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Acute Whiplash Injury Study (AWIS): a protocol for a cluster randomised pilot and feasibility trial of an Active Behavioural Physiotherapy Intervention in an insurance private setting

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ABSTRACT

Introduction: Whiplash-associated disorder (WAD) causes substantial social and economic burden internationally. Up to 60% of patients with WAD progress to chronicity. Research therefore needs to focus on effective management in the acute stage to prevent the development of chronicity. Approximately 93% of patients are classified as WADII (neck complaint and musculoskeletal sign(s)), and in the UK, most are managed in the private sector. In our recent systematic review, a combination of active and behavioural physiotherapy was identified as potentially effective in the acute stage. An Active Behavioural Physiotherapy Intervention (ABPI) was developed through combining empirical (modified Delphi study) and theoretical (social cognitive theory focusing on self-efficacy) evidence. This pilot and feasibility trial has been designed to inform the design of an adequately powered definitive randomised controlled trial.

Methods and analysis: Two parallel phases. (1) An external pilot and feasibility cluster randomised double-blind (assessor and participants), parallel two-arm (ABPI vs standard physiotherapy) clinical trial to evaluate procedures and feasibility. Six UK private physiotherapy clinics will be recruited and cluster randomised by a computer-generated randomisation sequence. Sixty participants (30 each arm) will be assessed at recruitment (baseline) and at 3 months postbaseline. The planned primary outcome measure is the neck disability index. (2) An embedded exploratory qualitative study using semistructured indepth interviews (n=3–4 physiotherapists) and a focus group (n=6–8 patients) and entailing the recruitment of purposive samples will explore perceptions of the ABPI. Quantitative data will be analysed descriptively. Qualitative data will be coded and analysed deductively (identify themes) and inductively (identify additional themes).

Ethics and dissemination: This trial is approved by the University of Birmingham Ethics Committee (ERN_15-0542).

Trial registration number: ISRCTN84528320.

Strengths and limitations of this study

- This is the first pilot and feasibility trial of the Active Behavioural Physiotherapy Intervention (ABPI), which may be a potential useful intervention in preventing patients with acute whiplash-associated disorder (WAD) II progressing to chronicity.
- Employing qualitative and quantitative methods, this trial is designed to evaluate procedures, feasibility and acceptability of the ABPI in managing acute WADII within the UK insurance private sector.

INTRODUCTION

Whiplash-associated disorder (WAD) describes the variety of symptoms experienced after a whiplash injury, caused by rapid acceleration–deceleration of the head and neck, most commonly following road traffic accidents.[1] The estimated annual economic cost related to motor vehicle crashes is $242 billion in the USA[2] and €180 billion in Europe.[3] WAD is associated with an increase in healthcare costs, reduced work productivity, lost earning capacity, socioeconomic costs and time contributed by caregivers.[4 5] For example, within the first 2 years after a whiplash injury, employment propensity declined by 20–25%.[4] Approximately 60% of patients with WAD progress to chronicity with up to 30% experiencing moderate to severe pain and disability,[6–8] leading to an decrease in quality of life.[9 10] Unfortunately, chronic WAD management is reported to have limited success.[6 7 11 12] A focus on effective management in the acute stage is therefore required and may be able to prevent patients progressing to chronicity.[11 13 14]

Over the past decade, an increase in minor cervical spine injuries and related costs after whiplash has been reported from insurance companies.[15] In the Western World, the cost of insurance claims is considerable, particularly in the UK where a substantial proportion of patients with WAD are managed within the private sector (private physiotherapy clinics) through insurance companies.[15–21] The UK has also been described as the 'whiplash capital of Europe' by the Association of British Insurers, who estimated that one person in 140 claims for whiplash injury annually.[19] In the UK, it is estimated that the cost of claims for personal injury have risen from £7 billion to £14 billion over the past decade.[19]

WAD has been classified into five grades.[1] WADII (neck complaint and musculoskeletal sign(s)) describes at least 70% of patients with whiplash,[22 23] who are commonly managed by physiotherapists. In the UK, patients with WADII are usually referred to private physiotherapy clinics.[19] Therefore, evaluating the effectiveness of management of WAD in the private context is important.

Our systematic review of randomised controlled trials (RCTs)[13 14] evaluating the effectiveness of acute WADII management found that active intervention may be useful for pain reduction medium (95% CI −17.19 to −3.23, p=0.004) to long term (95% CI −26.39 to −10.08, p<0.0001). Interestingly, the active intervention is also strongly recommended within whiplash management guidelines.[24 25] Second, the review suggested that behavioural intervention may be effective for pain reduction medium term (95% CI −15.37 to −1.55, p=0.016) and improvement of cervical mobility in the coronal (95% CI 0.93 to 4.38, p=0.003) and horizontal planes (95% CI 0.43 to 5.46, p=0.027) short–medium term compared with a standard/control intervention. The combination of active physiotherapy and behavioural interventions, termed 'Active Behavioural Physiotherapy Intervention (ABPI)', may be a useful strategy for acute WADII management to prevent chronicity.[14]

The existing evidence was inadequate to generate an intervention for managing patients with acute WADII. Therefore, the ABPI was developed using empirical (a modified Delphi study by international whiplash researchers, UK private physiotherapists and UK postgraduate musculoskeletal physiotherapy students) (T Wiangkham, J Duda, MS Haque. The development of an Active Behavioural Physiotherapy Intervention (ABPI) for acute Whiplash Associated Disorder (WAD)II management: a modified Delphi study. (Under review) 2016) and theoretical perspectives (social cognitive theory focusing on self-efficacy theory)[26] in line with the Medical Research Council Framework of Complex Interventions.[27] Having developed the intervention through a rigorous process, it is now important to explore the feasibility of delivering the intervention in preparation for a future definitive cluster randomised trial. For the UK, the delivery of the ABPI needs to take place in the private setting.[28]

Aims and objectives

To evaluate procedures, feasibility and acceptability of the ABPI in managing acute WADII within the UK insurance private sector to inform the design and sample size requirements for a future definitive randomised controlled trial.

