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Appraisal | Trial Protocol

The RESOLVE Trial for people with chronic low back pain: protocol for a randomised clinical trial

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Abstract

Introduction: Low back pain is the leading worldwide cause of disability, and results in significant personal hardship. Most available treatments, when tested in high-quality randomised, controlled trials, achieve only modest improvements in pain, at best. Recently, treatments that target central nervous system function have been developed and tested in small studies. Combining treatments that target central nervous system function with traditional treatments directed towards functioning of the back is a promising approach that has yet to be tested in adequately powered, prospectively registered, clinical trials. The RESOLVE trial will be the first high-quality assessment of two treatment programs that combine central nervous system-directed and traditional interventions in order to improve chronic low back pain. **Aim**: To compare the effectiveness of two treatment programs that combine central nervous system-directed and traditional interventions at reducing pain intensity at 18 weeks post randomisation in a randomised clinical trial of people with chronic low back pain. **Design**: Two-group, randomised, clinical trial with blinding of participants and assessors. **Participants and setting**: Two hundred and seventy-five participants with chronic low back pain that has persisted longer than 3 months and no specific spinal pathology will be recruited from the community and primary care in Sydney, Australia. **Interventions**: Both of the interventions contain treatments that target central nervous system function combined with treatments directed towards functioning of the back. Adherence to the intervention will be monitored using an individual treatment diary and adverse events recorded through passive capture. Participants are informed prior to providing informed consent that some of the treatments are not active. Blinding is maintained by not disclosing any further information. Complete disclosure of the contents of the intervention has been made with the UNSW HREC (HC15357) and an embargoed project registration has been made on the Open Science Framework to meet the Declaration of Helsinki requirement for transparent reporting of trial methods *a priori*. **Intervention A**: Participants randomised to Intervention A will receive a 12-session treatment program delivered as 60-minute sessions, scheduled approximately weekly, over a period of 12 to 18 weeks. All treatment sessions are one-on-one. The program includes a home treatment component of 30 minutes, five times per week. The intervention comprises discussion of the participant's low back pain experience, graded sensory training, graded motor imagery training and graded, precision-focused and feedback-enriched, functional movement training. Treatment progression is determined by participant proficiency, with mandatory advancement at set time points with respect to a standard protocol. **Intervention B**: Participants randomised to Intervention B will receive a 12-session treatment program of the same duration and structure as Intervention A. The intervention comprises discussion of the participant's low back pain experience, transcranial direct current stimulation to the motor and pre-frontal cortices, cranial electrical stimulation, and low-intensity laser therapy and pulsed electromagnetic energy to the area of greatest pain. Treatment is delivered according to published recommendations and progressed with respect to a standard protocol. **Measurements**: The primary outcome is pain intensity at 18 weeks post randomisation. Secondary outcomes will include disability, depression, pain catastrophising, kinesiophobia, beliefs about back pain, pain self-efficacy, quality of life, healthcare resource use, and treatment credibility. Assessment will occur at baseline and at 18, 26 and 52 weeks after randomisation. Treatment credibility will be assessed at baseline and 2 weeks after randomisation only. **Analysis**: A statistician blinded to group status will analyse the data by intention-to-treat using linear mixed models with random intercepts. Linear contrasts will be constructed to compare the adjusted mean change (continuous variables) in outcome from baseline to each time point between intervention A and intervention B. This will provide effect estimates and 95% confidence intervals for any difference between the interventions. **Significance**: Preliminary data suggest that combining treatments that target central nervous system function with traditional interventions is a promising approach to chronic low back pain treatment. In the context of modest effects on pain intensity from most available treatments, this approach may lead to improved clinical outcomes for people with chronic low back pain. The trial will determine which, if either, of two treatment programs that combine central nervous system-directed and traditional interventions is more effective at reducing pain intensity in a chronic low back pain cohort. Central nervous system-directed interventions constitute a completely new treatment paradigm for chronic low back pain management. The results have the potential to be far reaching and change current physiotherapy management of chronic low back pain in Australia and internationally.

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Trial registration: Australian and New Zealand Clinical Trials Registry. **Registration number**: ACTRN12615000610538. **Was this trial prospectively registered?** Yes. **Date of trial registration**: 11 June 2015. **Funded by**: National Health and Medical Research Council of Australia. **Funder approval number**: NHMRC1087045. **Anticipated completion date**: September 2019. **Provenance**: Not invited. Peer reviewed. **Corresponding author contact details**: Dr James H McAuley, Neuroscience Research Australia, Barker Street, Randwick, NSW 2031, Australia, and Prince of Wales Clinical School, University of New South Wales, Kensington, NSW 2052, Australia. E-mail: j.mcauley@neura.edu.au

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