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Predictors of short- and long-term outcome in patients with chronic non-specific neck pain undergoing an exercise-based rehabilitation program: a prospective cohort study with 1-year follow-up

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Abstract The aim of this study was to describe the clinical course of patients with chronic, non-specific neck pain undergoing a public health covered, exercise-based rehabilitation program and to identify predictors of poor outcome. A prospective cohort study was carried out on patients with non-specific neck pain (6 months or longer), referred by their general practitioner to a 6-session program, including education and individually tailored exercise. The primary outcome measure for the course of neck pain was the Northwick neck pain questionnaire (NPQ) administered on baseline, discharge, and 1 year from discharge. Poor outcome was defined as NPQ score improving <30% (minimal clinically important difference-MCID–NPQ). The potential predictors included demographics, general health and psychological factors, neck pain history, and the clinical features described by NPQ. From January 2008 to June 2009, 212 patients were consecutively assessed for eligibility: 178 were enrolled and 162 completed follow-up (mean age = 65.3; 75% women). Baseline NPQ average score (40.7 + 17.1) improved by MCID on discharge (26.1 + 16.3) and at 1 year (28.5 + 17.3%).

The poor outcome was reported by 45% patients on discharge and by 56% at follow-up. Pain-related medication intake independently predicted poor short- (OR 4.24; 95% CI 1.83–9.84; $p = 0.001$) and long-term (OR 2.69; 95% CI 1.19–6.06; $p = 0.017$) outcome, and catastrophizing (OR 2.91; 95% CI 1.31–6.48; $p = 0.009$) predicted poor outcome at 1 year. Our cohort of patients with chronic neck pain undergoing an exercise-based rehabilitation program reported improvement by or beyond MCID–NPQ in 55% cases on discharge and in 44% cases at 1 year. Poor outcome was predicted by pain-related medication intake in the short and long term, and by catastrophizing in the long term.

Keywords Chronic neck pain · Exercise · Rehabilitation · Predictors of outcome · Minimal clinically important difference

Introduction

Neck pain is a common life experience, and most individuals will be affected by neck pain at one time or the other in the course of their life [1]. Though acute neck pain is most often resolved in a few days, the estimated rate of recurrence and persisting symptoms is relatively high [2]. The prevalence of chronic neck pain is increasing [3, 4], with rising personal, social, and health costs [5]. Longitudinal studies suggest that about one-third of those who experience neck pain will develop chronic symptoms [6], and chronic patients consume the largest share of treatment resources, accounting for most of neck pain-related health care costs [7]. With limited healthcare resources, appropriate direction of funding to evidence-based, cost-effective treatments and early targeting of patients at risk for non-recovery who may need more complex and second

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level approaches is mandatory [8]. While several high quality studies have explored risk factors for developing chronic neck pain, research on the predictors of treatment outcome is less available [9–11].

Primary care referral to physiotherapy is a widely adopted treatment option for patients with chronic neck pain, and the best evidence suggests that therapies involving exercise and manual therapies are more effective than other conservative approaches to neck pain [12]. For chronic non-specific neck pain, the Philadelphia panel reports high quality evidence in favour of proprioceptive re-education and isometric or slow neck movement exercises, and recommends supervised exercise programs for the treatment of this condition [13]. Exercise-based physiotherapy is a widespread clinical approach, but exercise protocols may be very different in each clinical setting [7, 9].

Chronic disease management is a critical public health issue in all developed countries. In Italy, the National Health Care System provides a global legislative framework, but the various regions have wide autonomy in defining local health care policies [14]. With the purpose of implementing more constructive health policies for outpatient rehabilitation services and resource allocation in 2005, based on existing evidence-based guidelines [13], the Tuscany Region Public Health Authority stated that patients diagnosed and referred by their general practitioner (GP) for non-specific neck pain and neck pain-related disability persisting for more than 12 weeks are entitled to access within 1 month to an exercise-based physiotherapy program, delivered either by directly or by approved private clinics receiving coverage by the Local Public Health Agency (regional statements 595/2005 and 1081/2005) [15]. According to this resolution, a standardised protocol, including a codified array of proprioceptive, isometric and mobilizing exercises was developed in our outpatient rehabilitation clinic, and since January 2006, all patients referred by their GP for neck pain-related disability underwent the program including a preliminary physiotherapist's assessment.

This prospective study describes the outcome of chronic, non-specific neck pain patients who received this exercise-based rehabilitation program, aiming at the identification of the predictors of poor outcome on discharge and at the 1-year follow-up.

Methods

Patients

All patients referred by their general practitioner to the outpatient rehabilitation clinic of the Fondazione Don Carlo

Gnocchi, Scientific Institute, Florence, Italy, to receive rehabilitation for non-specific neck pain lasting for at least 12 weeks, as stated by the Tuscan regional resolutions [15, 16] were considered as potential participants. The Fondazione Don Carlo Gnocchi, Scientific Institute is a non-profit rehabilitation institution, delivering rehabilitation services with and without direct public health coverage in many Italian regions [17]. For the purpose of this study, neck pain reported intermittently to chronic, for at least the prior 6 months, with or without upper extremity symptoms, in persons aged 18 years or more was required for eligibility. The exclusion criteria were: neurological signs; serious spine conditions (spondylolisthesis >2nd degree, cervical stenosis, spondylolysis); previous spine surgery; recent trauma (<1 year) including whiplash injury, active infection, concurrent disabling musculoskeletal conditions, cancer, psychiatric disease, cognitive impairment, pregnancy, or pain-related litigation. All eligible patients were invited to participate to the trial and asked for a written consent.