Primary objectives:

- To evaluate the feasibility of procedures for a cluster randomised controlled trial (eg, randomisation, recruitment, collecting data, trial management and follow-up).[29–32]
- To evaluate the acceptability of the developed intervention.[30]
- To evaluate recruitment rates, refusal rates, compliance of participants in the private sector in the UK.[30 31]
- To evaluate loss of follow-up of participants in the private sector in the UK.[30 32]

Secondary objectives:

- To estimate the required sample size for a clustered definitive trial.[30–34]
- To evaluate the feasibility of data collection for cost-effectiveness analysis.[30]

METHODS

This trial will be conducted according to a predefined protocol (and subsequent deviations will be reported) to minimise potential biases. It follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines to ensure sufficient transparency for protocols of clinical trials.[35] Research methods and reporting are in accordance with the CONSORT 2010 statement: extension to cluster randomised trials[36] for phase I and COnsolidated criteria for REporting Qualitative research (COREQ): a 32-item checklist for interviews and focus groups[37] for phase II.

Trial design

There are two phases to this trial.

Phase I

An external pilot and feasibility trial of a prospective, cluster randomised double-blind (assessor and participants), parallel two-arm design, comparing ABPI with standard physiotherapy management, will evaluate procedures and feasibility of the ABPI. Six private physiotherapy clinics in the West Midlands, UK will be recruited (figure 1). There are many advantages of cluster randomisation in terms of administrative convenience,[38] obtaining cooperation of investigators, ethical considerations,[38] enhancing participant compliance, reducing treatment contamination,[28 36 38 39] participant blinding[36] and logistical conveniences.[38] However, the required sample size in a cluster RCT is larger than an RCT.[40]

Six private physiotherapy clinics will be invited to sign consent forms (cluster-level consent) prior to cluster

