

STUDY PROTOCOL

Detection and Management of Chronic Neck Pain Effects During Rehabilitation with the Application of Nursing Advisory Support

[Prot.Number:11682/18.3.11]

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Abstract

Background: In the general population 30–50% of adults will experience musculoskeletal neck pain in any given year. The traditional pathoanatomical (biomedical) approach to the diagnosis of neck pain disorders is widely acknowledged as inadequate. Psychosocial factors have been reported associated with increased risk for more disabling chronic neck pain.

Objective: The objective of this article is to present the design of a qualitative study in combination with a quantitative pretest posttest-control group design study. The aim of the described research is the construction and performance of a new, valid tool in the form of questionnaire, in order health professionals to administrate emotional reactions of patients suffering from chronic neck pain, the effectiveness of which will be explored in conjunction with the implementation of a specific treatment program and simultaneously, conducting advisory support.

Methods: A qualitative study using semi structured interviews will be conducted in 6 patients with CNP. The results of the interviews will arise a reservoir of questions available for the new questionnaire- tool for managing patients' emotional reactions. Validity and reliability of the questionnaire will be reassured checking conceptual validity, content validity and structural validity with the use of exploratory factor analyses and confirmatory factor analyses. Then, 30 participants will be separated in two groups: a) the control group where patients will follow the therapeutic exercise program without parallel counseling, b) the experimental group where participants will follow along therapeutic exercise program plus counseling.

Outcome measurement: Inclusion and exclusion variables, demographic variables, duration of neck pain, specific complaint characteristics, smoking, the McGill Pain Questionnaire, the Neck Disability Index, the Fear Avoidance Belief Questionnaire, the SF-36 Health Survey, the new questionnaire of this study, neck goniometry measurements will be the standardized outcome measures.

Keywords: biopsychosocial chronic neck pain, rehabilitation, multidisciplinary approach, musculoskeletal neck pain

Introduction

Background

Chronic neck pain (CNP) is one of the most serious and most common musculoskeletal disorders that appear in the general population and especially in developed countries, causing significant impact on both public health, and cost of hospitalization (Ferrari and Russel, 2003). Millions of people worldwide are affected by the consequences of chronic neck pain experience (Cote et al., 2004; Hogg-Jonson et al., 2008).

The traditional pathoanatomical- biomedical approach to the diagnosis of CNP disorders is widely known during the past decades. However, is well recognized that for the vast majority of the patients no pathology can be imaged which can reliably account for symptoms (Jull and Sterling, 2009). In our days, there is no agreement about the multidimensional nature of chronic back and neck pain, because chronic pain by its own is so complex. A modern approach to chronic pain includes a combination of therapies: drug therapies, psychological therapies, rehabilitative therapies, anesthesiological therapies, neurostimulatory therapies, surgical therapies and lifestyle changes, as well as complementary and alternative medicine (Dureja, 2006; Pool et al, 2010).

Available evidence

Researchers described a conceptualization of illness, in which symptoms were considered to be the result of a dynamic interaction between psychological, social and pathophysiological variables (Moradi et al, 2012).

Biopsychological pain disorders are, by definition, those disorders having three dimensions: biological, psychological and social (Disorbio et al, 2006). The biopsychosocial model was introduced as a diagnostic and management paradigm to recognize correctly the multidimensional nature of pain (Jull and Sterling, 2009). Evaluating a chronic pain condition such as CNP from one-dimensional perspective is limiting and often fails to explain the patients' symptoms.

Medical approach

In the treatment of CNP the medical team traditionally focuses on assessment of a physical base for the pain which composed from clinical examination, diagnosis, treatment and evaluation of the treatment. However, even when medications and invasive procedures effectively reduce pain, they often do not produce concomitant improvements in physical and emotional functioning (Turk et al, 2008). After patients receive appropriate treatment, because chronic pain is incurable, they are left to manage their residual symptoms on their own (Osborne et al, 2006)

Psychological approach

Psychological factors in CNP include the affective components of pain: depression, anxiety and anger. The above symptoms can lead to decreased energy and no motivation to participate in rehabilitative process (Adams et al, 2006). Physiologically, anxiety and distress may maintain autonomic arousal with consequent physical symptoms than arising (Osborne et al, 2006).

Social approach

The social variables are influence the pain experience at the individual level, because there is evidence that classical and operant conditioning processes can lead to pain behaviors and experiences being learned through interactions with the environment (Nicholas, 2008). Social factors include social learning factors, sources of inadvertent reinforcement of pain, current or resent stressors and compensation or litigation (Victor & Richeimer, 2003)

There are four components that comprise pain management treatment from a psychosocial perspective. These interrelated components are:

- 1) Patient education. The goal of patient education is to reestablish a sense of self-efficacy in a demoralized patient (Disorbio et al 2006; Turk et al, 2008).
- 2) Cognitive-behavioral therapy. This therapy combines cognitive techniques such as cognitive restricting and thought stopping, with behavioral techniques such as role playing and homework assignments (Turner

et al, 1982; Moorey, 1996; Lintin et al, 2005; Merlijn et al, 2005; Kroner et al, 2009).