Intervention

Therapists with a University degree in Physiotherapy and at least 5 years experience were involved in baseline assessment and delivery of the rehabilitation program. All therapists working in the clinic must have studied the manual of standard procedures with the operational definition of assessment and treatment procedure for all rehabilitation treatments, and practice treatment procedures under supervision for 3 months at the time they commence working at the clinic. The rearrangement of our previous protocols for assessment and treatment of chronic neck pain was designed by two physiatrists, two senior and one junior physiotherapist in the summer of 2005, adapted to the regional resolution that covers a package of five exercise sessions, lasting 60 min each. The standard manual of procedures was modified accordingly in September 2005 [18], and assessment and treatment procedures were discussed and practiced by all physiotherapists working in the clinic from September to December 2005.

Our protocol, still in use at present, was designed to include one additional preliminary 1-h session dedicated to a semi-structured physiotherapist's assessment. Patients must answer a self-administered structured questionnaire (pain history, psychological measures, measure of neck pain and disability by the Northwick Park neck pain questionnaire (NPQ) [19, 20]; furthermore, the physiotherapist enquires about repeated movements or prolonged postures that may be related to the pain complaint [21], and performs a physical examination, including the measure of cervical, thoracic, lumbar and shoulder active and passive mobility, direct observation of pain-eliciting movements, as well as the measure of weight and height.

The five exercise sessions followed the first session assessment on a daily basis, over an 8-days period altogether; groups of four neck pain patients are supervised by two therapists. The standardized exercise protocol was designed based on the Philadelphia panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain. Our protocol proposes a codified array of exercises, different for intensity and difficulty, which are grouped according to specific objective: strength training (isometric and dynamic exercises for the cervical spine and the shoulder girdle); active neck, back and shoulder mobilization; proprioceptive training; stretching for the neck and shoulders (i.e., sub-occipital muscles, levator scapulae, trapezium) [22]. An individually tailored set of 5–7 exercises is selected based on the physiotherapist assessment and proposed to the patient; the purpose of each exercise is discussed with the patient and each exercise is practiced under the therapist supervision. Since the first session, the therapist gives personalized advice on postures and specific gestures that may elicit pain in daily living activities and encourages the patient to start changing postures (for instance, the position of the computer at work) and to practice exercise at home; encountered difficulties are discussed. Each patient receives personalized practical suggestions based on ergonomics throughout the treatment period. On discharge, a personal exercise program, to be practiced at home, at the gymnasium, and sometimes at work is given; the regular practice of a low to moderate physical activity is generally recommended and specific advice is given according to the patients' clinical characteristics and preferences.

Outcome

Our primary outcome variable was the NPQ that we chose for the measure of neck pain and disability [19, 20]. The NPQ is an instrument that has shown high reliability and sensitivity to change [23]. Baseline NPQ consists of nine items including pain intensity, duration of symptoms, pins and needles or numbness at night in the upper extremities, pain affecting sleep, social life, carrying, reading, watching television, working/housework, and driving. Each item scores from 0 (no difficulty) to 4 (severe difficulty). The NPQ score is expressed as a percentage, calculated by adding the scores of each item, dividing the sum for the total potential score ($9 \times 4 = 36$) and multiplying the result by 100. If an item is not applicable, the total potential score is reduced by 4. Discharge and follow-up NPQ include one additional item on perceived global improvement [23]. At 1 year, we sought telephone contact with all enrolled patients for a follow-up interview, administered by a fellow researcher, that included reassessment of NPQ and questions about the course of their neck pain, including

drug intake and further treatments, and about compliance to treatment recommendations (practice of the home exercise program, practice of a regular physical activity).

For the purpose of this study, we considered patients as improved if their baseline NPQ score on discharge (short-term outcome) and at 1 year (long-term outcome) was improved by or beyond a minimal clinically important difference (MCID) [9, 24]. A consensus-based decision by the initiative on methods, measurement, and pain assessment in clinical trials group suggested a 30% reduction from baseline as a means to define the MCID of self-reported back pain measures [25]; thus, we defined poor outcome as no improvement or improvement by less than 30% of the patient's baseline NPQ score. As a secondary outcome we also considered global perceived improvement (GPI), as assessed by the additional item of the follow-up NPQ.

Potential predictors

Variables collected on baseline included demographics, weight, height, and data from a baseline self-administered questionnaire collecting information on identified predictors of the course of chronic neck pain [2, 9]. In detail, we asked about patients education, working and family status, practice of a physical activity, and one question on self-perceived health [26]. We also enquired about psychological features, such as life satisfaction [26], mood, assessed by one item of the SF36-mental health: in the past 4 weeks did you ever feel discouraged or in a low mood? [27, 28] and catastrophizing, assessed by a one item question from the pain catastrophizing scale: have you felt your neck pain is terrible and that it is never going to get any better? [9, 29]

Finally, we collected recent and past history of neck pain, recording time from onset, persisting or recurring symptoms from onset, previous treatment and present medication intake for neck pain.