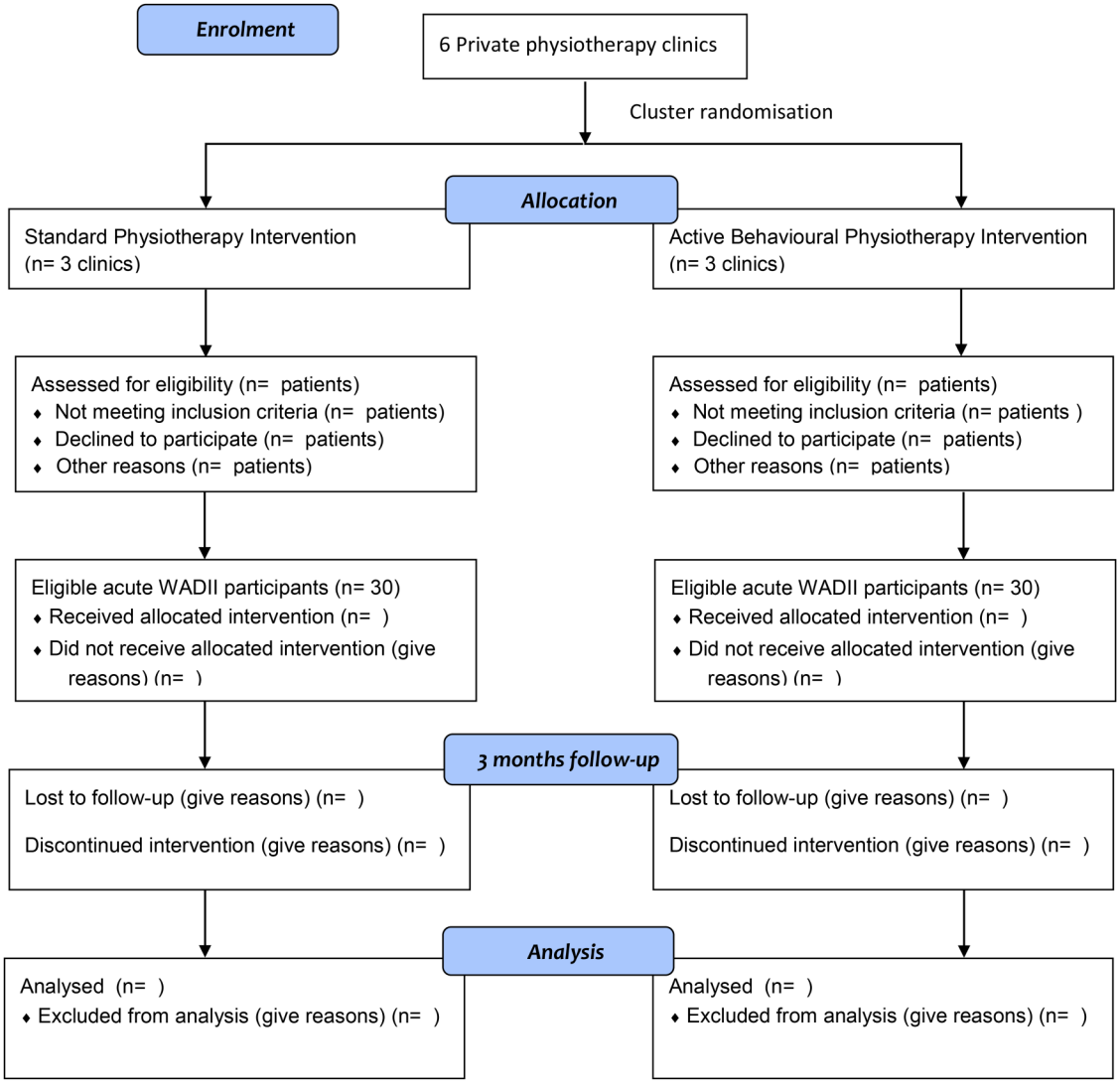

Figure 1 CONSORT flow diagram (adapted from CONSORT 2010). WAD, whiplash-associated disorder.

randomisation.[36] Following randomisation, consecutive potential participants, referred from an insurance company, will be screened and recruited by a clinical administrator by telephone to book an initial recruitment appointment. The Participant Information Sheet and consent form will be sent via email/post to interested patients to give them the opportunity to read it in advance of the appointment. At the appointment, the recruiting physiotherapist will discuss any issues relating to the trial, confirm eligibility and obtain written consent (individual-level consent). Following informed written consent, participants will be assessed on all outcome measures by a blinded assessor using standardised instruments with established measurement properties. Assessments will be taken at baseline (following recruitment and consent) and at 3 months postbaseline. All outcome assessments will be independent from treatment sessions and treatment clinics to ensure that the assessor is blinded to treatment allocation. The assessor will be a physiotherapist familiar with the outcome measures, and blinded to reduce potential biases. The assessor will not be able to access the booking system and participants' information, whereas participants will not know which intervention arm they will be allocated to ensure that assessor and participants will be blinded. At the end of the 3-month follow-up for each participant, the assessor will be asked 'what intervention the patient had received' and the participants will be asked which intervention arm they had allocated to evaluate the blindness. Two assessment centres central to all clinics will enable convenient attendance for participants. Participants will receive a reminder 2 days prior to the baseline assessment and 3-month follow-up. Providing a reason for participants' withdrawal is voluntary. In the consent form, participants will be asked to confirm if they would like their data removed or kept in the trial, in the situation that they would like to withdraw from the trial (please see online supplementary appendices for the participant information sheet and consent form).

Phase II

An embedded qualitative study will explore the acceptability of the ABPI for participants and physiotherapists, and to explore how trial procedures and processes worked in practice.[41] The qualitative study will employ two methods, namely semistructured individual interviews for physiotherapists and a focus group for participants from phase I. Potential participants in either method will be invited via email including an attached participant information sheet and consent form. Prior to performing individual interviews and the focus group, the participants will receive an opportunity to ask questions in order to decide whether they wish to complete the consent form. Demographic characteristics of the participants such as age, gender, occupation and ethnicity will be collected and reported.[37] Interviewer, moderator and facilitator will be independent from trial interventions, physiotherapy clinics and insurance companies to ensure confidential discussion and avoid potential biases. Transcripts will be returned to participants for any comment and clarification.[42] The lead researcher (TW) will be trained in individual and focus group interviews to enhance his qualitative skills prior to conducting an interview.

Personal characteristics of research team

- TW (male): MRes AHR, BSc PT (Hons), Cert GCP, MTPTC. Doctoral Researcher
- AR (female): EdD, MSc, Grad Dip Phys, Cert Ed, Dip TP, FCSP, Health and Care Professions Councils (HCPC), FHEA, FMACP. Senior Lecturer in Physiotherapy and Academic Lead Physiotherapy
- JD (female): PhD, MSc, BA. Professor of Sport and Exercise Psychology
- MSH (male): PhD, MSc, BSc (Hons), FRSS. Senior Lecturer in Medical Statistics
- JP (male): BSc PT. Head of Professional Development

Individual interviews for physiotherapists in the experimental arm

All physiotherapists who deliver the ABPI (3–4 physiotherapists) will be invited to an individual face-to-face interview by the lead researcher (TW) using a semistructure interview technique.[41 43] Each interview, which will take ~60 min and take place at physiotherapists' clinics, will explore the opinions about attitudes towards and acceptance of the ABPI in managing acute WADII. Furthermore, perceptions of the similarities and differences between standard physiotherapy and the ABPI will be examined. Topic guides for individual interviews will be tested by TW at least two times prior to implementation (table 1). The interview will be noted, audio recorded and transcribed by TW.

