General Section
Research Paper

PAIN REPORTS

A digital health intervention to support patients with chronic pain during prescription opioid tapering: a pilot randomised controlled trial

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Abstract

Introduction: Recent changes in opioid prescribing guidelines have led to an increasing number of patients with chronic pain being recommended to taper. However, opioid tapering can be challenging, and many patients require support.

Objectives: We evaluated the feasibility, acceptability, and potential efficacy of a codesigned digital health intervention to support patients with chronic pain during voluntary prescription opioid tapering.

Methods: In a pilot randomised controlled trial, participants received a psychoeducational video and 28 days of text messages (2 SMS/day) in addition to their usual care (intervention) or usual care alone (control). The feasibility, acceptability, and potential efficacy of the intervention were evaluated. The primary outcome was opioid tapering self-efficacy. Secondary outcomes were pain intensity and interference, anxiety and depression symptom severity, pain catastrophising, and pain self-efficacy.

Results: Of 28 randomised participants, 26 completed the study (13 per group). Text message delivery was high (99.2%), but fidelity of video delivery was low (57.1%). Most participants rated the messages as useful, supportive, encouraging, and engaging; 78.5% would recommend the intervention to others; and 64.2% desired a longer intervention period. Tapering self-efficacy (Cohen d = 0.74) and pain self-efficacy (d = 0.41) were higher, and pain intensity (d = 0.65) and affective interference (d = 0.45) were lower in the intervention group at week 4.

Conclusion: First evidence supports the feasibility, acceptability, and potentially efficacy of a psychoeducational video and SMS text messaging intervention to support patients with chronic pain during voluntary prescription opioid tapering. Definitive trials with longer intervention duration are warranted.

Keywords: Opioid, Pain, Tapering, Digital health, mHealth, Mobile health

1. Introduction

Opioid medications are commonly prescribed for managing chronic noncancer pain (CNCP).[8] However, evidence has revealed limited benefits and dose-related harms associated with long-term opioid therapy (LTOT).[17] Current guidelines recommend gradual tapering under clinical supervision and with regular reviews of progress,[17] and patients with CNCP are increasingly being advised to taper opioids.[9]

Tapering LTOT poses challenges for patients and clinicians. Patients often express concern about increased pain and

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withdrawal symptoms,[30,44,50] and clinicians report feeling concerned for patient safety and wellbeing when there are limited alternatives to opioids for chronic pain management and limited support for tapering from the health system.[28] Recent studies have raised concerns about the potential risk of overdose and harms associated with opioid tapering,[1] underscoring the need for additional support during this process.[4] Indeed, access to a range of supports, including pain education, monitoring, a strong patient-physician relationship, and strategies for managing pain and withdrawal symptoms, has been found to shape the trajectory of patients' tapering experience.[12,23,44,47] However, access to support for opioid tapering remains a pervasive challenge.[22,30,34]

Digital health technologies using mobile phones (mHealth) are emerging as a potential solution to the global challenge of providing patients with access to support for chronic disease self-management and health behaviour change.[20,41] These technologies can be cost-effective in delivering adjunctive health care support on a large scale and can be adapted to the needs of diverse demographic groups and health conditions.[20,29,51] Recent evidence suggests that digital health interventions which offer educational and socioemotional support may help to improve pain interference and severity, psychological distress, and health-related quality of life in people with chronic pain.[54] Evidence for the effectiveness of these interventions to support patients with CNCP during tapering LTOT is promising but limited.[4]

Patients with CNCP generally have positive attitudes toward using digital health technologies, particularly Short Message Service (SMS) text messages, to support them with opioid tapering.[38] Studies have also found that educational videos can effectively provide patients with information about chronic pain, pain self-management, and opioid tapering[13,19,31] and can increase self-efficacy for opioid tapering in people who are currently on LTOT for chronic pain.[19] We codesigned a mobile health (mHealth) intervention, consisting of a brief psychoeducational video and SMS text messaging, for patients with CNCP who are tapering prescription opioids under clinical supervision.[40] Both patients and clinicians have rated this intervention as appropriate, useful, and likely to be effective in supporting patients during voluntary opioid tapering.[40] The primary objectives of this pilot trial were (1) to assess the acceptability of this mHealth intervention in patients with CNCP and (2) to evaluate the feasibility of the intervention and the methodology for a future definitive trial. The secondary objectives of this trial were (1) to evaluate the potential efficacy of the intervention and (2) to obtain estimates that can be used to design a future definitive trial.

2. Methods

Full details of the study methods are described in the published study protocol.[39] The study was approved by the local Human Research Ethics Committee (2020/ETH03288) and preregistered at Australian & New Zealand Clinical Trials Registry (ACTRN12621000795897).

2.1. Trial design and study setting

The study was a pilot, single-blind randomised controlled trial (RCT) with 2 parallel arms (intervention and control group, with 1:1 ratio) conducted at outpatient multidisciplinary pain clinics located in 3 public hospitals in Sydney and Adelaide, Australia.

2.2. Participants and recruitment

Participants in this study were individuals with CNCP who were tapering opioids voluntarily, under clinical supervision. Those who met the eligibility criteria (**Table 1**) were referred by clinicians for an interview with a research team member (M.M.) to confirm their eligibility[14,15,21] and provide them with detailed study information (eg, randomisation, intervention, measurements).

