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1The Pain Course: 12- and 24-Month Outcomes From a Randomized Controlled Trial of an Internet-Delivered Pain Management Program Provided With Different Levels of Clinician Support

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Abstract: **Little is known about the long-term outcomes of emerging Internet-delivered pain management programs. The current study reports the 12- and 24-month follow-up data from a randomized controlled trial (n = 490) of an Internet-delivered pain management program, the Pain Course. The initial results of the trial to the 3-month follow-up have been reported elsewhere. There were significant improvements in disability, depression, anxiety, and pain levels across 3 treatment groups receiving different levels of clinician support compared with a treatment as the usual control. No marked or significant differences were found between the treatment groups either after treatment or at the 3-month follow-up. The current study obtained long-term follow-up data from 78% and 79% of participants (n = 397) at the 12-month and 24-month follow-up marks, respectively. Clinically significant decreases (average percent reduction; Cohen's *d* effect sizes) were maintained at the 12- and 24-month follow-ups for disability (average reduction ≥27%; *d* ≥ .67), depression (average reduction ≥36%; *d* ≥ .80), anxiety (average reduction ≥38%; *d* ≥ .66), and average pain levels (average reduction ≥21%; *d* ≥ .67). No marked or consistent differences were found among the 3 treatment groups. These findings suggest that the outcomes of Internet-delivered programs may be maintained over the long term.**

Perspective: This article presents the long-term outcome data of an established Internet-delivered pain management program for adults with chronic pain. The clinical improvements observed during the program were found to be maintained at the 12- and 24-month follow-up marks. This finding indicates that these programs can have lasting clinical effects.

Key words: *Chronic pain, depression, anxiety, randomized controlled trial, long-term outcomes, Internet, online, cognitive-behavioral therapy.*

Internet-delivered pain management programs have considerable potential for increasing access to evidence-based pain management.[16,25,31] Internet-delivered pain management programs are often based on the same principles and teach the same self-management skills as face-to-face programs. However, these programs use carefully designed online modules to teach pain management information and support patients in developing their self-management skills.[36] These programs can be offered in clinician-guided

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formats, where patients are provided weekly support throughout the program via telephone or email, or in more self-guided formats with little or no clinician contact. Similar to face-to-face programs, patients receiving Internet-delivered pain management programs work through treatment materials over several weeks, reflect on and apply the therapeutic information provided, and slowly integrate the self-management skills into their daily routines.

The findings of clinical trials examining Internet-delivered pain management programs have been encouraging.[2,10,30] However, little is known about the long-term outcomes of these programs. Reflecting this lack, recent reviews have identified only 2 small randomized controlled trials (RCTs) reporting 12-month follow-up data.[2,10] One of these trials (treatment n = 28) found that posttreatment improvements in depression, anxiety, and disability were maintained to the 12-month follow-up.[3] The other study (treatment n = 39) found evidence of improvements over time but no differences between the treatment and control groups at the 12-month follow-up.[20] Thus, although there is good evidence for the long-term benefits of traditional face-to-face pain management programs,[23,28,40] there is a critical need for long-term follow-up data from large trials of Internet-delivered pain management programs. Without such data, it is difficult to gauge the true public health potential of these programs.

The aim of the current study was to examine the long-term maintenance of clinical outcomes after an Internet-delivered pain management program, the Pain Course.[7] The current study reports the 12- and 24-month follow-up data of an RCT in which participants (n = 490) were randomized to either a treatment as usual waitlist control group or 1 of 3 treatment groups, specifically a group that received regular weekly contact with a clinician (regular contact group), a group that received the option of contact with a clinician (optional contact group), or a group that received no contact with a clinician (no contact group). The initial results of this trial (ie, data from baseline to the 3-month follow-up) have been reported in detail elsewhere.[7] In the initial report of this trial, significant improvements were observed in all clinical outcomes (eg, disability, depression, anxiety, and pain) across the treatment groups immediately after treatment compared with the treatment as usual controls, and these outcomes were maintained until the 3-month follow-up. Moreover, no marked or consistent differences in clinical outcomes were observed among the 3 treatment groups despite significant differences in the amount of clinician time required between the groups. In the current study, it was hypothesized that the outcomes observed at the 3-month follow-up would be maintained to the 12- and 24-month follow-up time points. It was hypothesized that no marked or consistent differences in outcomes would be observed at these time points.

Methods

Participants

The current study reports the long-term outcomes of a large RCT, the initial results of which are reported elsewhere.[7] Two other published studies have used data from the initial RCT, one examining predictors of clinical response[9] and another examining potential psychological mechanisms of clinical change.[13] Participants for the current study applied to participate in the Pain Course via the website of the eCentreClinic (available at https://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 via participation in clinical trials. The original RCT was promoted via paid advertisements placed in state newspapers and via unpaid general advertisements by a range of governmental and nongovernmental organizations, including Chronic Pain Australia, the Australian Pain Management Association, the New South Wales Agency for Clinical Innovation Pain Network, Pain Australia, and Arthritis Australia.

Participant flow is described in detail in the original report.[7] Briefly, 614 people with a range of chronic pain conditions submitted applications to participate, and 490 met inclusion criteria: 1) experienced pain for >6 months, 2) had their pain assessed by their general practitioner or a specialist within the previous 3 months, 3) were ≥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]). Participants were randomly allocated 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). The current article reports the outcomes for the 397 participants who were randomized to 1 of the 3 treatment groups. The control group data were not analyzed because participants were crossed over to treatment immediately after the treatment groups completed treatment.

Design and Measures

The present study is a report of the 12- and 24-month outcomes of an RCT with initial results until the 3-month follow-up reported elsewhere.[7] All participants provided informed consent. 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 ACTRN12613000252718. Numerous measures were administered to 3-month follow-up, but only the primary and secondary outcomes were assessed at the 12- and 24-month follow-ups. These measures are described elsewhere in this article. No monetary rewards were provided for participation or the completion of questionnaires. To encourage participants to complete the follow-up questionnaires, participants were sent emails and called on several occasions over a period of approximately 4 weeks. Participants were also provided with brief written feedback about their symptom scores

and responses to the questionnaires via email each time they completed the questionnaires.

