CHAPTER 5

Cognitive Treatment of Illness Perceptions in Patients with Chronic Low Back Pain: Results of a Randomized Controlled Trial

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ABSTRACT

Background: Chronic non-specific low back pain (CLBP), and resulting activity limitations, are a major challenge for health care and society. Illness perceptions have been shown to predict patient activities, and targeted illness-perception interventions for acute diseases have demonstrated promising results. However, there are no available interventions that focus on illness perceptions concerning CLBP.

Objective: The effectiveness of treatment of illness perceptions was compared with a waiting list control group.

Design: A single-blinded randomized controlled trial.

Setting: The study was conducted in the outpatient rehabilitation clinic of the Department of Rehabilitation Medicine and Psychology, Reade - Dr Jan van Breemen Institute, Amsterdam, The Netherlands.

Patients: Eligible patients (18–70 years) experienced back pain (> 3 months), and met the diagnostic criteria for CLBP. Patients (n=156) were randomly assigned to treatment or a waiting list.

Intervention: Treatment of illness perceptions was designed to reduce activity limitations by changing illness perceptions in CLBP patients. Trained physical and occupational therapists delivered 10 to 14, one hour, sessions according to treatment protocol.

Measurements: The primary outcome measure was patient-relevant physical activities. The secondary outcome was changes in illness perceptions.

Results: At 18 weeks, statistically significant (p=0.013) and clinically relevant effect (19.1 mm) was found on patient-relevant physical activities. Statistically significant changes were also found on the majority of illness perception scales.

Limitations: Further research should focus on longer term effectiveness and optimal candidates for the intervention, and on replication of the results in a larger multi-centre study.

Conclusions: This first trial evaluating cognitive treatment for illness perceptions concerning CLBP, showed statistically significant and clinically relevant improvements in patient-relevant physical activities for at least 18 weeks.
INTRODUCTION
Chronic non-specific low back pain (CLBP) is a major cause of activity limitations, absenteeism and high health care expenses (Tulder van, Koes et al., 1995). The prevalence of CLBP is estimated at approximately 23%, and activity limitations due to low back pain were found in 11-12% of the population (Airaksinen, Brox et al., 2006). There is broad evidence that illness perceptions, or patients’ personal thoughts about the symptoms they experience (Leventhal, Benyamini et al., 1997), predict health behaviour (such as visits to the doctor and medication adherence), and activity limitations in a variety of illnesses (Hagger & Orbell, 2003), including low back pain (Foster, Bishop et al., 2008; Foster, Thomas et al., 2010). Leventhal’s Self-Regulation Model (SRM) provided a theoretical foundation for these findings, showing that maladaptive illness perceptions can lead to maladaptive behaviour (Leventhal et al., 1997), i.e. activity limitations.

Illness perceptions are well recognized as a target for treatment (Foster et al., 2008; Moseley, 2004; Buchbinder, Jolley et al., 2001; Foster et al., 2010; Macfarlane, 2008), and illness perception interventions have shown promising results for patients with acute (Broadbent, Ellis et al., 2009; Ward, Donovan et al., 2008; Petrie, Cameron et al., 2002; Buchbinder & Jolley, 2004) and chronic conditions (Botha-Scheepers, Riyazi et al., 2006; Hagger et al., 2003). There are, however, no CLBP rehabilitation interventions that focus predominantly on illness perceptions as defined in the SRM. Therefore we developed and tested an intervention applying the SRM for CLBP: cognitive treatment of illness perceptions (CTIP) (Siemonsma, Schroder et al., 2008). CTIP is distinct from other rehabilitation interventions that have changing cognitions as one of their aim, first because the cognitions are well defined and theorized (i.e. illness perception and SRM) and second because the illness perceptions are the main target for change and not one among many targets of treatment. In addition CTIP is an innovative treatment by applying a health psychology theory (i.e. SRM) in physical and occupational therapy.

We investigated whether patient-relevant activity limitations in patients with CLBP can be reduced by adjusting maladaptive illness perceptions by applying CTIP. CTIP starts by exploring the patient’s own ideas about CLBP, based on SRM illness perception dimensions (identity, timeline, cause, consequences, control, coherence, and emotional responses). Socratic dialogue (Nelson, 1994) was the technique used to invite patients to elaborate on their illness perceptions and to arrive at illness perceptions that are conducive to physical activity. The aim of this study was to test the hypothesis that CTIP is more effective than a waiting
list (WTL) in reducing patient-relevant activity limitations, and in changing maladaptive illness perceptions.

