Objective: The aim of this study was to identify treatment-specific predictors of the effectiveness of a method of evidence-based treatment: cognitive treatment of illness perceptions. This study focuses on what treatment works for whom, whereas most prognostic studies focusing on chronic non-specific low back pain rehabilitation aim to reduce the heterogeneity of the population of patients who are suitable for rehabilitation treatment in general.

Design: Three treatment-specific predictors were studied in patients with chronic non-specific low back pain receiving cognitive treatment of illness perceptions: a rational approach to problem-solving, discussion skills and verbal skills. Hierarchical linear regression analysis was used to assess their predictive value. Short-term changes in physical activity, measured with the Patient-Specific Functioning List, were the outcome measure for cognitive treatment of illness perceptions effect.

Results: A total of 156 patients with chronic non-specific low back pain participated in the study. Rational problem-solving was found to be a significant predictor for the change in physical activity. Discussion skills and verbal skills were non-significant. Rational problem-solving explained 3.9% of the total variance.

Conclusion: The rational problem-solving scale results are encouraging, because chronic non-specific low back pain problems are complex by nature and can be influenced by a variety of factors. A minimum score of 44 points on the rational problem-solving scale may assist clinicians in selecting the most appropriate candidates for cognitive treatment of illness perceptions.

Key words: illness perceptions; low back pain; predictors; cognitive behavioural therapy; theory-driven approach; problem-solving.

INTRODUCTION

First-generation outcome studies (1) have provided proof of the (cost-)effectiveness of a variety of evidence-based methods of cognitive behavioural treatment (CBT) in the rehabilitation of patients with chronic non-specific low back pain (CLBP) (1, 2). Graded activity, gradual exposure in vivo, and cognitive treatment of illness perceptions (CTIP) are 3 such methods (3–5). First-generation prognostic studies, in turn, have identified predictors of chronicity in low back pain, including psychosocial distress, a depressive mood, and the severity of the pain (6). These prognostic studies have provided a set of predictors that can reduce the heterogeneity of the CLBP population. However, evidence with regard to predictors of rehabilitation outcome is still limited (7). Both types of first-generation studies have thus helped to legitimize CLBP rehabilitation by building a sound base of evidence for clinical practice, in response to the questions “Is the treatment effective?” and “Which patients are at risk?”.

It has been argued that second-generation studies should now focus more on improving rehabilitation treatment by addressing questions such as “What treatments work best for whom?” Rehabilitation research should therefore include more deliberate tests of theoretically driven a priori hypotheses (1), so that outcome research can investigate the relative value of different methods of CBT (4, 5). Similarly, the challenge for current prognostic studies is to identify and test potentially relevant treatment-specific predictors in a theory-driven approach (1, 8, 9).

We investigated how predictors, hypothesized from theory to be specific for CTIP, may assist in the selection of the most appropriate candidates for this treatment. CTIP is based on Leventhal’s Self-Regulation Model (SRM) (10), and is aimed at increasing physical activity by cognitive restructuring of maladaptive illness perceptions (the patient’s personal thoughts about the illness). Socratic dialogues are used to investigate the patient’s thoughts (illness perceptions) about the illness, and to identify and discuss any illness perceptions that are maladaptive (11).
A thorough analysis of the content of CTIP and the underlying theories resulted in the identification of 3 skills that were hypothesized to be necessary for the effectiveness of CTIP (12). These skills were tested as treatment-specific predictors in a hierarchical linear regression analysis, the results of which are reported in this paper. A rational approach to problem-solving was hypothesized as the most important treatment-specific predictor: in CTIP it is expected that perceptions are thought through in a logical and systematic way, that conclusions are drawn, and that the patient acts upon these conclusions. Adequate discussion skills were hypothesized to be a secondary predictor of CTIP: as prerequisites for successful Socratic dialogue, patients need to be open-minded, able to listen to others, and tolerant of other people’s opinions. A third treatment-specific predictor was hypothesized to be adequate verbal skills, because CTIP requires that patients are able to talk clearly and sensibly about their perceptions of their back problem with the therapist (12).