2.3. Treatment groups

2.3.1. Control

Participants in the control group received usual care only, defined as the care provided at the pain clinics by a multidisciplinary team of specialist pain medicine physicians, clinical psychologists, physiotherapists, and nurses. As an inclusion criterion, tapering was voluntary (**Table 1**). The decision to taper and the tapering schedule were negotiated between the patient and their physician.

2.3.2. Intervention

Participants in the intervention group received the mHealth intervention in addition to the usual care. The development of the mHealth intervention is described in detail elsewhere[40] with the content accessible in the published study protocol.[39] The intervention consisted of a psychoeducational video and twice daily text messages, which were codesigned with consumers and clinicians.[40] The 10-minute video provided information about pain, opioid tapering, and pain self-management strategies as well as socioemotional support in the form of testimonials. The content of the text messages reinforced the content of the video. After enrolment, participants received a link to the video through e-mail and 2 text messages per day (mid-morning and mid-afternoon) for 28 days. All participants received the same schedule of messages. The recipient's first name was used intermittently in messages to increase personalisation and engagement. SMS was sent using commercial software (Message Media, Message4U Pty Ltd, Melbourne, Australia). Participants were informed that the text messages were one-way. However, they could reply with "STOP" to opt out.

2.4. Allocation and blinding

After baseline assessments, participants were randomised to the study groups by REDCap software, ensuring allocation concealment. Participants were informed of their group allocation through e-mail. Clinicians were blinded to the participants' group allocation. Participants completed questionnaires online using REDCap software. If necessary, data collection through phone call was performed by a research team member who was blinded to participant allocation.[43] The statistician was also blinded to participant allocation.

2.5. Outcome measures

A complete list of outcome measures and an assessment timeline is provided in Supplementary Materials (Table S1, http://links.lww.com/PR9/A215).

2.5.1. Acceptability and feasibility measures

Participants in the intervention group provided their feedback on the acceptability and feasibility of the intervention. The feedback

Table 1

Eligibility criteria.

Inclusion criteria
Age 18 y or older
Diagnosed with a chronic (>3 mo) pain condition
Have been using opioid analgesics at a dose of at least 40 mg/d oral morphine equivalent for at least 4 wk
Have been advised by a clinician to taper opioids
Were tapering opioid medications voluntarily, as indicated by verbalised willingness and consent
Have been tapering or would be tapering their opioid medications at the time of enrolment
Able to understand written and spoken English
Own a mobile phone that receives SMS text messaging
Able to give written informed consent and comply with study procedures
Exclusion criteria
Cognitive impairment or intellectual disability
Evidence of severe opioid use disorder.[16] Illicit substance use was not an exclusion criterion unless indicating a severe opioid use disorder
History of primary psychotic disorder, bipolar affective disorder, bipolar disorder with psychotic features, depressive disorder with psychotic features, borderline personality disorder, antisocial personality disorder, or positive family history (first-degree relative) of psychotic disorder or bipolar affective disorder such that participants might be at more than low/negligible risk by participating in the study
Any other major, poorly controlled medical or mental health comorbidity
Participation in another clinical trial concurrently

survey (Supplementary Materials, http://links.lww.com/PR9/A215) included rating scales and open-text responses capturing likelihood of recommending the intervention to others, perceived usefulness of the intervention, level of engagement with the intervention, barriers to engagement, message readability, and preferred frequency and timing of the messages.[25,56] Feasibility was assessed by monitoring the successful delivery of the messages, reasons for exclusions and dropouts, and rates of questionnaire completion and missing data.

2.5.2. Potential efficacy measures

The primary efficacy outcome was general self-efficacy for tapering opioids. A one-item scale (OTSEQ, opioid tapering self-efficacy questionnaire) was developed using Bandura self-efficacy theory and guides for constructing self-efficacy scales (Supplementary Materials, http://links.lww.com/PR9/A215).[6] The scale asked participants to rate their confidence in reducing their dose of opioid medication by selecting a number from 0 ("not at all confident") to 100 ("completely confident"). Face validity and content validity of the scale were evaluated by interviewing clinicians and patients with CNCP who had experienced opioid tapering.

In addition, we measured pain intensity and interference using the three-item pain, enjoyment of life, and general activity scale (PEG)[35] and measured mood using the Generalised Anxiety Disorder 2-item[37] and the Patient Health Questionnaire-2.[36] These outcomes were measured at baseline and then every week for 4 weeks. Tapering self-efficacy was also measured in the intervention group immediately after watching the video. Opioid dose and its change were assessed weekly by self-report. Total daily opioid use was converted to mg of oral morphine equivalents.[5] Withdrawal symptoms were also assessed weekly with an open-ended question, and the cumulative incidence of withdrawal symptoms over the trial period was measured. Pain catastrophising was measured using the six-item Concerns about Pain Scale (CAP-6).[2] Pain self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire (PSEQ).[48] Pain catastrophising and self-efficacy were measured at baseline and then at week 4. Participants also rated their level of satisfaction with the care they received over the past 4 weeks using a 7-point Likert scale ranging from "very dissatisfied" to "very satisfied."[14]

2.6. Statistical analysis

2.6.1. Sample size

To assess whether the intervention was acceptable to 70% of the participants with a 20% precision rate, 18 participants were needed in the intervention arm. To evaluate the potential efficacy of the intervention, 12 participants were needed in each group assuming a medium standardised effect size (Cohen $d = 0.5$) and using the 80% one-sided confidence interval (CI) approach, which is recommended for pilot trials.[11] Therefore, the sample size was set at 20 participants for each study arm assuming a 10% loss to follow-up during the study period (see Supplementary Materials for more details, http://links.lww.com/PR9/A215).

