Original article

Prognostic factors and course for successful clinical outcome quality of life and patients' perceived effect after a cognitive behavior therapy for chronic non-specific low back pain: A 12-months prospective study

Karin Verkerk [a, b, c, *], Pim A.J. Luijsterburg [c], Martijn W. Heymans [d, e, f], Inge Ronchetti [b], Harald S. Miedema [a], Bart W. Koes [c], Annelies Pool-Goudzwaard [g]

[a] Rotterdam University of Applied Sciences, Rochussenstraat 198, 3015 EK Rotterdam, The Netherlands
[b] Spine & Joint Centre, Rotterdam, The Netherlands
[c] Department of General Practice, Erasmus MC, University Medical Center, Rotterdam, The Netherlands
[d] EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
[e] Department of Methodology and Applied Biostatistics, VU University, Institute for Health Sciences, Amsterdam, The Netherlands
[f] Department of Epidemiology and Biostatistics, VU University Medical Center, Amsterdam, The Netherlands
[g] Department of Neuroscience, Erasmus MC, University Medical Center, Rotterdam, The Netherlands

ABSTRACT

This study investigates the clinical course of and prognostic factors for quality of life (Short Form 36 items Health survey (SF-36)) and global perceived effect (GPE) in patients treated for chronic non-specific low back pain at 5 and 12-months follow-up. Data from a prospective cohort ($n = 1760$) of a rehabilitation center were used, where patients followed a 2-months cognitive behavior treatment. The outcome 'improvement in quality of life (SF-36)' was defined as a 10% increase in score on the SF-36 at follow-up compared with baseline. On the GPE scale, patients who indicated to be 'much improved' were coded as 'clinically improved'. Multivariable logistic regression analysis included 23 baseline characteristics. At 5-months follow-up, scores on the SF-36 Mental Component Scale (SF-36; MCS) and the Physical Component Scale (SF-36; PCS) had increased from 46.6 (SD 10.3) to 50.4 (SD 9.8) and from 31.9 (SD 7.1) to 46.6 (SD 10.3), respectively. At 5-months follow-up, 53.0% of the patients reported clinical improvement (GPE) which increased to 60.3% at 12-months follow-up. The 10% improvement in quality of life (SF-36 MCS) at 5-months follow-up was associated with patient characteristics and psychological factors. At 5-months follow-up, the 10% improvement in quality of life (SF-36 PCS) and GPE was associated with patient characteristics, physical examination, work-related factors and psychological factors; for GPE, an association was also found with clinical status. At 12-months follow-up GPE was associated with patient characteristics, clinical status, physical examination and work-related factors. The next phase in this prognostic research is external validation of these results.

1. Introduction

Chronic non-specific low back pain (CNSLBP) is one of the most prevalent health problems (Heneweer et al., 2007). Although it is known that physical, psychosocial and personal factors play a role, the way they interact with each other remains unclear. Several prognostic models for non-specific low back pain have been described; however, the prognostic factors varied depending on the choice of, for example, the prognostic variables, outcome definition, or the stage of pain (e.g. acute, sub-acute or chronic) (Kent and Keating, 2008; Costa Lda et al., 2009; Verkerk et al., 2012). A recent systematic review focusing on musculoskeletal complaints considered relevant for physical therapists in primary care, reported that the available prediction models are not yet ready to be applied in clinical practice because of their preliminary stage of development (van Oort et al., 2012). Also, the available models for

* Corresponding author. Rotterdam University of Applied Sciences, Health Care, Rochussenstraat 198, 3015 EK Rotterdam, The Netherlands. Tel.: +31 10 7945153, +31 102260187; fax: +31 10 7944023.
E-mail addresses: k.verkerk@hr.nl, karinsomt@gmail.com (K. Verkerk).

back pain patients need external validation and impact evaluation before applying them in daily practice (van Oort et al., 2012). Compared to patients with (sub) acute NSLBP, patients with CNSLBP are the least investigated regarding their course and prognosis, especially in relation to the outcomes 'quality of life' and 'global perceived effect' (GPE) (Verkerk et al., 2012). Therefore, clinicians and researchers increasingly recognize the importance of such patient-reported outcome measures in the evaluation of the effectiveness of treatment, prognosis or course of CNSLBP (Bombardier, 2000).

Achieving and maintaining the best possible quality of life is a primary goal of care and several questionnaires are available to measure this item, including the Short Form 36-items Health Survey (SF-36) (Aktekin et al., 2009). With regard to evaluating GPE, the patient can be asked to rate how much their condition (i.e. important aspects of recovery) has improved or deteriorated since some predefined time point (Kamper et al., 2010). The present study was designed to investigate the course of and identify prognostic factors (with internal validation) for quality of life and GPE in patients treated for CNSLBP.

2. Methods

2.1. Population

Patients were recruited between January 2003 and December 2008 in a prospective cohort study from a multidisciplinary outpatient rehabilitation clinic the Spine & Joint Centre (SJC; Rotterdam, The Netherlands). The Medical Ethics Committee of SJC approved the study protocol and all patients provided informed consent. Details on the study design are described elsewhere (Verkerk et al., 2011). Inclusion criteria were: 1) men and women aged ≥18 years; 2) having CNSLBP defined as a duration of LBP for ≥3 months; 3) having persistent low back complaints despite of treatment in primary and/or secondary care.

