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Original article

Does a combination of physical training, specific exercises and pain education improve health-related quality of life in patients with chronic neck pain? A randomised control trial with a 4-month follow up

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ABSTRACT

Aim: To investigate the effect of combining pain education, specific exercises and graded physical activity training (exercise) compared with pain education alone (control) on physical health-related quality of life (HR-QoL) in chronic neck pain patients.
Methods: A multicentre randomised controlled trial of 200 neck pain patients receiving pain education. The exercise group received additional exercises for neck/shoulder, balance and oculomotor function, plus graded physical activity training. Patient-reported outcome measures (Short Form-36 Physical and Mental component summary scores, EuroQol-5D, Beck Depression Inventory-II, Neck Disability Index, Pain Bothersomeness, Patient-Specific Functioning Scale, Tampa Scale of Kinesiophobia, Global Perceived Effect) and clinical tests (Aastrand Physical Fitness, cervical Range of Motion, Pressure Pain Threshold at infraspinatus, tibialis anterior and cervical spine, Cranio-cervical Flexion, Cervical Extension muscle function, and oculomotion) were recorded at baseline and after 4 months.
Results: The exercise group showed statistically significant improvement in physical HR-QoL, mental HR-QoL, depression, cervical pressure pain threshold, cervical extension movement, muscle function, and oculomotion. Per protocol analyses confirmed these results with additional significant improvements in the exercise group compared with controls.
Conclusions: This multimodal intervention may be an effective intervention for chronic neck pain patients.
Trial registration: The trial was registered on www.ClinicalTrials.gov NCT01431261 and at the Regional Scientific Ethics Committee of Southern Denmark S-20100069.

1. Introduction

Neck pain is a global health disorder affecting both individuals and society (Lidgren, 2009), ranking 4th in Years Lived with Disability (Hoy et al., 2014). The 12-month prevalence of neck pain is 30%–50% and activity-limiting prevalence is 11% (Hogg-Johnson et al., 2008). Chronic neck pain may include physical dysfunctions, such as decreased cervical mobility (Williamson et al., 2014) and neuromuscular dysfunctions (Falla et al., 2012), and psychological features, such as distress (Carroll et al., 2008), depression (Shahidi et al., 2015), fear avoidance (Sterling et al., 2011) and reduced health-related quality of life (HR-QoL) (Yalcinkaya et al., 2014). Intervention studies of chronic neck pain patients have focused on these aspects using specific (neck) exercises and pain education or a

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combination of these as treatment. In general, reviews regarding the management of chronic neck pain patients reveal some effect of active physiotherapy or multimodal management (Seferiadis et al., 2004; Damgaard et al., 2013).

There is also some evidence regarding the effect of single modalities for chronic neck pain patients. Specific neck exercises have been shown to improve pain and function (Jull et al., 2007; Falla et al., 2013; Ludvigsson et al., 2015) in this patient group. Recent reviews also support this in addition to improved strength and HR-QoL after neck exercises (Gross et al., 2015; O'Riordan et al., 2014). In general, chronic pain patients are at higher risk of being physically inactive with increased risk of associated lifestyle diseases (Mannerkorpi et al., 2008), so, it could be assumed, this applies also to chronic neck pain patients. Graded physical activity training has been shown to be effective for physical work capacity and psychological variables in chronic fatigue patients (Wallman et al., 2004), but in neck pain patients, this effect has not yet been studied (McLean et al., 2013). There seems to be some evidence for pain education combined with other modalities for chronic neck pain patients (Geneen et al., 2015; Gross et al., 2015).

In summary, previous studies have included a variety of modalities in multimodal approaches for chronic neck pain patients, but the effect of specific exercises combined with graded physical activity training in addition to pain education on HR-Qol is unknown. Therefore, the aim was to test the effect of a multimodal intervention on physical HR-QoL in patients with chronic neck pain, hypothesising that a combination of these modalities would be superior to pain education alone.

2. Methods

2.1. Design

The study was a randomised (1:1) controlled superiority multicentre trial, stratified by recruitment place and onset (traumatic/non-traumatic), with a 2-group parallel design, conducted in Denmark. Patients were randomised to either pain education (control group) or pain education combined with exercises and training (exercise group). The primary endpoint was the Physical Component Summary Score of the Short Form Health Survey (SF36-PCS) measured 4 months after baseline.