Primary Measures

Roland Morris Disability Questionnaire. The Roland Morris Disability Questionnaire (RMDQ)[33] is a 24-statement checklist designed to measure disability associated with chronic pain. The RMDQ asks participants to endorse their ability to do numerous day-to-day physical activities. A modified version of the RMDQ, which is applicable to a broader range of chronic pain conditions,[27] was used in the present study. Scores range from 0 to 21, and higher scores are associated with greater disability. The RMDQ has yielded good psychometric properties with high levels of internal consistency and test-retest reliability.[32]

Patient Health Questionnaire 9-Item. The Patient Health Questionnaire 9-Item (PHQ-9)[21] contains 9 items that measure the symptoms of depression. Scores range from 0 to 27, and higher scores indicate greater depression symptom severity. A total score $\geq$10 is indicative of a diagnosis of depression per the *Diagnostic and Statistical Manual of Mental Disorders, 4th edition*.[21] The PHQ-9 has been found to have good psychometric properties and to be sensitive to treatment-related change.[38]

Generalized Anxiety Disorder Scale 7-Item. The Generalized Anxiety Disorder Scale 7-Item (GAD-7)[37] contains 7 items designed to measure symptoms of anxiety and is sensitive to a diagnosis of generalized anxiety disorder, panic disorder, and social anxiety disorder per the *Diagnostic and Statistical Manual of Mental Disorders, 4th edition*.[37] Scores range from 0 to 21, and higher scores indicate greater severity of anxiety symptoms. The GAD-7 has been found to have good psychometric properties and to be sensitive to treatment-related change.[5]

Secondary Measure

Wisconsin Brief Pain Questionnaire. The Wisconsin Brief Pain Questionnaire (WBPQ) is designed to assess the location, severity, and duration of a person's pain, as well as the level of interference associated with pain.[4] Only the 4 WBPQ items concerning the intensity of participants' current pain, average pain, least pain, and worst pain over the previous month were used in the present study. Patients rate their pain on an 11-point scale from 0 (no pain) to 10 (the worst pain imaginable). Only scores on the average pain item are reported here.

Treatment Program

The Pain Course is a validated Internet-delivered pain management program that is based on the principles of cognitive-behavioral therapy and transdiagnostic psychological intervention.[6-8,11,12] The Pain Course is modeled closely on evidence-based face-to-face pain management programs, which are often provided by tertiary pain management services. Thus, it aims to provide information that helps participants understand chronic pain and their symptoms and to teach cognitive and behavioral self-management skills to help decrease pain-related disability, anxiety, and depression. A detailed description of the content and skills taught within the program is provided elsewhere.[7]

The Pain Course is accessed via a secure online login, and all participants are provided their own personal account and password. The Pain Course is designed to be suitable for participants with a range of different chronic pain conditions and pain-related difficulties. The Pain Course consists of 5 core online lessons, which are in the form of a slide show, and 5 downloadable lesson summaries, which provide homework assignments to assist participants in learning and applying the skills described in the lessons. Detailed case stories and examples are included and woven throughout all materials, which help normalize the challenges of managing pain and how other people have learned to use the skills taught within the program. Additional resources on related topics (eg, working with health professionals, managing sleep, problem solving, and assertive communication) are also available. 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. All materials were released systematically over 8 weeks. However, participants were provided 24 months' access to the course materials.

Clinical Contact

Clinician contact was provided and available over the 8-week treatment period as described in the original RCT.[7] Briefly, 2 registered psychologists with postgraduate qualifications in psychology and several years of clinical experience provided all clinical contact with participants, via telephone or a secure email system. B.F.D. provided training and supervision. 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 via telephone or secure email for between 10 and 15 minutes per contact unless more contact was clinically required. Participants in the optional contact group were 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. Participants in the no contact group were informed that they would not receive contact during the course unless they experienced technical difficulties or a mental health emergency.

Statistical Analyses

All analyses were conducted in SPSS version 24 (SPSS, Inc, Chicago, IL). Change in the clinical outcomes over the entire course of the current study was considered to occur in 2 distinct phases. In the initial phase, spanning from the initial assessment to the 3-month follow-up,

participants were expected to achieve and demonstrate significant clinical improvements associated with participation in the program.[7] In the second phase, the clinical outcomes were expected to remain stable from the 3-month to the 12- and 24-month follow-up time points, without the kinds of major changes observed during and immediately after treatment. This supposition reflects the statistical view that change over time is often a discontinuous process, where statistical parameters, such as the scale of variance and within-subject's correlations, vary over time.[22,35] To account for this and maximize statistical sensitivity, longitudinal analyses in the current study focused specifically on the maintenance and stability of changes from the 3-month to the 12- and 24-month follow-up time points—that is, the maintenance of changes and symptoms from the last time point reported in the initial report.[7]

Importantly, to handle missing data, adjusted longitudinal generalized estimation equation (GEE) models were used to generate replacement scores for all missing cases under intention-to-treat principles. Consistent with methodologic guidelines[24] and recent applied methodologic studies,[19] these adjusted GEE models accounted for participants' symptom levels at the 3-month follow-up and the number of treatment modules completed, both of which have been identified as important nonignorable missing data mechanisms.[7] GEE modeling was also used to examine differences among the 3 treatment groups (ie, the regular contact, optional contact, and no contact groups) from the 3-month to the 12- and 24-month follow-up time points.[17] In line with recent research[18] and the initial report,[7] a gamma distribution with a log link response scale was specified to address positive skewness and proportionally changing scores in the dependent variable. An unstructured working correlation structure was also applied to account for within-subject variances over these 3 time points.

Pairwise comparisons were used to examine the statistical significance of changes in the outcomes between the follow-up time points and the differences in the outcomes between the treatment groups at each follow-up time point. The alpha significance level for all analyses was set at .05. No adjustment was made to the alpha to compensate for the number of pairwise comparisons conducted given that this would increase the risk of type II statistical errors (eg, falsely concluding there are no differences between the groups), which are more problematic in the context of the current study than type I errors (eg, falsely concluding that there are differences between the groups). As a similar precaution, the power of the study to detect meaningful clinical differences was examined. Importantly, with power set at .80 and alpha set at .50, the sample of this study was determined to provide sufficient power for detecting small differences ($ES_{\text{between groups}} < .2$) between the groups at each of the time points and for each of the outcomes.

Consistent with the earlier report,[7] clinical change was assessed in 3 ways. First, the average percentage change over time was calculated, using the *exp(β)* change factors derived from the GEE models. Second, Cohen's *d* effect sizes were calculated based on the estimated marginal means. Third, consistent with recommendations,[26,29] the percentage of participants in each group reporting improvements in symptoms of ≥30% and ≥50% at the follow-up time points were calculated. Binary logistic regressions were used to examine the differences between the treatment groups in the numbers of participants reporting improvements at the 3-, 12-, and 24-month follow-up time points. For benchmarking and comparison purposes, the initial assessment was used as baseline to calculate percentage change, Cohen's *d*, and the proportions improving by ≥30% and ≥50% at each of the follow-up time points.

