Living well with chronic pain: a 12-month randomized controlled trial revealing impact from the digital pain self-management program EPIO

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Abstract

Introduction: Chronic pain affects a wide range of physical and psychological aspects of life for those impacted. Psychosocial treatment approaches may be of support, but outreach is still limited.

Objectives: To evaluate the efficacy of EPIO, an evidence-informed, user-centered digital self-management intervention for people with chronic pain, in a 12-month randomized controlled trial.

Methods: People living with chronic pain (N = 266) were randomized to the EPIO intervention (n = 132) or a usual-care control group (n = 134). The intervention was delivered in a simple blended care model, and outcome measures collected at baseline, 6 months, and 12 months. Generalized linear models for repeated measures were fitted to compare groups over time.

Results: Participants were primarily female (81%), median age 49 years (range 22–78), with heterogeneous pain conditions, and had lived with pain >5 years (77.6%). A mixed linear model with all timepoints included revealed no statistically significant group differences for the primary outcome of pain interference. Significant psychological benefits in favor of the intervention group were however detected for depression ($P = 0.022$), self-regulatory fatigue ($P = 0.024$), vitality ($P = 0.016$), and mental health ($P = 0.047$). Baseline to 12-month changes showed additional favorable effects for anxiety (between-group mean differences [MDs] = 0.79, $P = 0.047$), depression (MD = 1.08, $P = 0.004$), self-regulatory fatigue (MD = 2.42, $P = 0.021$), pain catastrophizing (MD = 2.62, $P = 0.009$), and health-related quality of life.

Conclusions: The EPIO program aims to improve outreach of evidence-based pain self-management interventions. Findings demonstrate how using EPIO can lead to sustainable psychological change, enhancing mental health and health-related quality of life for people suffering from pain, providing a chance to live well *with* the pain.

Keywords: Chronic pain, eHealth, Digital pain self-management, Psychosocial self-management, Pain interference, Cognitive behavioral therapy, Acceptance and commitment therapy, Self-regulatory fatigue, Anxiety, Depression

1. Introduction

Chronic pain continues to be a serious personal and public health concern, impacting physical and psychological well-being, sleep, physical and social activities, private and professional roles, and relationships.[44,52] Living with chronic pain naturally also impacts quality of life and ultimately ability to cope.[30,31,74] The multitude of

challenges presented by living with chronic pain may also impact ability to regulate thoughts, feelings, and behavior (ie, self-regulation).[46–48,58]

The significant impact and interference of chronic pain is accompanied by a recognition of chronic pain as a condition with contributing biological, psychological and social factors.[15] Evidence-based biopsychosocial treatment methods have therefore been recommended, including psychosocial self-management approaches such as cognitive behavioral therapy (CBT)[6,25,72] and more recently also acceptance and commitment therapy (ACT).[20,25,27,32] Despite the established, growing evidence of such approaches, outreach remains limited, indicating the need for innovative delivery methods.[20]

Digital solutions in the form of applications (apps) may have the potential to expand outreach of pain self-management approaches, and research has shown how digital interventions may reduce pain intensity and improve physical and psychosocial functioning.[45] Challenges with existing digital pain management interventions nevertheless include limited or lack of theoretical basis[19,75]; limited or lack of user (ie, people with chronic pain and health care providers) involvement during the design and development processes[60]; challenges with program attrition/adherence[2,41]; limited efficacy testing/evidence of effect,[38,61] particularly from trials longer than 3 months[45]; and also limited planning for, or evidence of, implementation poststudy.[67]

Aiming to improve outreach of pain self-management interventions, considering current issues with digital interventions, this research team developed EPIO (ie, inspired by the Greek goddess for the soothing of pain; Epione), a digital psychosocial pain self-management program.[10,11,36,37,66] EPIO was designed and developed using evidence-based, user-centered processes, with iterative user testing and evidence-informed content,[36,37,66] aiming to be of support to anyone living with chronic pain (ie, not sex, age, or pain type/diagnosis-specific). In accordance with the Medical Research Council framework for complex intervention evaluation,[16,57] the EPIO program was tested in a feasibility pilot study, with participants living with chronic pain rating the program as useful, with excellent system usability.[10] Participants also described EPIO as facilitating motivation to learn, aiding in making peace with the presence of pain, and experienced EPIO as a friend, promoting communication and support.[11]

