

The Pain Course: a randomised controlled trial examining an internet-delivered pain management program when provided with different levels of clinician support

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Abstract

The present study evaluated an internet-delivered pain management program, the *Pain Course*, when provided with different levels of clinician support. Participants (n = 490) were randomised to 1 of 4 groups: (1) Regular Contact (n = 143), (2) Optional Contact (n = 141), (3) No Contact (n = 131), and (4) a treatment-as-usual Waitlist Control Group (n = 75). The treatment program was based on the principles of cognitive behaviour therapy and comprised 5 internet-delivered lessons provided over 8 weeks. The 3 Treatment Groups reported significant improvements (between-group Cohen's *d*; avg. reduction) in disability ($d_s \geq 0.50$; avg. reduction $\geq 18\%$), anxiety ($d_s \geq 0.44$; avg. reduction $\geq 32\%$), depression ($d_s \geq 0.73$; avg. reduction $\geq 36\%$), and average pain ($d_s \geq 0.30$; avg. reduction $\geq 12\%$) immediately posttreatment, which were sustained at or further improved to 3-month follow-up. High treatment completion rates and levels of satisfaction were reported, and no marked or consistent differences were observed between the Treatment Groups. The mean clinician time per participant was 67.69 minutes (SD = 33.50), 12.85 minutes (SD = 24.61), and 5.44 minutes (SD = 12.38) for those receiving regular contact, the option of contact, and no clinical contact, respectively. These results highlight the very significant public health potential of carefully designed and administered internet-delivered pain management programs and indicate that these programs can be successfully administered with several levels of clinical support.

Keywords: Internet, Online, Pain management, Cognitive behaviour therapy, CBT, Pain, Chronic pain, Anxiety, Depression, Disability, Randomised controlled trial

1. Introduction

There is now substantial support for pain management programs for chronic pain.^{11,21,40} There is also a growing recognition that many people are unable to access these programs when they are administered in their traditional face-to-face format.^{24,31} Barriers to accessing face-to-face programs are numerous and include costs, mobility limitations, stigma, availability, and long waiting lists. Consequently, many people fail to receive or experience considerable delays in accessing evidence-based care.³¹

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One innovative approach with the potential to increase access to pain management programs is delivery through the internet.^{27,42} Internet-delivered programs use the same principles, content, and components as face-to-face programs but can be provided with varying levels of clinician support ranging from regular clinician contact through e-mail or telephone to no clinician support at all.^{1,2,13} To date, the majority of internet-delivered programs for chronic pain have been based on cognitive behaviour therapy (CBT) (eg, 7,8,10,12,15,41,56) but some are emerging based on mindfulness and acceptance therapies (eg, 9,18,23). Systematic reviews and a meta-analysis have found evidence of small but clinically significant improvements in the primary domains targeted in pain management programs (eg, disability, anxiety, depression).^{3,19,32} However, as with face-to-face programs,^{11,20,21,40} clinical improvements have not been consistently observed in all studies and the magnitude of improvements has varied considerably across studies.^{3,15,19,32}

One explanation for the inconsistent outcomes of internet-delivered programs for chronic pain has been the absence of regular clinician support in most studies.¹⁵ Highlighting this, one of the only studies (n = 62) to examine a CBT program involving regular clinical support (ie, average 81 minutes per participant), the *Pain Course*, found very high completion and satisfaction rates as well as moderate-to-large improvements across the primary domains of anxiety, depression, and disability.¹⁵ However, challenging the importance of clinical support, several

studies in the broader mental health literature have started to report good clinical outcomes without clinician support (eg, 4, 5, 50, 51). This has led a recent review to suggest that clinician support may be less important where internet-delivered programs are sufficiently credible, engaging, of a high quality and involve some level of screening for suitability.² Unfortunately, no studies have directly examined these issues or the importance of clinician support in the context of internet-delivered pain management programs.

The present study sought to replicate the results of the initial trial of the *Pain Course* and examine its efficacy when provided with different levels of clinical support. After a brief screening interview, participants were randomised to 1 of 4 groups: (1) Regular Contact Group, (2) Optional Contact Group, (3) No Contact Group, and (4) a treatment-as-usual Waitlist Control Group. It was hypothesised that participants in the 3 Treatment Groups would report significant improvements on clinical measures of disability, anxiety, depression, and pain relative to the Control Group, and that the Regular Contact Group would report greater improvements compared with the Optional Contact and No Contact Groups. It was hypothesised that outcomes would be maintained at 3-month follow-up and that the intervention would be found to be acceptable.

2. Methods

2.1. Participants

Participants read about the study and applied to participate through the website of the eCentreClinic (www.ecentreclinic.org). The eCentreClinic is a specialist research unit that provides information about common mental and chronic health conditions and offers the opportunity for free psychological treatment through participation in clinical trials. Because of the information offered and the potential to receive free treatment, the eCentreClinic can be located through online searches and is promoted by various health professionals and through numerous websites within Australia. The present trial was also promoted using paid advertisements placed in state newspapers and using unpaid general advertisements by a range of governmental and nongovernmental organisations providing services to adults with chronic pain, including Chronic Pain Australia, the Australian Pain Management Association, the NSW Agency for Clinical Innovation, Pain Network, Pain Australia, and Arthritis Australia. No monetary rewards were provided for participation or for completion of questionnaires.

Six hundred and fourteen people with a broad range of chronic pain conditions submitted applications to participate in the course, which involved completing several online questionnaires and a brief telephone assessment to ensure participants satisfied the inclusion and exclusion criteria. All applications were randomly allocated to 1 of 4 groups using a permuted block randomisation sequence (ie, with 14 randomisations per block) and a 2:2:2:1 allocation ratio with the Waitlist Control Group designed to have half the participants of the Treatment Groups. The randomisation sequence was created by B. F. Dear, using an online randomiser (www.random.org), and participant randomisation occurred at the point of application, through the eCentreClinic software system, before participants had any contact with the researchers or the researchers had the opportunity to review the details of participants' applications. Thus, the researchers were blind to group allocation until the participant was deemed to have made a successful or unsuccessful application. The researchers sought to recruit at least 350 participants, which, with alpha set at 0.05 and a power of 0.80,

would enable the detection of small effect sizes differences (ie, Cohen's d s > 0.35) between the Treatment Groups and moderate-to-large effect size differences (ie, Cohen's d s > 0.50) between the Treatment Groups and Control Group. However, more participants were recruited to compensate for both withdrawals and questionnaire nonresponse at posttreatment and follow-up. Of the 614 people who started an application, 490 met the following inclusion criteria: (1) experienced pain for more than 6 months, (2) had their pain assessed by their general practitioner or a specialist within the last 3 months, (3) were at least 18 years of age, (4) were a resident of Australia, (5) had regular access to a computer and the internet, and (6) were not currently experiencing an unmanaged psychotic illness or very severe symptoms of depression (ie, defined as a total score >22 or endorsing a score >2 to item 9 of the Patient Health Questionnaire 9-item [PHQ-9]²⁹). The CONSORT flowchart for the trial is displayed in **Figure 1**.

The 490 participants who met all the inclusion criteria were informed through e-mail of their randomisation to 1 of 4 groups: (1) Regular Contact Group ($n = 143$), (2) Optional Contact Group ($n = 141$), (3) No Contact Group ($n = 131$), or (4) treatment-as-usual Waitlist Control Group ($n = 75$). Participants' primary general practitioner or medical specialist was sent a letter notifying them of the patient's participation, describing the nature of the study and program, and inviting direct contact. 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 (ANZCTR) as ACTRN12613000252718. Participant demographic and pain-related characteristics are shown in **Tables 1 and 2**.

2.2. Design and measures

The study used a 4-arm CONSORT-revised compliant randomised controlled trial comparing an internet-delivered treatment for managing chronic pain, the *Pain Course*, provided with 3 different levels of clinical support: (1) Regular Contact Group, (2) Optional Contact Group and (3) No Contact Group with (4) a treatment-as-usual Waitlist Control Group. After treatment of the 3 Treatment Groups, participants in the Waitlist Control Group were provided access to the course; the majority of whom also volunteered to participate in a separate trial involving an enhanced version of the course (ACTRN12612000556842) and the results of which are not reported in this article. All outcome measures were administered online. The primary and secondary measures were administered at initial assessment, pretreatment, posttreatment and 3-month follow-up. Pain was considered a secondary outcome because the program focuses on the management of pain-related disability and emotional wellbeing. The tertiary measures were administered at pretreatment, posttreatment and 3-month follow-up and the acceptability and satisfaction questions were administered at posttreatment. The tertiary measures were administered to assess psychological variables, which have been identified in previous literature as important psychological targets of face-to-face pain management programs and as important factors in biopsychosocial models of chronic pain. However, a comprehensive examination of these variables is outside the scope of the current trial and will be reported in subsequent studies.