2.6.2. Statistical methods

Descriptive statistics were used for reporting feasibility and acceptability measures with an intention-to-treat approach. A linear mixed-effects model was used to analyse outcomes of potential efficacy. The main effect of the group was tested to estimate the overall difference in outcomes between the 2 groups across all time points (weeks 1–4). Pairwise contrasts were used to compare outcomes between the 2 groups at each week of the study. According to the preregistered analysis plan,[39] we used the one-sided 80% CI method in this pilot study. With this approach, we were interested in whether the difference estimates were larger or smaller than zero (depending on the predicted direction of the effect) and did not aim to formally undertake hypothesis testing procedures to prove the efficacy of the intervention.[11] Hence, there were no corrections for multiple comparisons in this pilot study. Data are presented as difference estimates and one-sided CI 80%. Cohen d (effect size) was calculated based on the estimates and standard errors. All analyses were conducted using SAS software (V.9.4, see Supplementary Materials for more details, http://links.lww.com/PR9/A215).

3. Results

3.1. Recruitment

Recruitment was open from August 2021 to November 2022. Thirty-nine potential participants were referred from the 3 study

sites. Of these, 28 (72%) were eligible, consented, and enrolled in the study. Recruitment was stopped before reaching the planned sample size of 40 as it exceeded the available funding period. All enrolled participants were randomised. After randomisation, 1 participant from each group (7.1%) dropped out of the study (loss to follow-up). In total, 13 participants in each group (92.8%) completed the study (**Fig. 1**). All participants were included in an intention-to-treat analysis. The mean age (±SD, range) was 50 (±12, 26–71) years, and 19 (67.8%) were female. Duration of pain and opioid therapy (median [25%, 75% quartiles]) were 10 (6, 23) and 6 (3, 10) years, respectively. There were no significant differences between the 2 groups in demographic or baseline characteristics (**Table 2**).

3.2. Feasibility and acceptability outcomes

Text message delivery was 99.2% successful (778/784). Eight (out of 14, 57.1%) participants in the intervention group confirmed that they had watched the educational video and completed the postvideo assessment of tapering self-efficacy. Participants rated the messages as useful (64.2%), easy to understand (78.5%), supportive (71.4%), and encouraging (85.7%), and 78.5% would recommend the intervention to others (**Table 3**). The data completion rate was 85.7% (132 of 154 assessments).

3.3. Potential efficacy outcomes

3.3.1. Opioid tapering self-efficacy

The main effect test showed a higher OTSEQ score overall across weeks 1 to 4 in the intervention compared with the control group (estimate [CI80%] = 16.1 [10.9, ∞], d = 0.89). Pairwise contrasts showed a higher OTSEQ score in the intervention group than the control at week 2 (estimate [CI80%] = 9.3 [3.2, ∞], d = 0.49) and week 4 (estimate [CI80%] = 15.6 [8.9, ∞], d = 0.74, **Fig. 2**, **Table 4**). Moreover, OTSEQ scores were higher after watching the video compared with the baseline in the intervention group (estimate [CI80%] = 9.4 [1.5, ∞], d = 0.27, Figure S2, http://links.lww.com/PR9/A215).

3.3.2. Pain, enjoyment of life, and general activity scale total score and subscales

The main effect tests showed a lower pain intensity score overall across weeks 1 to 4 in the intervention compared with the control group (estimate [CI80%] = −0.8 [-∞, −0.5], d = 0.77), but no difference in PEG scale total score or interference scores. Pairwise contrasts showed that, compared with the control, the intervention group had lower PEG scale total scores at week 4 (estimate [CI80%] = −0.5 [-∞, −0.009], d = 0.32); lower pain intensity scores at week 1 (estimate [CI80%] = −0.8 [-∞, −0.3], d = 0.60), week 3 (estimate [CI80%] = −0.8 [-∞, −0.3], d = 0.54), and week 4 (estimate [CI80%] = −0.9 [-∞, −0.4], d = 0.65); and lower affective interference scores at week 3 (estimate [CI80%] = −0.8 [-∞, −0.08], d = 0.35) and week 4 (estimate [CI80%] = −1.0 [-∞, −0.2], d = 0.45, **Fig. 3**, **Table 4**).