Table 1 Individual interview theme for the physiotherapists in the experimental arm

Themes	Questions
1	*Opinions and attitudes for the new intervention*
	Did you have any obstruction in using the ABPI for treating your patients?
	Do you think the ABPI is useful for acute WADII management? Why? Or why not?
	What is your opinion regarding the most effective treatment of WADII?
	What should be the treatment for acute WADII?
	With prompts for detail and elaboration of points
2	*Similarities and differences between the standard physiotherapy and the ABPI*
	What are the similarities and differences between standard physiotherapy and the ABPI?
	Which intervention do you feel may be more helpful in managing your patients? Why?
	With prompts for detail and elaboration of points
3	*Acceptance of the new intervention*
	Is the ABPI an effective intervention for acute WADII management? Why? Or why not?
	Do you think the ABPI should be used in managing acute WADII in general? Why?
	Would you like to change/modify the ABPI? If so how?
	With prompts for detail and elaboration of points

ABPI, Active Behavioural Physiotherapy Intervention; WAD, whiplash-associated disorder.

Focus group for participants in the experimental arm

A random sample of 6–8 participants who received the ABPI will be invited via email to participate in a focus group which is a standard and common procedure for evaluating the acceptability of an intervention.[42–44] There are several advantages of the focus group including reduced economic compared with one-on-one interviews, and the points that focus groups are conducive to tapping variability in attitudes and opinions due to the interaction facilitated, and provide a comfortable forum for the expression of individual and collective points of view.[45] A reminder email regarding date, time and location of the interview will be sent to the participants 1 day prior to the focus group. The focus group interview/discussion will last for ~1.5 hours, be held at the University and be led by an expert facilitator (AR) with a moderator (TW) to observe group interaction/dynamics and record main themes of discussion. An important reason for using an expert facilitator is to obtain sufficient quality of the data and to avoid potential biases (eg, consistency bias and dominant respondent bias).[45] The focus group topic guide will include the intervention that the participants received, the opinions and attitudes of the participants about the intervention, how the participants accepted the intervention and if and how behaviour has changed. Following consent, the focus group will start by agreeing 'ground rules' for the group, including not discussing the content of the group interview outside of the session. The facilitator will start with an introduction for the study and organise questions from general to specific related to interesting topics (table 2). The focus group will be observed,

Table 2 Focus group theme for the participants in the experimental arm

Themes	Questions
1	*Intervention*
	What was treatment that you received from your physiotherapist?
	How did your physiotherapist approach you?
	What was home programme that you were recommended to do by your physiotherapist?
	What did your physiotherapist suggest for managing your symptoms?
	With prompts for detail and elaboration of points
2	*Opinions and attitudes for the new intervention*
	Do you think the treatment was useful? Why? Or why not?
	What is your opinion of this treatment for WAD?
	What should be the treatment for acute WAD?
	Would you suggest anything in your treatment be changed or modified?
	Was there anything missing?
	With prompts for detail and elaboration of points
3	*Acceptance of the new intervention*
	How did you feel after receiving the treatment?
	Do you accept the treatment that your physiotherapist gave to you? Why?
	What is/are the benefit(s) of the treatment that you received from your physiotherapist?
	Do you think the treatment should be used for acute WADII management? Why? Or why not?
	With prompts for detail and elaboration of points
4	*Behavioural changes*
	What differences, in your lifestyle, did you notice after receiving the treatment?
	After going through this treatment, have you committed to adopting a more healthy lifestyle? If yes, how? If not, why not?
	With prompts for detail and elaboration of points

WAD, whiplash-associated disorder.

noted, audio recorded and transcribed by TW. The participants' names will not be linked to any information in the reporting of findings from the group discussion, and findings will be reported for the whole group rather than for individual participants. After the focus group, the moderator and facilitator will discuss the main findings and unexpected outcomes.[42]

Participants

Participants will be recruited from six UK private physiotherapy clinics. Demographic characteristics, including age, gender, accident history, present drugs, information regarding WAD symptoms, will be taken by the blinded assessor at the baseline assessment. The participants in this trial can normally claim all expenditures regarding their treatment sessions from their insurance company. The trial will pay for the participants' journeys at baseline and 3-month follow-up that are additional contact points.

Eligibility criteria for clusters: private clinics in the West Midlands, UK. Preliminary data have identified that each clinic has at least two patients presenting with acute WADII each month.

Inclusion criteria: Participants aged 18–70 years old, presenting with WAD grade II (neck complaint and musculoskeletal sign(s))[1] from a road traffic accident within the previous 4 weeks.[7 14 25 46–48]

Exclusion criteria: Signs and symptoms of upper cervical instability[49] or cervical artery dysfunction,[50] suspected serious spinal pathology, open wounds, active inflammatory arthritis, tumours, infection of the skin and soft tissue, bleeding disorders or using anticoagulant medication,[49] any current or previous treatment from any other third party or presenting with any serious injuries from other areas of the body resulting from the accident, history of cervical surgery,[51] previously symptomatic degenerative diseases of the cervical spine within 6 months before the road traffic accident,[52] previous history of whiplash or other neck pain,[47] alcohol abuse,[52 53] dementia,[52 53] serious mental diseases,[52 53] psychiatric diseases[54 55] and/or non-English speaking and reading.