All 4 groups completed questionnaires at initial assessment, pretreatment, and posttreatment, but only the 3 Treatment Groups completed questionnaires at 3-month follow-up, as the Waitlist Control Group had entered active treatment. The pretreatment measures were administered immediately before the start of the Course, and the posttreatment measures were

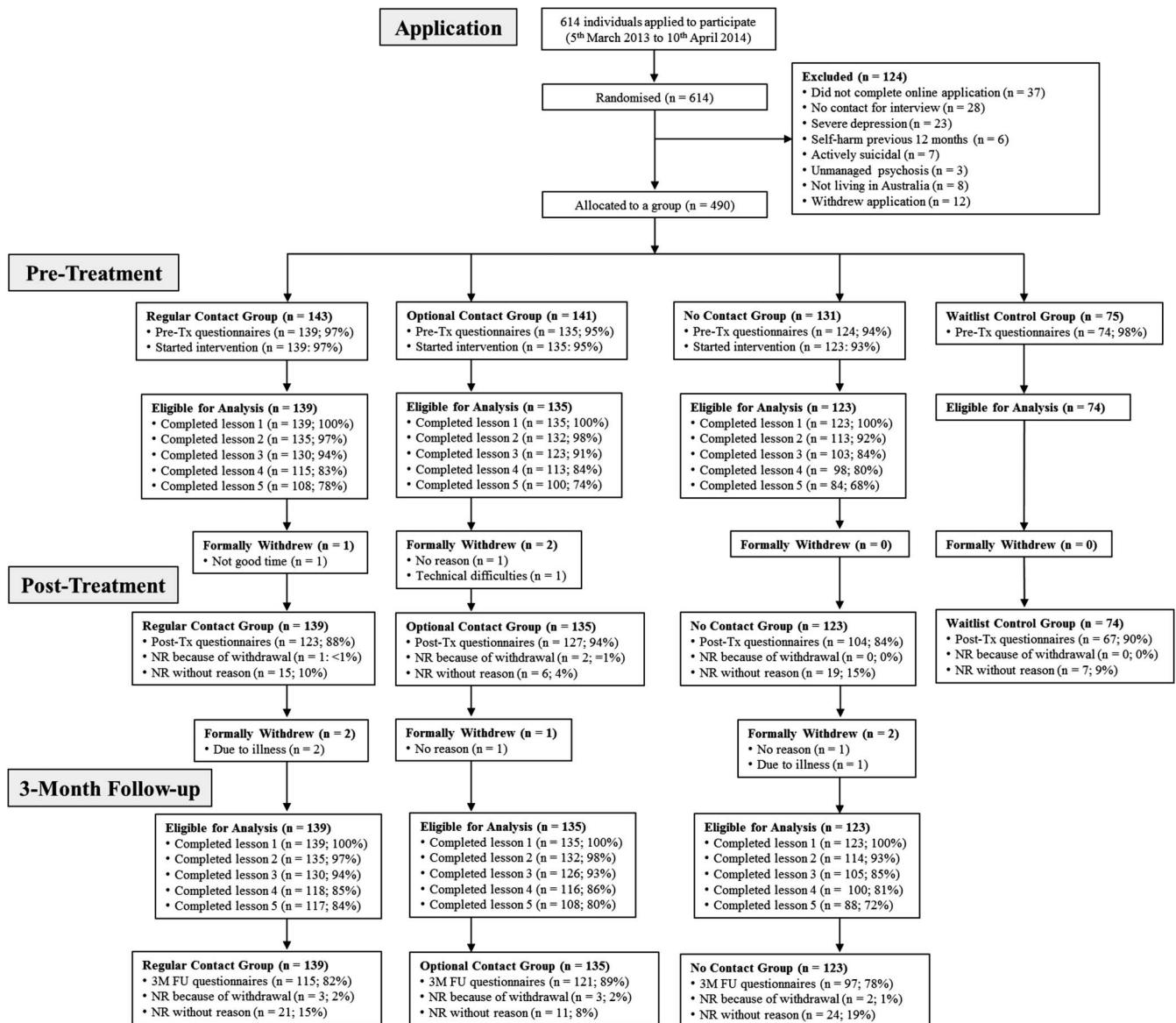


Figure 1. Participant flow from application to 3-month follow-up. Tx, treatment; 3M FU, 3-month follow-up; NR, Non-response.

completed after the completion of the 8-week Course. As a clinical trial of a psychological treatment with a treatment-as-usual Waitlist Control Group, it was not possible to blind participants or clinicians to group allocation.

2.2.1. Primary measures

2.2.1.1. Roland–Morris Disability Questionnaire

The Roland–Morris Disability Questionnaire (RMDQ) is a 24-statement checklist designed to measure disability associated with chronic pain.⁴³ The RMDQ asks participants to endorse their ability to do numerous day-to-day physical activities. Higher scores are associated with greater disability. A modified version of the RMDQ, which is applicable to a broader range of chronic pain conditions (ie, references to “my back pain” changed to “my pain”),³⁵ was used in the present study. This version of the RMDQ is widely used in Australia, and considerable normative data are therefore available for benchmarking purposes (eg, 35). The

RMDQ has yielded good psychometric properties with high levels of internal consistency and test–retest reliability.⁴⁴ In the present sample, Cronbach’s $\alpha = 0.86$.

2.2.1.2. Patient Health Questionnaire 9-item

The PHQ-9 contains 9 items that measure the symptoms and severity of depression according to *DSM-IV* criteria.²⁹ Higher scores indicate greater depression symptom severity, and a total score of ≥ 10 is indicative of a *DSM-IV* diagnosis of depression.²⁹ The PHQ-9 has been found to have good psychometric properties²⁹ and to be sensitive to treatment-related change.⁵⁴ In the present study, Cronbach’s $\alpha = 0.84$.

2.2.1.3. Generalized Anxiety Disorder 7-item Scale

The Generalized Anxiety Disorder 7-item (GAD-7) Scale contains 7 items designed to measure symptoms of anxiety and is sensitive to *DSM-IV* congruent generalised anxiety disorder, panic disorder, and social anxiety disorder, with higher scores indicating greater severity

Table 1
Demographic characteristics of the treatment and control group participants.

	Regular Contact		Optional Contact		No Contact		Waitlist Control		Overall		Statistical comparison between groups
	n	%	n	%	n	%	n	%	n	%	
Gender											
Male	27	19	24	18	25	20	20	27	96	20	$\chi^2 = 2.65, P = 0.448$
Female	112	81	111	82	98	80	54	73	375	80	
Age (years)											
Mean	50 (13)		49 (12)		50 (14)		52 (13)		50 (13)		F = 1.13, P = 0.336
Range	22-86		22-79		20-85		19-74		19-86		
18-29	10	7	12	9	9	7	6	8	37	8	$\chi^2 = 7.75, P = 0.559$
30-55	77	55	86	64	70	57	39	53	272	58	
56-64	30	22	23	17	23	19	12	16	88	19	
65+	22	16	14	10	21	17	17	23	74	16	
Marital status											
Single/never married	25	18	31	23	27	22	17	23	100	21	$\chi^2 = 13.36, P = 0.147$
Married/de facto	93	67	80	59	70	57	38	51	281	60	
Separated/divorced/widowed	20	14	16	12	22	18	17	23	75	16	
Education											
High school or less	38	27	33	24	26	21	22	30	119	25	$\chi^2 = 2.70, P = 0.845$
Certificate/diploma/other	36	26	39	29	39	32	20	27	134	28	
University	65	47	63	47	58	47	32	43	218	46	
Employment/vocational status*											
Full-time employment	39	28	29	22	28	23	13	18	109	23	$\chi^2 = 3.40, P = 0.334$
Part-time employment	18	13	28	21	19	15	14	19	79	17	
Casual employment	15	11	16	12	12	10	7	10	50	11	$\chi^2 = 3.37, P = 0.337$
Full-time student	3	2	4	3	3	2	2	3	12	3	
Part-time student	9	7	8	6	10	8	4	5	31	7	—
Unemployed	16	12	25	19	15	12	8	11	64	14	
Seeking employment	9	7	5	4	4	3	3	4	21	5	$\chi^2 = 3.99, P = 0.262$
Registered disability	27	19	29	22	27	22	20	27	103	22	
Retired	30	22	20	15	22	18	15	20	87	19	$\chi^2 = 1.65, P = 0.648$
											$\chi^2 = 2.27, P = 0.517$

SDs are shown in parentheses. All data were self-reported. Numbers and percentages are rounded to the nearest whole number. Chi-square statistics are not reported where cells have an n ≤ 5.

* Categories of employment and vocational status were not mutually exclusive; participants could indicate more than one to best describe their situation.

of anxiety symptoms.^{30,45} The GAD-7 has been found to have good psychometric properties³⁰ and to be sensitive to treatment-related change.¹⁶ In the current sample, Cronbach's $\alpha = 0.89$.

2.2.2. Secondary measure

2.2.2.1. Wisconsin Brief Pain Questionnaire

The Wisconsin Brief Pain Questionnaire (WBQP) is designed to assess the location, severity, and duration of a person's pain as well as the level of interference associated with pain.¹⁴ Only the 4 WBQP items concerning the intensity of participants' current pain, average pain, least pain and worst pain over the last month were used in the present study. These items ask for ratings of pain on a 10-point scale where 0 reflects no pain and 10 indicates the worst pain imaginable.

2.2.3. Tertiary measures

2.2.3.1. Pain Self-Efficacy Questionnaire

The Pain Self-efficacy Questionnaire (PSEQ) contains 10 statements regarding a patient's beliefs about his or her ability to undertake a number of daily tasks with pain.³⁴ Higher scores indicate greater pain-related self-efficacy. The PSEQ has been found to possess good internal consistency and test-retest reliability.³⁴ In the present sample, Cronbach's $\alpha = 0.91$.

2.2.3.2. Tampa Scale of Kinesiophobia

The Tampa Scale of Kinesiophobia (TSK) contains 17 statements and is designed to measure fears of movement and reinjury.²⁸ Higher scores indicate higher fears of movement and reinjury. The TSK has been found to predict behavioural performance on movement tasks⁵⁵ and has been found to possess good levels of internal consistency and reliability.⁴⁸ In the present sample, Cronbach's $\alpha = 0.80$.

2.2.3.3. Chronic Pain Acceptance Questionnaire 8-item

The Chronic Pain Acceptance Questionnaire 8-item (CPAQ-8) contains 8 items designed to measure acceptance in the context of chronic pain.²² It comprises 2 subscales, which measure engagement in meaningful activities in the presence of chronic pain (ie, the Activity Engagement Subscale) and willingness to experience pain without trying to control or avoid pain (ie, the Pain Willingness Subscale). Higher scores indicate greater willingness to experience and acceptance of pain. These 2 subscales can be examined separately or in combination, and the CPAQ-8 has been found to possess good psychometric properties.²² In the present sample, Cronbach's $\alpha = 0.79$.

2.2.3.4. Prescription medication and health care service use

Medication and health care service use data were collected using a previously used and purpose-built questionnaire^{17,53} based on the TIC-P.⁶ This questionnaire asks participants about their (1) primary and secondary health care consultations and admissions,

Table 2
Pain characteristics of the treatment and control group participants.

