hospitalisations or adverse events related to their pain medicines. The study will follow participants for one year.

You may be eligible if you are 18 or older, have low back pain, and have been prescribed an opioid medicine for your back pain by your GP within the past month. You need to hold an Australian Medicare card and be willing to complete questionnaires. You would not be eligible if you are already in the process of tapering your opioids, or if you are receiving treatment for active cancer or palliative care.

## Key Eligibility Criteria

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### Inclusion (13)

- Patient Inclusions
- Patient-participants greater than or equal to 18 years
- Low back pain of any duration at the time of presentation
- Has been prescribed an opioid analgesic for their low back pain by the participating GP within the past month
- Sufficient understanding of English to complete questionnaires, or translation available.

... and 8 more (see full listing online)

### Exclusion (5)

- Patient Exclusions:
  - Be engaged in an opioid tapering regimen at the time of enrolment into the study i.e. have already begun to reduce their opioid medicine within the past month
  - Be actively treated for cancer, or receiving palliative treatment
- General Practice Exclusions:
  - Participating GP at that practice have received an education visit by any organisation on judicious opioid prescribing in the previous 12 months

## Locations (1 total)

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NSW, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622001505796>

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