Living with chronic pain

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CHAPTER 7

A randomized controlled trial of an internet-based cognitive-behavioral intervention for non-specific chronic pain

This chapter is submitted as:
A randomized controlled trial of an internet-based cognitive-behavioral intervention for non-specific chronic pain. (submitted)
Abstract

Background: Cognitive-behavioral treatment can nowadays be delivered through the internet. This form of treatment can have various advantages with regard to availability and accessibility. Previous studies showed that internet-based treatment for chronic pain is effective compared to waiting list control groups.

Methods: We conducted a randomized controlled trial comparing an internet-based cognitive-behavioral intervention with e-mail therapist contact to a face-to-face cognitive-behavioral group intervention. Of the 72 participants who were randomly assigned to either an internet or a group course, 50 participants completed the intervention. Participant were assessed at base-line (T0), immediately after the 7-week course (T1) and at the booster session two months later (T2). Pain-related catastrophizing was the primary outcome measure. Pain intensity, fatigue, pain-related interference, locus of control, pain coping, global health related quality of life and medical expenses were included as secondary outcome variables.

Results: Significant improvement was found on catastrophizing, pain coping, locus of control and various aspects of global health-related quality of life in both the internet and the group course directly after the course and at the booster session. Pain intensity was improved in both courses at the booster session. At T2, improvement in catastrophizing, pain intensity, pain coping and some quality of life dimensions was significantly greater in the internet course than in the group course. Furthermore, the internet course was cost-effective compared to the group course.

Conclusions: We conclude that the internet-based cognitive-behavioral intervention was at least as effective as the face-to-face group intervention, and on some outcome measures even more effective.
7.1 Introduction

The cognitive-behavioral treatment of chronic pain focuses on gaining a sense of control over the effects of pain by learning more adaptive ways of thinking, feeling and behaving. In view of the enormous suffering and huge costs associated with chronic pain, this form of treatment is now widely used, often in the context of a group intervention. Cognitive-behavioral group interventions have been shown to be effective in patients with chronic headache (Johnson & Thorn, 1989; Nash et al., 2004), chronic low back pain (Nielsen & Weir, 2001), non-specific chronic pain (Cole, 1998; LeFort et al. 1998) and pain in rheumatoid arthritis (Barlow et al., 1998; Leibing et al., 1999). However, for many patients with chronic pain, cognitive-behavioral treatment is not easily available (Turk & Okifuji, 2002). In addition, the nature of chronic pain complaints often makes it difficult for patients to attend an intervention for which they have to travel to the hospital and sit for longer periods of time.

Nowadays, it is possible to administer cognitive-behavioral treatment through the internet. In recent years, there has been a rapid development of internet-based interventions for various patient groups. These developments have created the need for controlled trials to investigate the effectiveness of these new interventions. Currently, several studies investigating internet-based treatment for chronic pain syndromes have been reported. Significant improvement on pain-related outcomes was reported in internet-based treatment for chronic pain (Ruehlman et al., 2012), chronic back pain (Buhrman et al., 2004; Buhrman et al., 2011; Carpenter et al., 2012), chronic headache (Strom et al., 2000; Devineni & Blanchard, 2005) and fibromyalgia (Lorig et al., 2008; Williams et al., 2010).

These studies all show promising results. It can be concluded that internet-based treatment has the potential to effect positive changes in patients with various pain complaints. However, in these controlled trials comparison was merely made to waiting list control groups. Questions regarding the effectiveness of internet-based cognitive-behavioral interventions compared to standard non-internet-based cognitive-behavioral treatment cannot be answered in this way. It is particularly interesting to compare internet-based treatment with face-to-face treatment. Clinicians and policy makers need to have insight into the relative effects of internet-based treatment and the added value of this form of intervention. Are internet-based treatments at least as effective as face-to-face treatments? And, is internet-based treatment a satisfactory alternative to face-to-face treatment? These questions deserve further investigation.

Previous studies into internet-based treatment for subthreshold depression (Spek et al., 2007b) and panic disorder (Carlbring et al., 2005) indicate that internet-based treatment can be as effective as face-to-face treatment. To our knowledge, no studies comparing internet-based interventions to face-to-face treatment have been conducted in the area of chronic pain.

The aim of the current study was to evaluate the effects of a cognitive-behavioral internet-based intervention with e-mail therapist contact for patients with non-specific chronic pain complaints compared to the effects of a face-to-face cognitive-behavioral group intervention, which is care-as-usual in our clinic. To this effect, a randomized controlled trial with non-inferiority hypothesis was used. Since catastrophizing is a key factor in the adjustment
to pain (Sullivan et al., 2001), this was our primary outcome variable. Moreover, we included pain intensity, fatigue, pain-related interference, locus of control, pain coping, global health related quality of life and medical expenses as secondary outcome variables. We hypothesized that the internet intervention would be at least as effective on these outcome variables as the group intervention.

7.2 Methods

7.2.1 Participants and procedure

Participants were patients of the Pain Center of the University Medical Center Groningen who fulfilled specified inclusion and exclusion criteria. All new patients of the Pain Center are subjected to an interdisciplinary evaluation in which they are evaluated by an anesthesiologist, physical therapist and psychologist. Patients with non-specific chronic pain (defined as pain that lasts beyond the usual course of the acute disease or the expected time of healing) who were advised to take part in the course received an additional introductory interview with the course facilitator and were asked to fill in an informed consent form, after which they could participate in the course. Subsequently, patients were randomly assigned to either the group course or the internet course. A parallel-group design with permuted block randomization (ratio 1:1; block size of 14) was used. For allocation of participants computerized random numbers were used. The allocation sequence was concealed from the researcher enrolling and assessing participants in sequential numbered, opaque, sealed envelopes. The course was offered at no costs to the participants, nor did they receive compensation for participating in the course. The study took place at the Pain Center of the University Medical Center Groningen.

