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Choosing the most efficient and cost-effective treatment for acute whiplash associated disorders (WAD)

Submission date	Recruitment status	[ ] Prospectively registered
03/02/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/07/2009	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised three-group study, internet-based, face-to-face based and standard-management after acute whiplash associated disorders (WAD): choosing the most efficient and cost-effective treatment

Study objectives
The main purpose of this study is to try a new intervention strategy aimed to reduce the number of patients who have persistent problems after the whiplash injury. The goal is also to identify which of three different interventions that is most cost-effective for whiplash associated disorders (WAD) patients and the health care system. In this study we are controlling for two factors. First, the effect of behavioural medicine approach is evaluated. Second, the manner in which the treatment is administered, IT or face-to-face, is evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at Uppsala University, Uppsala, Sweden gave approval in May 2005 (ref: 01-229)

Study design
Randomised prospective experimental three-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute whiplash associated disorders

Interventions
Group 1: The new IT-based treatment (internet/e-mail) regimen for acute WAD patients, emphases self-monitoring and skills training, as well as discussions led by a therapist
Group 2: Face-to-face intervention involves groups of three to six patients led by therapists. The face-to-face program is planned to be similar to the IT-based treatment regimen described above, but differs in the way the treatment is administered.

Group 3: Standard care of these patients currently involves a visit to a physical therapist, which provides a home exercise program dealing with physical symptoms and advice of returning to normal activities as soon as possible. No further treatment is given except the home exercise program that all patients get at the emergency ward (standard care) before randomisation.

Both IT and face-to-face treatments:
Number of sessions: 7
Duration of sessions: 1 hour
Duration of treatment: about 7 - 9 weeks

Standard management:
1 hour only once.

Total duration of follow-up for all groups is 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Disability, measured with Pain Disability Index
2. Cost-effectiveness, evaluated with a cost-diary

Measured at pre-, post-treatment, 3, 6, 12, 24 months follow-ups.

Secondary outcome measures
1. The Patient Goal Priority Questionnaire (PGPQ)
2. Tampa Scale for Kinesiophopia
3. Pain Intensity Diary
4. Self-Efficacy Scale
5. Coping Strategies Questionnaire
6. 36-item short form health survey (SF-36)
7. Exercise diary

Measured at pre-, post-treatment, 3, 6, 12, 24 months follow-ups. QALYs are measured at 12 and 24 years follow-up.

Overall study start date
01/11/2006

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years, either sex
2. Satisfactory Swedish language skills
3. Fulfill criteria for the diagnosis of WAD grade I and II

4. Ongoing pain in the neck due to the accident
5. Access to a computer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180 participants

Key exclusion criteria
1. Prior neck injury
2. Other ongoing chronic pain problems
3. Ongoing treatment for pain or pain related symptoms

Date of first enrolment
01/11/2006

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Physiotherapy
Västerås
Sweden
S-72126

Sponsor information

Organisation
The Swedish Research Council (Sweden)

Sponsor details
Klarabergsviadukten 82
Stockholm
Sweden
S-10378

Sponsor type
Research council

Website
http://www.vr.se/

ROR
https://ror.org/03zttf063

Funder(s)

Funder type
Research council

Funder Name
The Swedish Research Council (Sweden)

Funder Name
Uppsala University (Sweden) - Faculty of Medicine

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/07/2009		Yes	No