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Research Trial Protocol

Implementation of a guideline-based clinical pathway of care to improve health outcomes following whiplash injury (Whiplash ImPaCT): protocol of a randomised, controlled trial

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Abstract

Introduction: Whiplash-associated disorders (WAD) are a huge worldwide health and economic burden. The propensity towards developing into chronic, disabling conditions drives the rise in health and economic costs associated with treatment, productivity loss and compulsory third party insurance claims. Current treatments fail to address the well-documented heterogeneity of WAD and often result in poor outcomes. A novel approach is to evaluate whether the care provided according to the estimated risk of poor prognosis improves health outcomes while remaining cost-effective. **Research questions**: (1) Does a guideline-based clinical pathway of care improve health outcomes after whiplash injury compared to usual care? (2) Does risk of recovery have a differential effect on health outcomes for the clinical pathway of care? (3) Is the clinical pathway of care intervention cost-effective? (4) What are the variations in professional practice between usual care and the clinical pathway of care? **Design**: Multi-centre, randomised, controlled trial conducted over two Australian states: Queensland and New South Wales. **Participants and setting**: 236 people with WAD (grade I-III, within 6 weeks of injury) and their primary healthcare providers. **Intervention**: A clinical pathway of care, with care matched to the predicted risk of poor recovery. Participants at low risk of ongoing pain and disability (hence, predicted to fully recover) will receive up to three sessions of guideline-based advice and exercise with their primary healthcare provider. Participants at medium/high risk of developing ongoing pain and disability will be referred to a specialist (defined as a practitioner with expertise in whiplash) who will conduct a more in-depth physical and psychological assessment. As a result, the specialist will liaise with the original primary healthcare provider and determine one of three further pathways of care. **Control**: Usual care provided by the primary healthcare provider that is based on clinical judgment. **Measurements**: Primary (global rating of change and neck-related disability) and secondary (self-efficacy, pain intensity, general health and disability and psychological health) outcomes will be collected using validated scales. Direct (eg, professional care, transportation costs, time spent for care, co-payments) and indirect (eg, lost economic productivity) costs will be obtained through an electronic cost diary. Health and cost outcomes will be assessed at baseline, 3, 6 and 12 months after randomisation. Professional practice outcomes will be evaluated through questionnaires completed by healthcare providers and their patients at 3 months. **Procedure**: Potential participants (patients) will be identified through emergency departments, primary health clinics and advertisements. Eligible participants will complete baseline assessments and will be categorised into low or medium/high risk of poor recovery using a clinical prediction rule. After this assessment, participants will be randomly allocated to either a control group ($n = 118$) or intervention group ($n = 118$), stratified by risk subgroup and treatment site. The participants' nominated primary healthcare providers will be informed of their involvement in the trial. Consent will be obtained from the primary healthcare providers to participate and to obtain information about professional practice. Participants in the intervention group will additionally have access to an interactive website that provides information about whiplash and recovery relative to their risk category. **Analysis**: Analysis will be conducted on an intention-to-treat basis. Outcomes will be analysed independently through cross-sectional analyses using generalised linear models methods, with an appropriate link function, to test for an intervention effect, adjusted for the baseline values. The risk category will be tested for its association with treatment effect by adding risk group to the regression equation. Cost-effectiveness will be calculated using utility weights and the resulting measure will be cost per quality-adjusted life year (QALY) saved. Professional practice outcomes will be analysed using descriptive statistics. **Discussion**: This research is significant as it will be the first study to address the heterogeneity of whiplash by implementing a clinical pathway of care that matches evidence-based interventions to projected risk of poor recovery. The results of this trial have the potential to change clinical practice for WAD, thereby maximising treatment effects, improving patient outcomes, reducing costs and maintaining the compulsory third party system.

Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR). **Registration number**: ACTRN12615001367538. **Was this trial prospectively registered?** Yes. **Date of trial registration**: 16 December 2015. **Funded by**: Partnership grant from the National Health and Medical Research Council, New South Wales Motor Accidents Authority, and the Motor Accidents Insurance Commission of Queensland. **Funder approval number**: NHMRC APP1075736. **Anticipated completion date**: 2019. **Provenance**: Not invited. Peer reviewed. **Corresponding author contact details**: Dr Trudy Rebbeck, Faculty of Health Sciences, Discipline of Physiotherapy, University of Sydney, New South Wales, Australia. Email: trudy.rebbeck@sydney.edu.au

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