3.3.3. Anxiety and depression

Anxiety and depression scores decreased over time in both the intervention and control groups (see Supplementary Materials for linear models, http://links.lww.com/PR9/A215). However, the main effect test showed that anxiety scores were higher in the intervention group than the control group overall across

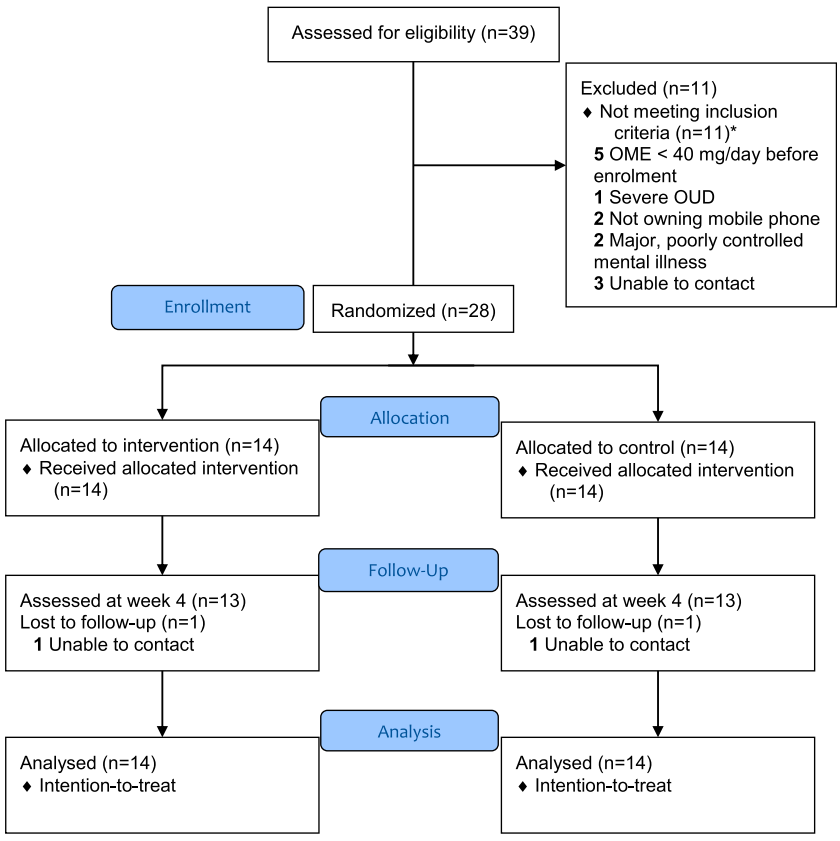

Figure 1. Study flow diagram. *Some applicants met multiple exclusion criteria. OME, oral morphine equivalent; OUD, opioid use disorder.

Table 2

Comparison of baseline and demographic characteristics between the 2 groups.

	Control n = 14	Intervention n = 14	*P*
Age, y	49.5 ± 13.8	50.5 ± 10.3	0.830*
Female	10 (71.4)	9 (64.2)	>0.999†
Education§			0.212‡
High school	4 (30.7)	3 (21.4)	
Vocational	7 (53.8)	5 (35.7)	
University	2 (15.3)	6 (42.8)	
Employed§	6 (42.8)	4 (28.5)	0.694†
Married/domestic partnership§	6 (42.8)	7 (50)	>0.999†
Place of usual residence			>0.999†
Metropolitan	10 (71.4)	9 (64.2)	
Regional	2 (14.2)	3 (21.4)	
Rural	2 (14.2)	2 (14.2)	
Number of other people in the household	1.6 ± 1.2	1.3 ± 1.2	0.539*
Pain conditions			
Neuropathic pain	8 (57.1)	6 (42.8)	0.706†
Arthritis	8 (57.1)	4 (28.5)	0.251†
Back/neck pain	7 (50)	10 (71.4)	0.440†
Other pain conditions	8 (51.7)	10 (71.4)	0.694†
Number of pain conditions	2.5 [1.2, 3.7]	3 [2, 3.7]	0.925‡
Pain duration, y	10 [6, 22]	12.5 [6, 28]	0.942‡
Comorbidities			
Psychiatric/mental health conditions	12 (85.7)	11 (78.5)	>0.999†
Cardiovascular	5 (35.7)	6 (42.8)	>0.999†
Respiratory	3 (21.4)	5 (35.7)	0.677†
Endocrinologic	3 (21.4)	5 (35.7)	0.677†
OME, mg/d	118 [99, 194]	105 [69, 195]	0.593‡
Duration of LTOT, y	6 [2, 10]	6.5 [4.1, 9.9]	0.846‡
Previous tapering attempts	13 (92.8)	10 (71.4)	0.325†

Data are presented as Mean ± SD, Median [IQR 25%, 75%], or Number (%).
* Independent Sample *t* test.
† Fisher exact test (Freeman–Halton extension was used for 2 × 3 contingency tables).
‡ Mann–Whitney *U* Test.
§ Missing data for some participants.
IQR, interquartile range; LTOT, long-term opioid therapy; OME, oral morphine equivalents.

weeks 1 to 4 (estimate [CI80%] = 0.7 [0.4, ∞], d = 0.64, **Fig. 4A**). In addition, pairwise contrasts showed that, compared with the control group, the intervention group had higher anxiety scores at week 2 (estimate [CI80%] = 0.5 [0.2, ∞], d = 0.56) and higher depression scores at week 2 (estimate [CI80%] = 0.7 [0.2, ∞], d = 0.50) and week 3 (estimate [CI80%] = 0.6 [0.004, ∞], d = 0.32).