By attempting to identify the relevant clinical features predicting the outcome, we also considered baseline NPQ score and each baseline item score of the NPQ describing pain characteristics or pain-related disability in an array of specific areas [19] as potentially independent predictors of poor outcome.

Statistical analysis

Statistical analysis was performed using the STATA 7.0 software (Stata Corporation, College Station, Texas, USA). Data are presented as mean \pm SD or as absolute number along with the percentage in brackets. A multivariable logistical analysis was carried out in which all potential predictors of poor outcome, defined as improvement of

baseline NPQ score by less than 30%, were included in the model, with the exception of car driving. Car driving was excluded because the question was not applicable for more than 50% participants. Estimates of association are presented as odd ratios (ORs), along with 95% confidence intervals. Type 1 error was set at the two-sided 0.05 level. Alongside the multivariable analysis, we examined the explained variance for the final model using the pseudo (Nagelkerke) R^2 statistics.

Results

From January 1st 2008 to June 30th 2009, 212 patients referred to the clinic by their GP for neck pain rehabilitation were assessed for eligibility. All of them met our inclusion criteria (non-specific neck pain often-always for at least 6 months and age 18 or above); 29 patients (mean age 65.3, 73% female), though receiving the rehabilitation program were not recruited for the study because of exclusion criteria (3 neurological signs, 3 previous spine surgery, 3 psychiatric disease, 4 recent trauma, 2 infective disease, 7 serious clinical condition, and 7 concurrent disabling musculoskeletal condition); five eligible patients received rehabilitation, but refused to participate in the study. Of the 178 enrolled patients: 3 discontinued treatment, 2 for subsequent acute illness, and 1 for family problems; at follow-up, we were not able to contact 13 patients. Dropouts were not different from the study population as to age and gender (mean age 64.8; 78% women). The study flowchart is shown in Fig. 1.

Data from the 162 patients that completed treatment were used for this analysis: the demographic and clinical characteristics of the study population are shown in Table 1. Our study population was mainly represented by middle-aged or elderly women; only 27% were employed. All patients reported chronic neck pain with recurrent symptom exacerbation, and most of them reported

Table 1 Baseline characteristics of the study sample ($n = 162$)

| | |
|--|-----------------|
| General factors | |
| Age, years (mean \pm SD) | 65 \pm 12.5 |
| Female sex [n (%)] | 125 (77) |
| Body mass index (mean \pm SD) | 24.7 \pm 3.2 |
| Working activity, Y/N [n (%)] | 43 (27) |
| Physical activity, Y/N [n (%)] | 48 (30) |
| Perceived health, Y/N [n (%)] | 2.5 \pm 0.6 |
| Psychological features | |
| Life satisfaction, Y/N [n (%)] | 2.9 \pm 0.7 |
| Mood, score 1–6, 6 best (mean \pm SD) | 4.1 \pm 1.3 |
| Catastrophizing, Y/N [n (%)] | 73 (45) |
| Neck pain history | |
| Time from onset-years (mean \pm SD) | 10 \pm 10 |
| Continuous neck pain, Y/N [n (%)] | 67 (41) |
| Neck pain-related use of drugs, Y/N [n (%)] | 88 (54) |
| Previous treatment for neck pain, Y/N [n (%)] | 93 (57) |
| Northwick Park neck pain questionnaire | |
| Neck pain intensity, score 0–4 (mean \pm SD) | 1.9 \pm 1.0 |
| Neck pain and sleeping, score 0–4 (mean \pm SD) | 1.7 \pm 1.1 |
| Pins and needles or numbness in the arms at night, score 0–4 (mean \pm SD) | 1.1 \pm 1.0 |
| Duration of symptoms, score 0–4 (mean \pm SD) | 2.6 \pm 1.2 |
| Carrying, score 0–4 (mean \pm SD) | 1.9 \pm 1.2 |
| Reading or watching TV, score 0–4 (mean \pm SD) | 1.8 \pm 1.1 |
| Working/housework, score 0–4 (mean \pm SD) | 1.4 \pm 0.9 |
| Social activities, score 0–4 (mean \pm SD) | 0.8 \pm 1.1 |
| Driving, score 0–4 (mean \pm SD) ^a | 1.1 \pm 1.1 |
| Global score, 0–100% (mean \pm SD) | 40.7 \pm 17.1 |

^a Not applicable for 68 participants

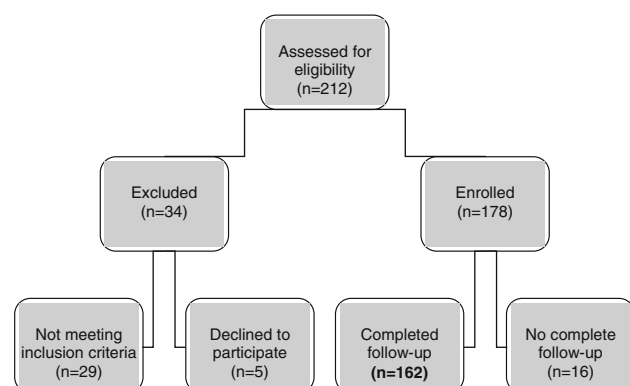


Fig. 1 Study flowchart

persistent or recurrent symptoms for many years (10 on average); 45% patients answered positively to the catastrophizing scale item and 54% patients reported neck pain-related medication intake on baseline. All patients presented one or more complaint at the NPQ with an average score indicating moderate neck pain-related disability (40.7%).

