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Effects of Multimodal Exercises Integrated With Cognitive-behavioral Therapy in Subjects With Chronic Neck Pain: a Randomized Controlled Study With One Year Follow-up

NCT ID not yet assigned

STUDY PROTOCOL

1. Background

The etiology of neck pain is multifactorial and includes age, sex, poor postures, repeated strains (1). Studies based on the bio-psychosocial model also link chronic neck pain to psychological factors. Among these, kinesiophobia has been reported as an significant factor (2,3). It is debatable whether interventions targeting cognitive processes and pain-associated behaviors can lead to clinically significant changes in terms of disability, pain and quality of life (4). Furthermore, there is uncertainty about the effectiveness of different types of exercises that can be proposed. This makes it difficult to choose between general exercises (aimed at improving cervical muscle and joint skills) and motor-oriented (or task-oriented) exercises (aimed at cervical functional recovery in an ecological context) (5). Over time, the use of multidisciplinary interventions for chronic vertebral pain (instead of segmental treatments) has grown in order to improve disability, pain and proactive behaviors towards the presented problem (6-9).

A recent review of the literature found that the rehabilitation treatment of neck pain with a cognitive-behavioral approach induces changes (in terms of short-term pain relief) compared with no treatment; however, these effects were not clinically significant (10).

In a randomized clinical trial authors evaluated the effectiveness of a multidisciplinary intervention compared to a short intervention, with the purpose of evaluating return to work, after one year, in subjects with neck and shoulder pain/disability; however, the results did not show significant differences between the two groups (11).

In a recent review of the literature the importance of multidisciplinary interventions also emerged for people in the workplace in order to improve pain, disability, thoughts and wrong behaviors (12).

Given these premises, it appears necessary to conduct studies aimed at evaluating the effectiveness of a multidisciplinary rehabilitation program that integrates cognitive-behavioral therapy focused on kinesiophobia with specific exercises in the treatment of workers with chronic neck pain.

2. Hypothesis

The hypothesis is that a multidisciplinary rehabilitation program induces clinically significant and long-term improvements in the disability, pain and quality of life of workers with chronic neck pain and that these would be maintained in the long term.

3. Objectives of the study

Primary objective: to verify the efficacy of a multidisciplinary program in inducing clinically meaningful and long-term improvements through changes in scores in disability assessment scales (Neck Disability Index, Tampa scale of Kinesiophobia, Pain Catastrophising Scale), in pain (Numeric Rating Scale) and in the quality of life (Short Form-36 Health Survey) of workers suffering from chronic neck pain.

Secondary objective: to evaluate changes in work discomfort (Work Ability Index, Anamnestic survey of the upper limbs and spine's pathologies) linked to the condition of chronic neck pain.

4. Methods

A randomized, parallel-group superiority-controlled trial will be conducted in a secondary care rehabilitation hospital and approved by the hospital's Institutional Review Board (ID: PG/2020/16818; date of approval: 30 september 2020).

a) Participants

The inclusion criteria will be a diagnosis of non-specific chronic neck pain (i.e. a documented history of pain lasting >3months), a good understanding of Italian and an age of >18years.

The exclusion criteria will be acute and subacute neck pain, cognitive impairment and all causes of specific neck pain (i.e. previous spinal surgery, deformity, disc herniation, infection, fracture, myelopathy or malignancy, whiplash injuries, and systemic or neuromuscular diseases) ruled out by means of case histories and imaging. Any subjects who had previously received cognitive-behavioural therapy will be also excluded.