The following inclusion criteria applied: (a) having non-specific chronic pain complaints and/or chronic pain complaints for which no somatic treatment could be offered, (b) a minimum age of 18 years, and (c) having access to the internet. Exclusion criteria were (a) severe psychopathology (as measured by a psychodiagnostic interview and scores on the Symptom Checklist 90 (cut-off score of 224; Groenman et al., 1993) and (b) limited intelligence (highest education level achieved less than primary education).

7.2.2 Ethics

The study was conducted with approval of the Ethics Committee of the University Medical Center Groningen (file UMCG-METc 2007.265).

7.2.3 The course

The group course

The group course, titled “Learning to live with pain”, consists of eight sessions of two hours (seven continuous sessions and a booster session two months after the last session). The group sessions took place in a meeting room at the hospital and were facilitated by a trained
psychologist of the Pain Center. The group was a closed entity; no new participants were admitted after the course had started. A structured protocol was used (De Boer et al., 2004), in which the program and content of the course is described. Use of this protocol ensured a standardized administration of the course. Patients were given a 25-page course book containing background information and relevant material for the homework assignments. During the study period, the course was given six times by three different psychologists.

Central to the course is the cognitive behavioral model of the pain circle (Figure 7.1). This model contains various aspects of the pain experience (e.g. pain sensations, behavior, feelings, cognitions) and shows the interrelationship among these diverse aspects of chronic pain. The model is presented to the patients as a vicious circle for which various approaches need to be used to escape this circle. These approaches are discussed in the sessions of the course, with each session focusing on one particular aspect of the pain circle. Sessions consist of brief lectures explaining the theory of chronic pain, group exercises and focussed group discussions. Moreover, each session contains homework assignments, which are subsequently discussed in the next session. These homework assignments ensure that patients are actively involved in the course and learn to apply the newly-learned material to their own personal situation.

Session 1 focuses on the introduction to the course and the question “What is chronic pain”. Session 2 is dedicated to pain and activities with a focus on graded activity. In session 3, pain and stress are discussed and relaxation exercises are taught. Session 4 and 5 focus on pain cognitions. In these sessions, cognitive restructuring techniques are applied. Next, in session 6 the focus is on attention for the body, with various exercises to learn to disengage attention from the pain. Finally, in session 7 all topics are recapitulated and integrated. Two months after session 7, a booster session (session 8) takes place, containing a short refresher course and a discussion of how to proceed on one’s own after the course is finished.

![Figure 7.1](image)

*Figure 7.1 The pain circle: the central model of the course*

**The internet course**

The internet course has the same program and content as the group course (described above). Before the start of the course, a manual containing information about how to access the internet course is sent to the participants. The entire content of the course has been placed on a secure website. Participants receive a login account with a personal password, with which they subsequently can access the internet course. The internet course consists
of eight modules (comparable to the eight sessions of the group course). Each week, participants get access to a new module. Each module contains information about pain and its contributing factors, multimedia applications (e.g. games, interactive animations, sound files for the relaxation exercises) and exercises. The content of the modules is identical to the sessions in the group course (see above).

Each module is followed by homework assignments. These assignments are filled in on the computer and are subsequently submitted by e-mail to the course facilitator (a psychologist of the Pain Center). Participants receive personal feedback from their psychologist. In this way, there is personal contact between the patients and their psychologist. The e-mail messages from the psychologist in response to the submitted homework assignments were to a large extent standardized. After the modules 2, 4, 7 and 8, additional e-mail contact took place, focused on discussing the progress in the course, experienced difficulties and any questions the participant had concerning the course. In case of technical problems or severe aggravation of symptoms, patients had the option to contact the course facilitator by e-mail as well as by telephone. During the study period, one psychologist treated all participants in the internet course.

7.2.4 Measures

Repeated measurements took place at the start of the course (T0), immediately after the 7-week course (T1) and at the booster session two months after the last session (T2). All questionnaire booklets were sent by post. The questionnaire booklet contained questions concerning demographics (gender, age, education, marital status) and the nature of the pain complaints (location, duration, origin).

Treatment effects

The primary outcome measure was the Pain Catastrophizing Scale. Visual Analogue Scales, the Pain Coping and Cognition List and the RAND-36 were included as secondary outcome measures.

Pain Catastrophizing Scale

The Pain Catastrophizing Scale (Sullivan et al., 1995) was used as a measure of pain-related catastrophizing; the primary outcome variable in our study. The PCS is a 13-item self-report questionnaire for use in both clinical and non-clinical populations, measuring the degree to which pain is perceived as threatening. Participants are asked to reflect on a painful experience (“When I’m in pain...”) and to indicate on a 5-point Likert scale the degree to which they experienced various thoughts and feelings. The PCS yields a total score with a range from 0 to 52, and three subscale scores (magnification, rumination, and helplessness). In the Dutch version of the PCS, the three factor structure has been confirmed across different patient samples and a non-clinical sample (Van Damme et al., 2002). The Dutch version of the PCS has a high internal consistency (Cronbach's alpha varies between 0.85 and 0.91; Van Damme et al., 2000) and the PCS has a good test-retest reliability ($r = 0.75$ over a period of six weeks and $r = 0.70$ over a period of ten weeks for the English version; Sullivan et al., 1995). For the Dutch
version of the PCS, norms are available for chronic pain patients (divided into chronic back pain patients and fibromyalgia patients) and healthy subjects (students, divided by gender) (Van Damme et al., 2000).

**Visual Analogue Scales**

VAS-scores (Visual Analogue Scale, with scores from 0 = “not at all”, to 10 = “extremely”) were used for a) the experienced pain intensity during the last two days (“How much pain did you experience during the last two days?”), (b) the extent of pain-related interference during the last two days (“To what extent did you experience interference in your daily activities because of your pain during the last two days?”), and (c) the extent of fatigue during the last two days (“How much fatigue did you experience during the last two days?”).