	Regular Contact		Optional Contact		No Contact		Waitlist Control		Overall		Statistical comparison between groups
	n	%	n	%	n	%	n	%	n	%	
Previously attended specialist pain clinic	68	48	76	56	72	58	35	47	251	53	$\chi^2 = 1.72, P = 0.632$
Compensation claim regarding pain	36	25	33	24	37	30	25	33	131	28	$\chi^2 = 2.64, P = 0.450$
Mean pain duration (years)	9.34 (8.33)		8.66 (6.78)		9.58 (9.05)		10.23 (10.83)		9.35 (8.22)		$F = 0.62, P = 0.596$
Average pain (last month)	5.71 (1.62)		5.70 (1.47)		5.90 (1.54)		6.01 (1.51)		5.80 (1.54)		$F = 1.00, P = 0.392$
Average number of pain sites	3.32 (1.29)		3.41 (1.21)		3.25 (1.23)		3.24 (1.18)		3.32 (1.23)		$F = 0.44, P = 0.724$
Pain-free period (last month)	6	4	11	8	10	8	3	4	30	6	$\chi^2 = 3.00, P = 0.391$
Pain location											
Head/face/mouth	54	38	54	40	45	36	25	33	178	38	$\chi^2 = 0.92, P = 0.819$
Neck/shoulders/upper back	108	77	106	78	94	76	56	75	364	77	$\chi^2 = 0.29, P = 0.962$
Arms/forearms/hands	79	56	80	59	65	52	40	54	264	56	$\chi^2 = 1.23, P = 0.745$
Lower back/pelvis/sacrum	114	82	117	86	108	87	60	81	399	85	$\chi^2 = 2.84, P = 0.417$
Legs/knees/feet	107	77	103	76	87	70	57	77	354	75	$\chi^2 = 1.77, P = 0.622$
Prescription medications											
Pain	107	76	98	72	93	75	55	74	353	75	$\chi^2 = 0.74, P = 0.862$
Mental health	66	47	57	42	54	43	31	41	208	44	$\chi^2 = 0.98, P = 0.805$
Prescription medications reported*											
Strong opioid analgesics	49	35	47	35	43	35	48	65	187	40	$\chi^2 = 7.88, P = 0.049$
Weak opioid analgesics	43	31	51	38	43	35	28	38	165	35	$\chi^2 = 1.41, P = 0.702$
Nonsteroidal anti-inflammatories	29	21	31	23	29	24	18	24	107	23	$\chi^2 = 0.59, P = 0.897$
Disease-modifying antirheumatics	9	6	6	4	11	9	4	5	30	6	—
Anticonvulsants	40	29	33	24	37	30	31	42	141	30	$\chi^2 = 3.79, P = 0.285$
Benzodiazepines	22	16	24	18	17	14	21	28	84	18	$\chi^2 = 5.93, P = 0.115$
Anxiolytics and antidepressants	88	63	90	67	65	53	42	57	285	61	$\chi^2 = 1.29, P = 0.731$
Other pain or psychotropic medications	19	14	23	17	21	17	13	18	76	16	$\chi^2 = 1.86, P = 0.603$
Number of prescription medications*											
0	28	20	23	17	17	14	6	8	74	16	$\chi^2 = 15.90, P = 0.388$
1	29	21	29	22	32	26	12	16	102	22	
2	27	19	26	19	23	19	18	24	94	20	
3	23	17	24	18	26	21	12	16	85	18	
4	17	12	17	12	16	13	11	14	61	13	
≥5	15	10	16	11	9	7	15	20	55	11	
Mean number of prescription medications*	2.15 (1.69)		2.26 (1.68)		2.16 (1.50)		2.77 (1.64)		2.28 (1.64)		
Self-reported causes/diagnoses for pain†											
Accident/injury	69	50	62	46	75	61	42	57	248	53	$\chi^2 = 6.87, P = 0.076$
Postmedical treatment	6	4	8	6	7	6	2	3	23	5	—
Complex regional pain syndrome	11	8	5	4	5	4	4	5	25	5	—
Fibromyalgia	28	20	39	29	17	14	11	15	95	20	$\chi^2 = 10.74, P = 0.013$
Neuropathic/neurological conditions‡	9	6	7	5	5	4	5	7	26	6	—
Rheumatic/autoimmune conditions§	9	6	8	6	5	4	2	3	24	5	—
Osteoarthritis	29	21	25	19	19	15	18	24	91	19	$\chi^2 = 2.64, P = 0.450$
Spinal cord injury	0	0	1	1	3	2	2	3	6	1	—

SDs are shown in parentheses. All data were self-reported. Chi-square statistics are not reported where cells have an $n \leq 5$.

* Only prescription medications for pain, a pain-related condition, anxiety, or depression are reported. Strong opioids: buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone; weak opioids: codeine, tramadol; anxiolytics and antidepressants: beta blockers, selective serotonin reuptake inhibitors, norepinephrine and serotonin–norepinephrine reuptake inhibitors, tricyclics and tetracyclics; other psychotropic or pain medications including corticosteroids, antispasmodics, serotonin agonists, dopamine agonists, antipsychotics, and psychostimulants.

† Self-reported causes or diagnoses related to pain: causes and diagnoses not mutually exclusive, and many others were reported.

‡ Conditions counted were peripheral neuropathy, postherpetic neuralgia, trigeminal neuralgia, and multiple sclerosis.

§ Conditions counted were rheumatoid arthritis, ankylosing spondylitis, and systemic lupus erythematosus.

and (2) the use of prescription pain, pain-related, antidepressant, and anxiolytic medications. To collect data about health service use, participants were presented with a range of relevant health professionals and services (ie, general practitioner, nurse, medical specialist, psychologist, counsellor, physiotherapist, telephone crisis service, and hospital emergency department) and asked to indicate how many times they had seen those health professionals or used those services in the previous 8 weeks due to pain, anxiety, or depression. To collect data about medication use, participants were asked to indicate the names of up to 5 medications they had been prescribed and were using for pain, pain-related conditions, anxiety, or depression and how long they had been using the medications.

These medications were categorised by the researchers based on the class of medications to which they belong (**Table 6**) and opioid medications were categorised based on their oral morphine equivalent with medications with a conversion factor ≥ 1 being considered strong and ≤ 1 being considered weak.³⁸

2.2.4. Acceptability and satisfaction

Treatment satisfaction and acceptability were assessed at posttreatment using 3 questions: (1) “Overall, how satisfied were you with the Course?” (2) “Would you feel confident in recommending this Course?” and (3) “Was it worth your time doing the Course?” Participants responded to the first question

using a 5-point Likert scale, which ranged from “Very Satisfied” to “Very Dissatisfied” and the latter 2 questions with a “Yes” or “No” response. These questions have been used in previous research examining the acceptability of other internet-delivered treatments (eg, 17,26,49,53) and were used in the first trial of the *Pain Course*.¹⁵ Several qualitative and free response questions were also posed to the participants in order to guide future revisions and improvements to the course.

2.3. Treatment program

The *Pain Course* is an efficacious internet-delivered pain management program based on the principles of CBT¹⁵ and has been developed alongside several other effective internet-delivered treatment courses for other conditions (eg, 17,49–53). The *Pain Course* is based on a pragmatic model of treatment that aims to: (1) provide information that helps participants to understand and deconstruct their symptoms and difficulties; (2) teach a range of CBT skills to help participants manage their symptoms and difficulties; and (3) reduce pain-related disability, anxiety, and depression by encouraging the practice and adoption of the skills taught within the program. Importantly, the *Pain Course* was designed based on the principles of transdiagnostic psychological intervention (eg, 52) and therefore provides therapeutic information and teaches self-management skills that are applicable to and effective for a broad range of pain conditions and psychological difficulties. Consequently, there is no tailoring of content or materials for individual participants; all

participants receive the same materials. An overview of the structure, content, and skills taught within the *Pain Course* is provided in **Table 3**.

The *Pain Course* consists of 5 core online lessons and 5 lesson summaries, which provide homework assignments to assist participants to learn and apply the skills described in the lessons. Participants are strongly encouraged to practice the skills taught within the course on a daily basis and to gradually adopt them into their everyday lives. Additional resources are provided to introduce additional topics and skills that are relevant for many participants, but which are not described within the core lessons, including materials on working with health professionals and treatments for chronic pain, managing sleep, problem solving, controlling attention and assertive communication. Comprehensive case stories are provided, which describe how people with chronic pain apply the information and skills covered in the course. All course materials are accessed through a personal password-protected login to the eCentreClinic software system, which is provided to participants once they are accepted into the Course. All materials are released systematically over 8 weeks and participants are unable to access materials in later weeks without first having read previous materials. However, once available, participants could view and review materials as desired and materials could be printed for offline use based on participant preference. The eCentreClinic system tracks participants’ logins and general use of the *Pain Course*, including the completion of lessons and the viewing and download of the lesson summaries and other additional resources. Participants were provided with

Table 3
Timetable and content of the Pain Course.

Lesson	Time before next lesson (weeks)	Lesson content	Primary skill taught	Additional resources
1	1	Education about the prevalence of chronic pain and symptoms of anxiety and depression. Information about pain perception and the nervous system. Introduction of a CBT model and explanation of the functional relationship between physical, thought, and behavioural symptoms. Instructions for identifying their own symptoms and how their symptoms interact	Symptom identification Symptom formulation	Sleep management What to do in a mental health emergency Working with health professionals and treatments for chronic pain
2	2	Introduction to the basic principles of cognitive therapy and importance of managing thoughts to help manage not only pain but also anxiety and depression. Instructions for monitoring and challenging thoughts	Thought monitoring Thought challenging	Structured problem solving and Worry Time Challenging beliefs
3	1	Introduction to the physical symptoms of anxiety (ie, hyperarousal) and depression (ie, hypoarousal) and their relationship to emotional well-being and managing the impact of chronic pain. Instructions about controlling physical symptoms using de-arousal strategies such as controlled breathing and scheduling pleasant activities	Controlled relaxation Pleasant activity scheduling	Attention management and chronic pain Chronic pain and panic attacks A list of 100 pleasant things to do
4	2	Introduction to the behavioural symptoms of anxiety, low mood, and chronic pain. Explanation of the overdoing–underdoing cycle of physical activity and issues around the fear and the avoidance of physical activities. Instructions for pacing and gradually and safely increasing physical activities	Activity pacing Graded exposure	Assertive communication
5	2	Information about the occurrence of lapses in pain, depression, and anxiety. Information about the signs of relapse and the importance of goal setting into the future. Instructions for creating a relapse prevention plan and goal setting	Relapse prevention Goal setting	—

CBT, cognitive behaviour therapy.

ongoing access to the course for the entire follow-up period and could complete lessons and access materials after the course had finished.