This study explored findings from a 12-month (ie, primary end point) randomized controlled trial (RCT) testing the use of EPIO in people living with chronic pain (ie, noncancer, nonmigraine pain lasting ≥3 months). Participants in the EPIO intervention group, compared with participants in a usual-care control group, were hypothesized to report significant improvements in pain interference (ie, primary outcome) and anxiety, depression, self-regulatory fatigue, health-related quality of life (HRQoL), pain catastrophizing, and pain acceptance (ie, all secondary outcomes). Short-term (ie, 3-month) explorations, published after 12-month RCT completion, showed decreased symptoms of depression and self-regulatory fatigue for participants having access to EPIO, with EPIO described as useful and easy to use.[9]

2. Methods

2.1. Study design

A 2-armed 12-month RCT with participants with chronic pain randomly assigned to (1) the digital pain self-management intervention program EPIO or (2) a usual-care control group.

2.2. Participants and recruitment

People living with chronic pain were recruited through a major medical institution, collaborating health care practices, social media, or patient organizations' web pages. Eligibility criteria (ie, self-reported) were as follows: (1) living with chronic pain (ie, not pain condition/diagnosis-specific), (2) having lived with pain ≥3 months, (3) being 18 years and older, (4) having access to a smartphone/tablet, (5) understanding oral/written Norwegian, and (6) being able to attend an introduction session either at a health care facility or through a secure video link. Exclusion criteria included self-reported cancer-related pain, migraine, or severe untreated psychological illness.

2.3. The EPIO intervention program

The EPIO program content is primarily CBT-based, with value aspects of ACT, and centers around well-known components for pain self-management,[36] with 9 modules containing a combination of psychoeducational information (eg, about pain, importance of activity pacing, and use of coping strategies) and exercises (eg, thought challenges and diaphragmatic breathing).[36] See **Figure 1** for program content overview. The EPIO program can be individualized through options for reading and/or listening, choice of favorites, and graphs related to sleep, rest, activity, and mood.[36] See **Figure 2** for example screenshots.

2.4. Study procedure

Study methods and results are reported following the CONSORT 2010 checklist for parallel group randomized trials,[53] and the intervention described in accordance with the TIDieR checklist.[28] The Regional Committee for Medical and Health Research Ethics (REK 2018/8911) and the Hospital Privacy Protection Committee (PVO 2017/6697) provided study approvals. The study was ClinicalTrials.gov (NCT 03705104) registered before enrollment, and all participants signed informed consent prior to preparticipation.

Study information was provided through a study website, related social media, or verbally/through flyers by collaborating health care practices. Interested participants could submit a contact form or call the study phone, receiving additional study information from a project team member.

Enrolled participants completed baseline outcome measures before computerized randomization (ie, using R-tool, a local software program), stratified by sex, to either the intervention or control group (ie, study arms 1:1, block size 20). Because patients were assigned to the EPIO intervention or not, true blinding was not possible. Outcome measures and system use data were collected electronically through a secure server (ie, Services for Sensitive Data, University of Oslo) using encrypted connections.

2.4.1. Intervention group

Participants randomized to the intervention group received (1) a face-to-face (ie, either in-person or by video during COVID-19) introduction session with study personnel, (2) access to the app-based EPIO program for 12 months, and (3) two brief follow-up phone calls at approximately 3 and 7 weeks to ask how participants were doing with the program and whether they had any program-related questions. The introduction session was conducted by 1 to 2 members of the project team using a structured manual, describing rationale for the EPIO program (ie, pain self-management), program downloading,

EPIO PROGRAM CONTENT

Module

1 About pain
Program introduction and rationale. Educational information about pain and pain self-management. Information about coping strategies, stress management, and the fight-or-flight response. Introduction to breathing and breathing exercises; rationale, techniques, and relaxation.