Table 3

Acceptability outcomes.*

	Median [IQR]	n (%) above neutral†
Useful	2.5 [0.75, 3]	9 (64.2)
Helpful	2 [0.75, 3]	9 (64.2)
Easy to understand	3 [3, 3]	11 (78.5)
Supportive	3 [1.75, 3]	10 (71.4)
Bothersome	1 [-2.25, 3]	5 (35.7)
Encouraging	3 [2, 3]	12 (85.7)
Would recommend	3 [1.75, 3]	11 (78.5)

* Assessed using 7-point Liker scale with responses ranging from −3 to 3, with 0 was anchored as neutral.
† Twelve participants completed the survey; intention-to-treat analysis was performed. IQR 25th and 75th percentiles.
IQR, interquartile range.

3.3.4. Other outcomes

Pain self-efficacy scores at week 4 were higher in the intervention group than the control group (estimate [CI80%] = 3.6 [0.7, ∞], d = 0.41, **Table 4**). At week 4 of the study and compared with baseline, 42.8% (12/28) of the participants had reduced their opioid dose, whereas 14.2% (4/28) had increased and 42.8% (12/28) had no change based on self-reported medications. Opioid dose reduction from baseline to week 4 was not different between the 2 groups (P = 0.892, **Table 5**). There was no difference between the control and intervention groups in the cumulative number of weeks in which they experienced withdrawal symptoms (median [interquartile range [IQR]] = 2 [1, 3] vs 3 [1.5, 3.5], P = 0.530). Satisfaction with care was also not different between the 2 groups at week 4 (median [IQR] = 6 [4, 7] vs 6 [6, 7] P = 0.878).

3.4. Open-text feedback

3.4.1. Preferred frequency, timing, and duration of the text messages

Eleven (out of 14, 78.5%) participants reported preferring 1 to 2 text messages per day (eg, "one massage is plenty" and "2 was perfect"), but others preferred fewer ("2 or 3 per week"). Nine participants (64.2%) found the timing of the messages

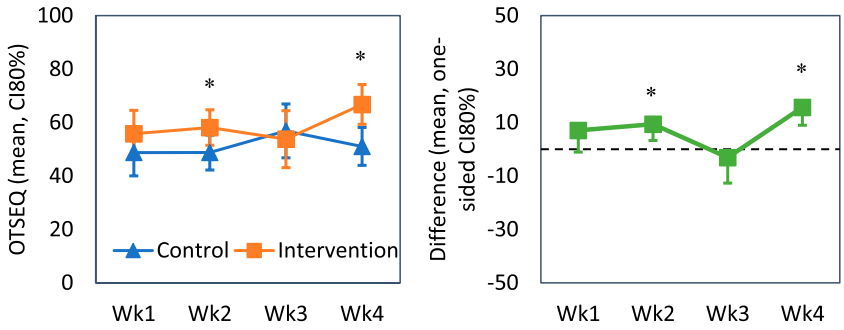

Figure 2. Opioid tapering self-efficacy (OTSEQ) scores over the study period and the difference between the 2 groups. *A significant difference based on one-sided CI 80%.

(mid-morning and mid-afternoon) suitable or had no preference (eg, "time did not bother me"). In addition, 9 (64.2%) participants reported that it would be helpful to continue receiving text messages for as long as they were tapering their opioid doses (eg, "another couple of months if you are on it").

3.4.2. Perceived impact on pain management and feelings about opioid tapering

The text messages helped to reinforce and remind them of pain education concepts and pain self-management strategies ("it reminded me that pain is temporary or the feelings are temporary, to exercise, to meditate"). Participants also reported that the messages were validating and normalising ("it was brilliant to help me understand what was happening, or what had been happening, to me") and informative and educational ("informative ones were interesting, particularly if it contained information you did not actually know"). Messages were also found to be supportive and reassuring ("at times tapering opioids I would feel it is just me, and [that] I was not alone was a helpful message"). Several participants reported the messages helped to keep them motivated ("it made me feel like I could actually succeed, and failure was not an option") and provided encouragement ("it gave me a sense of achievement").

3.4.3. Barriers to engagement

Many participants said there were no barriers to engagement with the intervention ("nothing got in the way of engaging with them at all. I always made time, I read the message"). Others said their attitude toward pain management and opioid tapering was not always positive, which made it difficult to engage with the text messages at times ("I was not in the right head space to make this change happen…, but I do believe if I was in the right head space I would have benefited greatly from the messages"). One participant mentioned that the text messages sometimes had the effect of reminding them of the unpleasant aspects of tapering when they had found distraction was more effective. One participant felt the automated nature of the messages was impersonal. However, for another participant, the automated messages felt like genuine social support ("it is helpful to know that someone has taken the time to send the messages. I thought you were thinking of me").

4. Discussion

This pilot RCT evaluated the acceptability and potential efficacy of a codesigned mHealth intervention to support people living with chronic pain during opioid tapering. The intervention, which included a psychoeducational video and twice daily SMS text messages, was found to be feasible, acceptable, and potentially efficacious: Preliminary data suggest that 4 weeks of text message support had a positive impact on opioid tapering self-efficacy, pain intensity, affective interference, and pain self-efficacy but not on activity interference and pain catastrophising.