Each lesson was presented in the form of a slide show, which took approximately 10 to 20 minutes to read, and was designed to be easily read by someone without high school reading proficiency. Each lesson comprised approximately 70 slides and each slide contained approximately 100 to 200 words. The lesson materials were presented in a didactic format and included realistic examples of skills practice and symptom management, which were strategically integrated throughout the lessons to aid learning. Each lesson began with a summary of the content of previous lessons. The lessons also included summaries of key points interspersed throughout and concepts and skills described in previous lessons were often repeated and integrated with novel information introduced in later lessons. Participants had complete control over their progression through the lesson materials and had buttons to navigate forward and backward through the lesson slides at their own pace. Importantly, to minimise technological requirements and maximise accessibility, the *Pain Course* involves no audio or video content or interactive or game-like treatment-related components.

Based on the findings of previous research,^{50,51} participants were sent regular automated e-mails throughout the course. Some e-mails were triggered based on participant behaviour; specifically, e-mails were triggered when (1) participants completed a lesson during the course and when (2) participants had not completed a lesson within 7 days of it becoming available. E-mails were also triggered according to the course timeline; specifically, e-mails were triggered (1) at the beginning of each week to let participants know about new materials made available that week and to suggest some tasks for participants to focus on for the week and (2) at set times when participants were known to commonly experience increases in symptoms or to have increased difficulties practicing skills (eg, during the early weeks of the course and again towards the end when activity pacing and graded exposure are introduced). Each e-mail was brief and comprised 2 to 3 paragraphs containing 3 or 4 concise sentences. Each e-mail used the participant's first name and was written to convey a warm and supportive tone. Participants were encouraged to complete 1 lesson every 7 to 10 days and to attempt to regularly practice the skills covered within the lesson summaries.

2.4. Clinical contact

Two registered psychologists (M.G. and L.J.) with postgraduate qualifications in psychology and several years of clinical experience provided all clinical contact with participants, which occurred through telephone or a secure e-mail system. Neither psychologist had significant previous clinical experience working with patients with chronic pain. B. F. Dear provided scheduled and weekly, 1 hour, supervision sessions to both psychologists during which all participants were reviewed. Supervision was provided at other times as required. B. F. Dear is a registered clinical psychologist with more than 7 years of clinical experience in the area of chronic pain. The details of contact with all participants were recorded.

Participants in the Regular Contact Group and the Optional Contact Group were assigned to one of the clinicians for the entire course. Clinicians aimed to provide weekly contact to participants in the Regular Contact Group, through telephone or secure e-mail, for a period of between 10 to 15 minutes per contact unless more contact was clinically required. Participants in the

Optional Contact Group were also informed that their clinician was available for around 10 to 15 minutes each week and that the participant could contact the clinician on an "as-needed" basis throughout the course. However, they were informed that the clinician would not attempt to contact them without an explicit request for contact. Clinicians provided the same kind of clinical contact to participants in the Regular Contact and the Optional Contact Groups; the only difference was that the clinicians did not attempt to initiate contact with the participants in the Optional Contact Group each week as they did with the participants in the Regular Contact Group. Participants in the No Contact Group were informed that they were in a group who would not receive contact during the course unless they experienced technical difficulties or a mental health emergency. The questionnaire responses of participants in the No Contact Group were monitored twice daily, alongside the other Treatment Groups, throughout the course but contact was only initiated if a deterioration in their mental health (ie, defined as an increase in the PHQ-9 total score of ≥ 5 with a total score ≥ 15) was observed. This contact involved the administration of a risk assessment and, if needed, referral to appropriate crisis services.

The primary purpose of clinician contact was to encourage and support participants to work through the *Pain Course* and to apply the skills in the context of their symptoms and circumstances; rather than providing psychological treatment themselves. Importantly, in accordance with previous research,^{15,26} clinicians were instructed to: (1) answer participants' questions; (2) summarise content; (3) encourage skills practice and reinforce progress; (4) enquire about participants' experiences with the course and use of the skills; and (5) normalise challenges in the learning and use of the core skills. Clinicians were instructed not to introduce new therapeutic skills not covered within the course and, unless clinically indicated, to limit the time spent in contact or contacting participants to approximately 10 to 15 minutes per week. Clinicians were instructed not to request participants to submit examples of their use of the skills or completed worksheets for evaluation or checking. However, the clinicians did provide feedback on skills use and worksheet completion where it was requested by participants.

2.5. Analytic plan

All analyses were conducted using SPSS version 21. Group differences in demographic and pain-related variables were analysed using χ^2 tests, nonparametric Mann–Whitney *U* tests, and parametric 1-way analyses of variance. The alpha significance level for the preliminary analyses was adjusted from 0.05 to 0.01 as a partial control for the very large number of analyses conducted. Chi-square analyses were not reported where any cell comprised $n \leq 5$.

A generalised estimation equation (GEE) modelling technique was used to examine changes in the measures over time. Generalised estimation equation emphasizes the modelling of change in an average group effect over time while accounting for within-subject variance with the specification of a working correlation structure. Rather than creating conditional interpretation with the use of individual intercepts or random slopes, as in traditional mixed linear models, the primary emphasis in GEE is to directly model the average group-related change over time.²⁵ The GEE analyses therefore provide model coefficients that represent multiplicative change in the dependent variable, and these coefficients form a change factor (ie, $\exp(\beta)$), which can be used to calculate the average percentage change from baseline to any time point for each group. An exchangeable working correlation

structure was selected, coupled with a robust error estimation, for all GEE analyses. All GEE models also specified a gamma distribution with a log link response scale to address skewness in the dependent variable distributions. Importantly, initial assessment was used as baseline for the primary and secondary outcomes in all analyses concerning the primary and secondary outcomes. However, because there was a 1- to 8-week period between initial assessment and pretreatment, the pretreatment data are also presented for the primary and secondary outcomes to demonstrate their stability before treatment. For the tertiary outcomes, which were not assessed at initial assessment, pretreatment is used as baseline for all analyses. Separate generalised linear models, utilising time effects and random intercepts, were used to impute missing data in the dependent variables consistent with intention-to-treat principles. Then, to compare the relative outcomes of the 4 groups, GEE analyses were run comparing the primary and secondary outcome variables from initial assessment to pretreatment, posttreatment and 3-month follow-up. SPSS pairwise comparisons were used to explore and understand any significant main and interaction effects observed in the GEE analyses.

Several different statistics were calculated for comparison and benchmarking purposes. First, the average percentage change across time was calculated from the GEE analyses for each of the outcome variables with 95% confidence intervals. Second, Cohen's *d* effect sizes and 95% confidence intervals were also calculated for the between-group effects based on the estimated marginal mean values derived from the GEE models. Third, based on previous recommendations^{33,39} and consistent with the initial trial,¹⁵ the percentage of participants in each group reporting improvements in symptoms of $\geq 10\%$, 20%, 30%, 40%, and 50% and the numbers needed to treat (NNT) to obtain each banding of change are reported. The NNT was calculated using the formula, $NNT = 1/ARR$, where ARR (Absolute Risk Reduction) = CER (Control Group Event Rate) – TER (Treatment Group Event Rate). Chi-square tests were used to examine differences between the Treatment Groups in the number of participants reporting improvements at posttreatment and 3-month follow-up.

To provide data about negative outcomes⁴⁵ and consistent with the previous trial,¹⁵ the number of participants reporting symptom deteriorations $\geq 30\%$ and symptoms in the clinical ranges at posttreatment (ie, above recognised clinical cutoffs) on the primary outcome measures are also reported. The clinical ranges were defined as total scores ≥ 8 on the GAD-7,⁴⁶ ≥ 10 on the PHQ-9,²⁹ ≥ 14 on the RMDQ,³⁵ and ≥ 6 on the average pain item of the WBPQ.³⁵ The clinical cutoffs used for the GAD-7 and PHQ-9 have been previously identified as indicating probable diagnoses of an anxiety disorder and depressive disorder.^{29,46} However, because of the absence of an established cutoff, the 50th percentile of all scores of patients presenting to a tertiary pain service was used as the cutoff for the RMDQ and WBPQ.³⁵ Importantly, these analyses are designed not to capture participants whose scores may have increased by $\geq 30\%$ but who, despite the increase, still have nonclinical symptoms. Thus, these analyses were designed not to include fluctuations in scores that are unlikely to represent an actual or meaningful deterioration in symptoms (eg, a change in score from 0 to 1).

The GEE analyses were also used to examine self-reported prescription medication use, health service use and changes in vocational status from pretreatment to posttreatment and 3-month follow-up. These GEE analyses for medication use, which was coded as a binary yes or no, used a suitable negative binomial distribution for the probability of observing medication

use over time. The GEE analyses for vocational status also used a binary yes or no response employing a binomial distribution for the probability of observing a change over time. These GEE analyses for medication use, service use and vocational status were conducted only on the observed data; that is, no imputation was used for missing data given the absence of an accepted protocol within the literature. For service use data, significant atypical and outlying responses, that is, those responses more than ≥ 5 SDs from the group mean or that were well outside the observed distribution of responses, were removed. These cases were removed to provide a more accurate and representative group-based estimate of service use over time. Some medication, health professional and vocational categories were also either not analysed or were combined due to very low use.