Methods

Setting and participants

Between December 2004 and May 2008, patients with CLBP received a written invitation (including information about the study and a screening questionnaire) to participate in the study, prior to their first consultation in our outpatient rehabilitation centre. The selection criteria were: age 18–70 years, non-specific low back pain with or without radiation to the leg(s) with a duration of at least 3 months, activity limitations (Roland Disability Questionnaire >3), current episode of back pain lasting for less than 5 years, no previous multidisciplinary treatment for CLBP, able to complete questionnaires without help (illiteracy, no language problems or cognitive problems), not pregnant, no substance abuse interfering with treatment, no involvement in litigation concerning CLBP or its consequences, absence of serious psychological or psychiatric problems interfering with the treatment or assessments, and written informed consent.

The selection criteria were checked in two steps: (1) on paper, from the completed screening questionnaires, and (2) in person, for patients who meet the criteria of step 1. Individual screening (step 2) was performed by physiatrists and psychologists from the multidisciplinary team, who established the patient’s suitability for rehabilitation treatment, double-checked the selection criteria, and provided the patients with oral information about the study. Patients who met all the selection criteria were referred for baseline assessment. No deliberate effort was made to select patients who were thought to be specifically suitable for CTIP, because this would limit the possibilities to study the predictors.

The Medical Ethics Committee of Slotervaart Hospital in Amsterdam approved the study protocol (number 0541); international trial register number: ISRCTN35108886.

Treatment

CTIP aims to improve patient-relevant physical activities in CLBP patients by cognitive restructuring of their maladaptive illness perceptions. The treatment phases were as follows: (i) identification and clarification of the illness perceptions, and identification of maladaptive illness perceptions; (ii) creating doubt about the maladaptive illness perceptions; (iii) formulating and testing alternative illness perceptions; and (iv) applying and practising the alternative illness perceptions in daily life (11). The theory underlying the CTIP working mechanism is that changes in maladaptive illness perceptions lead to improvements in physical activities (11). Socratic dialogue (13) was the technique that was used to invite patients to elaborate on their thoughts about their low back pain in relation to their activity limitations.

The CTIP consisted of 10–14 1-h individual treatment sessions, provided by experienced physical therapists, occupational therapists or psychologists, according to the treatment protocol. Treatment was considered to be incomplete if phase 3 (formulating alternatives) was not completed and the patient had attended less than 5 treatment sessions. The patients were asked not to participate in any diagnostic or therapeutic procedures for their CLBP during the study period. The therapists received extensive training before the trial started (a total of 21 h), consisting of an explanation of the rationale and the phases of the treatment, and training in the skills needed to apply the treatment techniques. Refresher courses were provided throughout the study period (a total of 20 h). The content of the courses was scheduled according to the therapists’ needs, and always included role-play and feedback. The protocol required that the therapists discussed the progress of each patient at least twice with an experienced psychologist supervisor.

Assessments

At the baseline assessment (week 0) the independent assessor provided the patients with oral information about the study, and the patients completed the baseline questionnaires (baseline characteristics, outcome measure, predictor variables and co-interventions), and gave written informed consent. Patients who were included in the study after the baseline assessment had been completed. The study was combined with a clinical trial for which the patients were randomly allocated to the treatment (immediate CTIP) or a waiting list. One-third of the patients were randomly assigned to an 18-week waiting list, after which they received CTIP (delayed CTIP) (12). Patients were unaware of the odds of randomization. The results of the clinical trial have been published elsewhere (3).

The treatment scores of immediate CTIP were collected in week 0, and in week 18 for delayed CTIP. Post-treatment scores were obtained 18 weeks later, i.e. in week 18 for immediate CTIP and in week 36 for delayed CTIP. Patients who were unable or unwilling to come to the department for pre- and post-treatment assessments, received the questionnaires by post. The post-treatment assessments were performed between April 2005 and March 2009. All patients, i.e. those who completed the treatment as well as those who did not complete the treatment, were invited for the post-treatment assessments.

Baseline characteristics

During the baseline assessment, data were collected in order to characterize the patient population and to facilitate comparison with other study populations. These data comprised: (i) demographic variables: age, gender, marital status, native language, level of education, and work status; and (ii) clinical variables: time since very first onset of the complaints, activity limitations (Roland Disability Questionnaire; RDQ) (14), current pain (100-mm visual analogue scale; VAS), symptoms of anxiety and depression (Hospital Anxiety and Depression Scale; HADS) (15), overall complaints (Symptom Check List; SCL-90) (16, 17), and fear of injury/ movement (Tampa Scale of Kinesiophobia; TSK) (18–20).