Table 4

Comparison of primary and secondary outcomes between the 2 groups.

	Control n = 14		Intervention n = 14	
	Baseline	Week 4	Baseline	Week 4
OTSEQ	62.1 ± 9.7	51.0 ± 5.4	57.1 ± 8.6	66.7 ± 5.7*
PEG total score	7.1 ± 0.3	6.6 ± 0.4	7.1 ± 0.5	6.1 ± 0.4*
Pain intensity	6.4 ± 0.3	6.8 ± 0.3	6.9 ± 0.4	5.9 ± 0.3*
Pain interference with enjoyment of life	7.7 ± 0.3	7.0 ± 0.5	7.2 ± 0.6	6.0 ± 0.6*
Pain interference with general activity	7.2 ± 0.4	6.2 ± 0.4	7.2 ± 0.6	6.3 ± 0.5
GAD-2	2.7 ± 0.4	2.2 ± 0.5	2.9 ± 0.5	2.3 ± 0.5
PHQ-2	2.9 ± 0.4	2.4 ± 0.4	2.8 ± 0.5	2.5 ± 0.4
PSEQ	29.2 ± 3.3	25.9 ± 2.2	23.2 ± 4.2	29.6 ± 2.4*
CAP-6	11.9 ± 1.1	10.1 ± 1.5	12.6 ± 1.8	9.2 ± 1.6

Data are presented as mean ± standard error. Data of week 4 are estimates from the mixed-effect model output, adjusted for baseline values. All data are presented as mean ± standard error.

* Significant difference vs control group at week 4 based on the 80% CI method.

CAP-6, concerns about pain 6-item; GAD, generalized anxiety disorder 2-item; OTSEQ, opioid tapering self-efficacy questionnaire; PHQ-2, patient health questionnaire-2; PSEQ, pain self-efficacy questionnaire.

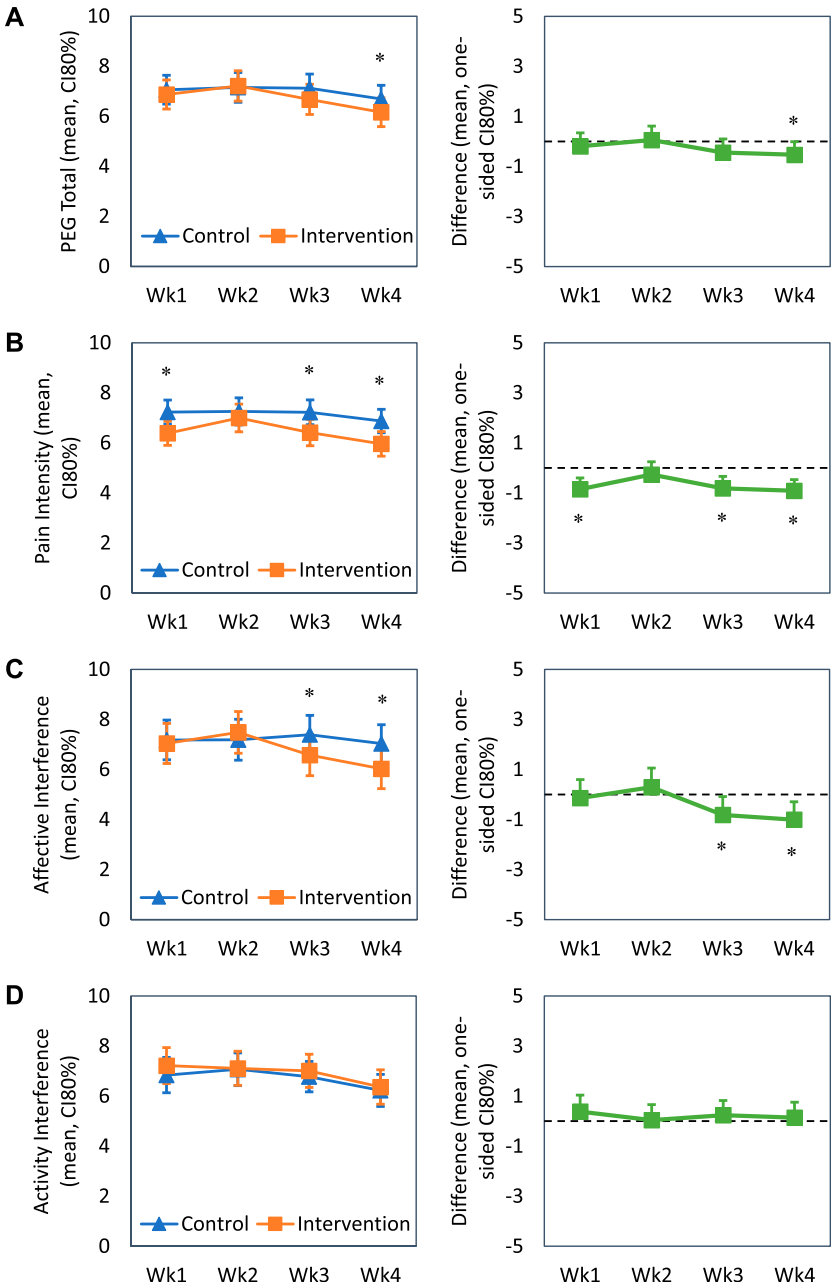

Figure 3. PEG scale total scores (A) and subscales (B-D) over the study period and the difference between the 2 groups. *A significant difference based on one-sided CI80%. PEG, pain, enjoyment of life, and general activity scale.