No adverse events were registered during treatment and no patient interrupted treatment because of worsening symptoms. NPQ average score on baseline was 40.7 \pm 17.1, decreasing significantly ($p < 0.001$) by MCID on discharge (26.1 \pm 16.3; 36% improvement), and at follow-up (28.7 \pm 17.3%; 30.2% improvement). Considering absolute changes from baseline NPQ score, 139 patients improved (86%), 6 (4%) worsened and 17 (10%) were stable on discharge; at 1 year, 115 patients had improved (71%), 28 (17%) worsened and 19 (12%) were stable. Those who reported GPI by answering felt better or much better (10th NPQ item) were 126 on discharge (78%) and 65 at 1 year (40%); 53 (33%) patients reported

improvement at both times, while 73 patients had improved on discharge but not at the follow-up, and 12 improved only at the follow-up.

Those who reported poor outcome as defined by MCID–NPQ by less than 30% were 73 (45%) on discharge and 90 (55.4%) at 1 year. As shown in Fig. 2, 55 (33%) patients reported MCID–NPQ improvement both on discharge and at follow-up, while 34 who had improved on discharge reported poor outcome at follow-up and 17 who reported poor outcome on discharge improved their baseline NPQ score by more than 30% at follow-up. Improving in the long-term was neither associated to regular exercise practice nor to higher reports of receiving further treatment (data not shown).

Table 2 shows the multivariable logistic regression modeling probability of poor outcome at the end of the treatment. Neck pain-related use of drugs was the only variable significantly associated with poor short-term outcome (OR: 4.24; 95% CI: 1.83–9.84). Drug intake was neither related to baseline higher pain intensity nor related to disability. The overall variance explained by this model was 20% (pseudo R^2).

Table 3 shows the multivariable logistic regression modeling the probability of poor outcome 1 year after the treatment. Neck pain-related use of drugs (OR: 2.69; 95% CI: 1.19–6.06; $p = 0.017$) and catastrophizing (OR: 2.91; 95% CI: 1.31–6.48; $p = 0.009$) were significantly associated with poor long-term outcome. The overall variance explained by this model was 16% (pseudo R^2).

Discussion

The prevalence of chronic neck pain is steadily increasing and the need for structural changes in its health and rehabilitation management is a critical public health issue in all developed countries [3, 14]. In our consecutive cohort of patients with pain lasting for 6 months or longer, referred to an outpatient rehabilitation clinic over 18 months to receive a public health covered, exercise-based

rehabilitation program, 45% patients reported poor outcome on discharge, while 56% reported poor outcome at 1 year. Medication intake predicted poor short- and long-term outcome, and catastrophizing predicted poor outcome at 1 year.

Neck pain outcome

We chose as our primary outcome measure the minimal clinically important difference by 30% or more of the NPQ global score (MCID–NPQ), but we also reported as a secondary outcome the global perceived improvement (GPI) as assessed by the 10th item of the NPQ on discharge and at 1 year. GPI is a widely used outcome measure in clinical studies providing highly relevant information from the patient's perspective, but its reliability and validity concerning neck pain has not yet been established [30]. To define the poor outcome, we preferred the use of a possibly stricter criterion [9] such as the MCID–NPQ, that allows a comparison of our results with existing evidence on the effects of conservative approach on the course of chronic neck pain. The best evidence synthesis on the course of chronic neck pain in the general population reports that most patients with chronic neck pain will have persistent or recurrent symptoms 1–5 years later [2]. Chronic patients receiving our standardized treatment program improved their overall average NPQ score by MCID both on discharge and at 1-year follow-up. Further, 78% patients had improved on discharge and 40% at 1 year by GPI, while 55% patients had improved on discharge and 44% at 1 year by MCID–NPQ.

A recent UK-randomized trial comparing the effect of advice and exercise therapy with or without the addition of manual therapy or pulsed wave ultrasound on patients with non-specific neck pain [31] reports a similar outcome, though it also included patients with pain lasting less than 3 months: 67% patients had improved by GPI on discharge (6 weeks) and 61% at 6 months, while 51% patients had improved by MCID–NPQ on discharge and 55% at 6 months. In another recent study comparing manipulation,

Fig. 2 Percentage and follow-up outcome of patients improved by MCID–NPQ on discharge