3. Results

3.1. Baseline data, adherence, and attrition

The demographic and pain-related characteristics of the sample are shown in **Tables 1 and 2**. Specific details of participant flow, treatment attrition, lesson completion, and questionnaire response are shown in **Figure 1**. One-way analyses of variance and χ^2 tests did not identify any significant differences between the Treatment and Control Groups on the demographic variables ($P_s > 0.01$). No differences were found between the number of lessons completed by the Treatment Groups at either posttreatment or 3-month follow-up ($P > 0.01$). Bonferroni-corrected comparisons revealed no significant differences between participants completing and not completing the questionnaires across the groups at posttreatment in terms of age ($P_s > 0.01$), pain duration ($P_s > 0.01$), number of pain sites ($P_s > 0.01$), average pain ($P_s > 0.01$), and initial PHQ-9, GAD-7, or RMDQ scores ($P_s > 0.01$).

3.2. Primary outcomes for the overall samples

The primary outcomes were disability, depression, and anxiety, which were assessed using RMDQ, PHQ-9, and GAD-7, respectively. The mean values, SDs, percentage reductions, and Cohen's *d* effect sizes for the 4 groups and the primary, secondary, and tertiary outcome variables are shown in **Table 4**. The GEE analyses revealed significant effects for Time (Disability: Wald's $\chi^2 = 280.90$, $P < 0.001$; Depression: Wald's $\chi^2 = 353.18$, $P < 0.001$; Anxiety: Wald's $\chi^2 = 240.23$, $P < 0.001$) and significant Time by Group interactions (Disability: Wald's $\chi^2 = 61.95$, $P < 0.001$; Depression: Wald's $\chi^2 = 144.73$, $P < 0.001$; Anxiety: Wald's $\chi^2 = 83.29$, $P < 0.001$). Planned contrasts revealed no significant differences between the groups at assessment (P range: 0.118-0.916). However, across the primary outcomes, planned contrasts revealed significant reductions from assessment to posttreatment for the Treatment Groups ($P_s < 0.001$) and not the Control Group (P range: 0.244-0.978). The contrasts revealed the Treatment Groups had significantly lower scores posttreatment compared with the Control Group ($P_s \leq 0.003$) and no differences between the Treatment Groups (P range: 0.132-0.890). The contrasts also revealed that both the depression and anxiety scores of the Regular Contact Group increased slightly from posttreatment to 3-month follow-up ($P \leq 0.003$), while the Optional Contact Group's anxiety scores decreased slightly from posttreatment to 3-month follow-up ($P = 0.032$) and that the 3 Treatment Groups all made further improvements from posttreatment to follow-up in their disability levels ($P_s \leq 0.003$). However, there were no differences between

Table 4

Mean values, SDs, percentage change, and effect sizes for the primary, secondary, and tertiary outcome measures.

	n	Estimated marginal mean values				Percentage change from baseline*			Between-group Cohen's <i>d</i> effect sizes at posttreatment			
		Initial application	Pretreatment	Posttreatment	3 month follow-up	Pretreatment	Posttreatment	3 month follow-up	Regular Contact	Optional Contact	No Contact	Waitlist Control
Primary outcomes												
Disability (RMDQ)												
Regular Contact	139	13.92 (5.08)	13.47 (5.23)	11.05 (5.63)	10.01 (5.78)	3 (−3 to 9)	21 (14 to 27)	28 (21 to 35)	—	−0.02 (−0.25 to 0.22)	0.06 (−0.19 to 0.30)	0.53 (0.24 to 0.82)
Optional Contact	135	13.43 (5.17)	13.24 (5.60)	10.95 (5.84)	10.05 (5.85)	1 (−6 to 8)	18 (11 to 25)	25 (17 to 32)	—	—	0.07 (−0.17 to 0.32)	0.54 (0.25 to 0.82)
No Contact	123	14.22 (4.76)	13.92 (5.06)	11.36 (5.22)	10.40 (5.37)	2 (−4 to 8)	20 (13 to 26)	27 (21 to 33)	—	—	—	0.50 (0.21 to 0.79)
Waitlist Control	74	14.35 (4.95)	13.93 (5.22)	13.97 (5.17)	—	3 (−6 to 11)	3 (−6 to 11)	—	—	—	—	—
Depression (PHQ-9)												
Regular Contact	139	11.25 (4.86)	11.55 (5.88)	6.30 (4.57)	7.49 (5.09)	−3 (−12 to 6)	44 (37 to 50)	33 (25 to 41)	—	0.18 (−0.05 to 0.42)	0.15 (−0.09 to 0.39)	0.98 (0.68 to 1.27)
Optional Contact	135	11.19 (5.48)	10.60 (5.33)	7.20 (5.25)	7.01 (4.71)	5 (−3 to 13)	36 (27 to 43)	37 (30 to 44)	—	—	−0.05 (−0.29 to 0.19)	0.73 (0.44 to 1.02)
No Contact	123	11.32 (4.89)	10.90 (4.76)	6.96 (4.29)	7.08 (4.32)	4 (−4 to 11)	39 (31 to 45)	37 (30 to 44)	—	—	—	0.87 (0.56 to 1.16)
Waitlist Control	74	11.04 (5.25)	10.37 (5.47)	11.11 (5.51)	—	6 (−6 to 17)	−1 (−13 to 10)	—	—	—	—	—
Anxiety (GAD-7)												
Regular Contact	139	9.00 (5.37)	8.40 (5.52)	4.91 (4.40)	5.67 (4.83)	7 (−4 to 16)	45 (37 to 53)	37 (27 to 45)	—	0.16 (−0.08 to 0.40)	0.06 (−0.18 to 0.30)	0.63 (0.34 to 0.92)
Optional Contact	135	8.28 (4.81)	7.98 (4.67)	5.66 (4.94)	4.99 (3.89)	4 (−6 to 13)	32 (21 to 41)	40 (31 to 47)	—	—	−0.11 (−0.36 to 0.13)	0.44 (0.15 to 0.73)
No Contact	123	8.01 (4.79)	8.28 (4.60)	5.16 (3.91)	4.92 (3.72)	−3 (−14 to 6)	36 (26 to 44)	39 (30 to 46)	—	—	—	0.61 (0.31 to 0.90)
Waitlist Control	74	7.87 (5.19)	8.21 (5.92)	7.89 (5.29)	—	−4 (−23 to 12)	0 (−17 to 14)	—	—	—	—	—
Secondary outcome												
Average pain (WBPQ)												
Regular Contact	139	5.70 (1.61)	5.74 (1.72)	4.86 (1.79)	4.96 (2.00)	−1 (−6 to 4)	15 (9 to 20)	13 (7 to 19)	—	−0.01 (−0.24 to 0.23)	0.19 (−0.05 to 0.43)	0.50 (0.21 to 0.79)
Optional Contact	135	5.70 (1.46)	5.54 (1.74)	4.85 (1.73)	4.68 (1.87)	3 (−2 to 8)	15 (10 to 20)	18 (12 to 23)	—	—	0.20 (−0.05 to 0.44)	0.52 (0.23 to 0.81)
No Contact	123	5.90 (1.53)	5.72 (1.63)	5.20 (1.80)	5.02 (1.93)	3 (−2 to 8)	12 (6 to 17)	15 (9 to 21)	—	—	—	0.30 (0.01 to 0.59)
Waitlist Control	74	6.01 (1.49)	5.98 (1.53)	5.71 (1.50)	—	0 (−6 to 6)	5 (−1 to 11)	—	—	—	—	—
Tertiary outcomes												
Pain self-efficacy (PSEQ)												
Regular Contact	139	—	28.86 (12.93)	35.94 (12.98)	37.10 (12.73)	—	20 (15 to 24)	22 (18 to 27)	—	−0.17 (−0.41 to 0.06)	−0.22 (−0.46 to 0.03)	−0.49 (−0.78 to −0.21)
Optional Contact	135	—	28.61 (14.08)	33.60 (13.83)	34.53 (12.96)	—	15 (9 to 21)	17 (11 to 22)	—	—	−0.03 (−0.27 to 0.21)	−0.30 (−0.58 to −0.01)
No Contact	123	—	26.80 (11.52)	33.21 (11.97)	33.99 (12.66)	—	19 (14 to 24)	21 (16 to 26)	—	—	—	−0.29 (−0.58 to 0.00)
Waitlist Control	74	—	28.63 (12.10)	29.68 (12.11)	—	—	4 (−6 to 12)	—	—	—	—	—
Fear of movement (TSK)												

(continued on next page)

Table 4 (continued)

n	Estimated marginal mean values		Percentage change from baseline*			Between-group Cohen's d effect sizes at posttreatment				
	Initial application	Posttreatment	3 month follow-up	Pre-treatment	Posttreatment	3 month follow-up	Regular Contact	Optional Contact	No Contact	Waitlist Control
Regular Contact	139	38.59 (7.99)	34.48 (7.00)	33.65 (7.54)	—	11 (8 to 14)	—	0.05 (−0.18 to 0.29)	0.02 (−0.23 to 0.26)	0.42 (0.13 to 0.70)
Optional Contact	135	37.60 (8.40)	34.88 (7.80)	34.24 (8.07)	—	7 (4 to 11)	—	—	−0.04 (−0.28 to 0.20)	0.34 (0.06 to 0.63)
No Contact	123	39.35 (7.37)	34.59 (6.80)	35.08 (7.55)	—	12 (9 to 15)	—	—	—	0.41 (0.11 to 0.70)
Waitlist Control	74	39.56 (8.67)	37.65 (8.60)	—	—	5 (0 to 10)	—	—	—	—
Pain acceptance (CPAQ-8)										
Regular Contact	139	22.58 (7.53)	26.79 (6.69)	27.79 (7.19)	—	16 (12 to 19)	—	−0.19 (−0.43 to 0.05)	−0.15 (−0.40 to 0.09)	−0.44 (0.73 to −0.16)
Optional Contact	135	23.30 (7.72)	25.40 (8.01)	26.45 (7.72)	—	8 (3 to 13)	—	—	0.05 (−0.20 to 0.29)	−0.22 (−0.50 to 0.06)
No Contact	123	22.26 (7.19)	25.76 (6.65)	25.81 (7.19)	—	14 (10 to 17)	—	—	—	−0.30 (−0.59 to −0.01)
Waitlist Control	74	22.67 (7.52)	23.66 (7.66)	—	—	4 (−3 to 11)	—	—	—	—

SDs are shown in parentheses for mean values and 95% confidence intervals are shown in parentheses for effect size and percentage change statistics.