To provide data about negative outcomes and also consistent with the initial report,[7] the numbers of participants reporting symptom deteriorations ≥30% and symptoms in the clinical ranges at each of the follow-up time points (ie, above recognized clinical cut-offs) are also reported. The clinical ranges were defined as a total score ≥8 on the GAD-7, a total score ≥10 on the PHQ-9, a total score ≥14 on the RMDQ, and a total score ≥6 on the average pain item of the WBPQ. The clinical cut-offs used for the GAD-7 and PHQ-9 have been identified previously as indicating probable diagnoses of an anxiety disorder and depressive disorder.[21,37] However, owing to the absence of an established cut-off, the 50th percentile of all scores of patients presenting to a tertiary pain service was used as the cut-off for the RMDQ and WBPQ.[27]

Results

Participant Characteristics

Information about participant characteristics is provided in Table 1, and further detail is provided in the original report.[7] Importantly, no significant differences were found between the treatment groups in participant characteristics at baseline. Of note, 80% of participants were female, and participants were an average of 50 years of age. Forty-eight percent had a university education, and only 23% were working full time. Participants reported an average of 3 pain sites, and only 6% experienced a pain-free period in the previous month. Fifty-three percent reported having attended a specialist pain clinic, and 75% and 44% reported taking prescription medication for their pain and mental health, respectively.

Adherence and Attrition

Details of participant flow from 3-month follow-up, treatment attrition, lesson completion, and questionnaire response are shown in Fig 1. Data were collected from 309 (78%) participants at the 12-month follow-up and 313 (79%) participants at the 24-month follow-up. Thus, missing data were imputed for 22% and 21% of participants at the 12- and 24-month follow-up time points, respectively.

Table 1. Brief Demographic and Clinical Characteristics

Variable	Regular Contact		Optional Contact		No Contact		Overall	
Female sex	112	(81)	111	(82)	98	(80)	375	(80)
Age, y								
Mean ± SD	50 ± 13		49 ± 12		50 ± 14		50 ± 13	
Range	22–86		22–79		20–85		19–86	
Marital status								
Single/never married	25	(18)	31	(23)	27	(22)	100	(21)
Married/de facto	93	(67)	80	(59)	70	(57)	281	(60)
Separated/divorced/widowed	20	(14)	16	(12)	22	(18)	75	(16)
Education								
High school or less	38	(27)	33	(24)	26	(21)	119	(25)
Certificate/diploma/other	36	(26)	39	(29)	39	(32)	134	(28)
University	65	(47)	63	(47)	58	(47)	218	(46)
Employment/vocational status*								
Full-time employment	39	(28)	29	(22)	28	(23)	109	(23)
Part-time employment	18	(13)	28	(21)	19	(15)	79	(17)
Unemployed	16	(12)	25	(19)	15	(12)	64	(14)
Registered disability	27	(19)	29	(22)	27	(22)	103	(22)
Retired	30	(22)	20	(15)	22	(18)	87	(19)
Previously attended specialist pain clinic	68	(48)	76	(56)	72	(58)	251	(53)
Compensation claim regarding pain	36	(25)	33	(24)	37	(30)	131	(28)
Number of pain sites	3.32 ± 1.29		3.41 ± 1.21		3.25 ± 1.23		3.32 ± 1.23	
Pain-free period (last month)	6	(4)	11	(8)	10	(8)	30	(6)
Pain location								
Head/face/mouth	54	(38)	54	(40)	45	(36)	178	(38)
Neck/shoulders/upper back	108	(77)	106	(78)	94	(76)	364	(77)
Arms/forearms/hands	79	(56)	80	(59)	65	(52)	264	(56)
Lower back/pelvis/sacrum	114	(82)	117	(86)	108	(87)	399	(85)
Legs/knees/feet	107	(77)	103	(76)	87	(70)	354	(75)
Prescription medications								
Pain	107	(76)	98	(72)	93	(75)	353	(75)
Mental health	66	(47)	57	(42)	54	(43)	208	(44)
Prescription medications†	2.15 ± 1.69		2.26 ± 1.68		2.16 ± 1.50		2.28 ± 1.64	

NOTE. Values are mean ± SD or n (%). All data were self-reported. Numbers and percentages are rounded to the nearest whole number.
* Categories of employment and vocational status were not mutually exclusive; participants could indicate >1 to best describe their situation.
† Only prescription medications for pain, a pain-related condition, anxiety, or depression are reported. Strong opioids are buprenorphine, fentanyl, hydromorphone, methadone, morphine, and oxycodone; weak opioids are codeine, tramadol, and tapentadol; anxiolytics and antidepressants are beta-blockers, selective serotonin reuptake inhibitors, norepinephrine and serotonin-norepinephrine reuptake inhibitors, tricyclics, and tetracyclics; other psychotropic or pain medications include corticosteroids, antispasmodics, serotonin agonists, dopamine agonists, antipsychotics, and psychostimulants.

Treatment Completion and Clinician Time

At the 12-month follow-up, 84%, 82%, and 74% of the regular contact, optional contact, and no contact treatment groups had completed all lessons of the course, respectively. As reported in the initial report, the average clinician time per participant was 67.69 minutes (standard deviation [SD] = 33.50 minutes), 12.85 minutes (SD = 24.61 minutes), and 5.44 minutes (SD = 12.38 minutes) during the 8-week treatment period for those receiving regular contact, the option of contact, and no clinical contact, respectively.

Primary Outcomes

The primary outcomes were disability, depression, and anxiety, which were assessed using the RMDQ, PHQ-9, and GAD-7, respectively. The means and SDs for the 3 treatment groups and the primary and secondary outcome variables are shown in Table 2. The means and 95% confidence intervals for the 3 treatment groups for all time points are shown in Figs 2 through 5.

Disability Outcomes at 12 and 24 Months of Follow-Up

The GEE analyses revealed no significant effects for time (Wald's $\chi^2 = 3.36$, $P = .186$) or group on disability (Wald's $\chi^2 = 2.04$, $P = .359$). However, there was a significant time by group interaction (Wald's $\chi^2 = 12.21$, $P = .016$). Pairwise comparisons revealed no change in disability levels from the 3- to 12-month follow-up for the regular contact and no contact groups ($P > .124$), but the optional contact group improved slightly over this period (mean difference = .92, $P = .007$). There were also no changes between the 12- and 24-month period for the optional contact and no contact groups ($P > .456$), but the regular contact group improved slightly over this period (mean difference = .97, $P = .009$). There was some evidence of a marginal difference between the groups at the 12-month follow-up, with the optional contact group reporting slightly lower levels of disability compared with the no contact group (mean difference = 1.49, $P = .048$) and the regular contact group (mean difference = 1.47, $P = .049$).