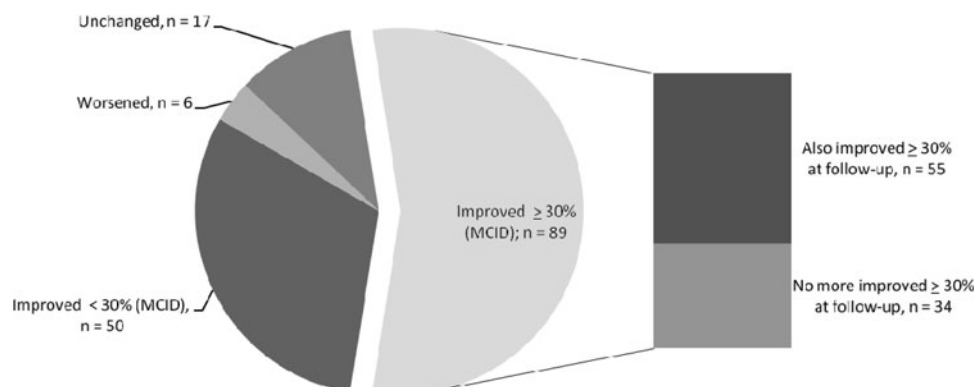


Table 2 Multivariable logistic regression modeling the probability of poor outcome at the end of treatment

| Poor outcome | OR (95% CI) | <i>p</i> |
|--|-------------------|--------------|
| General factors | | |
| Age, years | 0.98 (0.94–1.02) | 0.332 |
| Female sex | 1.75 (0.62–4.97) | 0.293 |
| Body mass index | 0.94 (0.82–1.07) | 0.333 |
| Working activity, Y/N | 0.68 (0.22–2.07) | 0.499 |
| Physical activity, Y/N | 1.39 (0.57–3.45) | 0.465 |
| Perceived health, Y/N | 1.19 (0.47–3.02) | 0.703 |
| Psychological features | | |
| Life satisfaction, Y/N | 3.09 (0.95–10.07) | 0.060 |
| Mood, score 1–6, 6 best | 0.95 (0.64–1.40) | 0.800 |
| Catastrophizing, Y/N | 1.28 (0.57–2.89) | 0.546 |
| Neck pain history | | |
| Time from onset-years | 1.03 (0.99–1.07) | 0.193 |
| Continuous neck pain, Y/N | 1.81 (0.79–4.15) | 0.163 |
| Neck pain-related use of drugs, Y/N | 4.24 (1.83–9.84) | 0.001 |
| Previous treatment for neck pain, Y/N | 0.59 (0.26–1.38) | 0.225 |
| Northwick Park neck pain questionnaire | | |
| Neck pain intensity, score 0–4 | 1.52 (0.74–3.12) | 0.254 |
| Neck pain and sleeping, score 0–4 | 1.54 (0.71–3.36) | 0.277 |
| Pins and needles or numbness in the arms at night, score 0–4 | 0.70 (0.33–1.48) | 0.348 |
| Duration of symptoms, score 0–4 | 1.95 (0.98–3.87) | 0.055 |
| Carrying, score 0–4 | 1.71 (0.88–3.30) | 0.111 |
| Reading or watching TV, score 0–4 | 1.07 (0.52–2.21) | 0.850 |
| Working/housework, score 0–4 | 0.73 (0.32–1.70) | 0.467 |
| Social activities, score 0–4 | 1.48 (0.67–3.25) | 0.331 |
| Driving, score 0–4 ^a | Not entered | – |
| Global score, 0–100% | 0.92 (0.76–1.11) | 0.394 |

Model: Obs 162; LR $\chi^2 = 42.01$; $p > \chi^2 = 0.006$; pseudo $R^2 = 0.197$

^a Not applicable for 68 participants

physiotherapy or usual care for persons with non-specific neck pain, the best rate of recovery (recovered or much improved), for patients receiving a treatment suggested by the predictive model identified by the authors, is 57.6% [10].

However, for both considered outcome measures in our study sample, only 33% patients reported consistent improvement on discharge and at 1 year, while a substantial proportion of patients who had improved on discharge eventually worsened or returned to NPQ baseline levels during the follow-up. This result is consistent with what we know on the course of chronic neck pain, alternating phases of remission and symptom exacerbation [2]; indeed, since we did not use an inception cohort, it is possible that our chronic patients were seeking care because of pain flare-ups, and this may have amplified our short- and long-term results. On the other hand, physiotherapy was rarely delivered immediately after medical prescription (within 30 days, generally in 3–4 weeks). However, the consistently higher reports of improvement in the short-term suggest that repeating the program every

few months or providing booster sessions throughout the year may help to maintain a better functional outcome in time.

We also found a relatively small proportion of persons who did not improve in the short-term, but did report significant improvement at 1 year. We could not find any association of late improvement either with home exercise practice or to having received further treatment in the follow-up period. Thus, we find it difficult to relate late improvement to the treatment under discussion, while possible reasons may more likely be found in the natural course of the condition or in factors that we may have not taken into consideration.