* The percentage change from baseline statistics are estimates of relative change derived from the GEE models conducted separately for each outcome.

CPAQ-8, Chronic Pain Acceptance Questionnaire 8-item; GAD-7, Generalized Anxiety Disorder 7-item Questionnaire; GEE, generalised estimation equation; PHQ-9, Patient Health Questionnaire 9-item; PSEQ, Pain Self-efficacy Questionnaire; RMDQ, Roland-Morris Disability Questionnaire; TSK, Tampa Scale of Kinesophobia; WBPO, Wisconsin Brief Pain Questionnaire.

the Treatment Groups on the primary outcomes at follow-up (*P* range: 0.154-0.958).

3.3. Secondary outcome for the overall samples

The secondary outcome was average pain, which was assessed using the average pain item of the WBPQ. The GEE analyses revealed significant effects for Time (Average pain: Wald's $\chi^2 = 174.40, P < 0.001$) and a significant Time by Group interaction (Average pain: Wald's $\chi^2 = 25.31, P = 0.001$). Planned contrasts revealed no significant differences between the groups at assessment (*P* range: 0.150-0.994) and that average pain scores significantly reduced from assessment to posttreatment for the Control Group (*P* = 0.020) and the 3 Treatment Groups (*P*s < 0.001). However, despite all groups improving, planned contrasts indicated that the 3 Treatment Groups had significantly lower average pain scores than the Control Group at posttreatment (*P*s ≤ 0.03) and that there were no differences between the Treatment Group pain ratings at posttreatment (*P* range: 0.111-0.933) or 3-month follow-up (*P* range: 0.146-0.780).

3.4. Tertiary outcomes for the overall samples

The tertiary outcomes were pain self-efficacy, fear of movement, and pain acceptance, which were assessed using PSEQ, TSK, and CPAQ-8, respectively. The GEE analyses revealed significant effects for Time (Pain self-efficacy: Wald's $\chi^2 = 167.90, P < 0.001$; Fear of movement: Wald's $\chi^2 = 196.43, P < 0.001$; Pain acceptance: Wald's $\chi^2 = 184.84, P < 0.001$) and significant Time by Group interactions (Pain self-efficacy: Wald's $\chi^2 = 27.41, P < 0.001$; Fear of movement: Wald's $\chi^2 = 19.17, P = 0.002$; Pain acceptance: Wald's $\chi^2 = 24.73, P < 0.001$). Planned contrasts revealed no significant differences between the groups at pretreatment on the tertiary outcomes (*P* range: 0.075-0.991). However, planned contrasts revealed significant improvements from pretreatment to posttreatment for the Treatment Groups across the outcomes (*P*s > 0.001), but not for the Control Group (*P* range: 0.067-0.198), which only exhibited significant improvements in their fear of movement (*P* = 0.004). The 3 Treatment Groups all had significantly improved pain self-efficacy and fear of movement scores compared with the Control Group (*P*s ≤ 0.046), and there were no differences between the Treatment Groups at posttreatment (*P* range: 0.078-0.895). Comparisons revealed that there were no differences between the Treatment Groups on fear of movement at 3-month follow-up (*P* range: 0.125-0.531) or pain self-efficacy (*P* range: 0.107-0.740), except for the No Contact Group, which reported marginally lower levels of pain self-efficacy compared with the Regular Contact Group (*P* = 0.048). The contrasts revealed no differences between the Treatment Groups on pain acceptance at posttreatment (*P* range: 0.120-0.695) and that only the Regular Contact Group had significantly higher scores than the Control Group (*P* = 0.003). However, at 3-month follow-up, the Regular Contact Group had marginally superior scores to the No Contact Group (*P* = 0.031) with no other differences between the Treatment Groups observed (*P* range: 0.158-0.490).

3.5. Clinical significance analyses

The percentage change estimates from the GEE models and between-group effect sizes for the outcomes at posttreatment are shown in **Table 4**. Significant percentage reductions were

found for disability (range: 18%-21%), depression (range: 36%-44%), anxiety (range: 32%-45%), and average pain (range: 12%-15%) across the treatment groups immediately posttreatment, which were maintained or further improved to 3-month follow-up (Disability: 25%-28%; Depression: 33%-37%; Anxiety: 37%-40%; Average pain: 13%-18%). Large between-group effect sizes (Cohen's *d*) were found for depression (*d* range: 0.73-0.98) and moderate between-group effect sizes for anxiety (*d* range: 0.44-0.63) and disability (*d* range: 0.50-0.54) for the Treatment Groups, relative to control, at posttreatment. Small-to-moderate between-group effect sizes were found for average pain levels (*d* range: 0.30-0.52) among the Treatment Groups, relative to control, at posttreatment.

The number of participants with scores on the primary and secondary outcomes improving by ≥10%, 20%, 30%, 40%, and 50% at posttreatment and follow-up is shown in **Table 5**. The NNT for the outcomes at posttreatment are also presented in **Table 5**. With 2 exceptions, no differences were found between the Treatment Groups in the proportions of participants improving (ie, ≥10%, 20%, 30%, 40%, and 50%) in disability, depression, anxiety, and average pain at posttreatment ($\chi^2 < 5.73$; $P > 0.05$). One significant difference was observed between the Treatment Groups in the proportions reporting improvements ≥10% in depression ($\chi^2 = 6.39$; $P = 0.041$), where the Regular Contact Group had a greater proportion of participants reporting improvements ≥10% compared with the No Contact Group at posttreatment. Another significant difference was observed between the Treatment Groups in the proportions reporting improvements ≥50% in depression ($\chi^2 = 7.89$; $P = 0.019$), where the Regular Contact Group had a greater proportion of participants reporting improvements ≥50% compared with the No Contact Group and Optional Contact Group at posttreatment. However,

no differences were observed between the Treatment Groups at 3-month follow-up ($\chi^2 < 5.41$; $P > 0.05$).

3.6. Clinical deterioration

Two percent (4/139), 2% (3/135), 1% (1/123), and 9% (7/74) in the Regular Contact, Optional Contact, No Contact, and Waitlist Control Groups, respectively, reported increases in disability scores ≥30% and scored within the clinical ranges at posttreatment. Three percent (5/139), 6% (9/135), 7% (9/123), and 14% (11/74) in the Regular Contact, Optional Contact, No Contact, and Waitlist Control Groups, respectively, reported increases in anxiety scores ≥30% and scored within the clinical ranges at posttreatment. Three percent (5/139), 5% (7/135), 3% (4/123), and 17% (13/74) of participants in the Regular Contact, Optional Contact, No Contact, and Waitlist Control Groups, respectively, reported increases in depression scores ≥30% and scored within the clinical ranges at posttreatment. Finally, 2% (4/139), 2% (3/135), 2% (3/123), and 4% (3/74) of participants in the Regular Contact, Optional Contact, No Contact, and Waitlist Control Groups, respectively, reported increases in average pain ≥30% and scored within the clinical ranges at posttreatment. Overall, participants in the Treatment Groups reported significantly fewer instances of deterioration in disability, depression, and anxiety compared with the Control Group (χ^2 range: 7.66-19.78; $P \leq 0.006$), but not in average pain levels ($\chi^2 = 0.54$; $P = 0.459$). No participants reported that the program caused clinical deteriorations in symptoms.

3.7. Prescription medication and health service use

Prescription medication use, health service use, and vocational status data for each group across the time points are shown in

Table 5
Percentages reporting ≥10, 20, 30, 40, and 50% improvements and the NNT to obtain improvements.

	n	≥10%			≥20%			≥30%			≥40%			≥50%		
		% post	% follow-up	NNT post	% post	% follow-up	NNT post	% post	% follow-up	NNT post	% post	% follow-up	NNT post	% post	% follow-up	NNT post
Primary outcomes																
Disability (RMDQ)																
Regular Contact	139	63	77	3.2	53	64	3.2	34	50	4.1	21	27	5.8	15	23	8.3
Optional Contact	135	64	72	3.1	50	60	3.5	34	46	4.1	21	27	5.8	14	20	9.0
No Contact	123	63	72	3.2	47	64	4.0	32	46	4.5	20	27	6.2	11	19	12.5
Waitlist Control	74	32	—	—	22	—	—	10	—	—	4	—	—	3	—	—
Depression (PHQ-9)																
Regular Contact	139	81	78	2.7	72	70	2.1	70	55	1.7	62	45	1.8	46	35	2.3
Optional Contact	135	71	81	3.8	65	70	2.5	60	60	2.1	56	52	2.0	34	36	3.2
No Contact	123	83	84	2.6	75	77	2.0	63	70	2.0	47	50	2.5	30	26	3.7
Waitlist Control	74	45	—	—	26	—	—	14	—	—	8	—	—	3	—	—
Anxiety (GAD-7)																
Regular Contact	139	78	68	2.6	70	63	2.7	65	55	2.4	57	48	2.5	48	38	3.0
Optional Contact	135	67	76	3.7	60	68	3.8	54	63	3.3	45	51	3.7	40	38	4.0
No Contact	123	70	72	3.3	66	68	3.1	58	60	2.9	50	55	3.1	33	43	5.5
Waitlist Control	74	40	—	—	34	—	—	24	—	—	18	—	—	15	—	—
Secondary outcome																
Average pain (WBPOQ)																
Regular Contact	139	63	58	4	36	32	5.5	19	24	9.0	12	16	8.3	7	8	14.2
Optional Contact	135	57	64	5.2	39	39	4.7	25	27	5.8	11	17	9.0	5	10	20.0
No Contact	123	56	65	5.5	30	37	8.3	19	24	9.0	9	13	11.1	5	7	20.0
Waitlist Control	74	38	—	—	18	—	—	8	—	—	0	—	—	0	—	—

NNT calculated using $NNT = 1/ARR$, where $ARR = CER - TER$.