Primary outcome

The aim of CTIP is to decrease those activity limitations that are relevant to the patient. Measures allowing for personal relevance and circumstances were therefore considered to be more fitting for CTIP than generic low back measures. A suitable measure for this purpose is the Patient-Specific Functioning List (PSFL) (PSk in Dutch, also known as the PSA, PSFS, PSC and MC) (21, 22). With the PSFL, patients first select their most important physical activities that are restricted by their low back pain, and in week 18 for delayed CTIP. Post-treatment scores were obtained 18 weeks later, i.e. in week 18 for immediate CTIP and in week 36 for delayed CTIP. Patients who were unable or unwilling to come to the department for pre- and post-treatment assessments, received the questionnaires by post. The post-treatment assessments were performed between April 2005 and March 2009. All patients, i.e. those who completed the treatment as well as those who did not complete the treatment, were invited for the post-treatment assessments.

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Predictor variables

Rational problem-solving. The Rational Problem-Solving (RPS) scale of the Social Problem Solving Inventory – Revised (SPSI-R) (24, 25) was used to measure a rational approach to problems. The SPSI-RPS scale comprises 20 items, which are rated on a 5-point scale ranging from 0 (not at all true for me) to 4 (extremely true for me) (26). The SPSI-R is a reliable and valid measure (24, 27). Higher scores on the SPSI-RPS indicate a more rational approach to problems. Such an approach was hypothesized to be drawn on by CTIP, as it is expected in CTIP that perceptions are thought through in a logical and systematic way, that conclusions are drawn, and that the patient acts upon these conclusions. Therefore, higher SPSI-RPS scores were expected to be associated with greater changes in physical activity, i.e. a decrease in PSFL post-treatment scores, and thus negative scores for PSFL change.

Discussion skills. The aggrievedness scale of the Dutch Personality Questionnaire (nPV-AGG) (28) was used to measure discussion skills. The score was calculated from the 19 statements on the scale: each statement was rated on a 3-point scale ranging from correct – 1 – incorrect (range 0–38). The nPV is valid and reliable (28). Low scores on this scale indicate that the patient has adequate discussion skills, such as being open-minded, able to listen to others, tolerant of other people’s opinions, friendly and understanding (28). Lower nPV-AGG scores were hypothesized to be associated with more negative scores for PSFL change.

Verbal skills. To objectify the vocabulary and verbal skills, and to avoid an undue disadvantage for certain sections of the population, we applied a test suitable for patients from diverse cultural backgrounds: the Multicultural Capacity Test (MCT) (29). We used the word relations scale (MCT-WR) (45 items in 9 min), and the word analogies scale (MCT-WA) (30 items in 9 min). The patients were instructed to complete correctly as many items as possible with the time limit. The scores were calculated by summing up the number of correct answers given within the time limit. The reliability of both is “good” (WR 0.93, WA 0.92) and their validity has been well studied (29). Higher MCT-WR and MCT-WA scores indicated better verbal capacities. Higher scores on these scales were expected to be associated with more negative PSFL change scores.

Co-interventions

Co-interventions were monitored in a cost-diary (30), in which the patients reported CLBP-related visits to general practitioners, medical specialists, physiotherapists, and any alternative medicine they had been visiting for 2 weeks at baseline and for 2 weeks at follow-up.

Statistical analyses

A minimum decrease of 18 mm on the PSFL was determined as a clinically relevant change in patients with low back pain (31). This study was combined with a randomized clinical trial, and for the trial the sample size was calculated with a minimum of 18 mm change, a 2-sided alpha of 0.05, a 1-beta of 0.90, and a standard deviation (SD) of 26.01. This SD was calculated from available PSFL data obtained from CLBP patients in our centre, and resulted in a total of 135 participants. Given the 135 patients available for the trial, a maximum of 9 variables could be studied to obtain a reliable regression equation in the prognostic study, i.e. allowing 15 patients per predictor (32).