3) Relaxation training and biofeedback. The goals of relaxation training include reduction of maladaptive neuromuscular behaviors. Whereas, biofeedback refers to the instrumentation that can be used in conjunction with relaxation training (Kelly, 1994; Dureja, 2006; Turk et al, 2008).

4) Active adaptation focuses on aspects of the patients' environment or lifestyle that have the potential to support or not rehabilitative process (Kelly, 1994; Bergmans, 2007; Nicholas, 2008).

Why a design article

The design of a research should be carefully examined before adopting its conclusions. Because a biased study design can produce incorrect conclusions (Moore, 2001).

A design article allows to examine the design objectively without being influenced by the study results, to check any resulting articles for protocol deviations, and may also reduce the temptation to search for associations during data analysis rather than presenting hypotheses in advance (Godlee, 2001).

Further, a published protocol informs others about which studies are in process thus reducing duplication of research effort (Godlee, 2001).

Finally, a design article prevents publication bias in the case that future articles are not published, because study results can be retrieved from the author and the study can therefore still be included in future reviews (Ostelo et al, 2002).

Aim

The main objective of this study is the construction and performance of a new, valid tool in the form of questionnaire in order health professionals to administrate emotional reactions of patients suffering from chronic neck pain, the effectiveness of which will be explored in conjunction with the implementation of a specific treatment program and simultaneously, conducting advisory support which will result from the completion of the questionnaire.

Methodology

Sample

Entry Criteria

Symptoms may be referred to the shoulder or upper end, without radicular origin. Patients should be diagnosed with cervical pain and duration of symptoms at least 3 months prior to conducting the initial assessment. The age of patients should be 18-70 years old and should become from both sexes. Voluntarily entrance on the research and understanding of the Greek language will be necessary. Patients will verbally assure that they will complete the process.

Exclusion criteria

The investigation will exclude patients who are seriously injured and in general in any medical condition that would contraindicate exercise. Patients with tumor, infection, inflammatory rheumatic disease, neurological disease, severe psychiatric illness and pregnancy will be excluded. Inflammatory conditions, such as nerve root pressure, tendonitis or bursitis in the shoulder will be also exclusion criteria.

1st stage of the research

Phenomenology

The approach to patients suffering from chronic neck pain will be through the phenomenological study, which is used to form peoples' perceptions in life experiences (Bowling, 2002; Sahini-Kardasi, 2000). Phenomenology is defined as "the direct investigation and description of phenomena as experienced in consciousness, without theories regarding the causal explanation and with the greatest possible freedom from prejudices that have not been addressed by existing cases» (Spiegelberg, 1981; Balls, 2009).

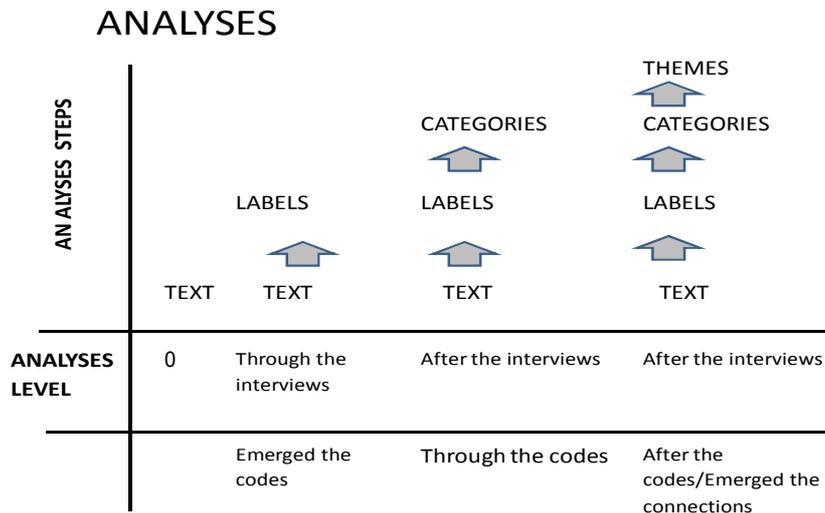
Semi structured interview

Researchers of this study will use the semi-structured interview. In this way, all participants will be asked the same structured questions, but as these questions will be open every participant can show different responses to the content (Amstrong et al., 1990). With the semi-structured interview the interviewer is likely to obtain data with

ripe content and close to the subject. The researcher can, simultaneously, observe reactions, facial expressions, and body language, which are important for the

development of the research (Burhard & Morrison, 199). The analyses of the interviews made according to Table 1.