2 Balance
Importance of activity pacing and planning. Using EPIO as a toolbox. Introduction to mindfulness. Engaging in self-care and pleasant activities. Introduction to progressive muscle relaxation and exercises.

3 Thoughts and feelings
More about pain. The relationship between thoughts and feelings. How to recognize and challenge negative thoughts/cognitive distortions. Role and importance of gratitude and positive thinking. Exercises addressing thought challenging, mindfulness, and autogenic muscle relaxation.

4 Stress and coping
Introduction to and information about stress and coping. Rationale for stress-management and related relaxation strategies. Introduction to acceptance, role, knowledge, and use of active and passive coping strategies. Use of visualization exercises.

5 What is important to me?
Introduction to individual values and goals, how to identify and make use of role models, and the role of self-image. How to recognize and deal with intruding thoughts. Use of planning and goal setting. Introduction to meditation and meditation exercises.

6 Health behaviors and lifestyle
Introduction to health behaviors and ways to health behavior change. Importance and awareness of health behaviors, such as physical activity, sleep and nutrition, as well as substance use and abuse. Introduction to stretch-based relaxation and exercises.

7 Communication, relations, and social support
The role and importance of good communication, ways of being assertive, and the importance of social support and networks. Introduction to, and exercises related to, awareness about and ways to strengthen social support. Progressive muscle relaxation exercises.

8 Coping during difficult times
Use of coping strategies in daily life. How to recognize and strengthen aspects related to self-regulation. Issues related to pain, frustration, and anger, including anger management. Rationale and use of distraction strategies. Visualization and stretch-based relaxation exercises.

9 Summary and the road ahead
Review of program content, questions, and suggestions on what to do next, caution, advice, and suggestions for the road ahead.
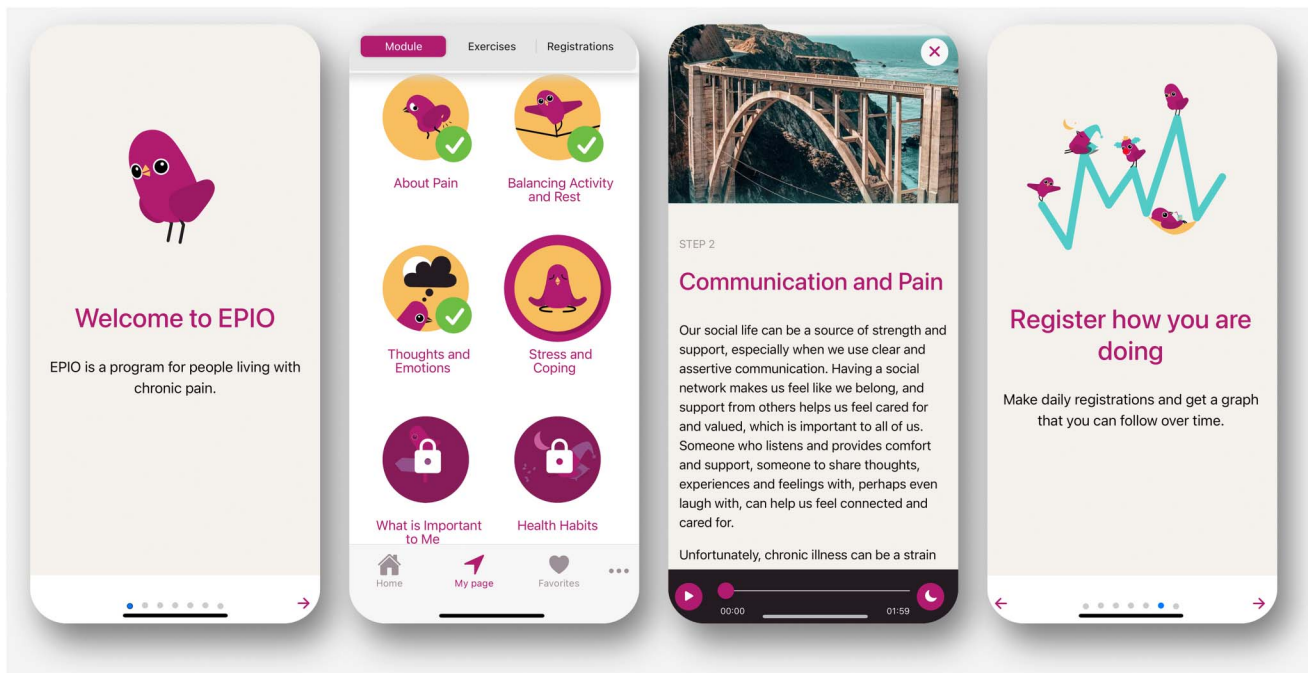
Figure 1. EPIO program content.