Interventions

Interventions are described based on Template for Intervention Description and Replication (TIDieR).[56] Participants in both intervention arms will attend face-to-face physiotherapy sessions lasting for up to 30 min once a week in a private physiotherapy clinic. The number of treatment sessions will vary between 6 and 8 sessions based on the individual physiotherapist's assessment. All physiotherapists in both intervention arms will have a minimum of a Bachelor Degree in Physiotherapy with 2 years of postregistration experience, and will be registered with the HCPC. To evaluate fidelity of the ABPI, a summary of treatment sessions will be systematically collected and sessions will be randomly observed by the lead researcher (TW). This will enable monitoring and feedback regarding the intervention to the treating physiotherapist.

Standard physiotherapy intervention

Patients will be managed according to current practice reflecting the recommendations provided in the clinical whiplash guidelines.[24 25 48] Physiotherapy interventions such as reassurance, education, manual therapy, exercise therapy and physical agents, including a home programme of exercises, are part of management depending on the individual physiotherapist's clinical reasoning for the individual patient. The treating physiotherapists select appropriate interventions based on examination findings and clinical reasoning.[50]

Active Behavioural Physiotherapy Intervention

The specific detail of this intervention including the underlying principles (eg, return to normal function/movement as soon as possible, encourage self-management, and

reduce fear avoidance and anxiety) and the specific treatment components in physical (eg, exercise programmes for stability and mobility) and psychological (eg, cognitive–behavioural therapy, whiplash education, advice to act as usual, reassurance, self-management and postural control and education) aspects were developed by international research and local clinical whiplash experts through a modified Delphi method (T Wiangkham, *et al* Under review). By consideration of empirical and theoretical perspectives in line with the Medical Research Council Framework of Complex Interventions,[27] social cognitive theory (with a particular focus on self-efficacy enhancement) will be used to underpin the ABPI to manage the patient with acute WADII.[26 57] Past research has found self-efficacy to correlate with quality of life and health status in physical (eg, pain and physical functions) and psychological (eg, anxiety and depression) perspectives in a rehabilitation context.[58 59]

The ABPI for acute WADII management consists of four phases in terms of the promotion of understanding, maturity, stamina and coping (figure 2). Table 3 presents a summary of the ABPI for acute WADII management. The number of treatment session in each phase will vary depending on individual patients' conditions based on physiotherapist's justification. The recommendation is ~1–3 visits in each phase.

Training of physiotherapists in the experimental arm to deliver the ABPI will be delivered in advance of data collection. The training will consist of a group tutorial and workshop followed by individual training sessions to construct the concept of how to design the intervention and how to manage patients with WADII using the ABPI programme based on the findings of the subjective and objective examinations, and evidence informed clinical reasoning.[50] The physiotherapists will have 4 weeks to practise their skills embedded in the ABPI in managing patients with acute WADII prior to participants' recruitment. They will be randomly observed by the lead researcher (TW) every week before starting participant recruitment and every month during data collection. Feedback will be provided throughout the trial.

Outcomes

Planned primary outcome measure

The neck disability index (NDI) is a patient-reported outcome measure and a valid, reliable and responsive tool in assessing pain and disability of neck in acute and chronic conditions.[60–63] The NDI is a self-administered questionnaire that includes 10 sections focusing on functional activities such as pain intensity, personal care, lifting, reading, headache, concentration, work, driving, sleeping and recreation.[60] Each section is scored 0–5, with 5 representing the greatest disability. The sum is calculated and converted into a percentage to indicate the participant's perceived level of disability.[60] The NDI is a robust predictor of outcome for acute WAD[64] and recommended to monitor patients with whiplash by several clinical guidelines, including NHS Library, New South Wales Motor Accidents Authority, British Columbia Physiotherapy Association, Royal Dutch Society for Physical Therapy and the South Australian Centre for Trauma and Injury.[25 48 62] Consequently, several previous whiplash intervention trials have used the NDI as the primary outcome.[47 65]

Planned secondary outcome measures

Visual analogue scale for pain intensity

The most common symptom in patients with whiplash is pain.[18] Pain will be measured using a 0 mm (no pain) to 100 mm (worst possible pain) visual analogue scale (VAS),[66] which is a simple and preferred tool for assessing pain intensity, with high validity and reliability in evaluating acute pain.[67–69] The identification of initial pain intensity using the VAS has been found to be an important prognostic factor in predicting poor recovery in patients with acute whiplash.[64 70]

Cervical range of motion

Decreasing cervical mobility is a common finding in patients with WADII.[71] Cervical range of motion (CROM) is highly sensitive and can be specifically tested for discrimination between asymptomatic and symptomatic whiplash[72] and for handicap prediction of acute whiplash injury.[73] In this trial, the CROM will be measured by the cervical range of motion device.[74] The cervical range of motion device is a highly valid and reliable device in measuring CROM and is attached to the head.[75–77] The participant sits on a comfortable chair with hips and knees flexed to 90°. CROM measurements are recorded three times in each movement direction. The mean of the three measurements will be used for data analysis.

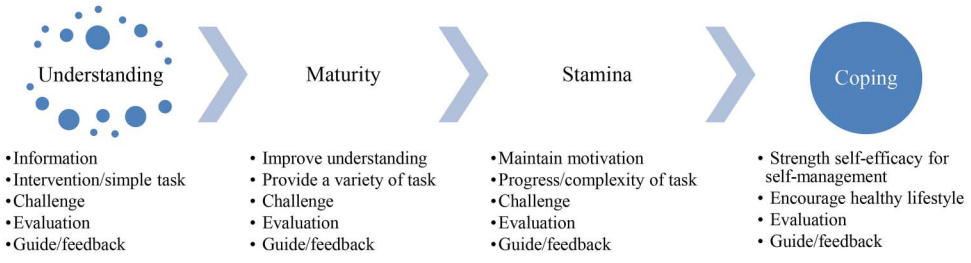

Figure 2 Active Behavioural Physiotherapy Intervention for acute whiplash-associated disorder II management.