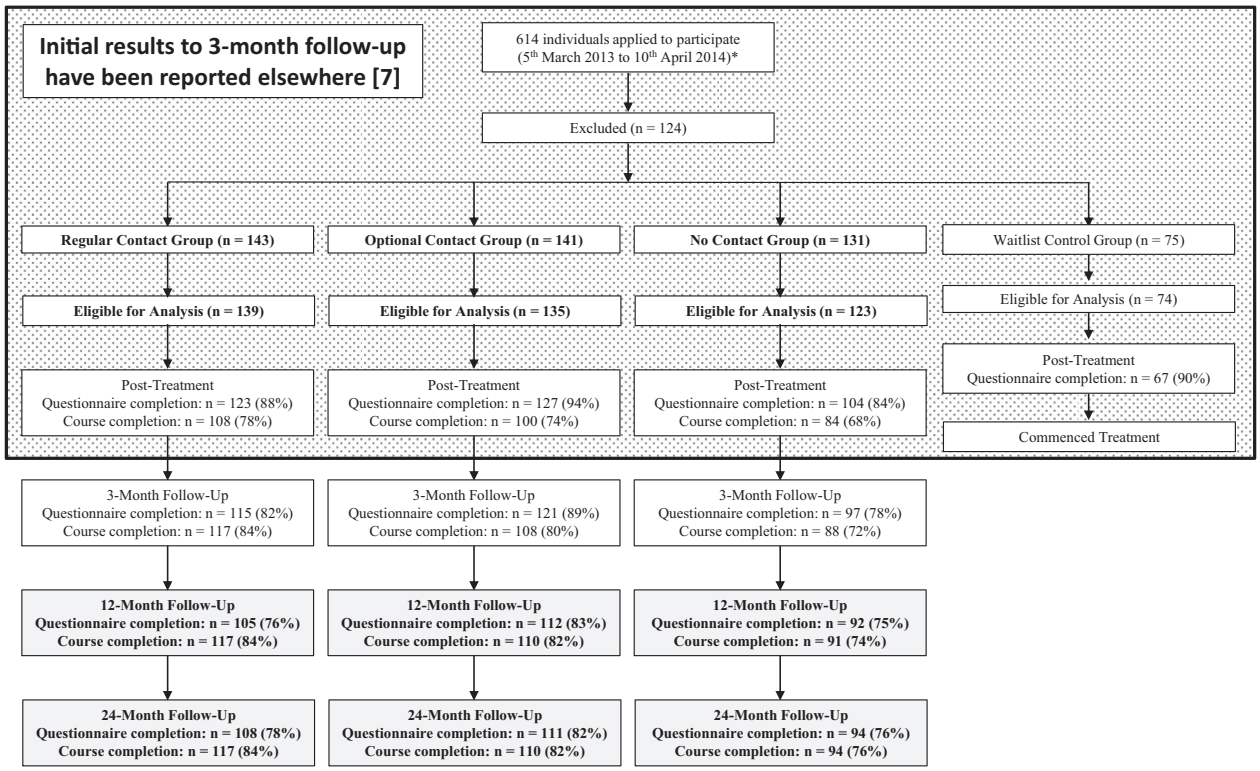

Figure 1. Participant flow from application to the 24-month follow-up.

However, there was no difference between the no contact and regular contact groups at the 12-month follow-up ($P = .980$) and no differences between any of the groups at 3- or 24-month follow-up time points ($P > .183$). Importantly, disability levels at the 12- and 24-month follow-ups were all significantly less than at initial assessment for each of the treatment groups ($P < .001$).

Depression Outcomes at 12 and 24 Months of Follow-Up

The GEE analyses revealed no significant effects for time (Wald's $\chi^2 = .17$, $P = .917$) or group on depression (Wald's $\chi^2 = .39$, $P = .821$). However, there was a significant time by group interaction (Wald's $\chi^2 = 20.58$, $P < .001$). Pairwise comparisons revealed no significant changes for any of the treatment groups between the 3- and 12-month follow-ups ($P > .207$), but there was some evidence of further improvement among the no contact group ($P = .051$). However, between the 12- and 24-month follow-ups, the depression levels of regular contact group improved slightly (mean difference = .96, $P = .006$) and the depression levels of the no contact group worsened slightly (mean difference = −1.05, $P = .005$). However, there were no significant differences in depression levels for any of the treatment groups at the 3-month ($P > .420$), 12-month ($P > .089$), or 24-month (Ps $> .070$) follow-up. Importantly, depression levels at the 12- and 24-month follow-up time points were all significantly less than at initial assessment for each of the treatment groups ($P < .001$).

Anxiety Outcomes at 12 and 24 Months of Follow-Up

The GEE analyses revealed no significant effects for time (Wald's $\chi^2 = .29$, $P = .861$), group (Wald's $\chi^2 = 1.85$, $P = .396$), or the group by time interaction on anxiety (Wald's $\chi^2 = 4.78$, $P = .310$).

Secondary Outcome

The secondary outcome was average pain, which was assessed using the WBPQ's average pain item. The GEE analyses revealed a significant effect for time (Wald's $\chi^2 = 27.46$, $P < .001$) and a significant time by group interaction (Wald's $\chi^2 = 12.75$, $P = .013$) but no significant effect for group (Wald's $\chi^2 = 3.33$, $P = .188$). Pairwise comparisons revealed that between the 3- and 12-month follow-up time point, the pain levels of the optional contact group (mean difference = .46, $P < .001$) and the no contact group improved slightly (mean difference = .35, $P = .015$). They also revealed that the pain levels of the regular contact group improved slightly between the 12- and 24-month follow-up (mean difference = .50, $P < .001$). There was some evidence of a marginal difference in pain levels at the 12-month follow-up, with the optional contact group reporting lower levels compared with the regular contact group (mean difference = .59, $P = .012$) but not the no contact group ($P = .058$). However, there was no difference between the no contact and regular contact groups at the 12-month follow-up ($P = .980$) and no differences between any of the groups at the 3- or 24-month follow-ups ($P > .129$). Importantly, pain levels at the 12- and 24-month follow-ups were all significantly less than at initial assessment for each of the treatment groups ($P < .001$).