**Pain Coping and Cognition List**

The Pain Coping and Cognition List (De Gier et al., 2004) is a questionnaire for the overall measurement of pain coping, locus of control and pain cognitions. The questionnaire consists of 42 items with a 6-point Likert scale and comprises the subscales Catastrophizing (negative thoughts about the catastrophic consequences of pain; higher levels indicating more catastrophic thinking), Pain Coping (ways of coping with pain, either active or passive; higher levels indicating better coping), Internal Pain Management (the extent to which a person thinks he/she is able to manage or control the pain; higher levels indicating more internal pain control) and External Pain Management (the extent to which a person believes that other persons or powers (e.g. God) are able to manage or control the pain; higher levels indicating more external pain control). Scale scores are calculated by averaging the item scores for that scale. Thus, the scale scores each have a range from 1 to 6. The subscales Catastrophizing, Pain Coping and Internal Management show high internal consistency (Cronbach’s alpha respectively 0.88, 0.82, and 0.83). The internal consistency of the subscale External Pain Management is somewhat lower (0.72), but still sufficient. The test-retest reliability over a period of two weeks is adequate to good ($r$ varies between 0.64 and 0.79).

**RAND-36**

Global health-related quality of life was measured with the RAND-36 (Van der Zee et al., 1996). The RAND-36 is a multidimensional self-report questionnaire assessing the following nine domains of global health-related quality of life: physical functioning, social functioning, role impairment due to physical problems, role impairment due to emotional problems, mental health, vitality, pain, general health appraisal and perceived health change. After recoding and transformation, scores for each scale range from 0 to 100, with a higher score representing better health. The internal consistency of the Dutch version of the Rand-36 is high (Cronbach’s alpha varies between 0.71 and 0.93) and the convergent and discriminant validity are supported.

**Cost-effectiveness**

Participants received a standardized questionnaire about their health care consumption and productivity losses. The questionnaire booklet contained questions about medication used
for the pain, work status, lost work hours, days of hospitalisation, visits to physician, medical specialist, physical therapist, psychologist/psychotherapist and other health care providers.

**Evaluation of the course by the participants**

After completing the course, participants in both the internet course and the group course were asked to evaluate their course. At T1, they were asked to rate the course as a whole on a scale from 1 (“very bad”) to 10 (“excellent”). Subsequently, at the booster session two months after the course, they were asked to what extent they had been able to proceed independently with the course instructions afterwards (on a 5-point scale from “very well” to “very bad”).

**7.2.5 Sample size calculation**

The sample size calculation was based on the primary outcome measure, the Pain Catastrophizing Scale (PCS). Based on a non-inferiority hypothesis, it was assumed that participants in the internet intervention would improve at least as much as in the group intervention. Based on a previous sample of comparable patients in our own clinic (unpublished results), a non-inferiority margin of 4.7 points on the PCS was chosen. With a standard deviation of 9.3, an alpha of 0.05 and a power of 80% (or beta of 0.80), each group should consist of 49 patients (total 98).

Because of expected slow inclusion of participants, an interim analysis was performed after half of the intended number of participants was included. A post hoc power calculation was performed to check the assumptions made. If enough power was achieved by a smaller sample, it was decided to stop the inclusion.

**7.2.6 Statistical analysis**

**Treatment effects**

Scale and subscale scores were calculated according to the manuals of the questionnaires used. The distribution of the outcome variables was inspected with histograms and P-P plots. Differences between drop-outs and “completers”, and between the two groups were analyses with t-tests and chi-square tests.

Repeated measures ANOVAs were performed to compare scores on the outcome variables between pre-test (T0) and both post-tests (T1 and T2) for both the internet course and the group course. “Time” was the within-subject factor and “group” was the between-subject factor. In view of our hypotheses, we were mainly interested in the within-subject contrast, describing the effect of time and the interaction effect of “time x group” for T0 versus T1 and T0 versus T2.

**Cost-effectiveness**

Units of health care consumption and days missed from work were valued according to the Dutch guidelines for costs studies (Hakkaart-Van Roijen et al., 2010). If no standard prices were available, tariffs were used (Dutch Healthcare Authority, 2013). Costs of medication were calculated based on Dutch cost prices as displayed by the Health Care Insurance Board (2013).
The price level used was that of 2012. Costs are displayed in Euro’s (€). The time horizon of the cost-effectiveness study was the total study period of 16 weeks. Mean total costs and cost per category per patient were calculated for both treatment arms separately.

In addition, a cost-effectiveness analysis was performed displaying the incremental cost effectiveness ratio (ICER) based on the primary outcome measure, the PCS. The ICER displays the additional costs or savings of the internet intervention per one point improvement on the PCS, as compared to the group intervention. In order to estimate confidence intervals, 5000 bootstrap replications of the original trial data were generated for both costs and the ICER.

7.3 Results

7.3.1 Sample characteristics

Eligible participants were recruited from October 2008 to September 2012. An interim power analysis was performed after 50 patients had completed the course. Result of this post hoc power calculation showed higher change-scores than expected. The post hoc power calculation showed an effect size of 0.78, which can be interpreted as a large effect. The actual power achieved with 50 participants included was 82%. Because power was achieved in this smaller sample, it was decided to stop the inclusion.

A total of 72 patients entered the study, of which 22 completed the internet course and 28 completed the group course. The flow of participants through the phases of the study is shown in Figure 7.2 (according to the CONSORT statement; Altman et al., 2001).

