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MASTERCLASS

A randomized, placebo-controlled trial of patient education for acute low back pain (PREVENT Trial): statistical analysis plan

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Low back pain;
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Abstract
Background: Statistical analysis plans increase the transparency of decisions made in the analysis of clinical trial results. The purpose of this paper is to detail the planned analyses for the PREVENT trial, a randomized, placebo-controlled trial of patient education for acute low back pain.
Results: We report the pre-specified principles, methods, and procedures to be adhered to in the main analysis of the PREVENT trial data. The primary outcome analysis will be based on Mixed Models for Repeated Measures (MMRM), which can test treatment effects at specific time points, and the assumptions of this analysis are outlined. We also outline the treatment of secondary outcomes and planned sensitivity analyses. We provide decisions regarding the treatment of missing data, handling of descriptive and process measure data, and blinded review procedures.

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Conclusions: Making public the pre-specified statistical analysis plan for the PREVENT trial minimizes the potential for bias in the analysis of trial data, and in the interpretation and reporting of trial results.

Trial registration: ACTRN12612001180808 (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12612001180808)

Background

Low back pain is the most burdensome health problem worldwide[1] and one that is seen commonly in primary care.[2] People with low back pain who seek healthcare place high-value on receiving information and education about the problem.[3] Indeed, all clinical guidelines endorse patient education in primary care.[4] There is good evidence that primary care-based patient education, both face-to-face and written format, reduces emotional distress and subsequent healthcare use for acute low back pain.[5]

Despite widespread recommendations, few practitioners provide patient education in practice.[6] One reason for lack of uptake could be the belief that conservative treatments such as patient education do not primarily change pain.[7] For patients with chronic low back pain there is good evidence that this belief is mistaken.[8] For patients with acute low back pain, however, evidence that patient education alone can reduce pain is lacking.[9] Furthermore, no study has subjected face-to-face patient education to the gold standard placebo controlled trial, to control for the effects of spending time with a professional.

The PREVENT Trial[10] was the first randomized, placebo-controlled trial of face-to-face patient education for acute low back pain. The purpose of this Statistical Analysis Plan is to outline planned statistical analysis methods for the primary and secondary outcomes of the trial.

Trial overview

The trial is a two-arm placebo-controlled trial. Patients were randomized to receive two, 1-h sessions of *Patient Education* based on Explain Pain[11] or two, 1-h sessions of *Sham Education* based on a reflective, non-directive approach,[12] in addition to guideline-based care for acute low back pain. The PREVENT Trial was funded by the National Health and Medical Research Council of Australia (NHMRC APP1047827). It was prospectively registered (ACTRN=12612001180808) and the study protocol has been published elsewhere.[10] Patients were followed up at 3, 6, and 12 months post-randomization.

Trial objectives

Primary objective

Determine whether *Patient Education* in addition to clinical guideline-based care for acute low back pain reduces the intensity of low back pain at 3 months compared to *Sham Education* in addition to clinical guideline-based care.

Secondary objectives

Determine whether any effect of *Patient Education* on the intensity of low back pain at 3 months compared the *Sham Education* can be maintained at 6 and 12 months.

Determine whether *Patient Education* increases the proportion of patients who recover from low back pain (i.e. who do not develop chronic low back pain) by 3 months compared to *Sham Education*.

Determine whether *Patient Education* can reduce disability, depression, or pain attitudes, or healthcare use at 3, 6 and 12 months, compared to *Sham Education*.

Statistical analysis

General principles

Two researchers blind to group allocation will perform the analysis independently. That is, the researcher will know which participants share a group, but not which group that is. All results will be cross-checked for errors. In cases where participants did not receive the treatment as allocated, treatment evaluation will be based on the principle of intention-to-treat. In other words, the analysis will only include observed responses from participants in the trial arm they were allocated to, regardless of whether they complied with the treatment and even if the last observed response was baseline. We will calculate and interpret between group differences and 95% confidence intervals for all outcomes. Statistical tests will be two-tailed with alpha set at $p = <0.05$.

Process measures

Adherence

We recorded attendance for all participants at both trial sessions using a study calendar. We will use these data to assess whether the proportion of participants who successfully completed both trial sessions was different between trial arms. If >5% of participants do not complete both trial sessions, we will compute a ''Complier Average Causal Effect''.[13]

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