Predictors of poor outcome

We performed a single arm study and we have no way of knowing whether these factors would generally predict poor prognosis, or may be real treatment effect modifiers [32]. The variables we chose included most categories of known prognostic factors for the course of non-specific

Table 3 Multivariable logistic regression modeling the probability of poor outcome 1 year after the treatment

| Poor outcome | OR (95% CI) | <i>p</i> |
|--|------------------|--------------|
| General factors | | |
| Age, years | 1.02 (0.98–1.06) | 0.400 |
| Female sex | 0.59 (0.21–1.67) | 0.319 |
| Body mass index | 0.98 (0.85–1.13) | 0.819 |
| Working activity, Y/N | 1.06 (0.36–3.15) | 0.917 |
| Physical activity, Y/N | 1.88 (0.76–4.64) | 0.172 |
| Perceived health, Y/N | 0.79 (0.32–1.94) | 0.605 |
| Psychological features | | |
| Life satisfaction, Y/N | 1.50 (0.50–4.50) | 0.469 |
| Mood, score 1–6, 6 best | 1.03 (0.70–1.52) | 0.879 |
| Catastrophizing, Y/N | 2.91 (1.31–6.48) | 0.009 |
| Neck pain history | | |
| Neck pain duration, mos | 1.02 (0.98–1.07) | 0.261 |
| Continuous neck pain, Y/N | 1.83 (0.79–4.23) | 0.159 |
| Neck pain-related use of drugs, Y/N | 2.69 (1.19–6.06) | 0.017 |
| Previous treatment for neck pain, Y/N | 1.64 (0.73–3.68) | 0.228 |
| Northwick Park neck pain questionnaire | | |
| Neck pain intensity, score 0–4 | 0.76 (0.37–1.56) | 0.458 |
| Neck pain and sleeping, score 0–4 | 0.79 (0.37–1.68) | 0.545 |
| Pins and needles or numbness in the arms at night, score 0–4 | 1.00 (0.50–1.95) | 0.975 |
| Duration of symptoms, score 0–4 | 1.18 (0.60–2.30) | 0.628 |
| Carrying, score 0–4 | 1.07 (0.58–1.95) | 0.830 |
| Reading or watching TV, score 0–4 | 0.67 (0.33–1.36) | 0.273 |
| Working/housework, score 0–4 | 0.93 (0.42–2.08) | 0.866 |
| Social activities, score 0–4 | 1.12 (0.52–2.43) | 0.774 |
| Driving, score 0–4 ^a | Not entered | – |
| Global score, 0–100 | 1.00 (0.83–1.20) | 0.997 |

Model: Obs 162; LR $\chi^2 = 34.79$; $p > \chi^2 = 0.041$; pseudo $R^2 = 0.164$

^a Not applicable for 68 participants

neck pain [2, 33]. However, the overall variance explained by our multivariable model was low. This result is in line with previous studies on predictors of neck pain response to treatment, concluding that predictors of chronic neck pain course are only partially useful to predict treatment outcome, while other variables, such as the patient's physical characteristics may provide more relevant information to this issue [9–11]. Indeed, we attempted to improve the explained variance of previous studies by considering separately the relevant clinical pain features described by each single item of the NPQ, but our results did not confirm the hypothesis that one or more of these specific clinical features would better predict outcome than the previously considered factors. On the other hand, we feel that the negative results of our study, consistent with other studies on neck pain treatment outcome [9, 10] are also clinically relevant. In fact, most factors predicting the course of neck pain in the general population, including age, gender and working status, as well as baseline pain intensity or disability, time from onset and receiving previous further treatment do not seem to predict who shall

improve after receiving treatment. These results, if confirmed by randomized controlled trials, may have relevant implications in changing both patient and therapist expectations concerning treatment [9].

In our study cohort, we found that neck pain medication intake at baseline predicted poor outcome. To our knowledge, this is a novel finding that is not reported in other studies. The Tuscany region resolution recommended treatment with non steroidal anti-inflammatory drugs (NSAIDs) before considering referral to physiotherapy, which was considered an alternative treatment option. Recommending NSAIDs before referral to physiotherapy might be a questionable policy, since the risk related to NSAID intake must not be underestimated, especially compared to the minimal risk of other conservative approaches to neck pain [34]. However, according to the regional resolution, most of our patients had been prescribed medication as a first step for the treatment of their neck pain, while continuing medication intake during the rehabilitation program was more likely a patient choice. In fact, drug intake was neither related to higher pain intensity

nor related to disability; thus, it is possible that our patients' choices and preferences influenced this data, which may in turn be related to lower physiotherapy expectations. Indeed, Hill et al. [9] find that lower treatment expectations concerning physiotherapy predict a poor treatment outcome. Exercise-based physiotherapy is a patient-centered approach that requires patient's awareness, efforts, compliance, and time. Some chronic patients are more inclined to rely on medications, because of the fear that exercise may exacerbate rather than alleviate symptoms or even damage the painful joints [35]. Unfortunately, we did not investigate whether patients who continued drug intake during the exercise program, though complying with their GP prescription to physiotherapy, also had lower treatment expectations.