Table 2. Means, SDs, Percentage Change, and Effect Sizes at 3, 12, and 24 Months of Follow-Up

			Estimated Marginal Means			*Percentage Change From Initial Assessment**			*Within-Group Cohen's d Effect Sizes From Initial Assessment*		
	n	*Initial Assessment*	*3-Month Follow-Up*	*12-Month Follow-Up*	*24-Month Follow-Up*	*3-Month Follow-Up*	*12-Month Follow-Up*	*24-Month Follow-Up*	*3-Month Follow-Up*	*12-Month Follow-Up*	*24-Month Follow-Up*
Primary Outcomes											
Disability (RMDQ)											
Regular contact	139	13.92 ± 5.1	10.02 ± 5.7	10.60 ± 6.2	9.63 ± 6.6	28% (21–35%)	24% (16–31%)	31% (22–38%)	.71 (.47– .96)	.58 (.33–.82)	.72 (.47–.97)
Optional contact	135	13.43 ± 5.2	10.05 ± 5.7	9.13 ± 5.9	9.31 ± 6.0	25% (17–32%)	32% (24–39%)	31% (22–38%)	.61 (.36–.86)	.76 (.51–1.01)	.72 (.47–.97)
No contact	123	14.22 ± 4.8	10.41 ± 5.3	10.62 ± 5.9	10.33 ± 5.9	27% (20–33%)	25% (17–32%)	27% (19–35%)	.75 (.48–1.01)	.66 (.40–.93)	.71 (.451–.98)
Overall	397	13.85 ± 5.0	10.15 ± 5.7	10.11 ± 6.1	9.74 ± 6.3	27% (23–31%)	27% (23–31%)	30% (25–34%)	.69 (.54–.84)	.68 (.54–.83)	.67 (.53–.82)
Depression (PHQ-9)											
Regular contact	139	11.25 ± 4.9	7.49 ± 5.0	7.45 ± 4.7	6.48 ± 4.4	33% (25–41%)	34% (26–41%)	42% (35–49%)	.75 (.50–1.00)	.78 (.53–1.03)	1.02 (.76–1.27)
Optional contact	135	11.19 ± 5.5	7.01 ± 4.6	7.46 ± 5.2	7.56 ± 5.5	37% (30–44%)	33% (25–41%)	32% (23–40%)	.81 (.56–1.07)	.68 (.43–.93)	.65 (.40–.90)
No contact	123	11.32 ± 4.9	7.09 ± 4.2	6.47 ± 4.4	7.53 ± 4.7	37% (30–44%)	43% (35–49%)	34% (25–41%)	.91 (.64–1.18)	1.03 (.76–1.30)	.78 (.51–1.04)
Overall	397	11.26 ± 5.1	7.20 ± 4.7	7.15 ± 4.9	7.17 ± 5.0	36% (32–40%)	36% (32–41%)	36% (32–41%)	.81 (.67–.96)	.81 (.66–.96)	.80 (.65–.94)
Anxiety (GAD-7)											
Regular contact	139	9.00 ± 5.4	5.68 ± 4.7	5.72 ± 4.5	5.23 ± 4.4	37% (27–45%)	36% (27–44%)	42% (33–50%)	.65 (.40–.89)	.65 (.41–.90)	.76 (.51–1.00)
Optional contact	135	8.28 ± 4.8	4.99 ± 3.8	4.94 ± 4.5	5.17 ± 4.3	40% (31–47%)	40% (30–49%)	38% (28–46%)	.75 (.50–1.00)	.70 (.45–.96)	.67 (.42–.92)
No contact	123	8.01 ± 4.8	4.92 ± 3.6	4.75 ± 4.1	5.29 ± 4.2	39% (30–46%)	41% (31–49%)	34% (24–43%)	.72 (.45–.98)	.72 (.46–.98)	.60 (.34–.86)
Overall	397	8.45 ± 5.0	5.21 ± 4.2	5.16 ± 4.5	5.23 ± 4.4	38% (33–43%)	39% (34–44%)	38% (33–43%)	.66 (.32–1.00)	.67 (.33–1.01)	.66 (.32–1.00)
Secondary Outcome											
Average Pain (WBPQ)											
Regular contact	139	5.70 ± 1.6	4.96 ± 2.0	4.81 ± 2.0	4.30 ± 2.1	13% (7–19%)	16% (9–21%)	24% (18–31%)	.40 (.16–.65)	.48 (.24–.73)	.73 (.48–.98)
Optional contact	135	5.70 ± 1.5	4.68 ± 1.8	4.22 ± 1.8	4.36 ± 2.0	18% (12–23%)	26% (20–31%)	24% (17–29%)	.61 (.36–.86)	.88 (.62–1.13)	.76 (.51–1.01)
No contact	123	5.90 ± 1.5	5.03 ± 1.9	4.67 ± 1.9	4.70 ± 2.0	15% (9–20%)	21% (15–26%)	20% (14–26%)	.49 (.23–.75)	.70 (.43–.96)	.66 (.40–.93)
Overall	397	5.77 ± 1.5	4.89 ± 1.9	4.57 ± 2.0	4.45 ± 2.1	15% (12–19%)	21% (17–24%)	23% (19–26%)	.49 (.35–.64)	.67 (.52–.81)	.71 (.56–.86)

NOTE. Values are mean ± SD or effect size (95% confidence interval) for percentage change statistics.
* The percentage change from baseline statistics are estimates of relative change derived from the GEE models conducted separately for each outcome.

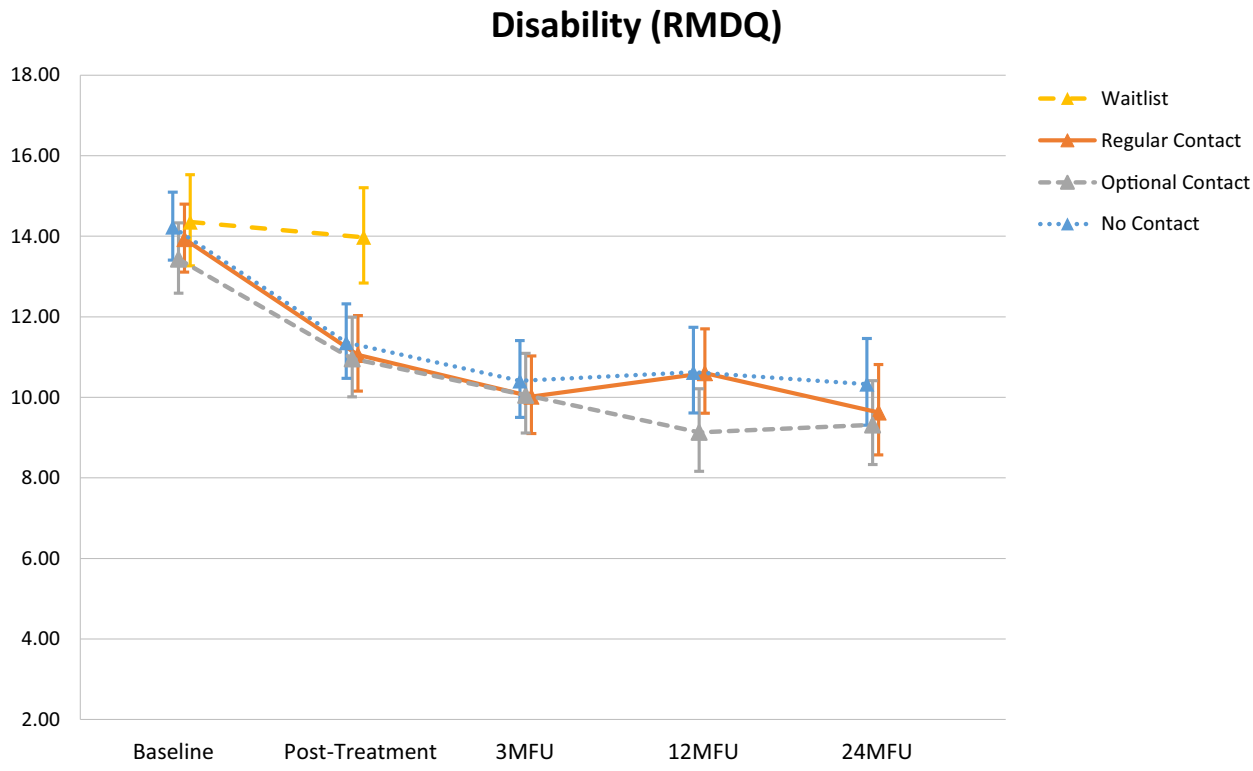

Figure 2. Disability scores from baseline to the 24-month follow-up (MFU).