Figure 2. EPIO program screenshots.

and introducing content examples. Study personnel conducting the introduction sessions and follow-up phone calls were public health scientists or registered nurses, trained and supervised by the Principal Investigator; a licensed clinical health psychologist. Participants could contact the project team through a study phone during regular working hours for study-related assistance.

2.4.2. Usual-care control group

The control group received no follow-up apart from reminders to complete outcome measures but could call the project study phone in case of questions. No information was obtained to control for engagement in other types of self-management interventions during the study period.

2.5. Data collection and outcome measures

Outcome measures were collected at baseline (ie, including a study-specific sociodemographic/disease-specific measure), 3,[9] 6, and 12 months. Notes from follow-up phone calls were written down immediately after phone calls.

2.5.1. Psychosocial outcome measures

2.5.1.1. Pain interference

Pain interference (ie, primary outcome) and *pain severity* were measured with the short version of the Brief Pain Inventory.[34] Brief Pain Inventory pain interference consists of 7 items measuring impact of pain on daily function, including activity/affective aspects of interference,[3] and 4 items measuring pain severity. The Brief Pain Inventory has been validated in a Norwegian cancer pain population[35] and has shown acceptable internal consistency and reliability in patients with noncancer pain.[34] Score range is 0 to 10, with higher scores indicating higher interference/severity.

2.5.1.2. Symptoms of anxiety and depression

Symptoms of anxiety and depression were measured with the Hospital Anxiety and Depression Scale,[76] a 14-item scale with 7 items gauging symptoms of anxiety and depression, respectively. Score range is 0 to 21 for each subscale, and higher scores indicate higher symptom presence. The Hospital Anxiety and Depression Scale has acceptable internal consistency and reliability and has been validated in a Norwegian sample.[39]

2.5.1.3. Self-regulatory fatigue

Self-regulatory fatigue was measured with the Self-Regulatory Fatigue scale,[47] with 18 items gauging cognitive, emotional, and behavioral components of capacity to self-regulate. The Self-Regulatory Fatigue-18 has been validated in Norwegian cancer populations[7,8] and has acceptable internal consistency and reliability.[47] Score range is 18 to 90, with higher scores indicating higher self-regulatory fatigue.

2.5.1.4. Health-related quality of life

Health-related quality of life was measured using the noncommercial SF-36 Short Form Health Survey, RAND-36,[70] with 36 items measuring physical, role, emotional, cognitive, and social function, as well as physical, general, and global health. The RAND-36 has acceptable internal consistency and reliability and has been validated in a Norwegian chronic pain sample.[40] Score range is 0 to 100, with higher scores indicating higher HRQoL.