**MATERIALS AND METHODS**

*Study population and setting*

Between December 2004 and May 2008, patients with CLBP were invited by letter (including written information 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) for at least 3 months, current episode of back pain lasting less than 5 years, activity limitations (Roland Disability Questionnaire, RDQ > 3) (Ostelo, Vet de et al., 2004), no previous multidisciplinary treatment for CLBP, no involvement in litigation concerning CLBP, absence of serious psychological or psychiatric problems, no substance abuse interfering with treatment, not pregnant, able to fill in questionnaires without help, and written informed consent.

Selection criteria were checked in two steps: 1) on paper, from the completed screening questionnaires, 2) in person for patients meeting the screening criteria, by physiatrists and psychologists from the multidisciplinary team. The Medical Ethics Committee of the Slotervaart Hospital in Amsterdam approved the study protocol (number 0541), the trial was registered (ISRCTN35108886), and the results were reported according to the Consolidated Standards of Reporting Trials (CONSORT statement) (Moher, Schulz et al., 2001). The Netherlands Organization for Health Research and Development (ZonMw) supported the first author (grant no. 014-32-041). The authors have no conflicts of interest.

*Intervention and waiting list*

Patients who met the selection criteria were included, and randomly assigned to intervention group (CTIP) or control group (WTL). CTIP consisted in general of 10-14 one-hour individual treatment sessions, and was provided weekly by experienced physical or occupational therapists according to the treatment protocol. Patients assigned to WTL waited received no treatment and were measures at 18 weeks.

The SRM is a central theory guiding the treatment. In the SRM it is assumed that an individual first forms a representation of the illness, and subsequently adopts behaviours to cope with this (Leventhal, Halm et al., 2004; Ogden, 2000; Petrie, Weinman et al., 1996). The SRM distinguished five
dimensions of illness perceptions: 1) identity, 2) time-line, 3) cause, 4) consequences, and 5) control/cure. The dimension, ‘identity’, refers to the symptoms experienced (e.g. pain, fatigue). The dimension, ‘time-line’, reflects the patient’s ideas about how long the illness will last, and whether it will be a temporary or a persistent problem, e.g. ‘I will have increasingly more back problems for the rest of my life’. The dimension ‘cause’, reflects the individual’s ideas about the cause of the illness, e.g. ‘we have weak backs in our family’. The dimension, ‘consequences’, refers to the individual’s ideas of the possible impact of the illness on his or her life, e.g. ‘I’ll end up in a wheelchair, and I’ll lose my job’. The dimension ‘control/cure’ includes the patient’s ideas about whether or not the illness can be controlled by him/herself or by treatment, e.g., ‘The only thing I can do to help my back problem is to lie down’ or, ‘Treatment won’t help, I’ve tried so many things and nothing has worked’ (Leventhal, Nerenz et al., 1984). To assess the patient’s illness perceptions, we included the Illness Perceptions Questionnaire-Revised (IPQ-R) (Moss-Morris, Weinman et al., 2002; Weinman, Petrie et al., 1996) in our diagnostic assessment.

In CTIP the first phase of treatment is mapping of existing illness perceptions. For mapping, the answers to the IPQ-R are used as a starting point, and with help of a Socratic style of dialogue (Nelson, 1994; Vincelli, Choi et al., 2000), patients are stimulated to elaborate on their thoughts about their low back pain in relation to their limitations in activity. The aim is to get an overview of the patient’s illness perceptions. An illness perception that might come up is: ‘I need to rest in bed in order to allow the pain to fade away’. The second phase is aimed at challenging maladaptive illness perceptions. Those illness perceptions that are most limiting for physical activity, and according to the therapist’s biomedical knowledge are maladaptive, are questioned with the aim of creating doubt about these illness perceptions. To continue the example: this might be done by questioning the patient’s perception that resting in bed will decrease the pain. In the third phase alternative illness perceptions are formulated. Socratic dialogue is used here to change maladaptive illness perceptions into alternative perceptions conducive to physical activity. The therapist initially fosters the exploration of alternative cognitions by asking the patient to compare his or her cognitions with those of significant others, searching for information in libraries or on the internet. This phase ends when both the patient and the therapist feel that plausible and intelligible alternative perceptions have been found. An alternative illness perception may for example be that ‘Doing light jobs is a suitable replacement for bed rest, as it allows the body to recuperate and it distracts my attention away from the pain’. In the fourth phase alternative perceptions are
Results of a Randomized Controlled Trial

tested and practiced in daily life activities. This phase is focused on strengthening the alternative cognitions by confirming their utility in daily practice. To continue the example: in this phase the patient practices the use of light jobs instead of bed rest. For further details on CTIP see Siemonsma et al. 2008 (Siemonsma et al., 2008).