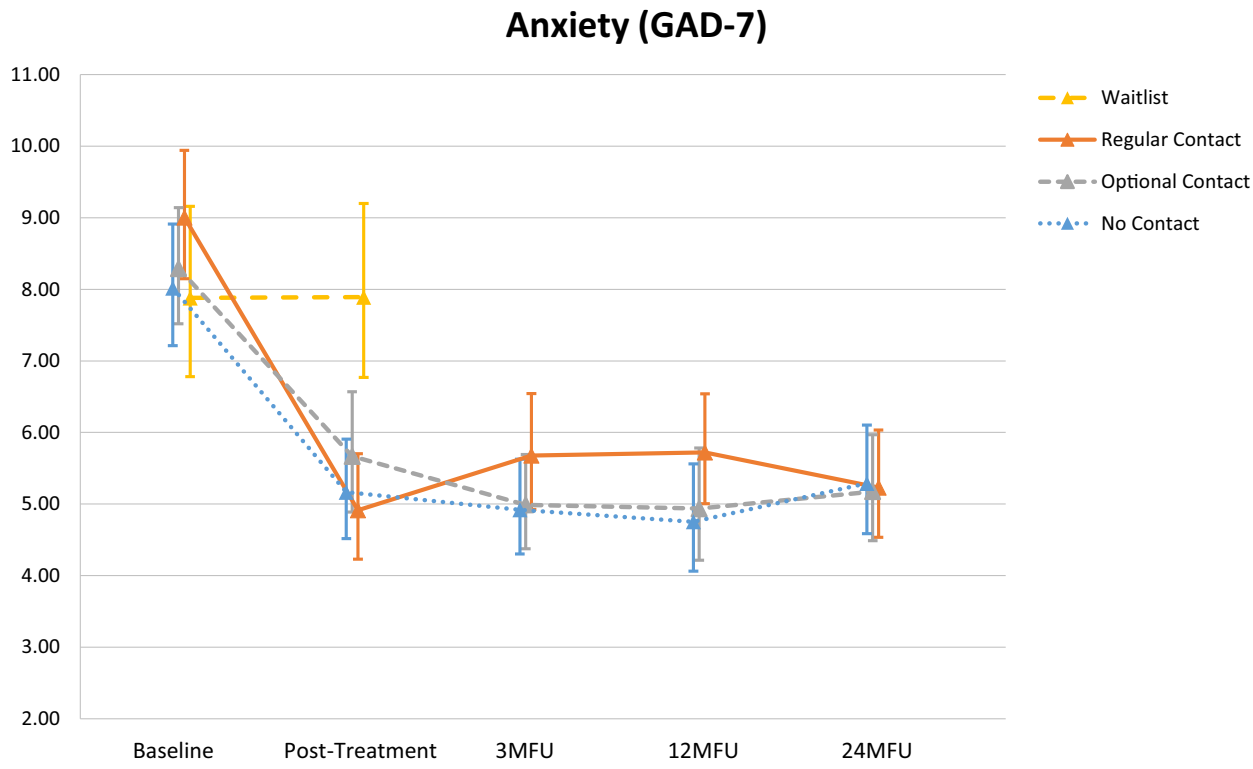

Figure 3. Anxiety scores from baseline to the 24-month follow-up (MFU).

Clinical Significance

The percentage change statistics and Cohen's *d* effect sizes for the 3 treatment groups are shown in Table 2. Significant percentage decreases and Cohen's *d* effect sizes found at the 3-month follow-up (from the initial assessment) were maintained to the 12- and 24-month follow-ups for disability (average improvement ≥27%, Cohen's $d \geq .67$), depression (average improvement ≥36%, Cohen's $d \geq .80$), anxiety (average