2.2. Population, settings

Eligible patients were minimum aged 18 years with: minimum of 6 months of neck pain; reduced neck function (Neck Disability Index > 10); completed diagnostic procedures (e.g. medical investigations); and the neck region as the primary pain area. Exclusion criteria were: clinically confirmed radiculopathies (Rubinstein et al., 2007); progressive medical treatment; unstable social/working conditions; pregnancy; known current fractures; Beck Depression Inventory-II score > 29; or conditions limiting participation.

Participants were recruited via the participating clinics/centres, by their treating physiotherapist or at their first contact with the clinic. The study involved both primary and secondary health care. The interventions were performed at the site of patient recruitment.

Because of recruitment difficulties, the initial inclusion criteria were adjusted (Hansen et al., 2011), to include both traumatic and non-traumatic neck pain patients. The change was registered on www.ClinicalTrials.gov NCT01431261 and at the Regional Scientific Ethics Committee of Southern Denmark S-20100069. Differences between traumatic and non-traumatic neck pain patients at baseline are presented in a separate paper (in submission). Due to insufficient reproducibility, the Joint Position Error test was removed from the test protocol (Jorgensen et al., 2014).

2.3. Interventions

All participants participated in 4 sessions (1½ hours each, once per month) of pain management focusing on understanding/acceptance of pain, goal setting, and participation in social- and work-related contexts based upon a cognitive concept (Linton, 2005; Brage et al., 2015). The exercise group received additional 8 sessions of 30 min instruction in exercises and physical training. The progressive exercises were individually tailored with a focus on: 1) neck flexor and extensor function, 2) standing balance, oculomotor training and neuromuscular function of the shoulder girdle (Jull et al., 2008a,b). Graded physical training was modified from a programme for patients with chronic fatigue (Wallman et al., 2005). This contained a self-chosen physical activity programme, e.g. walking or cycling, with the starting level of training duration set to 20% below the patient's indication of capability, increasing the time factor every second week by 20%. The training aimed at a rated perceived exertion level of 11–14 on a 6–20 Borg scale (Borg, 1990). Patients were instructed to perform the exercises twice daily and physical training 3 times a week (O'Riordan et al., 2014) for 4 months.

2.4. Outcomes

The primary outcome was change in SF36-PCS from baseline to the 4-month follow-up (Bjorner et al., 1998). Secondary outcomes (self-reported outcomes and clinical tests) were used to interpret the primary outcome results. The analyses of these outcomes were added for explorative or hypotheses-generating purposes (The European Agency for the Evaluation of Medicinal Products (2002)).

Self-reported outcomes measured HR-QoL using SF36-PCS and Mental Component Summary of the Short Form Health Survey (SF36-MCS) (Bjorner et al., 1998) and EuroQol-5D (EQ-5D) (Wittrup-Jensen et al., 2002), in addition to measuring neck pain and function with the Neck Disability Index (NDI) (Vernon and Mior, 1991). The Beck Depression Inventory-II (BDI-II) was used for measuring depression (Beck et al., 1961). Perceived impact of pain on daily life was measured with Pain Bothersomeness (PB) (Stewart et al., 2007), and perceived functioning level was measured by 3 patient-specific items on the Patient-Specific Functional Scale (PSFS) (Westaway et al., 1998). Tampa Scale of Kinesiophobia (TSK) (Cleland et al., 2008; Jorgensen et al., 2015) was used to examine fear of movement, injury or re-injury.

Clinical outcomes were physical fitness, to test for change in fitness after a graded physical activity programme, tested with Aastrand's one point submaximal cycle test (Smeets and Soest, 2009), and cervical range of motion (ROM) of flexion, extension and side bending using an inclinometer (Williams et al., 2010). Cervical rotation was tested with a semi-circular goniometer. Pressure pain threshold (PPT) was tested bilaterally using an algometer (Wagner, FPX algometer, USA) on anterior tibialis, infraspinatus and C5/6 level (Walton et al., 2014). The deep cervical flexors were tested with the cranio-cervical flexion test (CCFT) (Jull et al., 2008a,b), where the scores were merged into 3 categories: 22, 24 and 26+, due to few data in the categories of 28 and 30. The cervical extensor test (CE) was used to test the function of cervical extensor during isometric neck extension, grouping results in 4 levels (0–10 s: poor; 11–38 s: moderate; 39–119 s: good; 120 s: excellent). Oculomotor function was tested with gaze stability (GS), testing the ability to keep the gaze fixed, while moving the head; and the eye movement test (EMT), testing