The biographical and clinical data concerning the 50 “completers” is shown in Table 7.1. Participant of the internet and group intervention did not differ with regard to age \( t (48) = -0.791, p = 0.433 \), gender \( \chi^2 (1, n = 50) = 0.298, p = 0.585 \) and duration of pain complaint \( t (30.05) = 0.909, p = 0.371 \).
Figure 7.2 Flowchart of the study

Assessed for eligibility: n = 101
- Not included in the study: n = 29
  - Did not want to participate (n = 16)
  - No internet (n = 1)
  - Not possible to attend group course (timing/distance) (n = 2)
  - Not enough time for course (n = 3)
  - Other treatment chosen (n = 3)
  - Psychiatric problems (n = 1)
  - Other reason (n = 3)

Randomized (permuted block design): n = 72

Allocated to internet intervention: n = 38
- Did not start intervention: n = 5
  - Started the intervention: n = 33
    - Did not complete intervention: n = 11, due to:
      - Not enough time for course (n = 2)
      - Other issues require attention (n = 4)
      - Technical problems (n = 1)
      - Not motivated enough (n = 3)
      - No response (n = 1)
  - Completed the intervention: n = 22

Allocated to group intervention: n = 34
- Did not start intervention: n = 4
  - Started the intervention: n = 30
    - Did not complete intervention: n = 2, due to:
      - Not enough time for course (n = 1)
      - Other treatment chosen (n = 1)
  - Completed the intervention: n = 28

Follow up at
- T1: Week 7: n = 20
- T2: Week 15: n = 22

Follow up at
- T1: Week 7: n = 28
- T2: Week 15: n = 24
7.3.2 Drop-out

Of the 72 participants that were allocated to either the internet course or the group course, a total of 63 participants started with the intervention and 50 participants subsequently completed the intervention (drop-out rate of 20.6%). The drop-out rate in the internet course (n = 11 (33.3%)) was remarkably higher than in the group course (n = 2 (6.7%)).

Participants who dropped out during the course did not differ from the “completers” with regard to age, gender and duration of the pain complaints. However, drop-outs did report significantly higher VAS pain scores at the start of the intervention ($t (36.06) = -2.049; p =$
0.048). There were no differences between drop-outs and “completers” on the other outcome measures.

**7.3.3 Attendance**

A higher percentage of participants attended all modules/sessions in the internet course compared to the group course (95.2\% vs. 46.4\%; $\chi^2(1, n = 49) = 13.000, p < 0.001$). In the internet course, 1 participant missed 1 module. In the group course, 7 participants missed 1 session, 6 participants missed 2 sessions, and 2 participants missed 3 sessions.