The descriptive statistics of baseline variables and co-interventions were calculated, and Pearson’s correlations were calculated to study the collinearity of the predictors and the association of the predictors with the dependent variable PSFL change. Subsequently, a hierarchical linear regression analysis was performed to test the ability of the predictor variables to predict change in patient-relevant activity limitations (PSFL change).

In step 1 of the hierarchical analyses the variables “group” (immediate CTIP vs delayed CTIP) and baseline PSFL were entered, in order to correct for possible group effects and to correct for the phenomenon of regression to the mean (model 1). In the second step the SPSI-RPS was added to model 1 (model 2). Subsequently, in the third step, the nPV-AGG was added to the predictors of model 2 (model 3). In step 4 the verbal skill scales (MCT-WR and MCT-WA) were added to the predictors of model 3 (model 4).

In each step of the analysis we investigated whether the scale that was added was a significant predictor (p < 0.05) for PSFL change. Subsequently, we assessed whether the addition of the predictor(s) resulted in a significant improvement in the fit of the model, compared with the model obtained in the previous step. This is indicated by a significant R-squared change (p < 0.05). If a scale appeared to be a relevant predictor, we determined which scores on this scale were likely to result in a clinically relevant decrease in the PSFL of at least –18 mm. All statistical analyses were performed with SPSS statistical software 16.0 (SPSS, Inc., Chicago, USA), and were carried out according to the intention-to-treat principle.

Role of funding sources

The first author was supported by the Netherlands Organization for Health Research and Development (ZonMW) (grant number 014-32-041). This sponsor had no role in the study design, data-collection, data-analysis, data-interpretation or reporting. The first author had full access to all study data and the final responsibility for the decision to submit the manuscript for publication. The authors have no financial or other conflicts of interests.

RESULTS

Of the 352 patients who were invited to participate in the study, 32 were unwilling to participate and 116 did not meet the selection criteria (step 1). Inability to complete the questionnaires without help (65 patients), and a current episode of low back pain for longer than 5 years (21 patients) were the most frequent reasons for exclusion. The remaining 204 patients underwent a medical and psychological examination, and were given verbal information about the study (step 2). Of these 204 patients, 58 were excluded. The main reasons for exclusion were psychological problems (18 patients) and no activity limitations (16 patients). A total of 156 patients met all the criteria, and received CTIP, but 35 patients received “incomplete treatment”. The 121 patients who completed the treatment reported no serious adverse effects of CTIP. Due to missing values, no PSFL change could be computed for 11 patients in the immediate CTIP and 9 in the delayed CTIP group. The hierarchical regression analyses was thus based on data from 136 patients.

Demographic and descriptive clinical variables

The baseline characteristics and descriptive clinical variables are shown in Table I. Monitoring the co-interventions resulted in a mean of 0.18 (SD 0.5) visits to the general practitioner per patient. For medical specialists, physiotherapists and alternative medicine, the mean visits per patient were 0.06 (SD 0.3), 0.78 (SD 1.7) and 0.08 (SD 0.4), respectively.

Correlation analyses

Significant correlations (p < 0.05) were found between the SPSI-RPS and the MCT-WA and PSFL change, but these correlations were small (0.10–0.30) (33). Significant and large
collinearity (r > 0.50) was found between MCT-WR and MCT-WA. A significant, but small collinearity was found between MCT-WR and MCT-WA and nPv-agg (Table II).

Hierarchical regression model

The results of the 4-step hierarchical model that was used to explore the predictive value of the treatment-specific variables are shown in Table III. In the first step we corrected for group and PSFL baseline value. This resulted in a significant model (p < 0.000), which explained 13.8% of the variance. In the second step the predictive value of the SPSI-RPS was tested. The model improved significantly by 3.9%, and the SPSI-RPS appeared to be a significant (p = 0.014) predictor for PSFL change. In the subsequent third and fourth steps, the nPv-agg scale and MCT scales were included. The addition of these scales did not result in any significant improvement of the model. The scales were also not significant predictors for PSFL change.

