

# Managing Injuries of the Neck Trial (MINT): a randomised controlled trial of treatments for whiplash injuries

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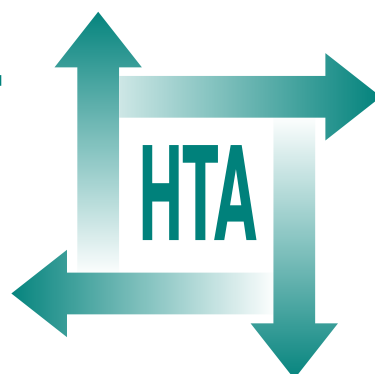


## *Executive summary*

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# Executive summary

## Background

Whiplash injuries are a common and costly problem. Improved management of acute injuries may be beneficial, but there is a well-recognised lack of research evidence to support treatments that are commonly advocated.

## Design

Two linked, pragmatic, randomised controlled trials (RCTs) evaluating a stepped care approach to management of whiplash injuries. The first step was cluster randomised: emergency departments (EDs) (clusters) were randomised to usual care advice (UCA) or *The Whiplash Book*/active management advice. In the second step, participants with persistent symptoms at 3 weeks were individually randomised to either a single session of advice from a physiotherapist, or a package of up to six sessions of physiotherapy treatments. An economic evaluation and qualitative study were run in parallel with the trial.

## Setting

Twelve NHS trusts in England, comprising 15 EDs.

## Control interventions

In the first step of the trial, the control intervention was UCA. A national survey of usual care was conducted in 251 EDs prior to the start of the trial, and used to benchmark UCA. In the second step of the trial, the control treatment was reinforcement of the advice provided in the first step, by a physiotherapist [either UCA or *The Whiplash Book*/active management advice (see below)].

## Experimental interventions

In the first step of the trial, the experimental intervention was a psychoeducational intervention comprising *The Whiplash Book* and active management advice. ED clinicians (doctors, nurses and allied health professionals) were given brief training on whiplash injuries and how to implement the active management approach. The clinicians were asked to provide all people who attended with an acute whiplash injury with *The Whiplash Book* and to provide advice consistent with the active management strategy. In the second step of the trial, the experimental intervention was a bespoke package of up to six physiotherapy treatments. Each participant was assessed and provided with an individually tailored package of treatments, from manual therapy, exercise, brief psychological interventions and advice.

## Recruitment

All people who attended the ED with an acute whiplash injury of whiplash-associated disorder (WAD) grades I–III (mild to severe, but excluding fractures or dislocations of the spine) were eligible for Step 1 of the trial. All eligible patients who were reported to the study co-ordinating centre were invited to participate. People who had attended participating EDs with whiplash injuries and had persistent symptoms 3 weeks after ED attendance (WAD grades I–III) and no contraindication to physiotherapy treatment were eligible for Step 2.

## Follow-up

We collected follow-up data at 2 weeks, 4 months, 8 months and 12 months after the ED attendance. The primary method of data capture was postal questionnaire. This was supplemented with telephone data collection for individuals who did not return a questionnaire but were happy to provide information.

## Clinical outcomes and analysis

The primary outcome was the Neck Disability Index (NDI), which measures both severity and frequency of pain, symptoms, and a range of activities including self-care, driving, reading, sleeping and recreation. Secondary outcomes included the mental and physical health-related quality-of-life (HRQoL) subscales of the Short Form questionnaire-12 items (SF-12) version 1 and the number of work days lost. NDI scores were also summarised to give an indicator of late whiplash syndrome (LWS) and a binary indicator of more severe symptoms at 4 months (acute whiplash injury). The planned sample size was approximately 3000 for Step 1 and 600 for Step 2. We used hierarchical regression modelling to include estimation of clustering effects from NHS trusts, and from therapists providing the treatment (Step 2 only). Models were adjusted for baseline covariates. Subgroup analyses were pre-specified for injury severity, psychological response to the injury, and pre-existing neck pain, and are presented for the primary outcome. Additional analyses explored the impact on and role of compensation.

