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The *Pain Course*: A randomised controlled trial of a clinician-guided Internet-delivered cognitive behaviour therapy program for managing chronic pain and emotional well-being

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ABSTRACT

The present study evaluated the efficacy of a clinician-guided Internet-delivered cognitive behaviour therapy (iCBT) program, the *Pain Course*, to reduce disability, anxiety, and depression associated with chronic pain. Sixty-three adults with chronic pain were randomised to either a Treatment Group or wait-list Control Group. Treatment consisted of 5 iCBT-based lessons, homework tasks, additional resources, weekly e-mail or telephone contact from a Clinical Psychologist, and automated e-mails. Twenty-nine of 31 Treatment Group participants completed the 5 lessons during the 8-week program, and posttreatment and 3-month follow-up data were collected from 30/31 and 29/31 participants, respectively. Treatment Group participants obtained significantly greater improvements than Control Group participants in levels of disability, anxiety, depression, and average pain levels at posttreatment. These improvements corresponded to small to large between-groups effect sizes (Cohen's *d*) at posttreatment for disability ($d = .88$), anxiety ($d = .38$), depression ($d = .66$), and average pain ($d = .64$), respectively. These outcomes were sustained at follow-up and participants rated the program as highly acceptable. Overall, the clinician spent a total mean time of 81.54 minutes (SD 30.91 minutes) contacting participants during the program. The results appear better than those reported in iCBT studies to date and provide support for the potential of clinician-guided iCBT in the treatment of disability, anxiety, and depression for people with chronic pain.

1. Introduction

Chronic pain is a common condition that affects approximately 1 in 5 adults [7]. Chronic pain results in enormous economic costs to society and large personal costs to individuals and their families. Pain is known to be one of the strongest predictors of poor quality of life [33], with as many as 27% of chronic pain patients experiencing high levels of disability [8]. Approximately 1 in 2 chronic pain patients meet diagnostic criteria for depression each year [6], and chronic pain is associated with greater risk of suicide [34].

There is substantial research indicating that cognitive-behaviour therapy (CBT) programs result in small but significant reductions in disability, anxiety, and depression associated with chronic pain [17]. Unfortunately, access to CBT programs is often limited due to numerous barriers including the direct and indirect costs, mobility limitations, long waiting lists, and insufficient numbers of appropriately trained health professionals. For these reasons, many people either fail to receive, or experience considerable delays in accessing, evidence-based care [19,20]. One approach to improving access to effective care for people with chronic pain is Internet-delivered cognitive behaviour therapy (iCBT) [4,24].

iCBT programs employ the same principles and components as face-to-face CBT programs, but are administered via a computer and the Internet [37,38]. iCBT programs can be clinician-guided or self-guided, and usually comprise structured online lessons and tasks, which patients work through themselves. The majority of iCBT studies have evaluated treatments for anxiety disorders and depression [1,3,13]. However, several studies have examined iCBT for chronic pain (eg, [5,9,10,12,44]). Recent systematic reviews and a meta-analytic study have found evidence of small improvements in average pain ratings and disability across studies, but inconsistent

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improvements in anxiety and depression levels [4,24]. With a few exceptions [9,10], most studies have examined self-guided iCBT with minimal clinician contact. However, because clinician support has consistently been shown to produce larger effects in other areas [11,37], the lack of data on iCBT combined with clinician support for chronic pain is a significant limitation of the current literature.

Given the small number of trials of clinician-guided iCBT treatments for chronic pain, the present study explored the efficacy of a new iCBT program, the *Pain Course*, which aims to teach self-management skills to adults with chronic pain to reduce disability, depression, and anxiety. Using a randomised controlled trial (RCT) design, it was hypothesised that patients in the *Pain Course* would report significant improvements on measures of disability, depression, and anxiety, relative to a waitlist control group. It was also expected that significant improvements would be observed on the average pain levels reported by participants.

2. Method

2.1. Participants

Advertisements about the trial were placed in newsletters and Websites operated by nongovernmental institutions, which offer information and services to people with chronic pain, including *beyondblue*, Chronic Pain Australia, Australian Pain Management Association, and Arthritis Australia. Interested people were directed to a Website (http://www.ecentreclinic.org) that conducts research trials of Internet-delivered psychological interventions, where they could read additional information about the trial and apply to participate. Eighty people applied for the trial with a variety of different chronic pain conditions. Sixty-four met the following inclusion criteria: 1) experienced pain for more than 3 months, 2) pain had been assessed by their General Practitioner (GP) or a specialist, 3) resident of Australia, 4) at least 18 years of age, 5) had access to a computer and the Internet, 6) not currently participating in CBT, 7) on a stable dose of medication (>1 month) prescribed for anxiety or depression, 8) not currently experiencing a psychotic illness or severe symptoms of depression (ie, defined as a total score >22 or responding with a score >2 to item 9 of the Patient Health Questionnaire 9-item [PHQ9] [22]). Details of participant flow are shown in Fig. 1.