Table II. Correlations between the dependent variable and predictors (n = 135)

<table>
<thead>
<tr>
<th>Variable</th>
<th>PSFL change</th>
<th>SPSI-RPS</th>
<th>nPv-agg</th>
<th>MCT-WR</th>
<th>MCT-WA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSFL change</td>
<td>1</td>
<td>-0.193</td>
<td>0.012</td>
<td>-0.125</td>
<td>-0.172</td>
</tr>
<tr>
<td>SPSI-RPS</td>
<td></td>
<td>1</td>
<td>-0.008</td>
<td>-0.029</td>
<td>0.063</td>
</tr>
<tr>
<td>nPv-agg</td>
<td></td>
<td></td>
<td>1</td>
<td>-0.195</td>
<td>-0.232</td>
</tr>
<tr>
<td>MCT-WR</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>0.628</td>
</tr>
<tr>
<td>MCT-WA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

Values presented are Pearson’s correlations (p-value).

Clinically relevant change

The hierarchical regression model resulted in a single predictor, i.e. SPSI-RPS. The estimate of −0.49 indicates that one unit...
increase on the RPS results in a decrease of 0.49 in the PSFL change if all other variables included in model 2 are constant. Patients with better rational problem-solving skills show more improvement in activities over time after CTIP.

A minimum decrease of 18 mm on the PSFL was determined as a clinically relevant change (23). To study the relationship between the RPS and the PSFL in more detail, and more specifically in relation to clinically relevant change, RPS quartile scores were computed, in order to determine which groups of patients are likely to experience a clinically relevant improvement (Table IV).

On average, patients scoring more than 43 points on the RPS scale showed a clinically relevant change on the PSFL. However, the confidence intervals of the third and fourth quartile indicate that this is probably not the case for all patients scoring in this range, because the upper limit is ≥ –18 mm. On the other hand, most patients with a score of < 37 on the RPS are not likely to show a clinically relevant change, because the lower limit is near –18.

### DISCUSSION

The aim of this study was to investigate how predictors, hypothesized to be specific for CTIP (11, 12), may assist in the selection of the most appropriate candidates for this treatment. The predictive value of the theory-derived variables (rational approach to problem-solving, discussion skills, and verbal skills) was investigated by means of a hierarchical linear regression analysis. The variable “rational problem-solving” was thereby identified as a significant predictor of the effectiveness of CTIP, whereas “discussion skills” and “verbal skills” were non-significant. How should these results be interpreted?

SPSI-RPS was theorized to be the strongest predictor for the effectiveness of CTIP, because cognitive change was hypothesized to precede physical change. More explicitly, it was argued that rational problem-solving skills are needed to change maladaptive illness perceptions into alternative perceptions that are more conducive to physical activity. This argument was supported by the results of the clinical trial focusing on CTIP, which demonstrated significant changes in both illness perceptions and physical activity (3).

The finding that SPSI-RPS explained 3.9% of the total variance is encouraging. Unlike other studies, we tested a priori hypotheses. Other predictor studies have yielded higher explained variances, e.g., 22% in a study carried out by Woby et al. (34), but they performed post-hoc analysis, searching for the best combination of a variety of variables. In general, the evidence that psychological variables can predict physical activity is weak (35). A further complication in comparisons with other studies is that different studies controlled for different variables, such as demographic and illness-related variables, which were all related to the specific question that was addressed in these studies “Which patients are at risk?” Therefore, our aim was to answer the question “What treatments work best for whom?” In addition, CLBP problems are complex by nature, and are influenced by a variety of factors (6), thus smaller explained variances are to be expected. Moreover, treatment-related factors that are related to treatment integrity should also be taken into account. A study of the integrity of CTIP (Siemonsma, personal communication) revealed that therapists had difficulty in identifying and changing maladaptive illness perceptions into alternative perceptions, i.e., in the patient files maladaptive illness perceptions were identified in 56% of the patients and alternative illness perceptions were formulated in 44% of the patients. So, when therapists actually appeal less than they had intended to a patient’s “mental experimentation” skills for formulating alternative illness perceptions, the hypothesized treatment-specific predictors will also manifest themselves less prominently. Indeed, it is very likely that the success of CTIP depends on the mental experimentation skills of both the patient and the therapist.