Table 1: Analyses of the semi structured interview results



Main questionnaire – The research tool

A reservoir of questions will be constructed after the qualitative analyses of the interviews’ results. To create the initial questionnaire a team of experts will select questions that will be tested about the content relevance, the clarity, the understanding and the phraseology.

Testing validity and reliability of the questionnaire checking conceptual validity - content validity of the questionnaire.

Initially, four evaluators-judges: a psychiatrist, a nurse, a psychologist and a physiotherapist will assess the relevance of the questionnaire content on the evaluation of CNP. The evaluators will be informed regarding the construction of the questionnaire and will be asked to assess the suitability (acceptance, delete, modify) of the questions in order to measure psychometric characteristics of the neck pain.

Then twenty patients will complete the questionnaire and the researchers will collect their responses in order to evaluate the validity of the content, the clarity, the understanding and the relevance of the questions. Also, participants will be asked to

categorize the questions according to assessment factors for CNP. Participants will evaluate the level that the questionnaire assesses the measured characteristics, according to a five-point scale where number 1 corresponds to the expression “low identification”, number 2 to “moderate identity”, number 3 to “good match”, number 4 to “very good match” and number 5 to the expression “great match”. The content validity index of “Aiken's item content validity coefficient” will be measured to evaluate the responses of the participants.

Checking structural validity and reliability of the questionnaire exploratory factor analyses

In the second study, the questionnaire will be administered to one hundred fifty (150) patients. This study will examine the construct validity of the questionnaire through the exploratory factor analysis and the reliability of the measurement instrument. Preliminary tests would include: a) Balle's test of sphericity for checking the independence between the variables and their suitability for factor analysis and b) Kaiser-

Meyer-Olkin measure of sampling adequacy for checking the adequacy of the sample (Kaizer, 1974).

The method of factor analysis was chosen to examine the construct validity of the instrument. The number of factors determined according the analysis of the main components in oblique and varimax rotation axes. The exploratory factor analysis determines the exact number of factors that will be drawn from the analysis (Kline, 1994). Both the varimax rotation and the oblique rotation ($\delta = 0$) of the axes will determine the interrelationships of factors and the degree of their association (Browne, 2001; Carmines & Zeller, 1979; Cudeck & MacCallum, 2007; Fabrigar, Wegener, MacCallum, & Strahan, 1999; Thompson, 2004; Widaman, 2007).

The following criteria will be used for selecting the number of factors:

- 1) the screen plot test,
- 2) the eigenvalue-greater-than-one rule,
- 3) the variance of each factor,
- 4) the total variation from the exported factors and
- 5) the number of factors that can conceptually be interpreted (Nunnally & Bernstein, 1994; Tinsley & Tinsley, 1987; Tabachnick & Fidell, 2006).

For internal consistency the researchers will use the following indicators:

- a) the coefficient Cronbach's α ,
- b) the inter-item correlation,
- c) the corrected item-total correlations
- d) the Spearman-Brown coefficient and
- e) the Guttman split-half coefficient.

Confirmatory factor analyses

Before the main analysis of the questionnaire with the method of confirmatory factor analysis in 300 patients, the researchers will test the distribution of the variables with the following indicators:

- a) univariate skewness),
- b) the univariate kurtosis and
- c) the Mardia coefficient-relative multivariate kurtosis (Mardia, 1970).

To test the appropriate fit of the models through confirmatory factor analysis the researchers will consider the following indicators:

- a) χ^2 (chi-square), df (degrees of freedom), the ratio of χ^2 / df (χ^2 / df ratio), Satorra-Bentler chi-square),
- b) the Comparative Fit Index, CFI,
- c) the Incremental Fit Index, IFI,
- d) the Adjusted Goodness of Index, AGFI,
- e) the Standardized Root Mean Squared Residual, SRMR, and
- f) the Root Mean Squared Error of Approximation, RMSEA (Bentler & Chou, 1987; Byrne, 1994; Bollen, 1989; Hoyle & Panter, 1995; Hu & Bentler, 1999; Tabachnick & Fidell, 2006). Concurrent validity and discriminant validity will also be examined.