The intervention was considered to be incomplete if less than five treatment sessions were attended. This number reflects the minimum number of treatments needed to map the illness perceptions (2 sessions), to challenge maladaptive illness perceptions (2 sessions) and to formulate alternative illness perceptions (1 session). Both CTIP and WTL patients were asked not to participate in any other diagnostic or therapeutic CLBP procedures during the study period. Co-interventions were monitored in a cost-diary (Goossens, Rutten-van Molken et al., 2000). In the diary both health care and other costs related to the back problem were recorded for two consecutive weeks. Patients were asked to report their back-pain related visits to the general practitioner, medical specialist, physiotherapist, alternative medicine, and any pain medication taken for their back problem. Data were collected to estimate comparability of co-interventions in the groups.

The four physical and three occupational therapists delivering CTIP according to protocol were experienced in treating chronic pain patients in a multidisciplinary rehabilitation setting. Before the trial started, the therapists received extensive training in CTIP, consisting of an explanation of the treatment rationale and structure, the protocol and skills training. Three refresher courses were provided each year throughout the study period. The protocol required that therapists discussed the progress of each patient at least twice with an experienced psychologist supervisor.

Randomization and blinding

Patients were randomized to CTIP or WTL after the baseline assessment. Randomization followed a predetermined computer-generated block-randomization schedule (block size 12), and opaque sealed and numbered envelopes were prepared by an independent fellow researcher before recruitment started. An independent randomization officer received the names and study numbers of eligible patients, opened the envelope with the corresponding number, and communicated the treatment or waiting list requirements. The researchers and independent assessors were thus blinded for both group allocation and randomization schedule.

To improve statistical power for a future study of predictors of the effect of CTIP, an unequal distribution (2:1) of patients over CTIP and WTL was chosen.
(Siemonsma, Schroder et al., 2010). To ensure equal treatment expectations for both groups, patients were informed that all study participants would eventually receive the same treatment, but that the timing was different. WTL patients received CTIP after 18 weeks. Patients and therapists could not be blinded for treatment allocation, but the therapists were blinded for the timing of CTIP.

**Data-collection**

The patients were assessed in the outpatient department by an independent assessor at baseline (week 0) and follow-up (week 18). Patients, who were unable or unwilling to come to the department for follow-up, received the questionnaires by mail. The follow-up assessments were performed between April 2005 and November 2008. All patients, whether or not they completed the treatment, were invited for the follow-up assessment.

At baseline, we collected data on 1) demographic variables: age, gender, marital status, native language, level of education, and work status, and 2) clinical variables: time since first onset of complaints, activity limitations (RDQ) (Ostelo et al., 2004), current pain (100 mm Visual Analogue Scale, VAS), symptoms of anxiety and depression (Hospital Anxiety and Depression Scale, HADS) (Bjelland, Dahl et al., 2002), overall complaints (Symptom Check List, SCL-90) (Arrindell & Akkerman, 2004; Peebles, McWilliams et al., 2001), fear of injury/movement (Tampa Scale of Kinesiophobia, TSK) (Goubert, Crombez et al., 2004; Swinkels- Meewisse, Swinkels et al., 2003), and health care use (Goossens et al., 2000).

**Outcome measures**

The aim of CTIP is to reduce patients’ activity limitations by changing their illness perceptions. The Patient Specific Functioning List (PSFL) (Beurskens, Vet de et al., 1999; Pengel, Refshauge et al., 2004) was the primary outcome measure. This measure allowed for personal relevance and circumstances, and was a logical consequence of using the SRM as the main treatment theory: SRM is focussed on the individual’s thoughts and aims (Leventhal, Brissette et al., 2003; Ogden, 2000). PSFL was administrated according to the procedure described by Beurskens et al. (Beurskens et al., 1999). This included a three step process leading the patient to the selection of their most important physical activities: 1) prioritizing activities, that are difficult to perform and important to improve upon in the next 3 months, using a list of 36 daily activities, 2) writing out the top three prioritized activities in patient-relevant terms, and 3) indicating on a VAS (0=no difficulty; 100=impossible) how difficult it was to perform each activity in the previous week. These activities are finalized in a second meeting (just before starting treatment),
therewith giving the patient time to think about what their most important activities are. The score on the most important activity was used as the primary outcome. The PSFL is valid, reliable and sensitive to change (Beurskens, Vet de et al., 1996).