2.5.1.5. Pain catastrophizing

Pain catastrophizing was measured with the Pain Catastrophizing Scale,[59] a 13-item scale measuring catastrophic thinking and maladaptive responses to pain, including subscales measuring helplessness, magnification, and rumination. The Pain
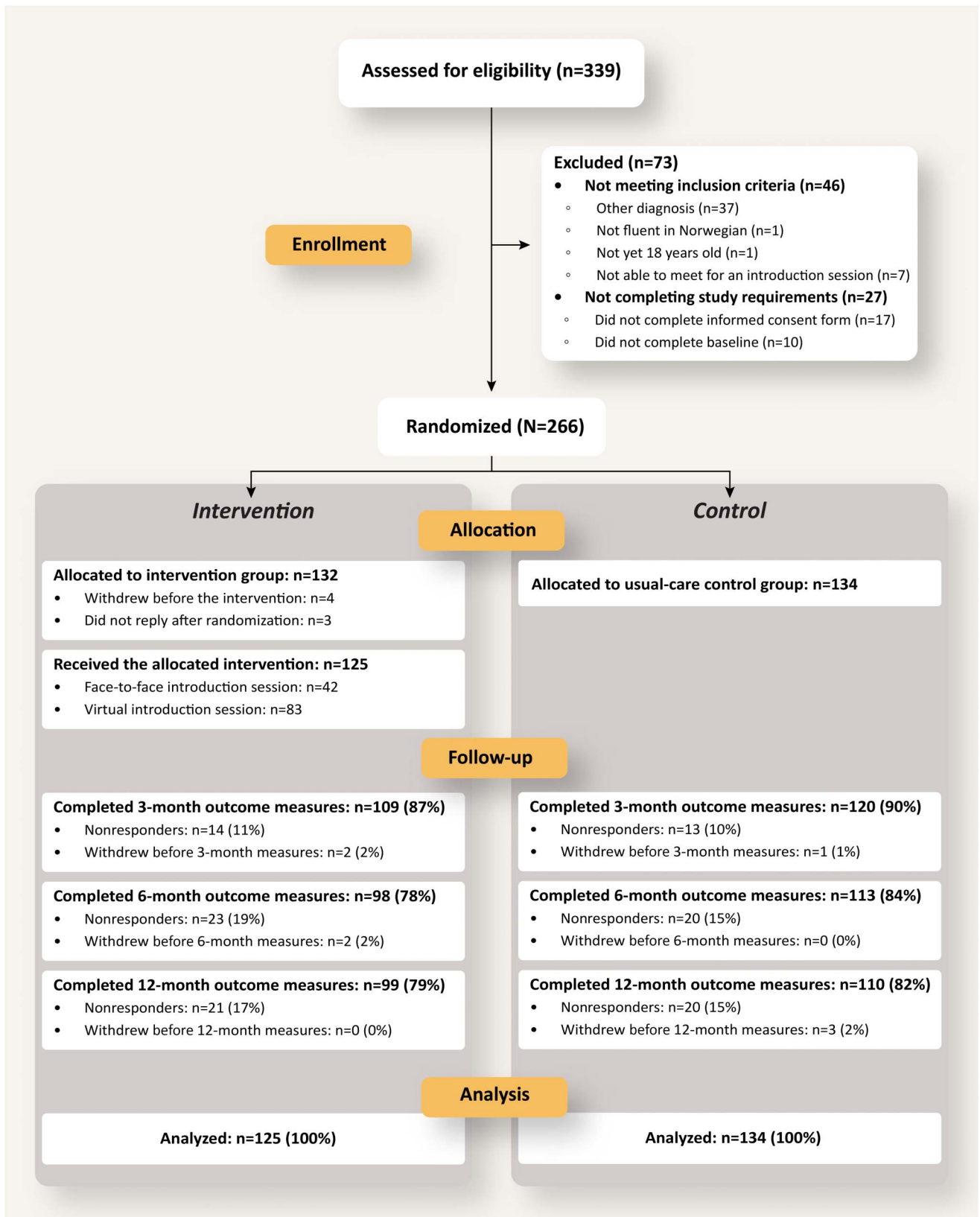
Figure 3. CONSORT flow diagram describing enrollment, allocation, follow-up for the 12-month EPIO study. Participants not completing outcome measures are referred to as "Nonresponders."