**7.3.4 Treatment effects**

At baseline (T0), the participants in the internet course and the group course did not differ on any of the outcome measures. On visual inspection, all outcome variables were normally distributed. Repeated measures ANOVAs were used to test for differences between the two post-tests (T1 and T2) compared to the pre-test (T0) for the internet course as well as the group course. Means and standard deviations at pre- and post-treatment and the contrasts of the repeated measures ANOVAs are presented in Table 7.2.
<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>N</th>
<th>T0 (M, SD)</th>
<th>T1 (M, SD)</th>
<th>T2 (M, SD)</th>
<th>Time Group x Time</th>
<th>Time Group x Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Internet intervention</td>
<td>20</td>
<td>19.82 (13.88)</td>
<td>12.55 (11.53)</td>
<td>11.00 (11.49)</td>
<td>F = 19.800; p &lt; 0.001*</td>
<td>F = 46.156; p = 0.023*</td>
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<td></td>
<td>Group intervention</td>
<td>24</td>
<td>20.38 (11.38)</td>
<td>17.13 (12.49)</td>
<td>16.10 (11.56)</td>
<td>p = 0.096</td>
<td>p = 0.023*</td>
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<td></td>
<td><strong>Contrasts T0-T1</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>PCS</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>6.59 (1.94)</td>
<td>5.53 (2.19)</td>
<td>5.19 (2.53)</td>
<td>F = 4.058; p = 0.051</td>
<td>F = 8.433; p = 0.006*</td>
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<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>5.61 (1.94)</td>
<td>5.32 (2.18)</td>
<td>5.49 (2.32)</td>
<td>p = 0.257</td>
<td>p = 0.020*</td>
</tr>
<tr>
<td></td>
<td><strong>Contrasts T0-T2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Internet intervention</td>
<td>20</td>
<td>5.89 (2.14)</td>
<td>5.66 (2.22)</td>
<td>5.13 (2.52)</td>
<td>F = 0.001; p = 0.972</td>
<td>F = 0.276; p = 0.602</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>5.93 (2.40)</td>
<td>6.18 (2.51)</td>
<td>6.33 (2.21)</td>
<td>p = 0.543</td>
<td>p = 0.101</td>
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<td><strong>VAS Pain</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>6.59 (1.94)</td>
<td>5.53 (2.19)</td>
<td>5.19 (2.53)</td>
<td>F = 4.058; p = 0.051</td>
<td>F = 8.433; p = 0.006*</td>
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<td></td>
<td>Group intervention</td>
<td>24</td>
<td>5.61 (1.94)</td>
<td>5.32 (2.18)</td>
<td>5.49 (2.32)</td>
<td>p = 0.257</td>
<td>p = 0.020*</td>
</tr>
<tr>
<td></td>
<td><strong>Contrasts T0-T2</strong></td>
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<td></td>
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<tr>
<td><strong>VAS Interference</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>5.89 (2.14)</td>
<td>5.66 (2.22)</td>
<td>5.13 (2.52)</td>
<td>F = 0.001; p = 0.972</td>
<td>F = 0.276; p = 0.602</td>
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<td>24</td>
<td>5.93 (2.40)</td>
<td>6.18 (2.51)</td>
<td>6.33 (2.21)</td>
<td>p = 0.543</td>
<td>p = 0.101</td>
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<td>Internet intervention</td>
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<td>6.34 (2.28)</td>
<td>5.99 (2.58)</td>
<td>5.91 (2.44)</td>
<td>F = 0.311; p = 0.580</td>
<td>F = 0.077; p = 0.782</td>
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<td>6.63 (2.23)</td>
<td>6.65 (2.05)</td>
<td>6.88 (2.32)</td>
<td>p = 0.524</td>
<td>p = 0.261</td>
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<td><strong>PCCL Catastrophizing</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>3.12 (0.72)</td>
<td>2.70 (0.90)</td>
<td>2.57 (0.86)</td>
<td>F = 6.208; p = 0.017*</td>
<td>F = 5.636; p = 0.022*</td>
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<td>3.03 (1.03)</td>
<td>3.11 (0.88)</td>
<td>p = 0.286</td>
<td>p = 0.080</td>
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<td><strong>PCCL Pain coping</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>3.17 (0.96)</td>
<td>3.74 (0.79)</td>
<td>3.72 (0.79)</td>
<td>F = 18.348; p = 0.001*</td>
<td>F = 14.928; p = 0.001*</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>3.00 (0.64)</td>
<td>3.32 (0.79)</td>
<td>3.14 (0.61)</td>
<td>p = 0.222</td>
<td>p = 0.024*</td>
</tr>
<tr>
<td><strong>PCCL Internal pain management</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>3.55 (0.67)</td>
<td>4.42 (0.76)</td>
<td>4.30 (0.73)</td>
<td>F = 36.681; p = 0.001*</td>
<td>F = 25.777; p = 0.001*</td>
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<tr>
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<td>Group intervention</td>
<td>24</td>
<td>3.15 (0.98)</td>
<td>3.84 (0.97)</td>
<td>3.57 (0.84)</td>
<td>p = 0.495</td>
<td>p = 0.162</td>
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<tr>
<td><strong>PCCL External pain management</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>2.23 (0.86)</td>
<td>2.08 (0.76)</td>
<td>1.99 (0.63)</td>
<td>F = 10.668; p = 0.002*</td>
<td>F = 5.723; p = 0.077</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>2.59 (0.94)</td>
<td>2.22 (1.03)</td>
<td>2.40 (0.92)</td>
<td>p = 0.178</td>
<td>p = 0.782</td>
</tr>
<tr>
<td><strong>RAND-36 Physical functioning</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>50.10 (17.20)</td>
<td>57.25 (21.58)</td>
<td>58.50 (22.37)</td>
<td>F = 7.862; p = 0.008*</td>
<td>F = 10.220; p = 0.180</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>52.50 (22.94)</td>
<td>55.00 (22.12)</td>
<td>55.88 (22.35)</td>
<td>p = 0.184</td>
<td>p = 0.03*</td>
</tr>
<tr>
<td><strong>RAND-36 Social functioning</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>49.34 (23.74)</td>
<td>61.84 (24.46)</td>
<td>65.79 (26.95)</td>
<td>F = 8.088; p = 0.007*</td>
<td>F = 12.563; p = 0.0119</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>47.92 (23.79)</td>
<td>56.25 (27.58)</td>
<td>54.17 (27.00)</td>
<td>p = 0.573</td>
<td>p = 0.119</td>
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<td><strong>RAND-36 Role impairment physical</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>15.79 (29.12)</td>
<td>31.58 (38.04)</td>
<td>37.24 (41.89)</td>
<td>F = 3.582; p = 0.065</td>
<td>F = 5.539; p = 0.023*</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>15.63 (24.24)</td>
<td>15.63 (23.10)</td>
<td>22.19 (34.89)</td>
<td>p = 0.065</td>
<td>p = 0.218</td>
</tr>
<tr>
<td></td>
<td>Internet intervention</td>
<td>Group intervention</td>
<td>( F )</td>
<td>( p )</td>
<td>( F )</td>
<td>( p )</td>
<td>( F )</td>
</tr>
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<td>---------</td>
</tr>
<tr>
<td><strong>RAND-36 Role impairment emotional</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>23</td>
<td>0.103</td>
<td>0.750</td>
<td>3.517</td>
<td>0.068</td>
<td>6.118</td>
</tr>
<tr>
<td><strong>RAND-36 Mental health</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>62.74 (18.95)</td>
<td>70.11 (17.81)</td>
<td>70.11 (20.76)</td>
<td>0.750</td>
<td>4.619</td>
</tr>
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<td></td>
<td>Group intervention</td>
<td>24</td>
<td>57.97 (44.06)</td>
<td>49.28 (44.80)</td>
<td>67.39 (40.97)</td>
<td>0.080</td>
<td>0.038*</td>
</tr>
<tr>
<td><strong>RAND-36 Vitality</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>41.32 (15.35)</td>
<td>49.47 (20.06)</td>
<td>52.63 (20.30)</td>
<td>0.046*</td>
<td>2.812</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>39.79 (16.84)</td>
<td>40.63 (15.49)</td>
<td>40.63 (14.69)</td>
<td>0.136</td>
<td>0.005*</td>
</tr>
<tr>
<td><strong>RAND-36 Pain</strong></td>
<td>Internet intervention</td>
<td>19</td>
<td>37.16 (14.73)</td>
<td>47.91 (21.06)</td>
<td>50.70 (18.16)</td>
<td>0.013*</td>
<td>2.315</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>38.76 (17.87)</td>
<td>41.58 (19.95)</td>
<td>39.80 (19.35)</td>
<td>0.124</td>
<td>0.005*</td>
</tr>
<tr>
<td><strong>RAND-36 General health appraisal</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>49.33 (23.35)</td>
<td>53.18 (22.69)</td>
<td>56.63 (27.69)</td>
<td>0.027</td>
<td>3.879</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>42.50 (22.84)</td>
<td>45.63 (21.58)</td>
<td>43.54 (20.51)</td>
<td>0.071</td>
<td>0.056</td>
</tr>
<tr>
<td><strong>RAND-36 Perceived health change</strong></td>
<td>Internet intervention</td>
<td>20</td>
<td>28.75 (24.70)</td>
<td>46.25 (24.70)</td>
<td>51.25 (23.61)</td>
<td>0.002*</td>
<td>3.243</td>
</tr>
<tr>
<td></td>
<td>Group intervention</td>
<td>24</td>
<td>38.54 (30.38)</td>
<td>43.75 (26.83)</td>
<td>38.54 (34.56)</td>
<td>0.017*</td>
<td>0.017</td>
</tr>
</tbody>
</table>
Chapter 7