For internal consistency the researchers will use the following indicators:

- a) the coefficient Cronbach's α ,
- b) the inter-item correlation,
- c) the corrected item-total correlations
- d) the Spearman-Brown coefficient and
- e) the Guttman split-half coefficient

Procedure of questionnaire administration

The questionnaire will be administered to patients with CNP personally and individually following by a cover letter. This letter will inform the participants about the university-department ID, the researchers' name, title, telephone number and e-mail. It will also indicate the significance and the purpose of the investigation, drawing the attention of participants during completion of the questionnaire in order to collect valid and reliable information. The participants will receive oral confirmation about the anonymity of responses and their ability to be informed about the results of the survey. The duration of completion the questionnaire is estimated at about ten (10) minutes. The researcher will be present during the process in order to resolve any questions and to give all necessary clarifications and instructions. Patients will complete the questionnaire in their treatment place.

2nd stage of the research: The real experiment

Study design

This research method is a pretest posttest-control group design. This type of study is designed to investigate how really effective is an additional intervention in daily practice. It also provides answers for the overall patients' benefits, suggesting evidence that will help healthcare professionals to make the right choices among appropriate interventions (Stevens, 2001; McCarney et al., 2002; McPherson , 2004).

Sampling

The sample size of this experiment will be 30 patients with CNP. The researchers will use the stratified random sampling from a patients' list that will fulfill the inclusion criteria. Participants will be separated in two groups:

a) the control group where patients will follow the therapeutic exercise program without parallel counseling, b) the experimental group where participants will follow along therapeutic exercise program plus counseling program which will result from the completion of the questionnaire.

The process will take place in the university department's laboratory (Physical Education and Sports Science at Democritus University of Thrace).

Therapeutic interventions

Hot compresses ten minutes before and ten minutes after the therapeutic program will be

applied on the neck for all patients in order to reduce the pain sensation. All patients will follow a program in collaboration with experienced physiotherapist with:

- a) stretching exercises for the neck muscles, the shoulder and the upper limbs,
- b) strength training of the flexor and extensor neck muscles from different positions,
- c) proprioception exercises,
- d) dynamic exercises of the shoulder and upper limbs with weights sets and elastic resistance bands,
- e) exercises to improve the kinesthetic ability, f) technique of progressive relaxation and diaphragmatic breathing exercises combined with inhalation-exhalation.

All patients will come for treatment 2-3 times per week until the completion of 12 sessions (about for 4-6 weeks). The duration of each session for all groups will be approximately 45 minutes.

Outcome measurements

In every intervention is necessary the determination and evaluation of the results and their comparison with the intended or projected results. Standardized outcome measures provide a common language with which to evaluate the success of interventions, thereby providing a basis for comparing outcomes related to different intervention approaches (Table 2).

Table 2: Overview of variables measured

Variable	Range of unit
Baseline Variables	
Inclusion and exclusion variables	X
Demographic variables	X
Specific complaint characteristics	X
Duration of neck pain	months
Smoking	yes /no
McGill Pain Questionnaire	marking the words
Neck Disability Index	marking the sentences
Fear Avoidance Belief Questionnaire	1-6 Likert scale
SF-36 Health Survey	marking words and sentences
The new questionnaire of this study	1-5 Likert scale
Neck goniometry measurements	Degrees
The strength of the flexors and extensors neck muscles with timer	Seconds
spirometer measurements	FVC/FEV

Discussion

According to the research assumptions the average of pain as well as the average of operating capacity, for patients suffering from CNP, will differ significantly in the experimental group after the application of therapeutic interventions combined with counseling program. One of the major limitations of this research that must be overcome is the factor of being an advisor or an interviewer because of the immediacy and personal involvement. In those kinds of studies, that combine qualitative and quantitative methods, the researcher is actively involved in the social life of the subjects with which it comes in contact many times forming the overall research agenda and its own research findings (Iosifidis, 2008). Therefore, the bias and the personal weaknesses of the researcher play an important role in the distortion of reality.

Recent studies prove that the use of counseling and educational resources combined with physical interventions increase physical activity through therapeutic programs (Gatchel et al., 2007; Jensen and Ringdahl, 2007) This study supports the biopsychosocial view of pain in the neck, based on the idea that biological, psychological and social variables can affect the development of chronic neck pain. Assessing all three dimensions of pain (biological, psychological and social) can put the patient's condition in a new perspective, and increases the likelihood of a positive outcome. Patients with chronic pain conditions are often unaware of the extent to which stress, anxiety, depression and other psychosocial factors affect their pain condition. It is important for health professionals to educate their patients about this, and to take steps to systematically evaluate the patient's pain complaints and psychosocial complications.

Current evidence for the management of neck pain disorders does not support any singular line of management whether biologically or psychologically based. Rather, the evidence supports multimodal approaches and a clearer understanding of the interactions between biological, psychological and social features of various

neck pain disorders will inform better management the aim of the biopsychosocial model (Jull and Sterling, 2009).

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