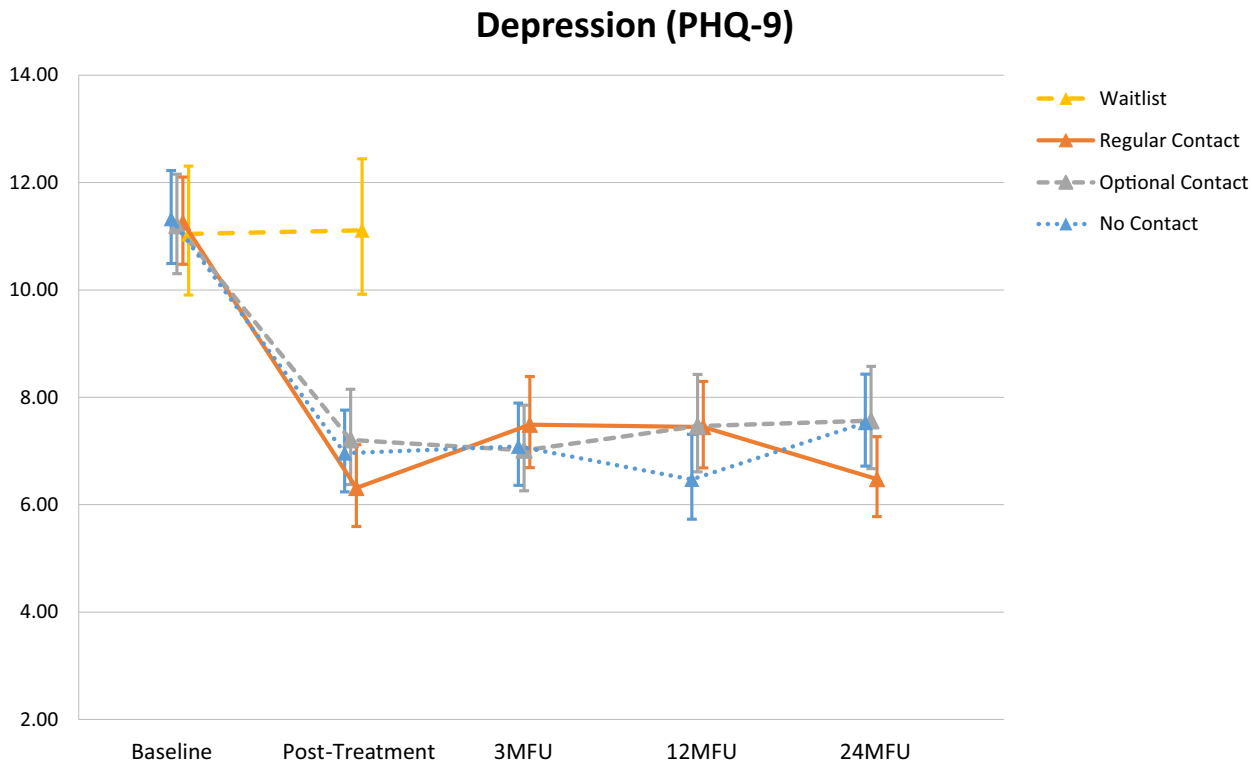

Figure 4. Depression scores from baseline to the 24-month follow-up (MFU).

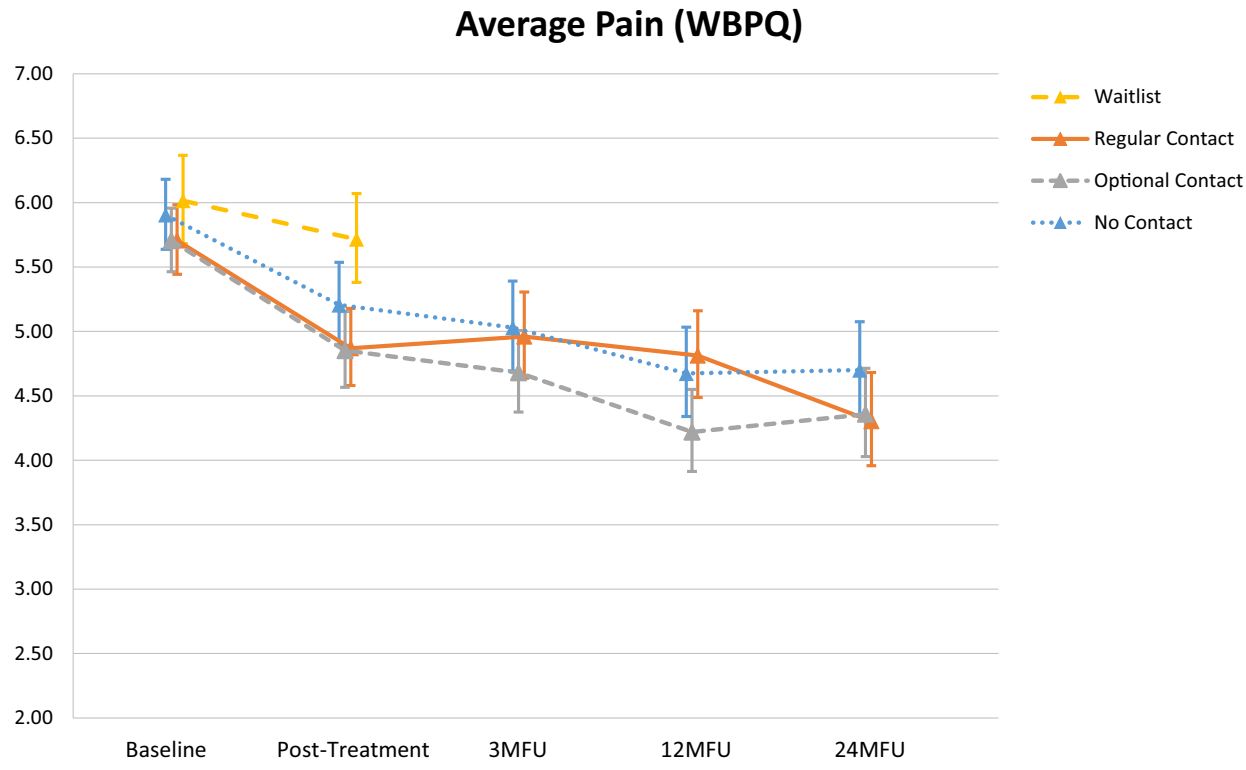

Figure 5. Average pain from baseline to the 24-month follow-up (MFU).

improvement ≥38%, Cohen's $d \geq .66$), and average pain (average improvement ≥15%, Cohen's $d \geq .49$).

The numbers of participants with scores on the primary and secondary outcomes improving by ≥30% and ≥50% from the initial assessment to the 3-, 12-, and 24-month follow-ups are shown in Table 3. Some statistically significant differences were found in the proportions of participants improving in disability, depression, anxiety, and average pain at some time points. Specifically, at the 12-month follow-up, the no contact group

had slightly fewer participants improving ≥30% in depression compared with the regular contact group ($P = .009$). The no contact group also had slightly more participants improving ≥30% in disability than the optional contact at the 12-month follow-up ($P = .011$) and the regular contact group at the 24-month follow-up ($P = .011$). The optional contact group had slightly fewer participants improving ≥30% in pain than either the no contact ($P = .025$) or the regular contact ($P = .004$) groups at the 12-month follow-up. However, this trend reversed at the 24-month follow-up, and the regular contact group had fewer participants improving ≥30% in pain than the no contact group ($P = .009$). No other statistically significant differences were found. Overall, no marked or consistent differences were observed across the treatment groups or across the time points.

Clinical Deteriorations

The numbers of participants meeting the criteria for clinical deterioration at 3, 12, and 24 months are shown in Table 3. No significant differences were found between the treatment groups in the proportions experiencing clinical deteriorations ($P > .214$). Overall, the levels of deterioration were low across the primary and secondary outcomes.

Discussion

The aim of the current study was to examine the 12- and 24-month outcomes of an Internet-delivered pain management program, the Pain Course. The current study builds on an earlier report of the same RCT, where participants with a broad range of chronic pain conditions were randomized to either a treatment as usual waitlist control group or 1 of 3 treatment groups that received different levels of clinician support. It was hypothesized that the outcomes observed at the 3-month follow-up, which were provided in an earlier report,[7] would be maintained at 12 and 24 months of follow-up. It was also hypothesized that no marked or consistent differences in outcomes would be observed over the long term among the 3 treatment groups. These hypotheses were largely supported. A large proportion of data was obtained at long-term follow-up with 78% and 79% providing data at the 12- and 24-month follow-up time points, respectively. The clinically significant decreases (average percent decrease; Cohen's *d* effect sizes) were maintained at the 12- and 24-month follow-ups for disability (average decrease ≥27%; $d \geq .67$), depression (average decrease ≥36%; $d \geq .80$), anxiety (average decrease ≥38%; $d \geq .66$), and average pain levels (average decrease ≥21%; $d \geq .67$). Although some minor changes in symptoms were observed over the follow-up period, no marked or consistent differences were found among the 3 treatment groups. These findings suggest that the outcomes of Internet-delivered pain management programs are maintained over the long term.

