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A comparison of conventional physiotherapy to physiotherapy and behavioural treatment for patients with chronic neck pain

Submission date
28/01/2011

Recruitment status
No longer recruiting

Registration date
14/03/2011

Overall study status
Completed

Last Edited
21/09/2015

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
08PHYSIO04

Study information

Scientific Title
Interactive behavioural modification therapy or a progressive neck exercise programme in patients with chronic neck pain: a randomised controlled trial

Study objectives
Adding interactive behavioural modification therapy (IBMT) to a progressive neck exercise programme (PNEP) will result in significantly larger reductions in levels of neck pain related disability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salford and Trafford Local Research Ethics Committee, 30/01/2008, ref: 07/H1004/218

Study design
Single-blind multicentre randomised controlled trial

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
Chronic non-specific neck pain

Interventions
The study will compare the efficacy of a progressive neck exercise programme (PNEP) in isolation to the same intervention in conjunction with interactive behavioural modification therapy (IBMT). The specific content of the interventions is described below.

Progressive Neck Exercise Programme:
Participants randomised to receive PNEP will receive reassurance and advice to increase their activity levels, but the use of specific IBMT techniques will be discouraged. Participants will also receive four, 30 minute sessions on a one-to-one basis with a physiotherapist experienced in the treatment of chronic neck pain. The treatment sessions will be delivered on consecutive weeks, over a four week period. Treatment will consist of progressive neck and upper limb

strengthening exercises and progressive neck stretching exercises. Rubber resistance band will be used to provide resistance for the strengthening exercises. The strength of the band will be progressed on subsequent treatment sessions.

Interactive Behavioural Modification Therapy:
Interactive behavioural modification therapy (IBMT) will consist of four group-based sessions, held on consecutive weeks, each lasting approximately two hours and is broadly based on an IBMT intervention shown to bring about changes in disability and cognitive factors in patients with chronic low back pain. The intervention will be delivered by physiotherapists who are experienced in delivering IBMT interventions to patients with chronic pain conditions. The primary aims of the programme will be to encourage self management of the participants' neck pain and to maximise function. The sessions will be interactive and will attempt to reduce pain-related fear and catastrophising and to enhance self-efficacy beliefs. Topics covered will include anatomy and common pathology of the spine, the chronic pain cycle, the role of thoughts, emotions and beliefs in pain and disability and returning to previously avoided activity. Participants will also complete the PNEP intervention described above, in a group environment. At the end of the first session, participants will be asked to set long term goals to work towards over the course of the programme and will set a functional goal at the end of each session to work towards over the coming week. Weekly goals will be reviewed at the beginning of each subsequent session, whilst long term goals will be reviewed at the final session. The aim of the goal setting approach is to return participants to activities they have ceased to engage in and to enhance their self-efficacy beliefs. Goals can be work related, exercise based, social or recreational. At the end of each session the participants will receive an educational pamphlet summarising the content of each session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Northwick Park Neck Pain Questionnaire (NPQ): the NPQ is a validated measure of neck pain and disability and consists of nine questions. Participants rate levels of pain and function on five point scales. Scores are then converted to a percentage. The NPQ will be completed prior to commencing treatment and again six months later. The primary measure for the trial will be the between group difference in six month change in NPQ score. The NPQ will be assessed pre and post treatment by means of a self-report postal questionnaire.

Primary and secondary outcome measures will be completed before the initial assessment and returned by postal questionnaire. At follow up they will be completed six months after completing the initial questionnaire.

Secondary outcome measures
1. Numeric pain rating scale (NPRS): The NPRS is an eleven point pain rating scale whereby participants highlight the number that best represents their current pain intensity. The scale will be anchored 0 = "no pain" and 10 = "worst possible pain"
2. Pain catastrophising scale (PCS): The PCS is a 13 item questionnaire, recording frequency catastrophic thoughts, with higher scores representing greater levels of catastrophising. Participants rate levels of agreement with 13 statements about levels of catastrophising on five point scales anchored "not at all" and "all the time"

3. Tampa Scale for Kinesiophobia (TSK): Pain-related fear was assessed by the TSK, a seven item questionnaire, with greater scores representing higher levels of pain-related fear. Participants rate levels of agreement with statements relating to pain-related fear on four point scales anchored "strongly agree" and "strongly disagree"
4. Chronic Pain Self-Efficacy Scale - Physical Function Sub Scale (CPSS-pf): The CPSS-pf is one of the sub-scales of the CPSS, a self report measure which assesses participants' confidence in performing physical tasks. Higher scores on the CPSS-pf represent greater confidence in performing physical tasks. Scales were scored from 0 - 8 and anchored 0 = "totally unconfident" and 8 = "totally confident"
5. Pain Vigilance and Awareness Questionnaire (PVAQ): Vigilance and awareness to painful sensations was measured by the PVAQ, a 16 item measure, where participants rate levels of agreement with statement regarding pain vigilance and awareness on six point scales. Scales are anchored 0 = "strongly disagree" and 5 = "strongly agree". Higher scores represent greater vigilance and awareness to pain
6. Global Assessment of Change: patients' global assessment of change will be measured by a five point scale assessing improvement in neck pain. The scale will be anchored "much better" and "much worse"
7. Patient satisfaction: patient satisfaction will be measured with a five point scale, anchored "very satisfied" and "very dissatisfied"

Primary and secondary outcome measures will be completed before the initial assessment and returned by postal questionnaire. At follow up they will be completed six months after completing the initial questionnaire.

Overall study start date
01/03/2008

Completion date
26/02/2011

Eligibility

Key inclusion criteria
1. Patients aged 16 years and over (no uppper age limit, either sex)
2. Have experienced non-specific neck pain for at least three months
3. Recruited from patients referred to the physiotherapy departments of three hospital physiotherapy departments and one primary care centre in the Greater Manchester region of the United Kingdom. Referrals will be from both primary and secondary care.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
28 participants per group (total: 56 participants)

Key exclusion criteria
1. Unable to speak or write English
2. Identified or suspected radiculopathy, inflammatory disorder, chronic fatigue syndrome /myalgic encephalitis, fibromyalgia or other suspected serious pathology (cervical fracture or dislocation, carcinoma or spinal infection)
3. Diagnosed with serious psychiatric disorder (e.g. bipolar disorder, schizophrenia or dementia)

Date of first enrolment
01/03/2008

Date of final enrolment
26/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Manchester General Hospital
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Sponsor information

Organisation
Pennine Acute Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.pat.nhs.uk/PortalVBVS/Default.aspx

ROR
https://ror.org/05ga8m074

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pennine Acute Hospitals NHS Trust (UK) - Research and Development Department (ref: 08PHYSIO4)

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	01/06/2016		Yes	No