Statistical analyses further revealed that the other two treatment-specific predictors, “discussion skills” and “verbal skills”, did not result in any additional explanation of the variance over the SPSI-RPS. A possible reason is that the measurement instruments were not specifically designed to assess the specific skills needed for CTIP. Appropriate measures for treatment-specific predictors are not readily available, thus new instruments may have to be developed (36–38), or less appropriate instruments have to be used. For example, in the present study the NPV-AGG was chosen to measure discussion skills, such as being open-minded, having ability to listen to others, and being tolerant of other people’s opinions, knowing that this scale was not specifically designed to assess the skills needed for Socratic dialogue. This also applies to “verbal skills”. On second thoughts, the pen and paper test of “word relations” and “word analogies” is more a test of knowledge than a test appealing to patients’ active communication. In fact, because of the lack of suitable measurement instruments in general, we decided not to include a fourth treatment-specific predictor, “problem-focused coping”, which was hypothesized to be a relevant predictor for CTIP in a previous publication in this journal (12).

A strength of this theory-driven predictor study is that it generated clinically relevant information that can be used to select the most appropriate candidates for CTIP. A minimum score of 44 on the RPS scale may, for instance, assist clinicians in selecting the most appropriate candidates for CTIP. A second strength of this type of study is that we have identified predictor variables that, without the use of treatment theory, would otherwise not have been investigated. The results of

<table>
<thead>
<tr>
<th>Quartile</th>
<th>SPSI-RPS score range</th>
<th>Average PSFL change</th>
<th>95% CI PSFL change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt; 37</td>
<td>–10.65</td>
<td>–19.92 to –1.37</td>
</tr>
<tr>
<td>2</td>
<td>37–43</td>
<td>–13.32</td>
<td>–21.59 to –5.05</td>
</tr>
<tr>
<td>3</td>
<td>44–51</td>
<td>–18.59</td>
<td>–25.95 to –11.24</td>
</tr>
<tr>
<td>4</td>
<td>&gt; 51</td>
<td>–24.20</td>
<td>–33.12 to –15.28</td>
</tr>
</tbody>
</table>

SPSI-RPS: Social Problem Solving Inventory—Rational Problem-Solving scale; CI: confidence interval; PSFL change: Patient-Specific Functioning List change score.
first-generation predictor studies have added to our knowledge concerning suitability for rehabilitation treatment in general, by focusing on demographic variables and other variables that are generic for the CLBP population. The accumulation of treatment-specific predictor studies may create a body of knowledge that can assist clinicians in their everyday decisions concerning “what treatment works for whom”. Deliberate tests of theory-driven hypotheses do, indeed, help to generate knowledge for the further understanding of the working mechanisms underlying different methods of treatment.

A limitation of treatment-specific predictor studies, in general, is that the measurement instruments are not as readily available as the generic instruments in first-generation studies. Indeed, the instruments need to be treatment-specific, which still requires the investment of a great deal of research into the development of new instruments. Treatment-specific predictor studies are still in their infancy, and the focus on treatment theory is increasing (39–41). For the present study, the number of cases per predictor was within the set limits for a reliable estimation of the regression equation; thus it is likely that the resulting model will cross-validate well. However, further research is needed to broaden our knowledge with regard to the exact nature of RPS as a predictor. For example, tests of the current model in an untreated group might demonstrate whether RPS is, indeed, treatment-specific. Testing the model in other methods of CBT might establish whether RPS is unique to CTIP, or can also predict physical change in other treatment methods. For instance, it cannot be ruled out that RPS is also predictive of physical change in gradual exposure in vivo, because this treatment also contains cognitive elements. However, we hypothesize that this would apply less to graded activity in its strict behavioural form. It is also important to establish the predictive value of RPS for longer-term outcomes. Obviously, replication of the present results is needed, and further research into the issue of treatment-specific predictors is warranted.

In conclusion, the aim of this study was to investigate how theory-derived predictors, hypothesized to be specific for CTIP, may assist in the selection of the most appropriate candidates for this treatment. We found that “rational problem-solving” was a significant predictor for the effectiveness of CTIP. Second-generation predictor studies are a rapidly developing field of research that may not only generate clinically useful results, but will also extend the field of prediction research from proving (that some patients react better to rehabilitation treatment than others) to improving (by tailoring different methods of treatment to specific subgroups of CLBP patients).

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