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Group-based multimodal exercises for chronic neck pain

Submission date
06/12/2015

Recruitment status
No longer recruiting

Registration date
16/12/2015

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Neck pain is a very common problem which affects more than two thirds of people at some point in their lives. Non-specific chronic neck pain is where the sufferer has been affected for at least 3 months, and no obvious cause can be identified. It has been found that in people suffering from chronic neck pain, sufferers often avoid movement for fear that it will make the pain worse (kinesiophobia). Studies have shown that when a person with a long-term pain condition is suffering from kinesiophobia, they are likely to experience disability to a greater extent, as lack of movement can make their condition worse. Cognitive behavioural therapy (CBT) is a type of taking therapy which aims to help people to manage their problems by changing the way they think and behave. The aim of this study is to find out taking part in a programme combining CBT with specific exercises designed for people suffering from chronic neck pain can help to reduce pain and disability in the short- and long-term, compared to exercises alone.

Who can participate?
Adults suffering from non-specific chronic neck pain.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group take part in a 10 week course with two experienced physiotherapists involving a range of different exercises designed to help reduce pain and increase range of movement in the neck. Participants in this group also receive 10 hour-long sessions of CBT with a trained psychologist, aiming to help to reduce their fear of movement. Participants in the second group take part in a 10 week course of general physiotherapy for the neck, involving muscle strengthening, stretching exercises and gentle movements designed to help the range of movement in the spine (spinal mobilization). These sessions last for one-hour and are delivered to groups of 5 patients at a time by two experienced physiotherapists. At the start of the study, after the 10-week exercise programme and 12 months later, participants in both groups complete a number of questionnaires to find out if there has been any change to their pain levels, or neck pain-related disability.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their pain levels and disability as a result of

taking part in the exercise programs. Additionally, participants may benefit from an improvement to their overall quality of life. There are no notable risks expected for those taking part in the study.

Where is the study run from?
Institute Of Hospitalization and Care Scientific (Italy)

When is the study starting and how long is it expected to run for?
January 2010 to December 2013

Who is funding the study?
Institute Of Hospitalization and Care Scientific (Italy)

Who is the main contact?
Dr Marco Monticone

Contact information

Type(s)
Scientific

Contact name
Dr Marco Monticone

Contact details
Istituto Di Ricovero e Cura a Carattere Scientifico
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Additional identifiers

Study information

Scientific Title
Group-based multimodal exercises integrated with cognitive-behavioural therapy improve disability, pain and quality of life of subjects with chronic neck pain: A randomized controlled trial with one-year follow-up

Study objectives
A 10-week rehabilitation programme of group-based multimodal exercises integrated with CBT mainly aimed at managing fear of movement would induce clinically significant improvements in disability, pain, and quality of life in subjects with chronic neck pain vs. group-based general physiotherapy, and that these would be maintained in the long term.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional Review Board of the Scientific Institute of Lissone of the Salvatore Maugeri Foundation, 03/12/2009, ref: 8

Primary study design
Interventional

Study design
Randomized parallel-group superiority-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic neck pain

Interventions
Participants are randomly allocated to one of two groups.

Experimental Group: Participants complete 10 hour-long group-based multimodal exercises for the neck, including cervical mobility, postural control, strengthening muscles, and stretching the neck in groups of 5. Patients specifically learn stabilizing techniques for deep neck muscles, progressively increasing the speed and complexity of the movements. Participants in this group also receive 10 hour-long sessions with a trained psychologist, in which they receive cognitive behavioural therapy (aimed at modifying fear of movement beliefs, and ensuring gradual reactions to illness behaviours) in groups of 5.

Control Group: Participants complete 10 hour-long group-based general physiotherapy for the neck, involving muscle strengthening, segmentary stretching and spinal mobilisation, in groups of 5 patients.

Interventions are delivered by a psychologist and two equally-experienced physiotherapists, separately responsible for the experimental and the control group. The exercise programme is planned individually by the physiotherapists based on a physical examination of each participant, consisting of postural observation, cervical range of motion examination, manual muscle testing, muscle length assessment, deep neck flexors endurance examination. Ergonomic advice is provided during the first session in order to facilitate the modification of daily living activities. A fidelity check, based on a treatment manual for exercise administration, is also conducted at the end of each session.

In both groups, during the treatment period, the questionnaires are administered by secretaries who checked them and returned any uncompleted part to the patients for completion. At follow-up, the patients are asked to return to the Institute or are contacted by phone by the same secretaries in order to repeat the questionnaires.

Intervention Type
Other

Primary outcome(s)
Extent of neck-pain related disability is measured using the Neck Disability Index (NDI) at baseline, 10 weeks and 12 months.

Key secondary outcome(s)
1. Fear of movement is measured using the Tampa Scale for Kinesiophobia at baseline, 10 weeks and 12 months
2. Pain is measured using the Pain Catastrophizing Scale and Pain Numerical Rating Scale at baseline, 10 weeks and 12 months
3. Health outcomes are measured using the Short-Form Health Survey at baseline, 10 weeks and 12 months

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. A diagnosis of non-specific chronic neck pain (i.e. a documented history of pain lasting more than 3 months
3. A good understanding of Italian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Acute and subacute neck pain
2. Cognitive impairment
3. All causes of specific neck pain such as previous spinal surgery, deformity, disc herniation, infection, fracture, myelopathy or malignancy, whiplash injuries, and systemic or neuromuscular diseases
4. Previously received cognitive behavioural therapy

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Italy

Study participating centre
Istituto Di Ricovero e Cura a Carattere Scientifico
Physical Medicine and Rehabilitation Unit
Scientific Institute of Lissone
Salvatore Maugeri Foundation
Institute of Care and Research
Via Monsignor Bernasconi 16
Lissone
Italy
20851

Sponsor information

Organisation
Istituto Di Ricovero e Cura a Carattere Scientifico

ROR
https://ror.org/04tfzc498

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institute Of Hospitalization and Care Scientific (Istituto Di Ricovero e Cura a Carattere Scientifico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017	29/01/2019	Yes	No