The revised Illness Perception Questionnaire (IPQ-R) (Moss-Morris et al., 2002; Weinman et al., 1996) (secondary outcome measure) was included to diagnose illness perceptions and to measure changes, and was designed to specifically measure the dimensions of the SRM, e.g. 1) timeline, 2) timeline cyclical, 3) consequences, 4) personal control, 5) treatment control, 6) coherence and 7) emotional responses (Moss-Morris et al., 2002). IPQ-R included 37 statements, scores ranged from 1= strongly agree to 5 strongly disagree. Higher scores indicate 1) longer duration (range 1-30), 2) more cyclical nature (range 4-20), 3) more consequences (range 6-30), 4) more personal control (range 6-30), 5) more treatment control (range 5-25), 6) lower coherence (range 5-25) and 7) more emotional reactions (range 6-30). Scales are not to be summarized into a total score.

The Quebec Back Pain Disability Scale (QBPDS) (Verbunt, 2008) was added to the study design to facilitate comparison with other studies. Including such an internationally accepted measure in a trial makes comparison with the results of other studies possible, and might facilitate the inclusion of the trial in future reviews and meta-analyses (Moher et al., 2001). The QBPDS includes 20 physical activities, rated from 0 = no difficulty to 5 = impossible. Total scores range from 0 to 100. This measurement instrument is a reliable and valid outcome measure in the field of research on chronic low back pain (Schoppink, Tulder van et al., 1996). No changes are expected to be found on this generic physical activities scale at 18 weeks.

Statistical analysis
A decrease of 18-24 mm on the PSFL was determined as a clinically relevant change in patients with low back pain (Beurskens et al., 1996). The sample size was calculated with a minimum of 18 mm change, a two-sided Alpha of 0.05, a 1-beta = 0.90, and a standard deviation (SD) of 26.01. This SD was calculated from available PSFL data from CLBP patients in our centre, and resulted in a total of 135 participants.

Descriptive statistics of baseline variables were calculated to compare the two study groups. The level of education was classed ‘low’ (primary education), ‘intermediate’ (secondary education), or ‘high’ (higher education and university). For both groups PSFL change scores were calculated (follow-up minus baseline),
to determine whether the changes were clinically relevant (Beurskens et al., 1996), and the odds ratio (OR) was computed to estimate the chance of obtaining a clinically relevant change in the CTIP group, compared to the WTL group. A baseline-adjusted analysis of covariance was performed to test the effectiveness of CTIP in reducing patient-relevant activity limitations in the two groups. Group (CTIP versus WTL) was the independent variable, and follow-up PSFL score was the dependent variable. Covariates were: baseline PSFL score, age, gender, time since first onset of CLPB, and level of education. Level of education was included as a covariate because the skills needed for CTIP might be associated with a higher level of education. Identical analyses were performed for the IPQ-R and the QBPDS. Interactions of clinical variables (RDQ, VAS pain, HADS, SCL, and TSK) with the group variable were analyzed in order to check whether clinical variables were potential effect modifiers. Non-significant (p > 0.05) interaction terms were removed from the model, and significant (p < 0.05) interactions were analysed within strata.

To estimate the effectiveness of the treatment, the number needed to treat (NNT) was computed. The NNT is computed by subtracting the proportion benefiting from the WTL from the proportion benefiting from the CTIP and then taking the inverse. A -18 mm change on the PSFL, was used as to define a beneficial outcome. All analyses were performed with SPSS statistical software 16.0 (SPSS, Inc., Chicago), and carried out according to the intention-to-treat principle. No imputation of missing data was performed.

RESULTS

Study population

352 patients received a written invitation to participate in the study. Of those patients 28 refused participation prior to the first appointment, 4 patients preferred to (remain to) be treated elsewhere, and 116 patients did not meet the inclusion criteria. The two inclusion criteria most frequently not met were: 65 patients were unable to fill in the questionnaires without help, and in 21 patients the current episode of low back pain existed for more that 5 years. The remaining 204 patients were medical examined, psychologically screened, and received verbal explanation of the study. A total of 156 patients met all criteria, gave written informed consent to participate in the study, completed baseline measurements and were randomized. Of the 104 patients being treated, 19 received less than 5 treatments and were registered as 'incomplete treatment' in Figure 1. In total, 12 patients were not assessed at 18 weeks follow up. Reasons for withdrawal from the study or from the treatment are also shown in Figure 1.
Results of a Randomized Controlled Trial

Figure 1. Trial profile
Baseline characteristics

Baseline characteristics (Table 1) and co-interventions (Table 2) were similar between the two groups for all but two variables. A small difference was observed for native language, where the CTIP group had more patients with Dutch as their native language. Furthermore a small difference was observed for education where the CTIP group had fewer patients with a high level of education. However, this variable was a priori used as covariate in our analyses. Please note that although the selection criterion was ‘current episode of back pain lasting less than 5 years’, the ‘time since first onset back pain’ can be longer than 5 years.