Outpatients visiting the hospital between September 2020 and December 2021 will be evaluated by two physiatrists coordinated by the principal investigator. Those who meet the inclusion criteria will be asked to declare their willingness to comply with any treatment option, to which they will be randomly assigned. Once the patient gave their consent, the biostatistician will randomize the subject to one of the two treatment programmes using a permuted-block randomization procedure. The list of treatment codes will be previously generated and stored in Matlab and an automatic assignment system, also developed in Matlab, will be used to conceal the allocation. The principal investigator obtaining and assessing the data and the biostatistician making the analyses will be blinded to treatment allocation. The physiotherapists, the psychologist and the patients will not be blinded.

b) Interventional programmes

Interventions will be delivered by a psychologist and two equally experienced physiotherapists, separately responsible for the multidisciplinary and the general exercise group. Each participant will be evaluated individually by means of postural observation, cervical range of motion examination, manual muscle testing. Based on this evaluation, the exercises will be planned and carried out for each patient. Given that the Italian National System allows for 10 rehabilitative sessions for outpatients and owing to the complex nature of chronic complaints, the physiotherapists will arrange one 60-minute session of physical training per week for ten weeks and will ask the patients to repeat the exercises at home. The multidisciplinary group will meet with the psychologist once a week for a 60-minute session as described below. Thus, the multidisciplinary programme will last for a total of 20 hours, while the general exercise programme will last for 10 hours.

c) Multidisciplinary group

Multimodal exercises will be first introduced to improve, by means of graded exposure, cervical mobility, postural control, strengthening muscles and stretching the neck. Patients will learn stabilizing techniques for neck deep muscles, progressively increasing the speed and complexity of the movements. Subsequently, task-oriented exercises while maintaining spinal deep muscle activation will be introduced. Under the supervision of the psychologist, subjects will also be involved in group-based cognitive-behavioural therapy aimed at

modifying fear of movement and maladaptive illness behaviour. The situations to handle will be identified on the basis of the fear-avoidance beliefs emerging from the group discussion of the activities more frequently reported, the administered questionnaires and the presentation of images showing neckstressing activities.

d) General exercise group

General physiotherapy will include exercises for muscle strengthening, regional stretching and spinal mobilization.

e) Both groups

Ergonomic advice was provided by means of a booklet given to the participants during the first session in order to facilitate the modification of daily living activities. At the end of treatment, patients were asked to continue with the exercises at home. A fidelity check, based on a manual including the complete list of exercises to be delivered, will be conducted at the end of each session to verify that all of the planned exercises will be actually performed.

No other treatments (e.g. physical modalities, nerve blocks, pharmacological agents) will be offered. Family doctors will be asked to avoid referrals for other treatments while the participants will be undergoing the programmes.

f) Type of data collected

- Demographic, anthropometric and clinical characteristics of the participants
- Disability (primary outcome): assessed using the validated Italian version of the self-reported 10-item Neck Disability Index (13).
- Kinesiophobia: assessed using the validated Italian 13-item version of the self-report Tampa Scale for Kinesiophobia (14).
- Catastrophizing: evaluated by means of the 13-item validated Italian version of the selfreported Pain Catastrophizing Scale (15).
- Pain intensity: assessed using an 11-point numerical rating scale (16).
- Quality of life was assessed using the Italian version of the self-report Short-Form Health Survey (17,18).
- Work ability: assessed using Work Ability Index (19).

- Anamnestic and clinical evaluation of the pathologies affecting the upper limbs and spine (20).

The questionnaires will be completed before treatment, ten weeks later (posttraining), and 12months after the end of treatment (follow-up). At the end of treatment, the subjects will be also asked to rate the effectiveness of the treatment using the 5-point Likert Global Perceived Effect scale (21). Using a specific form, patients were asked to report any symptoms they experienced during the study that required further treatment.

5. Sample size and statistical analysis

The sample size will be computed using the Italian Neck Disability Index, for which it will be estimated that a between-group difference of 7 points should be considered as clinically important (22). In order to assure 80% statistical power and 5% type I error, and considering a standard deviation of 15.4 points, 154 patients will be required, but 170 will be recruited to allow for a drop-out rate of 10%. The differences between the two groups relating to measures with non-normal distribution will be analyzed by Mann-Whitney U test. The null hypothesis will be rejected for p values> 0.05 (two-tailed test).

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