Percentages are rounded to the nearest whole number. NNTs are not rounded.

ARR, absolute risk reduction; CER, control group event rate; GAD-7, Generalized Anxiety Disorder 7-item Scale; NNT, number needed to treat; PHQ-9, Patient Health Questionnaire 9-item; RMDQ, Roland-Morris Disability Questionnaire; TER, treatment group event rate; WBPOQ, Wisconsin Brief Pain Questionnaire.

Table 6. The GEE analyses revealed significant effects for Time on strong opioid use (Wald's $\chi^2 = 11.45$, $P = 0.003$), weak opioid use (Wald's $\chi^2 = 17.69$, $P < 0.001$), nonsteroidal anti-inflammatory use (Wald's $\chi^2 = 7.09$, $P = 0.029$), benzodiazepine use (Wald's $\chi^2 = 13.38$, $P = 0.001$), and antidepressant and anxiolytic use (Wald's $\chi^2 = 16.54$, $P < 0.001$), but no Time by Group interactions for these medications (strong opioids: Wald's $\chi^2 = 4.34$, $P = 0.502$; weak opioids: Wald's $\chi^2 = 6.16$, $P = 0.291$; nonsteroidal anti-inflammatories: Wald's $\chi^2 = 4.99$, $P = 0.417$; benzodiazepines: Wald's $\chi^2 = 4.31$, $P = 0.431$; antidepressants and anxiolytics: Wald's $\chi^2 = 4.31$, $P = 0.506$). Overall, these analyses indicated that use of these medications reduced by up to 29% from pretreatment to 3-month follow-up across the groups.

The GEE analyses revealed significant effects for Time on visits to general practitioners (Wald's $\chi^2 = 31.23$, $P < 0.001$), medical specialists (Wald's $\chi^2 = 16.60$, $P < 0.001$), physiotherapists (Wald's $\chi^2 = 12.83$, $P = 0.002$) and use of telephone crisis and emergency department services (Wald's $\chi^2 = 8.44$, $P = 0.015$), but only a Time by Group interaction for visits to medical specialists (Wald's $\chi^2 = 13.09$, $P = 0.022$). Pairwise comparisons revealed that the rate of reduction in visits to medical specialists was marginally greater among the Optional Contact and No Contact groups compared with the Control Group (P s < 0.034), but there were no differences between the Treatment Groups at 3-month follow-up (P s > 0.079). Overall, the analyses indicated that use of general practitioner, medical specialist, physiotherapist, and telephone crisis and emergency department services reduced by up to 41% from pretreatment to 3-month follow-up across the groups.

The GEE analyses did not reveal any significant effects for Time or Time by Group interactions for full-time work (Wald's $\chi^2 < 9.34$, $P > 0.095$), part-time and casual work (Wald's $\chi^2 < 5.34$, $P > 0.096$), full-time and part-time study (Wald's $\chi^2 < 4.20$, $P > 0.188$), unemployment and seeking work (Wald's $\chi^2 < 3.66$, $P > 0.284$), or registered as disabled (Wald's $\chi^2 < 4.85$, $P > 0.088$). However, a marginally significant effect for Time was found for retirement (Wald's $\chi^2 = 6.45$, $P = 0.040$), but no Time by Group interaction was found (Wald's $\chi^2 = 8.37$, $P = 0.137$). Pairwise comparisons revealed that there was a significant overall increase in the number of participants reporting themselves as retired at 3-month follow-up ($P = 0.011$).

3.8. Treatment satisfaction

Of the participants completing the treatment satisfaction questions, 92% (108/117), 82% (102/123), and 89% (89/100) of participants in the Regular Contact, Optional Contact, and No Contact Groups, respectively, reported being "satisfied" or "very satisfied" with the course. Similarly, 96% (113/117), 95% (118/123), and 97% (97/100) of participants in the Regular Contact, Optional Contact, and No Contact Groups, respectively, reported that they "would recommend the course" to others. Moreover, 96% (113/117), 92% (114/123), and 95% (95/100) of participants in the Regular Contact, Optional Contact, and No Contact Groups, respectively, reported that "the course was worth their time." There were no significant differences between the groups in the proportions of participants being satisfied with the course, being willing to recommend the course or finding the course was worth their time (χ^2 range: 0.19-5.12; $P > 0.05$).

3.9. Time spent and summary of contacts

Significant differences were found between the Treatment Groups in the amount of clinician time required ($F = 240.67$,

$P < 0.001$) with the Regular Contact Group requiring more time than both the Optional Contact and No Contact Groups ($P < 0.001$) and the No Contact Group requiring less time than the Optional Contact Group ($P = 0.02$). The mean total clinician time per participant for the Regular Contact Group over the 8 weeks of the course was 67.69 minutes (SD = 33.50), which comprised answering and making calls (Total = 890; M = 6.40; SD = 2.84; range: 1-12) as well as reading, sending, and responding to secure e-mails (Total = 783; M = 5.63; SD = 2.39; range: 0-11). Fifty-six percent (76/135) and 39% (48/123) of participants in the Optional Contact and No Contact Groups received 1 or more contacts through e-mail or telephone during the course, respectively. The mean total clinician time per participant for the Optional Contact Group was 12.85 minutes (SD = 24.61), which comprised answering and making calls (Total = 100; M = 0.74; SD = 1.28; range: 0-8) as well as reading, sending, and responding to secure e-mails (Total = 104; M = 0.77; SD = 1.08; range: 0-5). The mean total clinician time per participant in the No Contact Group was 5.44 minutes (SD = 12.38), which comprised answering and making calls (Total = 30; M = 0.24; SD = 0.657; range: 0-4) as well as reading, sending, and responding to e-mails (Total = 75; M = 0.61; SD = 1.02; range: 0-4). However, this contact was focussed on assessing and managing mental health crises rather than the provision of treatment or course-related clinical support. An additional 20.34 minutes (SD = 6.66; range: 5 minutes to 50 minutes) was required on average per participant to conduct the initial assessment through telephone before participation in the course.

4. Discussion

The present study sought to replicate the results of an earlier trial of a new internet-delivered pain management program and to explore its efficacy when provided with different levels of clinical support. It was hypothesised that all Treatment Groups would report improvements on clinical measures of anxiety, depression, and disability relative to a Control Group and that those participants receiving regular clinician contact would exhibit superior outcomes. These hypotheses were partially supported. All 3 Treatment Groups reported significant improvements (between-group Cohen's d ; avg. reduction) in disability (d s ≥ 0.50 ; avg. reduction $\geq 18\%$), anxiety (d s ≥ 0.44 ; avg. reduction $\geq 32\%$), depression (d s ≥ 0.73 ; avg. reduction $\geq 36\%$) and average pain (d s ≥ 0.30 ; avg. reduction $\geq 12\%$) immediately posttreatment, which were sustained or further improved to 3-month follow-up. No marked or consistent differences emerged between the Treatment Groups in clinical outcomes. Treatment completion and satisfaction rates were also high and did not differ across the Treatment Groups.

These findings replicate those of the initial trial¹⁵ and compare favourably with those reported for other internet-delivered^{3,19,32} and face-to-face pain management programs.^{11,21,40} For example, a recent Cochrane review of internet-delivered programs found evidence of moderate effect sizes for disability ($d = 0.50$) and small effects for anxiety ($d = 0.19$) and depression ($d = 0.19$),¹⁹ where the current study found moderate-to-large effect sizes for the primary outcomes of disability, anxiety, and depression (all d s ≥ 0.44 ; avg. reductions $\geq 18\%$) immediately posttreatment. The present study also found small-to-moderate effect sizes for the secondary outcome of average pain (all d s ≥ 0.30 ; avg. reductions $\geq 12\%$) consistent with the recent review¹⁹ and small-to-moderate effect size improvements on the tertiary outcomes of pain self-efficacy ($d \geq -0.29$; avg. increases $\geq 15\%$), fear of movement ($d \geq 0.34$; avg. decreases $\geq 7\%$), and

Table 6

Prescription medication use, health service use, and vocational status with estimates of relative change from pretreatment to posttreatment and 3-month follow-up.