Table 1: Summary of baseline characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>CTIP (n=104)</th>
<th>WTL (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>45.6 (12.9)</td>
<td>47.1 (11.1)</td>
</tr>
<tr>
<td>Gender: female n, (%)</td>
<td>56 (53.8)</td>
<td>31 (59.6)</td>
</tr>
<tr>
<td>Marital status: living alone, n (%)</td>
<td>26 (25.0)</td>
<td>10 (19.2)</td>
</tr>
<tr>
<td>Native language Dutch, n (%)</td>
<td>94 (90.4)</td>
<td>41 (80.4)</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>39 (37.5)</td>
<td>16 (31.4)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>47 (45.2)</td>
<td>17 (33.3)</td>
</tr>
<tr>
<td>High</td>
<td>18 (17.3)</td>
<td>18 (35.3)</td>
</tr>
<tr>
<td>Work status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>38 (41.8)</td>
<td>22 (47.8)</td>
</tr>
<tr>
<td>Disability pension</td>
<td>19 (20.0)</td>
<td>7 (15.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical variables</th>
<th>CTIP (n=104)</th>
<th>WTL (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time since first onset back pain (months)</td>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td>Activity limitations (RDQ)</td>
<td>12.2 (4.2)</td>
<td>12.7 (4.7)</td>
</tr>
<tr>
<td>Current pain (VAS)</td>
<td>55.7 (21.6)</td>
<td>55.8 (20.8)</td>
</tr>
<tr>
<td>Anxiety (HADS)</td>
<td>5.5</td>
<td>5.0</td>
</tr>
<tr>
<td>Depression (HADS)</td>
<td>5.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Overall complaints (SCL-90)</td>
<td>132.5</td>
<td>126.0</td>
</tr>
<tr>
<td>Fear of movement (TSK-R)</td>
<td>29.1 (6.1)</td>
<td>28.3 (6.5)</td>
</tr>
</tbody>
</table>

*Values presented are means (SD), values presented are medians since skewness exceeded -1 or 1. CTIP = cognitive treatment of illness perceptions; WTL = waiting list; RDQ = Roland Disability Questionnaire; VAS = Visual Analogue Scale; HADS = Hospital Anxiety and Depression Scale; SCL-90 = Symptom Check List 90; TSK-R = Tampa Scale for Kinesiophobia–revised
Primary outcome analysis

Table 3 shows estimates of the group effect and the covariates for PSFL resulting from the baseline-adjusted covariance analysis. A significant group effect was found (p=0.013). No significant effects were found for the covariates, except for the contrast of high versus low level of education. There was no indication for effect modification, as none of the interactions between the clinical variables and group were significant (p>0.05). CTIP resulted in a clinically relevant PSFL change of -19.1 (95% confidence intervals [CI]: -24.3; -13.9), compared to -5.2 (95% CI: -14.7; 4.2) for WTL (details not shown). In the CTIP group, 46 of the 93 patients (49%) showed a clinically relevant change compared to 12 of the 46 patients (26%) in the WTL group. This resulted in an odds ratio (OR) of 2.77 (95% CI 1.28; 6.01), and a NNT of 4 which implies that out of every four patients at least one would have a beneficial effect of CTIP.

Table 2: Summary of co-interventions during the trial

<table>
<thead>
<tr>
<th>Co-interventions</th>
<th>CTIP (n=104)</th>
<th>WTL (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner</td>
<td>8 (8)</td>
<td>6 (13)</td>
</tr>
<tr>
<td>Medical specialist</td>
<td>5 (5)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>26 (27)</td>
<td>14 (29)</td>
</tr>
<tr>
<td>Alternative medicine</td>
<td>3 (3)</td>
<td>6 (13)</td>
</tr>
<tr>
<td>Pain medication</td>
<td>52 (50)</td>
<td>27 (52)</td>
</tr>
</tbody>
</table>

Values represent number of patients and (percentage of group). CTIP = cognitive treatment of illness perceptions; WTL = waiting list