**Pain Catastrophizing Scale**
On the primary outcome measure the PCS, we found a main effect for time on both T1 ($F(1, 42) = 19.800; p < 0.001$) and T2 ($F(1, 42) = 46.156; p < 0.001$) compared to pre-treatment. On T2, there was also an interaction effect between group and time ($F(1, 42) = 5.546; p = 0.023$). Thus, participants in both the internet course and the group course showed significant improvement on the PCS on both T1 and T2, but at T2 this improvement was significantly larger in the internet course than in the group course. This is illustrated in Figure 7.3.

![Figure 7.3](image)

**Figure 7.3** Mean scores on the Pain Catastrophizing Scale at the three time point

**VAS pain, interference and fatigue**
On the VAS pain, there was a significant main effect for time ($F(1, 41) = 8.433; p = 0.006$) on T2, but not on T1. On T2, there was also an interaction effect between group and time ($F(1, 41) = 5.877; p = 0.020$). Thus, at T2 VAS pain scores had dropped significantly in both groups, and this improvement was significantly larger in the internet course than in the group course. On the VAS interference and VAS fatigue, no main effects for time or interaction effects for group and time were found on either T1 or T2.

**Pain Coping and Cognition List**
On all four subscales of the PCCL, a main effect for time was found at both T1 and T2. Thus, in both the internet course and the group course participants improved on the subscales Catastrophizing, Pain Coping, Internal pain management and External pain management. An interaction effect between group and time was seen on the subscale Pain Coping on T2 ($F(1, 42) = 5.470; p = 0.024$). Thus, on T2 improvement on Pain Coping was significantly larger in the internet course than in the group course. There were no interaction effects on the other subscales of the PCCL.
**RAND-36**

On the RAND-36, significant main effects for time on both T1 and T2 were observed on the subscales Physical functioning, Social functioning, Vitality, Pain, and Perceived health change. On the subscales Role impairment physical and Role impairment emotional, no effect of time was observed on T1, but later a significant effect was shown on T2.

On T2, there were interaction effects between group and time on the subscales Vitality \( F(1, 41) = 6.567; p = 0.014 \), Pain \( F(1, 41) = 6.394; p = 0.015 \), and Perceived health change \( F(1, 42) = 6.206; p = 0.017 \), indicating that improvement on these subscales on T2 was significantly larger in the internet course than in the group course.

### 7.3.5 Cost-effectiveness

Total average costs per patient amount to € 1745,- in the internet course \( (n = 22) \) and € 1717,- in the group course \( (n = 28) \) (difference € 28; CI -1293 to 1338). The major cost driver in both interventions was the cost of productivity loss (€ 922,- in the internet course versus € 802,- in group course). Costs of visits to health care professionals and hospital admission were € 649,- in the internet course versus € 707,- in the group course. Medication use was € 175,- in the internet course versus € 208,- in the group course. The costs per group are presented in Table 7.3.

For the incremental cost effectiveness ratio (ICER), effectiveness data of 4 patients in the group treatment were missing. Due to this, these patients were excluded from the cost-effectiveness analysis, which led to a slightly different cost estimate. The cost effectiveness analysis showed that in the internet course, the costs were € 199,- lower, and 5 points on the PCS were gained compared to the group course. This means that the ICER is 40 (CI; -228 to 56), meaning that when one additional point improvement is gained on the PCS, € 40,- are saved.

**Table 7.3 Costs (in €) per intervention for the total study period (16 weeks)**

<table>
<thead>
<tr>
<th></th>
<th>Internet intervention</th>
<th>Group intervention</th>
<th>Difference (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care professionals and admission</td>
<td>649</td>
<td>707</td>
<td>58 (-600 to +386)</td>
</tr>
<tr>
<td>Medication</td>
<td>175</td>
<td>208</td>
<td>33 (-185 to +114)</td>
</tr>
<tr>
<td>Productivity losses</td>
<td>922</td>
<td>802</td>
<td>120 (-1065 to 1324)</td>
</tr>
<tr>
<td>Total</td>
<td>1745</td>
<td>1717</td>
<td>28 (-1293 to +1338)</td>
</tr>
</tbody>
</table>

### 7.3.6 Course evaluation

Immediately after the course (at T1), participants were asked to rate the course as a whole on a scale from 1 ("very bad") to 10 ("excellent"). This overall evaluation of the course did not differ significantly for participants in the internet course \( (M = 7.37; SD = 1.50) \) and the group course \( (M = 7.46; SD = 0.78) \) \( (t(24.64) = -0.256; p = 0.800) \). However, the range of scores in the internet course was larger (4.0 – 10.0) than in the group course (6.0 – 9.3).

At T2, participants were asked to what degree they had been able to proceed independently with the course instructions afterwards (on a 5-point scale from "very well" to "very bad"). In the internet course, 11 participants (55%) indicated this went well, 8 (40%) said this
went reasonably well, and 1 (5%) indicated it went very badly. In the group course, 3 (12.5%) participants said this went very well, for 9 (37.5%) participants this went well, 10 (41.7%) said reasonably well, and 2 (8.3%) indicated this went badly.