Catastrophizing Scale has acceptable internal consistency and reliability and has been validated in a Norwegian chronic pain sample.[26] Score range is 0 to 52, with higher scores referencing higher level of catastrophic thoughts/feelings about pain.

2.5.1.6. Pain acceptance

Pain acceptance was measured through the Chronic Pain Acceptance Questionnaire short form,[42] an 8-item pain acceptance measure gauging pain willingness and activity engagement (4 items each). The Chronic Pain Acceptance Questionnaire has acceptable internal consistency and reliability and has been validated in a Norwegian chronic pain sample.[23] Score range is 0 to 24, with higher scores indicating higher pain acceptance.

2.5.2. Program use

Data related to program use and progress were collected automatically through a secure research server. Program completers were defined as participants completing at least 6 of the 9 EPIO modules (67%) during the study period.[8–10,71]

2.6. Power analysis and sample estimates

Previous studies with digital health interventions have reported Cohen d effect sizes of 0.30 to 0.40 on pain interference (ie, primary outcome here) for comparable samples.[13,62] To allow a detection of d = 0.4 for the primary outcome, with an alpha of 0.05% and 80% power (based on a 2-sided t test), a sample size of 200 participants was required. Considering probable attrition, and adequate power in potential secondary analyses, total study sample included 266 participants.

2.7. Statistical and thematic analyses

Baseline characteristics and user patterns were summarized with mean and SD for normally distributed variables, and median and ranges for variables with skewed distributions. Categorical data were presented as counts and percentages. For the analysis of between-group differences in outcome measurements, generalized linear models (GLMs) for repeated measures were fitted. To account for statistical dependencies as each individual was measured several times and time spans between completed measurements varied, an unstructured covariance matrix was used to model covariances. Models for each outcome consisted of 3 covariates: measurement (time), group, and interaction term (ie, time and group). All measured timepoints (ie, for outcome variables) were considered, and all overall between-group differences were, therefore, adjusted for baseline differences.

Because statistically significant differences were observed between the intervention and the usual-care control group for age, disability benefits at baseline, and years living with pain, these variables were included in the analysis as possible confounders. All analyses were conducted according to intention-to-treat principles, including all participants in each group independently of how much the intervention group used the intervention. Between-group differences are reported as the intervention group change from the baseline to 6 and 12 months, minus the usual-care control group change from baseline. Exploratory subgroup analyses for the intervention group only, using GLMs, were performed to detect potential differences in outcomes between intervention completers and noncompleters of the EPIO program. In addition, the effect of years living with pain (3 categories; <5, 5–10, >10 years), level of education (3 categories; Elementary/high school, University/college ≤4 years, University/college >4 years), and diagnosis group (4 International Classification of Diseases version 11 (ICD-11) categories; primary pain, nociceptive pain/secondary musculoskeletal pain, neuropathic pain, posttraumatic/postoperative) were explored. The effect of these variables on the outcome was assessed using a GLM model with an interaction term (the assessed variable × group) to explore whether such a variable might affect the groups differently (ie, intervention vs controls). P-values < 0.05 were considered statistically significant. The results are presented as marginal means evaluated at mean age and given timepoint, estimated mean differences (MDs) between groups, with 95% confidence intervals and effect sizes (ie, Standardized Coefficients β).[54] Effect sizes were interpreted as small (0.10–0.29), medium (0.30–0.49), and large (≥0.50).[50] Statistical analyses were performed using the Statistical Package for the Social Sciences (release 28; SPSS, Inc, Chicago, IL) and Stata (version 17).

Qualitative data (ie, derived from 267 follow-up phone call notes, equaling approximately 55 single-line pages) were uploaded by coauthor K.B. to the software program NVivo version 12 (QSR International, Victoria, Australia) and analyzed using a thematic analysis process (ie, coding reliability).[12,14] Authors L.S.N., E.B., and E.B.S. then further analyzed findings and discussed until consensus was achieved.

