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Acute whiplash injury study

Submission date
17/06/2015

Recruitment status
No longer recruiting

Registration date
18/06/2015

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Whiplash associated disorder (WAD) is a neck injury usually caused by a road traffic accident. More people are affected by whiplash each year and it can lead to pain and disability. Therefore, it is important for a physiotherapist to prevent the condition becoming chronic (i.e. persisting over a longer period) by using effective management in the acute stage (i.e. just after the injury occurs). The evidence so far suggests that a combination of active and behavioural treatment programme when the patient is still acute may be a useful strategy to manage WAD. We have developed an active behavioural physiotherapy treatment programme using international experts that we plan to use in a large clinical trial to see if it works. The aim of this study, therefore, is to evaluate procedures, feasibility and acceptability of the active behavioural physiotherapy treatment for acute WAD.

Who can participate?
Adults between 18-70 who have neck problems that were caused by a road traffic accident within the last four weeks. Their neck problems are classified as whiplash associated disorder (WAD) II.

What does the study involve?
There are two phases to this trial. In phase 1 (pilot and feasibility trial), six private physiotherapy clinics in West Midlands, UK are randomly allocated into one of two groups. Participants attending clinics in group 1 (control) are given standard physiotherapy treatments. Participants attending clinics in group 2 (intervention) are given the active behavioural physiotherapy intervention. This phase of the study tests the procedures used and feasibility of the intervention in managing acute WADII in preparation for a larger study. In phase 2, the acceptability of the developed intervention is explored. All physiotherapists in the intervention group are interviewed by a researcher to evaluate the acceptability of the active behavioural physiotherapy intervention for acute WADII management compared with standard physiotherapy. Around six to eight participants in the intervention group are invited to participate in a focus group to evaluate the acceptability of the active behavioural physiotherapy intervention to the patients.

What are the possible benefits and risks of participating?
Participants will receive physiotherapy treatment as part of this study. Some participants will receive current standard care and others will receive an active behavioural physiotherapy

treatment. We are interested in whether one treatment is better than the other to improve management of patients with WAD and to prevent chronic problems. If we can prevent chronic problems, patients can return to their quality of life, direct and indirect medical costs will be reduced. No serious adverse event has been reported in physiotherapy management for WADs.

Where is the study run from?
Six private physiotherapy clinics, West Midlands (UK)

When is the study starting and how long is it expected to run for?
October 2013 to December 2015

Who is funding the study?
The Royal Thai Government.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Acute Whiplash Injury Study (AWIS): a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Acronym
AWIS

Study objectives
To evaluate procedures, feasibility and acceptability of the active behavioural physiotherapy intervention in managing acute WADII within the UK insurance/private sector to inform the design of a future definitive (phase III) trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS ethical approval and R&D approval is not required as the trial sits outside of the UK national health system. The insurance / private clinics do not require any other regulatory approval. Support for the trial is in place by the insurance / private clinics and the insurance companies. Ethical approval will be obtained from the University of Birmingham's Ethics Committee.

Study design
A pilot and feasibility clinical trial of a prospective cluster randomised double blind parallel 2 arm design, with an embedded qualitative study to explore the acceptability of the developed intervention

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Whiplash associated disorder (WAD)

Interventions
1. Standard physiotherapy intervention:
Each participant will attend a physiotherapy session lasting for 30 minutes once a week. Patients with acute whiplash associated disorder II (WADII) will be managed using the recommendation from clinical whiplash guidelines. Physiotherapy interventions such as manual therapy, exercise therapy and physical agents including a home programme of exercises will be considered to manage WADII patients depending on the individual physiotherapist's clinical reasoning for the individual patient. The treating physiotherapists will select appropriate interventions based on examination findings and scientifically clinical reasoning. Physiotherapists in this treatment arm will be recalled regarding the current standard physiotherapy intervention which is comes from clinical guidelines. A day in June will be established for the recalled meeting prior to recruitment of participants.
2. Active behavioural physiotherapy intervention:
The specific detail of this intervention including the underlying principles and the components was developed by whiplash experts across the world in the previous study: "The development of an active behavioural physiotherapy intervention for acute WADII management" using a modified Delphi method. This study has been approved by the University of Birmingham's Ethical Committee (ERN_ 14-1339) before piloting, recruiting participants and implementing the modified Delphi study.

Intervention Type
Mixed

Primary outcome measure
Neck Disability Index (NDI)

Secondary outcome measures
1. Visual Analogue Scale (VAS) for pain intensity
2. Cervical Range of Motion (CROM)
3. Pressure Pain Threshold (PPT)
4. Impact of Events Scale (IES)
5. Fear Avoidance Beliefs Questionnaire (FABQ)
6. Quality of Life (EQ5D-5L)

Overall study start date
01/01/2015

Completion date
01/10/2016

Eligibility

Key inclusion criteria
Participants:
1. aged from 18 to 70 years old
2. presenting with WAD grade II from a road traffic accident within the previous four weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

Total final enrolment
28

Key exclusion criteria
1. Signs and symptoms of upper cervical instability or cervical artery dysfunction
2. Suspected serious spinal pathology
3. Open wounds
4. Active inflammatory arthritis
5. Tumours
6. Infection of the skin and soft tissue
7. Bleeding disorders or using anti-coagulant medication
8. 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
9. History of cervical surgery,previously symptomatic degenerative diseases of cervical spine within 6 months before road traffic accident
10. Previous history of whiplash or other neck pain
11. Alcohol abuse
12. Dementia
13. Serious mental diseases
14. Psychiatric diseases
15. Non-native English speaking

Date of first enrolment
06/11/2015

Date of final enrolment
02/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Junction 1 Fitness
High Street
West Bromwich
West Midlands
United Kingdom
B70 6JT

Study participating centre
Bannatyne's Health Club
3 Brunswick Arcade
Brindley Place
Birmingham
United Kingdom
B1 2JF

Study participating centre
Spirit Health Club (Holiday Inn Birmingham M6 Jct 7)
Chapel Lane
Great Barr
Birmingham
United Kingdom
B43 7BG

Study participating centre
Moseley
1 Salisbury Road
Moseley
Birmingham
United Kingdom
B13 8JS

Study participating centre
Bannatyne's Health Club
Princess Alice Drive
Sutton Coldfield
Birmingham
United Kingdom
B73 6RB

Study participating centre
Fitness First
Ulleries Road
Solihull
West Midlands
United Kingdom
B92 8DS

Sponsor information

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School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham

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B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology of Thailand under the Royal Thai Government

Results and Publications

Publication and dissemination plan
Planning to submit our protocol to a journal for protocol publication in July 2015. The target journal for protocol publication is BMJ Open. We also plan to submit in January 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/07/2016		Yes	No
Participant information sheet		08/04/2016	29/07/2016	No	Yes
Results article		09/05/2019	10/07/2023	Yes	No