Variable	Pretreatment					Posttreatment					3 month follow-up					Overall estimates of relative change*, %	
	Regular Contact	Optional Contact	No Contact	Waitlist Control	Overall	Regular Contact	Optional Contact	No Contact	Waitlist Control	Overall	Regular Contact	Optional Contact	No Contact	Waitlist Control	Overall	Pre to post	Pre to follow-up
n	139	135	123	74	471	123	127	104	67	421	115	121	97	333	—	—	
Prescription medications reported†, %																	
Strong opioid analgesics	27	26	28	43	30	24	24	23	37	26	20	21	23	—	21	−12 (−21 to −2)	−23 (−34 to −11)
Weak opioid analgesics	27	30	31	35	30	20	24	27	31	25	19	23	31	—	24	−25 (−36 to −9)	−26 (−36 to −14)
Nonsteroidal anti-inflammatories	19	22	23	23	22	18	15	18	22	18	17	17	22	—	18	−22 (−35 to −6)	−19 (−35 to −6)
Anticonvulsants	27	23	29	35	28	29	21	27	34	27	30	26	27	—	28	−6 (−17 to 6)	−2 (−15 to 15)
Benzodiazepines	15	16	13	26	16	11	13	11	22	13	13	10	12	—	12	−27 (−39 to −12)	−29 (−44 to −10)
Anxiolytics and antidepressants	54	56	50	51	53	50	48	40	51	47	47	47	45	—	47	−25 (−35 to −14)	−21 (−30 to −10)
Health service use																	
General practitioner	2.68 (0.264)	2.65 (0.236)	2.78 (0.282)	2.86 (0.356)	2.74 (0.143)	1.89 (0.207)	2.18 (0.218)	2.17 (0.258)	2.41 (0.254)	2.15 (0.117)	1.67 (0.237)	1.84 (0.159)	1.89 (0.182)	—	1.79 (0.115)	−22 (−31 to −12)	−33 (−42 to −24)
Medical specialist	1.07 (0.148)	1.48 (0.203)	1.48 (0.215)	0.78 (0.139)	1.16 (0.088)	1.08 (0.178)	1.03 (0.151)	0.77 (0.108)	0.94 (0.142)	0.95 (0.072)	0.87 (0.132)	0.85 (0.144)	0.77 (0.123)	—	0.83 (0.077)	−23 (−36 to −7)	−34 (−46 to −19)
Psychologist/counsellor	1.18 (0.19)	0.96 (0.14)	0.79 (0.16)	1.15 (0.29)	1.01 (0.95)	0.81 (0.13)	0.82 (0.13)	1.00 (0.18)	0.83 (0.18)	0.86 (0.08)	0.82 (0.16)	0.84 (0.17)	0.79 (0.16)	—	0.81 (0.09)	−15 (−30 to 4)	−20 (−36 to 1)
Physiotherapist	2.74 (0.346)	2.00 (0.310)	2.15 (0.359)	2.71 (0.527)	2.36 (0.185)	1.63 (0.244)	2.01 (0.311)	1.70 (0.240)	1.80 (0.419)	1.79 (0.148)	1.56 (0.262)	1.88 (0.235)	1.61 (0.264)	—	1.70 (0.144)	−25 (−37 to −9)	−28 (−40 to −13)
Telephone crisis/hospital emergency department service	0.19 (0.06)	0.18 (0.05)	0.32 (0.07)	0.18 (0.05)	0.22 (0.03)	0.28 (0.10)	0.26 (0.08)	0.22 (0.07)	0.20 (0.06)	0.25 (0.04)	0.09 (0.05)	0.18 (0.06)	0.13 (0.05)	—	0.13 (0.03)	12 (−19 to 57)	−41 (−62 to −6)
Employment/vocational status‡, %																	
Full-time employment	28	21	22	17	23	22	24	21	17	21	25	22	21	—	23	−6 (−17 to 5)	0 (−13 to 13)
Part-time/casual employment	23	32	24	28	27	26	30	24	35	28	23	27	21	—	24	−4 (−20 to 11)	9 (−7 to 24)
Full-time/part-time student	9	9	11	8	9	12	9	13	11	11	13	7	10	—	10	−21 (−57 to 7)	−8 (−45 to 21)
Unemployed/seeking work	16	20	15	12	16	13	14	16	13	14	11	18	15	—	14	15 (−7 to 33)	13 (−11 to 33)
Registered disability	19	21	22	27	22	19	22	21	24	21	16	17	21	—	18	−5 (−20 to 14)	−20 (−34 to −3)
Retired	21	14	17	20	19	26	15	23	25	22	26	13	26	—	21	14 (−1 to 31)	20 (4 to 39)

Percentages, SEs, and 95% confidence intervals are shown in parentheses. All data were self-reported. Percentages are rounded to the nearest whole number.

* The overall estimates of relative change are derived from the GEE model, which combined the 3 Treatment Groups and the Control Group as only a significant time effect was found across the outcomes.

† Only prescription medications for pain, a pain-related condition, anxiety, or depression are reported. Strong opioids: buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone; weak opioids: codeine, tramadol, tapentadol; anxiolytics and antidepressants: beta blockers, selective serotonin reuptake inhibitors, norepinephrine and serotonin–norepinephrine reuptake inhibitors, tricyclics and tetracyclics.

‡ Categories of employment and vocational status were not mutually exclusive; participants could indicate more than one to best describe their situation.

GEE, generalised estimation equation.

pain acceptance ($d \geq -0.22$; avg. increases $\geq 8\%$), which have been identified as important targets of CBT-based pain management programs.^{36,37} The present study also found evidence of significant reductions in medication use and health service use, but these were observed across the Treatment and Control Groups. These clinical outcomes were obtained with a mean clinician time per participant of 67.69 minutes (SD = 33.50), 12.85 minutes (SD = 24.61), and 5.44 minutes (SD = 12.38) for participants receiving regular contact, optional contact, and no clinical contact, respectively. The clinician time required for the Regular Contact Group was less than the previous trial (81.54 minutes; SD = 30.91),¹⁵ which may reflect reduced demands for clinician contact following iterative revisions to the *Pain Course* since the initial trial. Importantly, consistent with findings of trials in other areas (eg, 4,5,50,51), these findings suggest that good clinical outcomes can be obtained by internet-delivered programs involving very little or nonclinical contact. This is consistent with a recent review, which concluded that, following a screening procedure and provided the content is of a high quality and is sufficiently engaging for patients, clinician expertise and time may be less important in internet-delivered than face-to-face interventions.²

More research is needed to explore the characteristics of people who do and do not benefit from internet-delivered programs. The findings of the current study are encouraging with, for example, the demographic and pain characteristics of participants in this study appearing similar to those of patients attending face-to-face pain management programs (eg, 36,37), except that a larger proportion had higher levels of education. Given the considerable variability in the findings of existing studies,^{3,19,32} there is also a need for more research to explore the essential components and parameters of effective, safe, and acceptable internet-delivered programs. For example, while the current program obtained high completion rates and levels of satisfaction, many internet-delivered programs have reported significant levels of participant dropout and program non-completion (eg, >50% in some cases) (eg, 18,47). It is noteworthy that, while often thought to be essential components of internet-delivered interventions, the present study obtained very good outcomes without any audio or video content and without any interactive treatment-related components. Thus, more research is needed to understand the essential components of effective internet-delivered programs and when and for whom these programs are effective. This is essential to guide the integration of internet-delivered pain management programs into existing health care systems.

There are a number of limitations that need to be considered in the present study. First, the use of a treatment-as-usual Waitlist Control Group design limits our ability to control for nonspecific therapeutic effects and leaves open the possibility that participants in the Control Group may have recovered without treatment. However, it is important to note that participants had marked difficulties with chronic pain that were unlikely to spontaneously remit and, in fact, the Control Group reported a significant number of symptom deteriorations while on the waitlist. It is also important to note that, as there is now evidence for efficacy of the *Pain Course* it is becoming increasingly difficult to obtain ethical approval for research designs (eg, attention control designs, noncrossover longitudinal control designs) that do not involve timely access to either the *Pain Course* or some other equivalent active treatment, thus, limiting the designs the research team could use in the present study. Second, while longer term follow-up is planned and will be reported in the future, it is currently unclear whether the current results will be

maintained over the longer term. Third, participants were not restricted in the treatments they could receive during the trial and so participants started, changed, and stopped various treatments during the trial. Unfortunately, this means that it is not possible to completely rule out the positive and negative effects of other treatments in the current trial, although the use of a treatment-as-usual Waitlist Control Group means that these other treatments were at least partially controlled and are unlikely to have affected the major outcomes. Fourth, participants in the present study sought to participate in a pain management program and, consequently, it is unclear how the results would generalise to patients who were not seeking such a program. Fifth, while prescription medications use, health service use and vocational status were examined, the present study relied on self-report data. Sixth, it is unclear from the current study how important the observed changes in the tertiary outcomes, which are believed to be important psychological targets of face-to-face pain management programs, are to the improvements in the primary outcome variables. Further research is needed to explore whether these and other tertiary psychological outcomes are as important to internet-delivered treatments as has been suggested and observed in some face-to-face pain management programs.^{36,37} Finally, the aim of the present study was to examine the overall efficacy of an internet-delivered pain management program provided with 3 levels of clinical support rather than comprehensively examine the characteristic of people who benefit from these programs. Thus, future research is needed to focus on the characteristics of participants who are suitable for and benefit from internet-delivered and face-to-face pain management programs.

The present study has a number of notable strengths. First, it is the largest in the literature to explore an internet-delivered pain management program and to directly compare several different models of support. Second, it directly replicates an earlier trial and, consistent with the initial trial,¹⁵ obtained high questionnaire response rates, providing confidence in the outcomes observed. Third, it included a heterogeneous group of participants with chronic pain including participants reporting pain as a result of various pain conditions, injuries, medical treatments as well as a broad range of other significant health conditions (eg, cancer, multiple sclerosis, epilepsy, diabetes, spinal cord injuries). Fourth, it is the first study of an internet-delivered program for chronic pain to examine medication use, health service use and vocational status over time. Fifth, it is one of a very limited number to report on the acceptability of the program and to report on negative outcomes and symptom deterioration.¹⁹ Notably, the number of symptom deteriorations was significantly less among the Treatment Groups and no participants identified the program as the cause of their deterioration. Finally, it employed standardized and widely used clinical measures and assessed across the outcome domains targeted by pain management interventions (ie, disability, anxiety, and depression) and provides a broad range of data in several widely used formats and clinical metrics to enable benchmarking and comparison of outcomes.^{33,39}

In summary, the present study replicates and extends the findings of an earlier trial. Significant improvements in levels of disability, anxiety, depression, and pain were observed and no consistent or marked differences were found across the levels of clinician support provided. More research is needed to realise the potential of internet-delivered pain management programs and properly understand the participant, treatment and other factors affecting clinical efficacy, safety, and acceptability. However, while caution and further research is needed, the findings of the

present study add to the existing literature in highlighting the very significant potential of carefully developed and administered internet-delivered pain management programs as a way of increasing access to evidence-based care.

Conflict of interest statement

B. F. Dear and N. Titov are authors and developers of the Pain Course but derive no personal or financial benefit from it. They are funded by the Australian Government to develop and provide a free national online assessment and treatment service, the MindSpot Clinic (www.mindspot.org.au), for people with anxiety and depression. The remaining authors have no conflicts of interest to declare.

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