4.1. Key considerations

4.1.1. Intervention duration

Notably, effect sizes and estimates of differences became larger over the 4-week measurement period. This trend suggests that a longer intervention period might be associated with larger and more clinically meaningful effects. The period of observation was limited to 4 weeks for the purpose of pilot testing the acceptability and feasibility of the intervention. It is possible that a longer intervention period would show larger effects on opioid tapering self-efficacy, pain, and pain interference. A longer observation period would also allow time for changes in participants' opioid dose (many participants are advised by their doctor to remain on the same dose for 4 weeks when being tapered slowly).[44] It is possible that with longer exposure to the intervention, increasing opioid tapering self-efficacy may facilitate opioid dose reductions.[44]

4.1.2. Intervention acceptability

Overall, approximately 78% of the participants would recommend the intervention to others, which is a positive indicator of acceptability.[56] However, some participants reported that the intervention was bothersome to some extent, and some others suggested that they would prefer more personalised support. On closer analysis, participants who reported less positive experiences with the intervention also reported a lack of readiness to taper. Hence, it is possible that engagement with and attitudes toward the intervention depend on patients' attitudes toward opioid tapering.

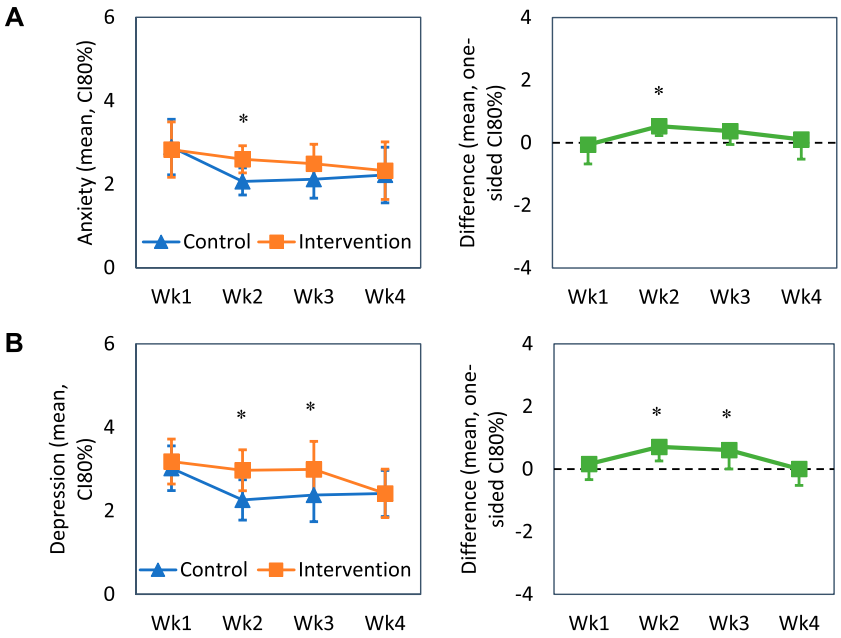

Figure 4. Anxiety (GAD-2 scale, A) and depression (PHQ-2 scale, B) scores over the study period and the difference between the 2 groups. *A significant difference based on one-sided CI80%. GAD-2, generalized anxiety disorder 2-item; PHQ-2, patient health questionnaire-2.

4.1.3. Potential unwanted effects

Participants' anxiety and depression symptom severity reduced over the study period in both study groups, and there was no difference between the anxiety and depression scores of the intervention and control groups at the end of the 4-week intervention. However, the intervention group did report anxiety and depression scores that were higher than the control group during weeks 2 and 3 of the study. Intervention feedback provided by participants suggested that most found the text messages to be helpful for managing their pain and providing motivation and support for tapering. At the same time, there was clear variation among participants in the preferred frequency and timing of the messages. It is possible that people have varying tolerance for receiving text messages and that those who received more messages than they would have preferred experienced a degree of message fatigue. Indeed, previous research has identified message fatigue as a potential negative effect of text messaging interventions.[49,55]

4.2. Strengths and limitations

This study contributes to growing evidence for the acceptability and efficacy of mHealth support for pain and introduces new evidence related to opioid tapering. Recent systematic reviews have found beneficial effects of pain self-management mobile apps[45] and text messages (when provided in addition to multidisciplinary care) on quality of life in patients with chronic pain.[24] Moreover, psychoeducational interventions delivered through mobile text messaging have been found to reduce postoperative opioid use.[3,52] To the best of our knowledge, however, this study is the first RCT to explore the efficacy of an mHealth intervention specifically designed to support patients with chronic pain to reduce their opioid dose.