The participants were telephoned and received a structured interview to confirm they met the inclusion criteria and were then administered the Mini International Neuropsychiatric Interview Version 5 [32]. Sixty-three applicants met all inclusion criteria, agreed to participate, and were randomised via a permuted randomisation process to either the Treatment Group (n = 32) or the waitlist Control Group (n = 31). Group allocation preceded the telephone interview. One participant withdrew before beginning the program, resulting in 31 Treatment and 31 Control Group participants. The demographic characteristics, pain profiles, and psychiatric diagnoses of the sample are shown in Table 1.

Participants volunteered from every state and territory in Australia, and all assessments were conducted via telephone and online questionnaires. In order to participate, participants had to have seen their GP or specialist within the past 3 months. A letter was also sent to their treating GP, notifying him or her of their patient's participation in the Course and inviting contact if they had any questions or concerns about their patient's participation. The study was approved by the Human Research Ethics Committee of Macquarie University, Sydney, Australia, and the trial was registered on the Australian and New Zealand Clinical Trials Registry as ACTRN12612000556842.

2.2. Design and measures

The design comprised a Consolidated Standards of Reporting Trials-revised compliant RCT comparing an immediate Treatment Group with a waitlist Control Group. Following treatment of the Treatment Group, participants in the Control Group were provided access to the Course, and half volunteered to participate in a separate trial involving an enhanced intervention version of the Course (ACTRN12612000556842), the results of which are not reported here. Both groups completed questionnaires at pretreatment and posttreatment, but only the Treatment Group completed questionnaires at 3-month follow-up, as the Control Group had entered active treatment. The pretreatment questionnaires were administered immediately prior to starting the Course, and the posttreatment questionnaires were completed after the 8-week Course finished. As the study involved a psychological intervention with a waitlist Control Group, blinding was not possible. The following outcome measures were administered online via the Website.

2.2.1. Primary measures

2.2.1.1. Patient Health Questionnaire 9-Item (PHQ-9) [22]. The PHQ-9 is a 9-item measure of the symptoms and severity of depression. It is based on *Diagnostic and Statistical Manual of Mental Disorders*, 4th Revision (DSM-IV) criteria with a total score of 10 being identified as predicting a DSM-IV diagnosis of depression, and increasing scores indicating greater symptom severity [22]. Psychometric studies indicate that the internal consistency is high (α range: .74–.89) [22,40], and the measure is sensitive to change [40]. Cronbach α in the present study = .84.

2.2.1.2. Generalized Anxiety Disorder 7-Item (GAD-7) [35]. The GAD-7 is a 7-item measure designed as a brief screening questionnaire for generalised anxiety disorder. The GAD-7 is increasingly used in research and in large-scale dissemination studies as a generic measure of anxiety symptoms [29]. Evidence suggests that the GAD-7 is sensitive to DSM-IV-congruent GAD, social phobia, and panic disorder, with increasing scores indicating greater severity of symptoms [23]. The GAD-7 has good internal consistency (α = .79–.91) and good convergent and divergent validity with other anxiety and disability scales [16,23]. In the present sample, Cronbach α = .86.

2.2.1.3. Roland Morris Disability Questionnaire (RMDQ) [31]. The RMDQ is a checklist designed to assess disability associated with back pain. It is comprised of 24 statements about day-to-day physical activities that are either endorsed or not endorsed. The RMDQ has yielded internal-consistency coefficients ranging from .84 to .93 and test-retest coefficients ranging from .72 to .91 [30]. The RMDQ used in this study was modified (ie, references to "my back pain" changed to "my pain") so as to be applicable to a broader range of chronic pain patients. The validity of this modified version has been established [27]. In the present sample, Cronbach α = .84.

2.2.2. Secondary measures

2.2.2.1. Wisconsin Brief Pain Questionnaire (WBPQ) [14]. The WBPQ is a brief self-administered questionnaire designed to ascertain the duration, severity, and location of a person's pain, as well as the level of interference caused by pain [14]. Importantly, only 4 questions were utilised from the WBPQ; these were the questions enquiring about the intensity of participant's average pain, least and worst pain over the last month, and their current pain. These items are all scored on a 10-point scale, where 0 indicates no pain and 10 reflects the worst pain imaginable.