Consistent with the above mentioned similar study by Hill et al. [9], in our study population we found that catastrophizing predicted poor long-term outcome. Catastrophizing has been defined as "excessively negative and unrealistic thoughts or self-statements about pain" and it is a key factor as to how cognition, beliefs, coping strategies and functioning are related to the experience of pain. In fact, a central role in the development of chronic disabling pain seems to be played by catastrophic thinking [36, 37]. According to the biopsychosocial model, catastrophizing is a central variable in the fear-avoidance cycle, leading to chronic pain-related disability [38]. Thus, addressing the cognitive distortions occurring in catastrophizing, for instance by an evidence-based cognitive behavioral approach, may interrupt the fear-avoidance cycle and help to reduce the pain chronicity and disability [39]. The possible implications to health policy makers may involve considering the long-term cost-effectiveness of a more expensive and articulated multi-modal approach, including cognitive-behavioral therapy, dedicated to patients with chronic neck pain with baseline catastrophic thinking [8, 40].

Limitations

This is a prospective cohort study and we do not have any control group. So, if we can conclude that the appropriateness of referral and the safety of the program were substantially confirmed in the short and long term and that a significant improvement beyond MCID was registered in our patient cohort, we cannot claim effectiveness for the considered exercise program. Besides, as already acknowledged, we chose not to use an inception cohort, thus we may not exclude that our chronic patients were seeking care because of temporary symptom exacerbation. Another previously outlined study limitation is that, presenting a single-arm intervention prospective study, we cannot say whether different treatment options would have

led to different results concerning the predictors of outcome. Furthermore, our study cohort included mostly elderly and middle aged women; these demographic features reflected the case-mix of persons receiving public health covered musculoskeletal rehabilitation in our region [15], but caution must be taken as to the generalizability of our findings, both the positive and negative, to the general population of persons affected by chronic, non-specific neck pain. For instance, only 27% of our sample was employed and this may have led to an underestimation of the relevance of working status in our model. Finally, the potential predictors that we selected included variables that could be rapidly collected, to be easily incorporated into routine clinical practice: thus, psychological factors such as catastrophizing and mood were investigated by a single question rather than by validated screening measures, and this choice is likely to have reduced the accuracy and sensitivity of our findings.

Conclusions

In our study cohort of patients with chronic, non-specific neck pain and disability, including mostly elderly and middle-aged women, who were referred by their GP to a public health covered, exercise-based physiotherapy program, we found reports of pain and disability improvement by or beyond a minimal clinically important difference in 55% cases on discharge and in 44% cases at 1 year. The poor outcome was independently predicted by neck pain-related medication intake both in the short and in the long term, while catastrophizing predicted a poor outcome only in the long term.

Conflicts of interest None.

References

1. Binder A (2006) Neck pain. *Clin Evidence* 15:1654–1675
2. Carroll LJ, Hogg-Johnson S, van der Velde G, Haldeman S, Holm LW, Carragee EJ, Hurwitz EL, Côté P, Nordin M, Peloso PM, Guzman J, Cassidy JD (2008) Course and prognostic factors for neck pain in the general population: results of the bone and joint decade 2000–2010 task force on neck pain and its associated disorders. *Spine* 15(4 Suppl):S75–S82
3. Picavet HSJ, Schouten JSAG (2003) Musculoskeletal pain in the Netherlands: prevalence, consequences and risk groups, the DMC3 study. *Pain* 102:167–178
4. Corti MC, Rigon C (2003) Epidemiology of osteoarthritis. Prevalence, risk factors and functional impact. *Aging Clin Exp Res* 15:359–363
5. Hoving J, de Vet H, Twisk J, Devillé W, van der Windt D, Koes B, Bouter L (2004) Prognostic factors for neck pain in general practice. *Pain* 110(3):639–645

