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The effectiveness of manual therapy or pulsed shortwave diathermy (PSWD) in addition to exercise and advice for neck disorders; a pragmatic study in physiotherapy clinics

Submission date
15/07/2002

Recruitment status
No longer recruiting

Registration date
15/07/2002

Overall study status
Completed

Last Edited
05/01/2011

Condition category
Musculoskeletal Diseases

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

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
D0566

Study information

Scientific Title

Acronym
The PANTHER study

Study objectives
To determine whether manual therapy or pulsed shortwave diathermy (PSWD), in addition to advice and exercise, provide better clinical outcome at six months than advice and exercise alone in primary care patients with nonspecific neck disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was granted by the West Midlands Multicenter Research Ethics Committee and 10 local Research Ethics Committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non-specific neck pain

Interventions
1. Manual therapy: defined as hands-on, passive or active assisted movements/mobilisations, graded as appropriate to the patient's signs and symptoms
2. PSWD: delivered according to the best available evidence appropriate for UK clinical practice. It is not prescriptive but incorporates professional guidelines to good practice.
3. No additional treatment to advice and exercise

All subjects receive a standard package of home exercises, advice and an information leaflet about care of their neck based on the ARC publication. Further management of the patients in the no manual therapy/no PSWD group is based on this information.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in self-reported neck pain related disability at six months as measured on the Northwick Park Neck Pain Questionnaire.

Secondary outcome measures
1. Participants' global assessment of change compared with baseline
2. Average pain severity over the past three days
3. Severity rating of main problem
4. Number of days lost from paid employment
5. Co-interventions e.g. visits to general practitioner (GP), use of analgesia
6. Quality of life (EuroQoL EQ-5D) and 12-item short form health survey (SF-12)

Overall study start date
01/09/2000

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Males and females aged 18 years and over
2. Clinical diagnosis of neck pain and/or stiffness, including unilateral referred pain into the arm
3. No consultations for this problem with health care professionals other than the Primary Health Care Team in the previous six months
4. Ability to understand and to cooperate and capable of giving written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

350

Key exclusion criteria
1. Weight loss
2. Fever
3. Progressive neurological signs including bilateral arm pain
4. Evidence of muscle weakness or disturbance in normal sensation
5. History of malignancy
6. Inflammatory arthritis
7. Polymyalgia rheumatica
8. Osteoporosis or gross structural or neurological abnormality affecting the neck
9. Contra-indications to the study treatments (e.g. patients on anti-coagulants)
10. Any injury awaiting a compensation claim (e.g. deceleration or industrial injury)
11. Pregnancy

Date of first enrolment
01/09/2000

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Sciences Research Centre
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Gate
Chesterfield
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Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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?
Results article	Results	15/04/2005		Yes	No