The results of this study should be interpreted with caution. First, owing to delays in ethics approval processes and smaller than expected numbers of eligible patients, recruitment was significantly delayed, and the planned sample size was not reached. As a result, the sample size was small, which reduced our statistical power and the reliability of results. Moreover, since we did not aim to formally undertake hypothesis testing procedures to prove the efficacy of the intervention in this pilot study, no correction was done for multiple comparisons (eg, Bonferroni test).[11] However, this approach increases the risk of type I error (false-positive). Second, many participants in the intervention group did not confirm that they watched the psychoeducational video, bringing into question the fidelity of this component of the intervention. Consequently, it is possible that the results of this study reflect the impact of text messages alone (with no psychoeducational video). Because all participants were recruited from multidisciplinary pain management programs which provided psychoeducation to participants, it is certainly possible that the video component of this intervention was not needed. However, we expect that failing to watch the psychoeducational video component of the intervention would reduce the effectiveness of the intervention in a community sample who may be naïve to pain self-management strategies. Third, intervention efficacy was evaluated using a single-item measure of opioid tapering self-efficacy (OTSEQ), which was developed together with patients for the purpose of this study. Previous research has found that very brief measures of opioid tapering self-efficacy

Table 5

Opioid dose changes from baseline to week 4 between the study groups.

	Control n = 14	Intervention n = 14	P
Opioid dose changes			>0.999*
Reduced	6 (42.8)	6 (42.8)	
Increased	2 (14.2)	2 (14.2)	
No change	6 (42.8)	6 (42.8)	
Opioid dose change, OME mg/d	0 [0, 12.3%]	0 [0, 10.2%]	0.458†

Data are presented as number (%) or median [IQR 25%, 75%].
* Fisher exact test with Freeman–Halton extension for 2 × 3 contingency table.
† Mann–Whitney U test.
IQR, interquartile range; OME, oral morphine equivalent.

are associated with intentions to taper.[19] However, it is not known whether tapering self-efficacy is associated with tapering behaviour. Furthermore, although there are distinct benefits to developing a scale in collaboration with patients to ensure that measures are understood and acceptable,[46] the psychometric characteristics of this scale are unknown, and a multi-item scale may have greater sensitivity.

4.3. Implications and future research directions

Future research is needed to investigate whether there are short-term negative effects associated with receiving SMS text message interventions. Recent systematic reviews of text message–based interventions for pain do not report evidence of adverse events.[10,24] However, lack of reported adverse events may be underestimated due to lack of monitoring,[24,27] which is a common limitation of studies on psychological treatments for chronic pain.[16] Accordingly, in subsequent trials,[27] we will use the Negative Effects Questionnaire[53] and interview participants to investigate the incidence of a wide range of unwanted events and whether they are attributed to the intervention received. Negative Effects Questionnaire is a self-report measure of common unwanted effects associated with psychological treatments[53] which has previously been used in clinical trials of digital health interventions[18,32,33] including an ongoing study on chronic pain management.[7]

Our preliminary findings indicate that the burden or negative effects associated with receiving text message support for opioid tapering may be associated with readiness to taper. Darnall and colleagues similarly found that readiness to taper was a key predictor of engagement in opioid tapering.[42] There are likely to be a variety of individual differences which influence the acceptability of mHealth support for opioid tapering. Future research should seek to identify "what works for whom" to minimize the risk of negative or adverse effects of digital interventions and to optimise responsiveness to treatment. The current intervention could also be tailored to suit individual preferences by varying the frequency of messages and the content of messages. These adaptations may also help to prevent message fatigue, which is a potential negative effect of text messaging interventions.[55]

5. Conclusion

This pilot study shows that patients with CNCP who are attending a multidisciplinary pain clinic and tapering their opioid dose voluntarily may find it acceptable and beneficial to be provided with adjunctive support in the form of a codesigned mobile health intervention which includes a brief psycho-educational video and daily SMS text messaging. Further research is being conducted to investigate whether patients in primary care can benefit from this intervention, to understand individual differences in the acceptability and efficacy of the intervention (and negative effects), and whether the intervention delivers greater benefits when provided over a longer period (12 weeks).

Disclosures

Dr. Darnall is Chief Science Advisor at AppliedVR, and her consulting role with this company (personal fees) is unrelated to the current research. Dr. Darnall receives royalties for 4 pain treatment books she has authored or coauthored. She is the current principal investigator for 2 pain research awards from the Patient-Centered Research Outcomes Research Institute and 2 NIH pain research grants. She serves on the Board of Directors for the American Academy of Pain Medicine, the Board of Directors for the Institute for Brain Potential, and the Medical Advisory Board for the Facial Pain Association. Dr. Darnall is a scientific member of the NIH Interagency Pain Research Coordinating Committee, a former scientific member of the Centers for Disease Control and Prevention Opioid Workgroup (2020–2021), and a current member of the Pain Advisory Group of the American Psychological Association. Other Authors have no conflict of interest.

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Author contributions: P.G. and C.E.A.J. conceptualized the interventions and acquired funding and should be considered joint senior authors. A.G., M.R.M., A.G.M., L.D., A.S., M.F., B.D.D., P.G., and C.E.A.J. contributed to the design of the study protocol. M.R.M. coordinated the recruitment and intervention delivery. C.E.A.J., P.G., T.B., A.A., M.C., and I.H. supervised the recruitment at the study sites. A.G., M.R.M., and A.G.M. collected the data. A.G. performed the statistical analysis and drafted the manuscript. All authors contributed to the interpretation of the results, critically reviewed and edited the manuscript, and approved the final submitted version.

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