Table 3: Results of the covariance analysis of PSFL

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>β (SE)</th>
<th>95% CI</th>
<th>Beta</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>33.34 (13.7)</td>
<td>6.32 to 60.36</td>
<td>0.016</td>
<td></td>
</tr>
<tr>
<td>Baseline PSFL</td>
<td>0.45 (0.11)</td>
<td>0.23 to 0.66</td>
<td>0.351</td>
<td>0.000</td>
</tr>
<tr>
<td>Group</td>
<td>-11.54 (4.59)</td>
<td>-20.61 to -2.47</td>
<td>-0.206</td>
<td>0.013</td>
</tr>
<tr>
<td>Age</td>
<td>-0.06 (0.20)</td>
<td>-0.45 to 0.33</td>
<td>-0.029</td>
<td>0.749</td>
</tr>
<tr>
<td>Gender</td>
<td>4.65 (4.29)</td>
<td>-3.84 to 13.13</td>
<td>0.088</td>
<td>0.281</td>
</tr>
<tr>
<td>Time since first onset of back pain</td>
<td>0.02 (0.02)</td>
<td>-0.02 to 0.06</td>
<td>0.090</td>
<td>0.315</td>
</tr>
<tr>
<td>Level of education intermediate vs low</td>
<td>-7.14 (5.08)</td>
<td>-17.18 to 2.91</td>
<td>-0.134</td>
<td>0.162</td>
</tr>
<tr>
<td>Level of education high vs low</td>
<td>-11.51 (5.83)</td>
<td>-23.03 to 0.02</td>
<td>-0.180</td>
<td>0.050</td>
</tr>
</tbody>
</table>

β (SE) = Beta (Standard Error); CI = Confidence Intervals; PSFL= Patient Specific Functioning List
Table 4: Baseline and follow-up scores of PSFL, QBPDS and IPQ and group effects resulting from baseline-adjusted covariance analyses

<table>
<thead>
<tr>
<th></th>
<th>CTIP (n=104)</th>
<th>WTL (n=52)</th>
<th>Group Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline ^</td>
<td>Follow-up ^</td>
<td>Baseline ^</td>
</tr>
<tr>
<td>PSFL</td>
<td>76.2</td>
<td>56.7</td>
<td>71.3</td>
</tr>
<tr>
<td></td>
<td>(72.2;80.3)</td>
<td>(51.2;62.1)</td>
<td>(65.8;76.9)</td>
</tr>
<tr>
<td>QBPDS</td>
<td>40.4</td>
<td>36.9</td>
<td>40.3</td>
</tr>
<tr>
<td></td>
<td>(37.6;43.1)</td>
<td>(33.8;40.0)</td>
<td>(35.8;44.8)</td>
</tr>
<tr>
<td>Timeline</td>
<td>23.6</td>
<td>23.9</td>
<td>23.3</td>
</tr>
<tr>
<td></td>
<td>(22.9;24.3)</td>
<td>(23.1;24.6)</td>
<td>(22.0;24.5)</td>
</tr>
<tr>
<td>Timeline cyclical</td>
<td>13.6</td>
<td>14.1</td>
<td>13.0</td>
</tr>
<tr>
<td></td>
<td>(12.9;14.4)</td>
<td>(13.4;14.7)</td>
<td>(12.1;14.0)</td>
</tr>
<tr>
<td>Consequences</td>
<td>19.0</td>
<td>17.7</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>(18.3;19.8)</td>
<td>(16.7;18.7)</td>
<td>(17.0;19.3)</td>
</tr>
<tr>
<td>Personal control</td>
<td>19.1</td>
<td>21.1</td>
<td>19.2</td>
</tr>
<tr>
<td></td>
<td>(18.3;20.0)</td>
<td>(20.2;21.8)</td>
<td>(18.0;20.3)</td>
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<td>Treatment control</td>
<td>17.1</td>
<td>15.9</td>
<td>17.1</td>
</tr>
<tr>
<td></td>
<td>(16.6;17.6)</td>
<td>(15.2;16.7)</td>
<td>(16.4;17.8)</td>
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<tr>
<td>Coherence</td>
<td>14.3</td>
<td>11.7</td>
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<tr>
<td></td>
<td>(13.4;15.2)</td>
<td>(10.8;12.5)</td>
<td>(12.3;15.1)</td>
</tr>
<tr>
<td>Emotional response</td>
<td>16.9</td>
<td>15.5</td>
<td>17.5</td>
</tr>
<tr>
<td></td>
<td>(16.0;17.8)</td>
<td>(14.5;16.4)</td>
<td>(16.1;18.9)</td>
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^ Values represent mean scores and 95% Confidence Intervals; ^ scale of the Illness Perception Questionnaire. CTIP = cognitive treatment of illness perceptions; WTL = waiting list; PSFL = Patient Specific Functioning List; QBPDS = Quebec Back Pain Disability Scale