7.4 Discussion

In the present study, we investigated the effectiveness of a cognitive-behavioral internet-based intervention with e-mail therapist contact for patients with non-specific chronic pain complaints compared to a face-to-face cognitive-behavioral group intervention. Both the internet course and the group course were effective in improving pain-related catastrophizing, pain coping strategies, locus of control and various aspects of global health-related quality of life, both directly after the 7-week course and at the booster session two months later. In both groups, pain intensity and experienced role impairment showed no improvement directly after the 7-week course, but were significantly improved at the booster session two months later.

With regard to catastrophic thinking about pain, pain intensity (over the past two days and over the past four weeks), ways of coping with pain, feelings of vitality and overall health compared to one year ago, participants in the internet course showed significantly more improvement two months after the course than participants in the group course. Thus, the group as a whole showed significant progress on these measures, but in the internet course participants improved even more than in the group course. With regard to costs for health care, medication and productivity loss, we found that the cost difference between the two groups over the study period was negligible. Combined with a better effect on pain-related catastrophizing, it can be concluded that the internet intervention is cost-effective compared to the group intervention. Overall, the results support our hypothesis. The internet intervention is at least as effective as the group intervention, and on some outcome variables even more effective.

The present results corroborate previous findings regarding the effectiveness of cognitive-behavioral treatment in helping patients deal with chronic pain (McCracken & Turk, 2002; Vlaeyen & Morley, 2005). Our findings are also consistent with previous studies on internet-based treatment for chronic pain, in which improvements on catastrophizing, control over pain, pain coping and aspects of quality of life were also reported (Buhrman et al., 2004; Brattberg, 2006; Buhrman et al., 2011; Carpenter et al., 2012; Ruehlman et al., 2012). However, in these previous studies internet-based treatment was compared to waiting list control groups, while in the present study a comparison was made to face-to-face treatment. Thus, our result that an internet course for chronic pain is at least as effective, and on some outcome measures superior to regular face-to-face treatment is a rather new and surprising finding. Why is it that patients benefit more from an internet-based program than from a group course with the same cognitive-behavioral content? There are several possible explanations.

Because of its flexibility, an internet format may be a suitable way to treat chronic pain patients. In an internet-based course, participants have access to the course wherever and whenever they want. This may especially be an advantage for chronic pain patients, who often find it difficult to travel to the hospital or sit for longer periods of time. In an internet
course, participants are more flexible to follow the course in a way that suits them. This is confirmed by the significantly higher attendance rate in the internet course. Participants in the internet course were capable of following all modules, whilst in the group course a large percentage of participants missed at least one session, which could have negatively influenced the effectiveness of the group intervention.

Furthermore, internet-based treatment can have advantages for people who are reluctant to engage in face-to-face contact due to fear of stigmatization. Some people find it easier to reveal their thoughts and feelings to a computer screen than to a real person. Thus, internet-based treatment may lower the barriers that prevent patients from fully engaging in treatment (Lange et al., 2003), which may particularly apply to pain patients who are not easily inclined to seek treatment by a psychologist.

Also, participants in the internet course may be more intensely stimulated to adopt a self-management approach. Being able to use the course at their own pace and convenience may give participants a greater sense of control over their situation. Furthermore, the internet course imposes a certain degree of independency on the participants. In this way, the format of the course implicitly contributes to the aim of increased self-efficacy and self-management skills. Thus, internet may not simply be a new way of delivering treatment, but may actually change the nature of treatment (Eccleston, 2011).

It is often suggested that a group format has added value in the treatment of chronic pain (Thorn & Kuhajda, 2006). Pain patients may benefit from the interaction with fellow patients, and as a result may feel less alone in having to deal with their pain. In this way, a group format fulfills a supportive function. However, a group format may also have disadvantages. Some participants may find it difficult to listen to other people talking about their problems. A group also has the risk of participants amplifying each other’s dysfunctional pain cognitions or somatic fixations. In the internet course, there was no contact with fellow patients, thus excluding the possible negative influences of group contact.

It needs to be stressed that our course included e-mail therapist contact, while various programs in previous studies were without contact and completely self-managing in nature (for example, Williams et al., 2010; Ruehlman et al., 2012). The addition of e-mail therapist contact may be one of the factors influencing the effectiveness of the course. In a meta-analysis of internet-based cognitive-behavioral therapy for symptoms of depression and anxiety, larger effects were found in interventions with therapist support compared to treatment without support (Spek et al., 2007a). Thus, it appears that e-mail therapist contact has an added value. However, the optimal level of therapist contact deserves further investigation.

The dropout rate in our study was remarkably higher in the internet course than in the group course. The participants in the internet course may have been a select group, which could have influenced the results. Those who successfully completed the course may be those patients who are more able to profit from a self-management approach. People who lack a certain degree of motivation, insight, discipline or learning skills may drop out more quickly. Dropout may also be due to the relative anonymity and distance inherent in this medium. High dropout is common in studies on internet-based interventions (Rosser et al., 2009; Bender et al., 2011; Macea et al., 2010). The degree of therapist contact appears to make a difference in dropout rates. Significantly lower dropout rates were seen in studies with some
therapist contact compared to those without therapist involvement (Rosser et al., 2009).

There are some further methodological concerns in this study. Effects of spontaneous improvement cannot be ruled out, but the long duration of pain complaints in our sample makes this highly unlikely. However, non-specific therapy effects could have played a role. The present study used only self-report outcome measures, which may be subject to several kinds of biases. Our study group was smaller than initially anticipated. However, post hoc power calculation showed that power was achieved even in this smaller sample. It needs to be stressed that our sample consisted of patients from a tertiary pain clinic with longstanding, disabling pain complaints, and thus may not be representative for all persons with chronic pain. However, the present result that even in this sample of patients with longstanding pain complaints significant improvement was seen on various pain-related outcomes may imply that gains could also be achieved in patients with less longstanding pain complaints. Furthermore, patients who did not have access to a computer with an internet connection could not participate in the study. This could also have influenced the representativeness of our sample. However, this would only apply to a slight fraction of the Dutch population, since in 2012, 94% of the households in the Netherlands had access to the internet (Statistics Netherlands, 2013).