## Economic analysis

We considered the cost–utility of the various treatment options from the UK NHS perspective. We included all NHS costs needed to deliver the interventions and to provide health care associated with whiplash injuries over a 12-month time horizon. Quality-adjusted life-years (QALYs) were calculated from the European Quality of Life-5 Dimensions (EQ-5D). We collected resource data from participant questionnaires. Costs were in UK pounds (£) actualised to 2009 using the Retail Price Index. Discounting was not applied.

## Results

Between December 2005 and November 2007 we recruited 3851 patients to the first step of the trial: 1598 people attended EDs that were randomised to the UCA, and 2253 people attended departments randomised to the active management/*The Whiplash Book* advice (WBA).

Nearly 57% of participants were female, mean age was 37 years and the most frequent WAD grade at ED presentation was grade I (complaint of pain, stiffness or tenderness, with no physical signs). Outcome data were obtained at 12 months for 70% and 80% of participants of the Step 1 and Step 2 stages of the trial, respectively. The majority of people recovered from the injury. Eighteen per cent of the Step 1 cohort had LWS. However, the average SF-12 scores are consistent with the majority of the cohort returning to expected population values of HRQoL by 12 months.

There was no statistically or clinically significant difference observed in any of the outcomes for participants attending EDs randomised to usual care or active management advice [difference in NDI 0.5, 95% confidence interval (CI) -1.8 to 2.8]. In the second step of the trial, the physiotherapy package resulted in improvements in neck disability at 4 months in comparison with a single advice session, but these effects were small at the population level (difference in NDI -3.2, 95% CI -5.8 to -0.7). The physiotherapy package was accompanied by a significant reduction in the number of work days lost at 4-month follow-up (difference -41.4%, 95% CI -45.4% to -37.0%). There was no difference in generic HRQoL between the two treatments tested in Step 2.

There was no evidence that the effects of the advice interventions (Step 1) or physiotherapy versus advice (Step 2) were affected by severity of the initial injury, adverse psychological reactions to injury, or with pre-existing neck problems.

## Economics

The mean total cost of health care provided to people in the WBA and UCA packages was £311.22 and £283.47, respectively. The mean total cost of health care provided to people in the physiotherapy package and reinforcement of advice arm was £440.22 and £336.00, respectively. Although there were small additional benefits in terms of QALYs, these were in favour of both control interventions. In terms of incremental cost-effectiveness ratios from a health-care perspective *The Whiplash Book* and physiotherapy package were dominated. When personal health-care costs were included, the UCA was cost-effective at £7106 per QALY.

## Qualitative study

We explored user perspectives on the acceptability and experience of the treatments provided in the trial, and how future interventions might be improved. Semi-structured interviews were completed in a purposive sample of 20 participants in Step 2 of the trial, with equal sampling from each of the four treatment pathways (UCA + physiotherapy package; UCA + physiotherapy advice session; *The Whiplash Book* and active management + physiotherapy package; *The Whiplash Book* and active management + physiotherapy advice session). Some messages from the ED consultation were retained, in particular those relating to the need to exercise. *The Whiplash Book* was recalled by most participants, but many reported, despite reading the contents and understanding them, they felt unable to self-manage their condition owing to fear of reinjury and needing reassurance. The single advice session of physiotherapy was welcomed, and most people gained considerably in terms of reassurance and confidence to self-manage their condition. Likewise the physiotherapy package was generally well received, although some participants reported difficulty in being able to balance the commitment of work with the limited availability of appointments.

## Conclusions

This definitive, large scale RCT suggests that enhanced psychoeducational interventions in EDs are no more effective than UCA in reducing the burden of acute whiplash injuries. A physiotherapy package provided to people who have persisting, significant symptoms within the first 6 weeks of injury produced additional small, short-term benefits in neck disability in comparison with a single physiotherapy advice session. However, from a health-care perspective, the physiotherapy package was not cost-effective at current levels of willingness to pay. Both experimental treatments were associated with increased cost with no discernible gain in HRQoL. However, an important benefit of the physiotherapy package was a reduction in work days lost, and as such, the intervention may prove cost-effective at the societal level.

## Trial registration

This trial is registered as ISRCTN33302125.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

## Publication

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# NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 02/35/02. The contractual start date was in November 2004. The draft report began editorial review in October 2009 and was accepted for publication in May 2010. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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