Secondary outcome analyses

Table 4 shows the means and 95% CI of the PSFL, IPQ-R scales and QBPDS for both groups at each time point. Baseline-adjusted covariance analyses for IPQ-R and QBPDS were performed identically to the PSFL analyses (details not shown). The p-values corresponding to the group effect are shown in Table 4. Significant differences between WTL and CTIP were found for four IPQ-R scales: timeline cyclical, consequences, personal control and coherence (Table 4). Regression analysis revealed that the change scores of these four IPQ-R scales explained 14.4% of the variance of the PSFL change. Of the scales only personal control and consequences contributed significantly to the model (p=.023 and p=.006). No significant differences were found for QBPDS (results not tabled).
**Summary of key findings**
CTIP significantly improved patient-relevant activity (PSFL) in CLBP patients at 18 weeks, compared to the WTL, which is in accordance with our hypothesis. The changes in patient-relevant activity were also clinically relevant; thereby indicating the CTIP is a relevant treatment for clinical practice. The NNT is 4, indicating that 4 patients have to be treated for one to achieve a clinically relevant improvement in physical activities in comparison to the waiting list. Statistically significant changes were found on the following illness perception dimensions timeline cyclical (p=0.007), consequences (p=0.048), personal control (p=0.001), and coherence (p=0.022), indicating that the illness perceptions changed. These changes were related to changes in patient-relevant activities and explained 14.4% of the variance, which seems to support CTIP's working mechanism. No significant differences were found for generic physical activities (QBPDS), which is in line with our expectations and might reflect the strong focus of CTIP on patient-relevant physical activities.

**DISCUSSION**

*Study population*
We included a sample of low back pain patients with an average complaint duration of 63 months. The average disability score was 12 activity limitations on the RDQ. The patient characteristics were comparable to other trials in rehabilitation settings (Leeuw, Goossens et al., 2008; Smeets, Vlaeyen et al., 2006) which have reported back pain durations of 60-108 months and average scores of 14 to 15 on the RDQ. The recruitment process in our study resulted in inclusion of 48% (156/352 patients) of all potential patients and 76% (156/204) of paper-screened patients. These rates were identical to a study by Leeuw et al. (Leeuw et al., 2008) including 48% (85/177) of all potential patients and were fairly similar to a study by Smeets et al. (Smeets et al., 2006) including 72% (223/309 patients) of pre-selected patients. Hereby we were satisfied that a relatively chronic and fairly disabled population of back pain patients was recruited, with patient characteristics and recruitment rates that were similar to other studies on CLBP. Thus, the study sample seems representative for the general rehabilitation population, and the results are likely to generalize to other CLBP patients referred for rehabilitation in the Netherlands.

The statistically significant and clinically relevant changes found in this study are very encouraging, as no effort was made to specifically select the best candidates for CTIP (for example patients with maladaptive illness perceptions). It is likely that even greater treatment effects can be obtained when such sub-
groups of best candidates for CTIP can be identified. This issue was anticipated upon by incorporating a further study on treatment-specific predictor variables of CTIP effect in the research design (Siemonsma et al., 2010) and the results are forthcoming (Siemonsma, Stuve et al., 2010).

**Randomisation**
Baseline characteristics, except for the variables “high versus low” level of education and of native language, were comparable between groups. Unequal distribution of those two variables might be due to the unequal group sizes following randomisation. Education was an a priori covariate in the statistical analyses, and was therefore corrected for. The slightly higher percentage of native language speakers in the CTIP group might have caused some advantage, assuming that not being a native speaker is associated with being less skilled in verbalizing one’s thoughts during treatment. The impact of this factor is expected to be small.

**Intervention and waiting list**
To our knowledge this is the first intervention study specifically targeting illness perceptions in CLBP. Illness perception-based interventions are an emerging field which have mostly been focussed on more acute diseases. Positive results have been found for individual interventions on myocardial infarction (Broadbent et al., 2009; Petrie et al., 2002) and cancer pain (Scharf Donovan & Ward, 2001) and for a population based intervention on acute back pain (Buchbinder et al., 2004).

CTIP was well accepted by patients, with only 19 out of 104 patients (18%) withdrawing from treatment. Since no effort was made to select the best candidates for CTIP, for example by selecting patients who wanted a cognitive treatment rather than a physical treatment, withdrawal from treatment was expected to be somewhat higher than in other studies. This percentage however was lower that the 33% reported by Leeuw et al. (Leeuw et al., 2008) and the 23% reported by Smeets et al. (Smeets et al., 2006). In addition, no adverse effects were reported and co-interventions were comparable to those in other studies (Smeets, Vlaeyen et al., 2008).