The findings of the current study are encouraging and demonstrate the potential of Internet-delivered pain management programs to provide durable improvements in clinical outcomes over the long term. There is already considerable evidence that the clinical

Table 3. Percentages Reporting ≥30% and ≥50% Improvements From Initial Assessment as Well as Deteriorations at Each Follow-Up Time Point

		≥30% Improvement			≥50% Improvement			Deteriorations		
	N	3 Months	12 Months	24 Months	3 Months	12 Months	24 Months	3 Months	12 Months	24 Months
Primary Outcomes										
Disability (RMDQ)										
Regular contact	139	50	45	56	23	22	32	1	3	3
Optional contact	135	46	56	53	20	28	26	1	2	4
No contact	123	46	41	41	19	27	23	2	2	1
Overall	397	47	47	50	21	26	27	2	2	3
Depression (PHQ-9)										
Regular contact	139	55	55	65	35	30	42	7	4	2
Optional contact	135	60	59	59	36	32	36	3	5	4
No contact	123	70	71	53	26	41	29	4	3	7
Overall	397	61	62	59	33	34	36	5	4	4
Anxiety (GAD-7)										
Regular contact	139	55	58	68	38	36	35	5	4	6
Optional contact	135	63	68	61	38	44	33	5	7	4
No contact	123	60	65	59	43	44	32	5	8	7
Overall	397	59	64	63	40	41	34	5	6	6
Secondary Outcome										
Average pain (WBPQ)										
Regular contact	139	24	25	42	8	8	17	6	5	1
Optional contact	135	27	41	33	10	14	13	2	4	4
No contact	123	24	28	27	7	12	15	4	5	3
Overall	397	25	31	34	9	11	15	4	5	3

NOTE. Values are a percentage unless otherwise noted. Percentages are rounded to the nearest whole number.

outcomes of traditional face-to-face pain management programs are maintained over the long term.[23,28,40] The current study extends on this evidence and indicates that outcomes observed immediately after Internet-delivered pain management programs can be maintained over the long term. This finding is consistent with the available data for similar Internet-delivered programs being used in mental health.[14,15,39] The findings of the current study, however, also indicate that the clinical outcomes can be maintained whether people are provided with regular clinician support, the option of clinician support, or no clinician support during treatment. This finding is very encouraging and highlights the public health potential of Internet-delivered programs involving very little support to produce lasting clinical improvements. Nevertheless, some caution is needed given that the program used in the current study has been carefully developed over many years,[6-8,11,12] and even when no clinician contact was provided during treatment, participants still needed to have an initial telephone assessment and discussion with a trained clinician before they could commence treatment. Thus, it is possible that the current findings might not be replicated with other less developed programs or where the program is provided in a fully automated or standalone format without the need or ability to engage with a clinician.

It is important to note that Internet-delivered pain management programs are unlikely to be suitable or helpful for all patients with chronic pain. For example, although most participants maintained their clinical improvements over time, there was evidence of a small proportion of participants reporting deteriorations over the long term. Specifically, approximately 2%, 4%, 6%, and 4% reported deteriorations in disability, depression, anxiety, and pain levels at the 12- and 24-month follow-ups. However, these are very small proportions of patients who experienced a deterioration in any of their symptoms. For ethical reasons, all participants with marked deteriorations were contacted; encouraged to re-engage with the program; and, where necessary, referred back to their primary health care provider. This practice is consistent with the idea that Internet-delivered programs could form part of stepped-care models of treatment.[1,34,36]—that is, where patients are provided with less resource-intensive and more accessible care (eg, Internet-delivered programs) and are stepped up to more resource-intensive and less accessible care (eg, face-to-face programs) based on clinical need. However, there are numerous ways in which Internet-delivered pain management programs could be used, and there are too few data at the moment to know for whom these programs are most suitable.[9,25] Reflecting this finding, a recent study failed to find any clear patient characteristics (eg, initial pain severity, pain chronicity, age, gender, education level, or employment status) that predicted clinical benefit from the Pain Course.[9] Future research is needed to explore whether certain participants require less or more clinician contact throughout Internet-delivered programs to benefit and, for example, whether certain patients should be referred directly into more intensive face-to-face programs instead of a lower-intensity Internet-delivered program.

There are several limitations that should be considered when interpreting the findings of the current study. First, the long-term outcomes were not assessed alongside a control group, because the original treatment-as-usual waitlist control group participating in the program shortly after the treatment groups had finished the program. Thus, it is not possible to say whether the current outcomes might have been observed over the long term in the absence of treatment. However, the initial report of the current RCT[7] clearly demonstrated the program to result in marked clinical improvements across all clinical outcomes, which were not observed in the control group. The current findings show that these clinical improvements are maintained over time. Second, the current study only reports on the outcomes of disability, depression, anxiety, and average pain; however, there are other important outcomes of pain management programs that were not assessed (eg, work status, medication use). Third, the current study used a treatment-seeking sample of participants who were open to an Internet-delivered pain management program and being followed for several years. It is unclear whether the current findings would generalize to patients in routine care settings and those who are less open to psychologically based pain management. Fourth, although decreases in health service use were observed in the initial trial,[7] participants were not restricted in the treatments that they could receive while participating in the current trial or over the 24-month follow-up period. Thus, some participants started, changed, and stopped various treatments, and the outcomes of these treatments are likely to have had some impact on the overall outcomes. Fifth, because very few participants met the criteria for clinical deterioration, the current study was underpowered to examine clinical characteristics and other factors that might be associated with deterioration. However, this is an important issue for future research and will become more possible to explore as more data from Internet-delivered programs become available. Sixth, the current study only reports the long-term outcomes of 1 specific Internet-delivered pain management program, and there is considerable variability between Internet-delivered pain management programs in therapeutic content and delivery methodologies.[2,10] Some caution is therefore needed in generalizing the outcomes of the current study to other Internet-delivered pain management programs.

In summary, the present study provides important information about the long-term clinical outcomes of an Internet-delivered pain management program provided with different levels of clinician support. Significant improvements observed in disability, depression, anxiety, and average pain levels immediately after treatment were maintained at 12 and 24 months of follow-up. No marked or consistent differences were observed

on the basis of the level of clinical support provided. These findings highlight the ability of carefully developed and administered Internet-delivered pain management programs to produce lasting clinical improvements that persist well after initial treatment completion. This study highlights the significant public health potential of Internet-delivered pain management programs for cost effectively increasing access to effective pain management.

Acknowledgments

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