6. Côté P, Cassidy JD, Carroll LJ et al (2004) The annual incidence and course of neck pain in the general population: a population-based cohort study. *Pain* 112:267–273
7. Borghouts AJ, Janssen HJ, Koes BW et al (1999) The management of chronic neck pain in general practice. A retrospective study. *Scand J Prim Health Care* 17:215–220
8. Haldorsen EM, Grasdøl AL, Skouen JS, Risa AE, Kronholm K, Ursin H (2002) Is there a right treatment for a particular patient group? Comparison of ordinary treatment, light multidisciplinary treatment, and extensive multidisciplinary treatment for long-term sick-listed employees with musculoskeletal pain. *Pain* 95(1–2):49–63 PubMed PMID: 11790467
9. Hill JC, Lewis M, Sim J, Hay EM, Dziedzic K (2007) Predictors of poor outcome in patients with neck pain treated by physical therapy. *Clin J Pain* 23(8):683–690
10. Schellingerhout JM, Verhagen AP, Heymans MW, Vonka F (2008) Which subgroups of patients with non-specific neck pain are more likely to benefit from spinal manipulation therapy, physiotherapy, or usual care? *Spine* 139(3):670–680
11. Cleland JA, Childs JD, Fritz JM, Whitman JM, Eberhart SL (2007) Development of a clinical prediction rule for guiding treatment of a subgroup of patients with neck pain: use of thoracic spine manipulation, exercise, and patient education. *Phys Ther* 87:9–23
12. Hurwitz EL, Carragee EJ, van der Velde G (2008) Treatment of neck pain: non-invasive interventions. Results of the bone and joint decade 2000–2010 task force on neck pain and its associated disorders. *Spine* 33:S123–S152
13. The Philadelphia panel members and Ottawa methods group (2001) Philadelphia panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain. *Phys Ther* 81:1701–1717
14. Pedace C (2007) Difficult hospital discharges and disease management. *Intern Emerg Med* 2:74
15. La Guida della Salute. http://www.regione.toscana.it/regione/multimedia/RT/documents/2009/09/18/c70d732e97a45800ef914a51973fb793_asl10firenzeintmedia.pdf. Accessed 6 Sept 2010
16. Bogduk N (1999) The neck. *Best Pract Res Clin Rheumatol* 13:261–285
17. Fondazione Don Carlo Gnocchi. <http://www.dognocchi.it>. Accessed 6 Sept 2010
18. Guidomei M, Boni R, Paperini A, Pasquini G, Debolini PL, Molino-Lova R, Cecchi F (2009) La riabilitazione della rachialgia meccanica lombare e cervicale: sviluppo e validazione di protocolli di chinesiterapia individualizzata. *La GinnasticaMedica* 57:7–16
19. Leak AM, Cooper J, Dyer S, Williams KA, Turner-Stokes L, Frank AO (1994) The Northwick park neck pain questionnaire, devised to measure neck pain and disability. *Br J Rheumatol* 33(5):469–474
20. Bonaiuti D (2005) Le scale di misura in riabilitazione. Soc Editrice Universo, Roma, pp 117–120
21. Sahrmann S (2005) Diagnosis and treatment of movement impairment syndromes. Mosby Inc, St Louis, Mo
22. Sarig-Bahat H (2003) Evidence for exercise therapy in mechanical neck disorders. *Man Ther* 8:10–20
23. Chiu TTW, Lam TH, Hedley AJ (2001) Subjective health measures used on Chinese patients with neck pain in Hong Kong. *Spine* 26:1884–1889
24. Sim J, Jordan K, Lewis M et al (2006) Sensitivity to change and internal consistency of the Northwick park neck pain questionnaire and derivation of a minimal clinically important difference. *Clin J Pain* 22:820–826
25. Gatchel RJ, Mayer TG (2010) Testing minimal clinically important difference: consensus or conundrum? *Spine J* 10(4):321–327
26. Cecchi F, Debolini P, Molino Lova R, Macchi C, Bandinelli S, Bartali B, Lauretani F, Benvenuti E, Hicks G, Ferrucci L (2006) Epidemiology of back pain in a representative cohort of Italian persons 65 years of age and older: the InCHIANTI study. *Spine* 31:1149–1155
27. Ware JE, Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36). *Med Care* 30(6):473–483
28. Apolone G, Mosconi P (1998) The Italian SF-36 health survey: translation, validation and norming. *J Clin Epidemiol* 51:1025–1036
29. Sullivan MJL, Bishop SR, Pivik J (1995) The pain catastrophizing scale: development and validation. *Psychol Assess* 7:524–532
30. Norman GR, Stratford P, Regehr G (1997) Methodological problems in the retrospective computation of responsiveness to change: the lesson of Crombach. *J Clin Epidemiol* 50:869–879
31. Dziedzic K, Hill J, Lewis M, Sim J, Daniels J, Hay EM (2005) Effectiveness of manual therapy or pulsed short wave diathermy in addition to advice and exercise for neck disorders: a pragmatic randomized controlled trial in physical therapy clinics. *Arthritis Rheum* 15:214–222
32. Hancock M, Herbert RD, Maher CG (2009) A guide to interpretation of studies investigating subgroups of responders to physical therapy interventions. *Phys Ther* 89:698–704
33. Schellingerhout J, Heymans M, Verhagen A, Lewis M, de Vet H, Koes B (2010) Prognosis of patients with non-specific neck pain: development and external validation of a prediction rule for persistence of complaints. *Spine* 35(17):E827–E835
34. Dabbs V, Lauretti WJ (1995) A risk assessment of cervical manipulation vs. NSAIDs for the treatment of neck pain. *J Manipulative Physiol Ther* 18(8):530–536
35. Bredahl TVG, Puggaard S, Roessler KK (2008) Exercise on Prescription. Effect of attendance on participants' psychological factors in a Danish version of exercise on prescription. A study protocol. *Health Serv Res* 26:8–139
36. Miró J, Nieto R, Huguet A (2008) Predictive factors of chronic pain and disability in whiplash: a Delphi poll. *J Pain* 12(1):30–47
37. Vlaeyen J, Kole-Snijders A, Boeren R (1995) Fear of movement/(re) injury in chronic low back pain and its relation to behavioural performance. *Pain* 62:363–372
38. Schutze R, Rees C, Preece M, Schutze M (2010) Low mindfulness predicts pain catastrophizing in a fear-avoidance model of chronic pain. *Pain* 148(1):120–127
39. Vangronsveld K, Peters M, Goossens M, Linton S, Vlaeyen J (2007) Applying the fear-avoidance model to the chronic whiplash syndrome. *Pain* 131(3):258–261
40. Michaelson P, Sjolander P, Johansson H (2004) Factors predicting pain reduction in chronic back and neck pain after multimodal treatment. *Clin J Pain* 20(6):447–454