3. Results

3.1. Enrollment and sample description

From November 2019 to February 2021, 339 adults living with chronic pain were screened and 266 enrolled. Of these, 7 participants randomized to the intervention group were excluded or withdrew from the study, resulting in a total study sample of 259 participants, allocated to the intervention (n = 125) or control (n = 134) groups. See **Figure 3** CONSORT flow diagram for an overview of recruitment and retention details.

Two-thirds (66%) of the included participants were primarily recruited through social media, and the remainder (34%) through collaborating health care practices. The final 259 participants were primarily self-identified female (81%) and Anglo-American (97%). At inclusion, participants were median 49 years (range 22–78), most reported being on sick leave or disability benefits (186/259, 72%), suffered from fibromyalgia or unspecific musculoskeletal pain (166/259, 64%), and described having lived with pain ≥10 years (158/259, 61%; **Table 1**). Follow-up phone calls were conducted with n = 184 participants {(ie, at 3 [n = 102] and 7 [n = 82] weeks)}.

Participants in the intervention group were statistically significantly older compared with the control group (median 50 and 48 years, respectively), and more participants in the intervention group reported having lived with pain ≥10 years compared with the control group (87/125, 69.6% vs 71/134, 53%, respectively). In addition, a higher proportion of the intervention group reported being on 100% disability at baseline (24/125, 36.6% vs 33/134, 24.6%). Age, years living with pain, and disability status were therefore included in the linear mixed model analyses as potential confounders. No harm or unintended effects were reported or detected in either group during the study.

3.2. Between-group differences

Including all timepoints in the mixed model, no statistically significant between-group differences were observed over the

Table 1

Sociodemographic-related and disease-related characteristics at baseline (N = 259).

Characteristics	All participants (N = 259)		Intervention (n = 125)		Control (n = 134)		P
Age (y), median (range)	49	22–78	50	26–74	48	22–78	0.020
Gender, n (%)							0.601
Female	210	81	103	82.4	107	79.9	
Male	49	19	22	17.6	27	20.1	
Marital status, n (%)							0.291
Married/cohabitating	172	66.4	79	63.2	93	69.4	
Single/divorced	87	33.6	46	36.8	41	30.6	
Education, n (%)							0.482
Elementary/high school	108	41.7	49	39.2	59	44.0	
University/college ≤4 y	104	40.2	55	44.0	49	36.6	
University/college >4 y	47	18.1	21	16.8	26	19.4	
Employment, n (%)							0.583
Full-time/part-time work	57	22.0	30	24.0	27	20.1	
Sick leave/disability benefits	186	71.8	86	68.8	100	74.6	
Retired/others	16	6.2	9	7.2	7	5.2	
100% disability benefits, n (%)	78	30.1	45	36.6	33	24.6	0.042
Income status, (EUR*), n (%)							0.913
<40.000	54	20.8	28	22.4	26	19.4	
>40.000–60.000	41	15.8	19	15.2	22	16.4	
>60.000–80.000	63	24.3	32	25.6	31	23.1	
>80.000–100.000	55	21.2	24	19.2	31	23.1	
>100.000	56	17.8	22	17.6	24	17.9	
Self-reported pain conditions,† n (%)							
Unspecific musculoskeletal pain‡	59	22.8	27	24.1	32	26.0	0.736
Unspecified disk disorder§	31	12.0	15	13.4	16	13.0	0.931
Osteoarthritis§	48	18.5	22	19.6	26	21.1	0.776
Rheumatoid arthritis§	30	11.6	16	14.3	14	11.5	0.521
Fibromyalgia‡	107	41.3	53	47.3	54	43.9	0.599
Neuropathic pain‖	19	7.3	10	8.9	9	7.3	0.651
Postinjury or postsurgery¶	24	9.3	13	11.6	11	8.9	0.501
Other‡‖#	43	16.6	25	22.5	18	14.6	0.120
Years living with pain, n (%)							0.029
<3 years	34	13.1	12	9.6	22	16.4	0.104
3–5 years	24	9.3	7	5.6	17	12.7	0.049
>5–10 years	43	16.6	19	15.2	24	17.9	0.558
>10 years	158	61.0	87	69.6	71	53.0	0.006