CTIP was delivered according to a protocol in a single setting. Therapists were well trained and booster sessions and continuing supervision were provided to ensure therapist competence and adherence to protocol throughout the trial period. Fidelity to treatment protocol was monitored throughout the study and threats to fidelity were addressed in the training and booster session. Fidelity to treatment protocol was assessed using all patient notes after the trial, results of
this are forthcoming. Also the issue of physical therapists and occupational therapists delivering a predominantly cognitive intervention is under investigation, i.e. treatment effects are being compared to those of psychologists delivering CTIP according to protocol. Future studies may focus not only on replication of the results and longer term effectiveness, but also on optimizing the treatment and its delivery (e.g. the optimal content, mode of delivery, length and dose of the treatment).

The use of a WTL group as the control group was a suitable choice for this first study on the effectiveness of CTIP. Future studies should consider different types of (active) control groups in order to separate out specific effects of CTIP over non-specific effects.

Outcome measures
The changes in patient-relevant activity, measured with the PSFL, were statistically significant and clinically relevant as defined within our study. Several acronyms are used for the PSFL, with PSK (Beurskens et al., 1996) being its original Dutch acronym. It should be noted that the measure was also referred to with acronyms such as PSFS (Maughan & Lewis, 2010) and MC (Smeets et al., 2006; Leeuw et al., 2008). The PSFL was shown to be highly responsive to change in patients who reported improvement in back pain symptoms (Beurskens et al., 1999; Frost, Lamb et al., 2008). However, unlike more generic measures, PSFL was unable to detect deterioration (Frost et al., 2008) in patients with mild to moderate disability (RDQ scores 4.8 – 6.1). Therefore, in the interpretation of the positive results on PSFL the possibility of measurement bias should not be ruled out. Clinically relevant changes were found for 46 of the 93 patients in CTIP compared to 12 of the 46 patients in the WTL group (OR 2.77 and NNT of 4). The best method to define and determine a clinically relevant change is however under debate (Terwee, Roorda et al., 2010). Fundamental statistical issues currently cloud the precise estimation of clinically relevant changes in general (Terwee et al., 2010). Therefore, some caution in the interpretation of our results is warranted. Despite these measurement and statistical issues, we judge the first results of CTIP on the PSFL as very positive.

That statistically significant changes were found on the majority of IPQ-R scales, seem in support of CTIP’s working mechanism, i.e. that CTIP resulted in changes in illness perceptions. However, the design of the study does not allow causal inferences. Of the results on the IPQ-R scale, timeline cyclical was hardest to interpret: timeline cyclical scores increased in the CTIP group and decreased in the WTL group. This might indicate a greater acceptance of CLBP as being cyclical
and unpredictable, however this does not explain the findings in the WTL group. The scores on the IPQ-R scale consequences decreased in the CTIP group and revealed no changes in the WTL group, thus indicating that CTIP resulted in reducing the expected consequences or impact of CLBP on daily life. Personal control scores increased in the CTIP group and decreased in the WTL group, reflecting that CTIP resulted in feeling more in control of the CLBP problem. Coherence scores decreased in both groups, however to a greater extent in the CTIP group. As lower scores on the coherence dimension indicate higher coherence, these changes indicated that CTIP resulted in a better understanding of the CLBP problem. Overall, the changes on the IPQ-R were in line with our expectations.

The changes on the IPQ-R scales were shown to be related to those on the PSFL, i.e. the changes explained 14.4% of the variance. The scales ‘consequences’ and ‘personal control’ were found to significantly contribute to this model. As this study is the first intervention study to examine illness perceptions in chronic low back pain patients, little information is available to interpret our results. However, the results seem to be in line with findings by Foster et al. (Foster et al., 2010) who found the scales ‘consequences’ and ‘personal control’ (among other scales), to be predictive of disability scores (RDQ) at 6 months in a mixed population consulting their general practitioner with low back pain. Although our results seem to be in support of CTIP’s working mechanism, other studies are needed to further examine and understand such relationships. For example, studies identifying which illness perceptions are predictive of natural recovery of physical activity and which illness perceptions should be targeted in treatment in order to achieve changes physical activity. The QBPDS showed no statistically significant changes at 18 weeks follow-up, this is in line with our expectations.

CONCLUSIONS
This first study of a cognitive intervention focussing on illness perceptions in CLBP patients, showed statistically significant and clinically relevant improvements in patient-relevant physical activities, and significant changes in illness perceptions for at least 18 weeks. Notwithstanding some methodological limitations of this study, the results are very encouraging. These results add to the increasing awareness that illness perceptions are a factor well worth considering in patients with chronic low back pain. Illness perceptions are recognized as an important predictor of outcome, and we showed that targeted treatment resulted in both an increased physical activity and changes in illness perceptions. Further studies are needed to determine for whom and under what circumstances CTIP can best be
implemented in clinical practice and longer term results on the effectiveness are needed.

REFERENCE LIST


Chapter 5


Chapter 5