Table 3 ABPI for acute WADII management

Phases	Strategies	Goals	Interventions
1. Understanding	▶ Information ▶ Intervention/simple task ▶ Challenge ▶ Evaluation ▶ Guide/feedback	▶ Increase self-efficacy to reduce psychological stress and confidence in exercises by education. ▶ Initiate gentle exercise for maintain/improve neck stability and mobility. ▶ Promote self-management psychological and physical management.	▶ Increase self-efficacy using physiotherapist provided verbal persuasion with the aim of reducing psychological stress and confidence in exercises by whiplash education. ▶ Initiate gentle exercises and home programmes including challenge for neck stability and mobility exercises (eg, isometric neck exercises, chin in and active CROM with pain free). ▶ Promote self-management to include psychological (eg, stress management and relaxation techniques) and physical (eg, pain reduction and physical functions) aspects. ▶ Other physiotherapy programmes based on clinical reasoning.
2. Maturity	▶ Improve understanding ▶ Provide a variety of task ▶ Challenge ▶ Evaluation ▶ Guide/feedback	▶ Increase self-efficacy to reduce psychological stress and confidence in exercises. ▶ Exercises for neck and shoulder stability and mobility. ▶ Promote self-management for pain and physical functions.	▶ Increase self-efficacy (reduce psychological stress and improve confidence in performing exercises) – Performance accomplishment (eg, relieve pain and increase CROM); – Verbal persuasion (eg, further whiplash education/feedback when patients need, continue exercises with challenge); – Increase emotional stages with good relationship. ▶ Exercises+home programmes including challenge for neck and shoulder stability and mobility exercise (eg, resisted neck and shoulder, and AROM exercises). ▶ Promote self-management for pain and physical functions (psychological management when patients need). ▶ Other physiotherapy programmes based on clinical reasoning.
3. Stamina	▶ Maintain motivation ▶ Progress/complexity of task ▶ Challenge ▶ Evaluation ▶ Guide/feedback	▶ Increase/maintain self-efficacy to make confidence in self-management and exercises. ▶ Progressive exercises for stability and mobility. ▶ Promote self-management for physical functions.	▶ Increase/maintain self-efficacy for self-management and exercises – Performance accomplishment (eg, relieve pain, increase CROM, improve physical functions); – Verbal persuasion (eg, guide/feedback, continue exercises with challenge); – Increase/maintain emotional stages with good relationship. ▶ Progressive exercises+home programmes including challenge for strengthening and ROM exercises. ▶ Promote self-management for physical functions. ▶ Other physiotherapy programmes based on clinical reasoning.

Continued

Table 3 Continued

Phases	Strategies	Goals	Interventions
4. Coping	▶ Strength self-efficacy for self-management ▶ Encourage healthy lifestyle ▶ Evaluation ▶ Guide/feedback	▶ Maintain/increase self-efficacy for self-management and exercises. ▶ Promote self-management for physical functions. ▶ Facilitate long-term goal for healthy lifestyle.	▶ Maintain/increase self-efficacy – Performance accomplishment (eg, physical functions); – Verbal persuasion (eg, guide/feedback, continue exercises with challenge to be a healthy lifestyle person); – Increase/maintain emotional stages with good relationship. ▶ Home programmes for strengthening and ROM exercises. ▶ Promote self-management for physical functions. ▶ Facilitate the adoption/maintenance of a healthy lifestyle. ▶ Other physiotherapy programmes based on clinical reasoning.

ABPI, Active Behavioural Physiotherapy Intervention; CROM, cervical range of motion; WAD, whiplash-associated disorder.

Pressure pain threshold

Pressure pain threshold (PPT) is measured using minimal pressure force to identify the threshold of stimulating pain.[78] Patients with whiplash frequently report regarding central hyperexcitability in acute (<1 month)[79–81] and chronic stages.[82] The investigation of PPT at remote pain-free muscles suggests that a component of hypersensitivity in patients with whiplash may come from central sensitisation.[83] A digital pressure algometer is a highly valid and reliable instrument, used to detect sensitivity of symptomatic areas and distal pain-free areas.[84 85] The speed of applied force is 30 kPa/s.[81] The participants are required to press a button when their sensation changes from pressure to perceived pain.[81] PPT will be assessed at the insertion of the levator scapulae[81] and the upper one-third of the tibialis anterior muscle[85] on both sides, three times each side, with an interval of 1 min between each test.[86 87] The mean of the three measurements will be used for data analysis. The starting position of the assessment is comfortable upright sitting with hip and knee flex 90° for the levator scapulae and supine lying with the knee of an assessed side flex 90° for the tibialis anterior.