Exclusion criteria were insufficient knowledge of the Dutch language; signs indicating radiculopathy, asymmetric Achilles tendon reflex and/or (passive) straight leg raise test restricted by pain in the lower leg; positive MRI findings for disc herniation; recent (<6 months) fracture, neoplasm or recent previous surgery (<6 months) of the lumbar spine, the pelvic girdle, the hip joint, or the femur; specific causes such as ankylosing spondylitis and systemic disease of the locomotor system; and being pregnant or ≤6 months post-partum at the moment of consultation.

A total of 2545 patients [mean age 40.4 (10.9) years; 73.3% women] visited the SJC for an intake consultation between 2003 and 2008, but 785 patients [mean age 41.3 (11.5) years; 70.3% women] decided not to start therapy (e.g. only wanted consultation, diagnose, advise, referred to another specialist, decided later not to come). Data were collected at baseline ($n = 1760$) and at 2 ($n = 1696$), 5 ($n = 1564$) and 12 ($n = 965$) months-follow-up (Verkerk et al., 2011) during regular daily care at the SJC.

2.2. Measurements

2.2.1. Outcome measures and defining recovery

To determine the course of quality of life in patients with CNSLBP the SF-36 was used and, at 5 months, represented by the two SF-36 domains the Mental Component Scale (SF-36; MCS) and the Physical Component Scale (SF-36; PCS), both ranging from 0 to 100 (high quality of life) (Gandek et al., 1998; Walsh et al., 2003; Davidson et al., 2004; Gandek et al., 2004). Clinical improvement was measured at 2, 5 and 12-months follow-up with the GPE score, which consists of a 5-point scale on global change (1 = much improved, 2 = slightly improved, 3 = no change, 4 = slightly

worsened, 5 = much worsened) (Ostelo and de Vet, 2005). The two instruments have shown to be reliable and valid (Walsh et al., 2003; Hagg et al., 2003b; Davidson et al., 2004; Gandek et al., 2004; Kamper et al., 2010).

Recovery was defined as a 10% improvement on the MCS or PCS compared to baseline. The scale was dichotomized into 'no improvement in MCS or PCS' and 'improvement in MCS or PCS' based on an increase of 10% at follow-up compared to the baseline value; we considered this to be a clinically relevant difference. A clinically relevant improvement for these scales has not yet been defined, but beside empirical evidence an expert clinical interpretation and judgment is of value. By expert opinion the most appropriate value for questionnaires on 'quality of life' is 10% since the changes are smaller than the more common outcomes measures on pain and disability. The SF-36 was only followed up to 5 months because this was done electronically at the SJC. The predefined time point for the GPE score (Kamper et al., 2010) was measured following 2 months of therapy at the SJC. In addition, patients judged their own improvement compared with this previous measurement, at 5 and 12-months follow-up. Patients who indicated 'much improved' were coded 'clinically improved' and patients who indicated 'slightly improved', 'no change', 'slightly worsened' or 'much worsened' were coded as 'clinically not improved' (Ostelo and de Vet, 2005).

2.2.2. Potential prognostic factors

The selection of relevant prognostic factors was performed in two steps: 1) the literature on prognosis for CNSLBP and quality of life and GPE were reviewed (Verkerk et al., 2012), and 2) a clinical group of 8 experts on CNSLBP composed a list of 23 of the 47 potential prognostic factors. All factors were retrieved from step 1 (with exception of the factor previous rehabilitation) in combination of the available variables at the SJC. Using the Policy Delphi method (scored on a 4-point Likert scale ranging from 1 = very important to 4 = not important) (Verhagen et al., 1998; Snyder-Halpern, 2001), there were 3 rounds and each time the responses were aggregated, tabulated, summarized, and returned to the experts. In the third round the experts were asked to decide whether to keep or remove the factor from the list, through consensus meeting. The final list consisted of factors that were included by at least 80% consensus. Using these 23 variables, in the analysis we complied with the rule of at least 10 events per variable (which avoids incorrect estimation of variables), we had to restrict the total number of potential prognostic factors (Peduzzi et al., 1996) (Box 1). We described the baseline values of these 23 potential prognostic factors in Table 1 in several domains (e.g. patients characteristics) to be transparent with other studies (Bombardier, 2000; Pincus et al., 2008; Kamper et al., 2010; Verkerk et al., 2012) studying on outcome measurements and clinical improvement. The excluded prognostic factors can be obtained from the first author.

2.3. Treatment at the Spine & Joint Centre

The multidisciplinary treatment at the SJC centre used a biopsychosocial approach consisting of 16 sessions of 3 h each during a 2-month period (total of 48 h). Patients were coached by a multidisciplinary team (e.g. a physical therapist, physician, health scientist, psychologist) (Verkerk et al., 2011).

2.4. Data analysis

2.4.1. Course of quality of life and GPE

Descriptive analysis was performed to describe the course of quality of life (SF-36; PCS and MCS) and GPE in CNSLBP patients according to their characteristics.