Based on the present study, we conclude that an internet-based intervention appears to be an effective treatment option for patients with chronic pain, with the benefits of accessibility, flexibility and an inherent focus on self-management. However, not all chronic pain patients may benefit from an internet-based intervention. The high dropout rate seen in studies on internet-based treatment is cause for concern. Also, for patients with a lack of motivation, lesser degrees of discipline, limited computer skills or insufficient reading and writing abilities, internet treatment may not be the best option. Future research should focus on the question which type of intervention works best for which type of pain patient. Thus, which patients thrive best in a face-to-face treatment program, and for which patients is an internet-based course a suitable or most effective treatment option?

To the best of our knowledge, this is the first randomized controlled study comparing an internet-based cognitive-behavioral intervention for chronic pain to a face-to-face intervention. Further studies comparing internet-based treatment to face-to-face counterparts are needed. Comparison to individual face-to-face treatment could increase our understanding of the relative value of internet-based treatment compared to face-to-face interventions.

The present study suggests that internet-based treatment can be a good alternative to traditional forms of treatment. The internet makes treatment more accessible. One important aspect of the usefulness of internet-based treatment is the possibility of treating people who would not otherwise seek treatment. Thus, internet-based treatment seems to be a useful and cost-effective addition to the field of chronic pain treatment.
Internet-based intervention

References


The (fictional) case of Mrs. A: Psychological treatment

After multidisciplinary evaluation in our Pain Center, the multidisciplinary team concluded that the problem at hand was longstanding fibromyalgia complaints in a physically and mentally overworked woman, who sets very high standards for herself. Mrs. A was advised to start psychological treatment by a primary care psychologist, with the aim of increasing her coping skills and psychological strength and decreasing her tendency to catastrophize. Mrs. A agreed with the conclusions and advice, and a referral to a primary care psychologist from our regional network was effected.

Mrs. A followed a treatment of eight sessions by the primary care psychologist. In accordance with the psychologist, Mrs. A set the following goals for the sessions:

- Learning to better cope with the pain and to worry less
- Being able to relax better
- Gaining more energy and sleep better

In the treatment, the psychologist used cognitive-behavioral techniques, problem-solving techniques and relaxation training. Also, the sessions were aimed at gaining insight and giving support.

After eight sessions the treatment was ended by mutual consent and with a satisfactory result for both Mrs. A and the psychologist. Mrs. A described the treatment as a positive experience. The treatment was effective. Mrs. A’s ability to deal with her pain improved. She learned to take more time for herself and not go beyond her limits. Also, it became easier for her to communicate her limits to others and to say no to demands made on her. She learned new ways of relaxation, which led to a better sleeping pattern, more energy during the day and a better mood. Cognitive therapy helped her in worrying less and thinking more realistically. Her experienced levels of pain intensity did not change much, but after the treatment Mrs. A felt less helpless in dealing with her pain. However, she continues to have difficulty with accepting her pain. Thoughts such as “why does this happen to me” still do come up from time to time, but she is now able to correct her own irrational thoughts better. Also, she continues to strive to do the best she can in her work and other activities.

A post-test of her psychological evaluation showed substantial decreases in PCS-scores measuring levels of catastrophizing, and SCL-90 scores (especially on the sleeping problems (SLA) and depression (DEP) scale). The MAAS en AAQ-II were not filled in again after treatment.
The (fictional) case of Mr. B: Psychological treatment

After multidisciplinary evaluation in our Pain Center, it was concluded that Mr. B had chronic myogenic low back pain that was sustained by work related influences. Mr. B was advised to resume physical therapy, with an emphasis on muscle strengthening exercises, and to participate in our Pain Center’s course “Learning to live with chronic pain”. Mr. B approved this advice and signed up for the course. The course being a research project, he took part in the randomization procedure, assigning him to either the group course or the internet course. The outcome of the randomization was that Mr. B was to participate in the internet course.

The cognitive-behavioral internet course consisted of seven weekly modules, each with a specific topic related to dealing with chronic pain. After the module about graded activity, Mr. B gradually noticed that he could do more than he previously thought. Increasingly, he became more active and he learned to recognize his limitations. The relaxation techniques in module 3 taught him to relax better. The modules about cognitive therapy helped him further, by teaching him techniques to recognize and alter his dysfunctional negative thoughts, although he did find these exercises difficult to do on his own. Furthermore, Mr. B learned to lessen his focus of attention on the pain, which made it become less overwhelming.

After the course, Mr. B felt better. He was less tired and did not worry so much about his pain. He no longer had the conviction that there was something seriously wrong with his back. Instead, he focused less on his pain and became more engaged with resuming activities and social contacts. Mr. B wanted to return to work and together with the company doctor he has set up a reintegration trajectory.

In retrospect, Mr. B said the internet course did take some getting used to, but in the end suited him well. The flexibility of the course appealed to him, and during the course he became more and more aware that how he dealt with the pain was in his own hands. The e-mail feedback from the course facilitator on his homework assignments was very useful. It helped him in applying the course material to his own situation.

The post-test of his psychological evaluation showed substantial decreases in TSK-score, measuring fear of movement, and SCL-90 scores (especially on the anxiety (ANG) and sleeping problems (SLA) scale). Also, his PCS-score measuring levels of catastrophizing dropped slightly. Asked about the intensity of his pain, he now gave a score of 6 on the NRS-scale.