Impact of events scale

The impact of event scale (IES) is a valid and reliable 15-item questionnaire assessing current stress and indicating the symptoms of post-traumatic stress[88–90] that may contribute to a high risk of persistent symptoms.[54 91–93] The IES is recommended by some clinical whiplash guidelines to monitor whiplash management.[25 48]

Fear-Avoidance Beliefs Questionnaire

The physical disability of patients with WAD can be influenced by fear-avoidance beliefs and associated behaviours following whiplash injury.[94–96] Patients with dysfunctional illness beliefs need to have these addressed to prevent chronicity.[97] The Fear-Avoidance Beliefs Questionnaire is a 16-item valid and reliable tool administered to patients with neck pain,[98] to assess their perceptions of the impact of physical activity and work on their levels of pain and disability.

Assessment of outcome

Masked assessment of outcomes will take place at baseline and at 3 months postbaseline. After 3 months, the patients with whiplash who continue with symptoms and problems are defined as chronic.[7 25] In the future definitive trial, the primary end point will be 3 months and the number of recovered patients with WADII within 3 months will be evaluated. Longer term follow-up is also planned to 1 year. Participants who do not attend the 3-month follow-up assessment will be contacted by telephone and asked if they would like to make a new appointment. If they cannot make a new appointment, the researcher will ask them to complete the NDI via telephone interview, which has established reliability and validity.[99]

Feasibility of cost-effectiveness analysis

Direct and indirect medical costs will be collected to assess the feasibility of data collection for the planned cost-effectiveness analysis in the definitive trial. Participants will receive a diary pocket book to record any activities related to whiplash management such as using medication, consulting other health professionals; along with any costs they incur, days of sick leave, benefits claimed that relate to whiplash management. In the first page of the diary pocket book, general information on participants (eg, postcode, work status and income) will be collected. Costs related to physiotherapy management will be collected from the physiotherapy clinics.

Training costs of physiotherapists in the experimental ABPI arm will also be recorded. The quality-adjusted life years will be estimated using the advocated EuroQol-5 Dimensions.[100]

Sample size

As this is a pilot and feasibility trial, a power calculation is not required.[30] Although establishing targeted sample sizes for pilot/feasibility trials is controversial, 60 participants (30 per arm) will be recruited to provide sufficient power of parameters for designing an adequate power randomised controlled trial.[101] Data from the physiotherapy clinics provided evidence of 18 eligible participants available per month across the six private physiotherapy clinics. The recruitment rate of this trial will be considered adequate if it is at least 50% of eligible participants are recruited. Based on this estimate, the trial may take 6–7 months for participant recruitment with 3-month follow-up.

Randomisation

To minimise selection bias at the cluster level, a computer-generated randomisation programme will be used by the lead researcher (TW) to randomise six private physiotherapy clinics into two groups: standard physiotherapy intervention (n=3 clinics) and ABPI (n=3 clinics). Allocation will be concealed prior to assignment. Only TW will be involved in this process. Cluster randomisation will be implemented before participants are recruited (see figure 1 for CONSORT flow diagram).

Data analysis

Phase I

Data will be analysed and summarised based on quantitative synthesis using a prespecified protocol to evaluate eligible, recruitment and follow-up rates. Quantitative data will be analysed using IBM SPSS V.22. Descriptive statistics will assess the feasibility of the ABPI for acute WADII management to inform the design of the future definitive trial (table 4). The participants who receive other treatments from the initial randomised treatment allocation will not be disregarded in the trial and their data will be included in intention-to-treat analyses. The planned primary end point of this trial is evaluation of the NDI at 3-month follow-up. Evaluation of the drop-out rate of participants will be a criterion to confirm the primary end point. Upon completion of the pilot and feasibility trial, the following possible decisions will be considered by evaluating the feasibility criteria (table 4) for conducting the definitive trial:[31]

Table 4 Feasibility assessment criteria

Objectives	Criteria of success
To evaluate the feasibility of procedures (eg, randomisation, recruitment, collecting data, management, follow-up)[29–32]	The trial will be considered feasible if this trial can be run smoothly without serious problems or obstructions which are able to stop the study.[29 31]
To investigate the acceptability of the developed intervention[30]	The trial will be considered feasible if the physiotherapists and the participants find the developed intervention acceptable.
To evaluate recruitment rates, refusal rates, retention, compliance of participants in the private sector in the UK[30 31]	The trial will be considered feasible if ▶ ≥50% of eligible participants can be recruited; ▶ at least three participants a week per intervention arm can be recruited; ▶ ≥80% of all recruited participants complete the follow-up at 3 months.
To evaluate dropout rates of participants in the private sector in the UK[30 32]	The trial will be considered feasible if ≤20% of all recruited participants dropout.
To estimate the required sample for a definitive trial[30–34]	The trial will be considered feasible if the sample size for a cluster RCT is feasible to achieve based on recruitment data.
To evaluate the feasibility of data collection for cost-effectiveness analysis[30]	The trial will be considered feasible if the following components of the cost-effective analysis can be collected with minimal missing data. ▶ General information (eg, current work status and salary). ▶ Direct medical costs – Medical costs (eg, physiotherapy, general practice and complementary medicine); – Resource uses (eg, diagnosis tests). ▶ Indirect medical costs – Participant journey costs; – Training costs for physiotherapists in the experimental arm.

ABPI, Active Behavioural Physiotherapy Intervention; RCT, randomised controlled trial; WAD, whiplash-associated disorder.

- Stop if the main trial is not possible or valuable.
- Continue but modify the protocol if the main trial is possible and valuable.
- Continue without modifications but monitor closely if the main trial is possible and valuable with close monitoring.
- Continue without modifications if the main trial is possible and valuable.

The intracluster correlation coefficient will also be calculated to prepare information for sample size calculation within a clustered definitive trial.

Phase II

Qualitative data of individual interviews and focus group will be coded and by the lead researcher (TW). QRS NVivo 10 will be employed to identify themes regarding the acceptability of the ABPI to physiotherapists and participants, and how trial procedures and processes worked in practice.[102 103] In the focus group, a key aim of the analysis is to identify any emerging group consensus regarding attitudes towards and experiences of the ABPI.[104] The participants' name will not be linked to any information in the reporting of findings from the group discussion, and findings will be reported for the whole group rather than for individual participants. The data will be analysed deductively (to identify themes) and inductively (to identify additional themes).[44 105] The analysis and findings emanating from the qualitative data will be discussed with the research team at each stage (TW, AR, JD and MSH). The mapping and interpretation of the data will be used to explore and explain relevant patterns. The interpretation of qualitative data will be carried out in parallel to the quantitative findings.

Trial management and monitoring

The trial will be managed by the Trial Management Group consisting of TW, AR, JD and MSH. The trial combines the Trial Steering Committee and the Data Monitoring Committee functions in line with the nature of the trial, into the Acute Whiplash Injury Study (AWIS) Steering Group, consisting of TW, AR, MSH, JP, a WADII patient, an external member and an independent chair. The committee will meet at the start of recruitment, after 3 months of recruitment and at completion of data collection. The lead researcher (TW) has qualified for Good Clinical Practice (certificate number: 33951-36-41796).

Adverse events

Adverse events in this trial are considered as low risk. First, WADII (neck complaint and musculoskeletal sign(s)) is not normally a cause of serious adverse events.[11 65] Second, the ABPI and standard physiotherapy intervention are conservative treatments without existing reporting of serious adverse events.[11 65] As a result, patients are unlikely to receive any serious harm from either intervention. Generally, only minor adverse events are likely to occur after the physiotherapy intervention. The most common adverse events for the physiotherapy intervention are muscle soreness that commonly recovers within 1–2 days.[106]

Serious adverse events

This trial will have a very low risk of serious adverse events in terms of patient pathology, treatment nature and treatment management. Participants will be evaluated by a physiotherapist prior to seeking consent to ensure that the participants are classified as WADII (presented only musculoskeletal sign(s) without any neurological sign(s)) to meet the eligibility criteria, thereby excluding patients with high severity. All physiotherapists in this trial manage their patients based on the International Federation of Orthopaedic Manipulative Physical Therapists cervical framework[50] that provides a framework for clinical reasoning to avoid risk of any adverse events regarding the vascularity and instability of the neck from physical therapy intervention. However, progressive symptoms within 3 days and admitted in the hospital due to whiplash problems will be reported for serious adverse events. If any serious adverse events occur, the patients will be able to continue with the trial when their symptoms are resolved.

Procedures for reporting adverse and serious adverse events

An adverse event reporting form will be provided to all clinics. If a participant experiences any unpleasant symptoms, they will be asked to report them to their physiotherapist. The physiotherapist will report any event to the researcher (TW) within 24 hours. The researcher will report to the AWIS steering committee within 24 hours to enable analysis of the event and any required action. Although this trial may have low risk of adverse events, any sign(s) and/or symptom(s), which would cause life-threatening situations, inpatient hospitalisation and significant disability (eg, unable to work), may occur. Any unexpected serious adverse events will be immediately reported with a written form and verbal contact by physiotherapists to the researcher (TW). Then, the researcher will report to the AWIS steering committee immediately.

Research governance

The trial will maintain research governance by using the principles of the Research Governance Framework for Health and Social Care.

Data management

All information collected on and from the participants will be kept safely from any third party to maintain the participants' privacy. All collected documents will be stored in a secure place. All electronic data will also be confidentially stored in a password protected computer during the trial. Data can only be accessed by members

of the research team. The findings will be submitted for publication to medical journals and presented at conferences and local seminars. The trial will only be published in a completely unattributable format or at an aggregate level in order to ensure that no participant can be identified. After completing the trial, all data will be destroyed after being kept for 10 years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham.

R&D considerations

NHS ethical approval and R&D approval is not required as the trial sites are outside of the UK National Health Service. The insurance/private clinics do not require any other regulatory approval. Support for the trial is in place by the private clinics and the insurance companies.

DISCUSSION

Before designing and conducting an adequate powered, high-quality cluster RCT examining the ABPI for managing acute WADII, this pilot and feasibility trial is required. If the pilot and feasibility trial is successful (ie, the ABPI is found to be feasible), a future definitive trial will be implemented to compare the effectiveness of the ABPI and standard physiotherapy intervention, inclusive of cost-effectiveness analysis. If it is demonstrated that the ABPI is effective in managing patients with acute WADII, the ABPI will be a valuable intervention to prevent patients with acute WADII progressing to chronicity.

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Acute Whiplash Injury Study (AWIS): a protocol for a cluster randomised pilot and feasibility trial of an Active Behavioural Physiotherapy Intervention in an insurance private setting

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