* EUR, 1 EURO is approximately 1.1 USD; approximately 10 Norwegian kroner (fall 2023).
† Participants could report having several types of self-reported conditions.
‡ Categorized for study purposes as *primary pain* (ICD-11).
§ Categorized for study purposes as *nociceptive pain/secondary musculoskeletal pain* (ICD-11).
‖ Categorized for study purposes as *neuropathic pain* (ICD-11).
¶ Categorized for study purposes as *posttraumatic/postoperative pain* (ICD-11).
# Includes categories such as (chronic fatigue syndrome) CFS/ME, Complex Regional Pain Syndrome, and nonspecific "other."

12 months for the primary outcome of pain interference (**Table 2**). There were however statistically significant differences in favor of the EPIO intervention group for the secondary outcomes of depression and self-regulatory fatigue, as well as for the HRQoL subscales vitality and mental health (**Table 2**).

The largest intervention effects in favor of the intervention group were observed at 12 months, and between-group changes from baseline to 12 months were statistically significant in favor of the intervention group for several measures, including symptoms of anxiety (between-group MD = 0.79, P = 0.047), symptoms of depression (MD = 1.08, P = 0.004), self-regulatory fatigue (MD = 2.42, P = 0.021), HRQoL subscales general health (MD = −3.94, P = 0.043), vitality (MD = −4.97, P = 0.021), role-emotional (MD = −14.52, P = 0.029), and mental health (MD = −4.5, P = 0.035), as well as pain catastrophizing rumination (MD = 1.06, P = 0.016), magnification (MD = 0.57, P = 0.035), and total (MD = 2.62, P = 0.009; **Table 2**).

3.3. Program use

Timespan from first to last use varied from 1 to 364 days (medium 182), with use 1 to 315 days (medium 30). Two-thirds (82/125, 66%) of the participants in the intervention group completed ≥6/9 modules within the 12-month study period (ie, completers). Of those, 55% completed all 9 modules. No statistically significant differences in outcome measures were observed between intervention completers and noncompleters.

3.4. Exploratory analyses

There were no statistically significant differences for the separate activity and affective components of pain interference, and no outcome differences in time trajectories between intervention and control groups when stratified by years living with pain, level of education, or diagnosis group.

Table 2

Effects of EPIO at 6 and 12 months.*

	Intervention group n = 125	Control group n = 134	Between-group differences			Time-trend
	M (95% CI)	M (95% CI)	MD (95% CI)	P	Effect size β†	P
Pain interference (BPI)‡						0.795
Baseline	5.1 (4.7–5.5)	5.6 (5.2–6.0)				
6 months	4.6 (4.2–5.1)	5.0 (4.6–5.4)	−0.16 (−0.67 to 0.34)	0.515	−0.04	
12 months	4.6 (4.1–5.1)	5.0 (4.5–5.4)	−0.14 (−0.67 to 0.40)	0.612	−0.03	
Pain severity (BPI)§						0.450
Baseline	5.1 (4.8–5.4)	5.4 (5.1–5.6)				
6 months	4.9 (4.5–5.6)	5.3 (5.0–5.6)	0.16 (−0.18 to −51))	0.354	0.06	
12 months	4.7 (4.3–5.1)	5.2 (4.9–5.6)	0.27 (−0.07 to 0.62)	0.122	0.10	
Anxiety (HADS-A‖)						0.253
Baseline	7.1 (6.2–7.9)	7.7 (6.8–8.5)				
6 months	6.3 (5.4–7.2)	7.2 (6.4–8.0)	0.30 (−0.48 to 1.07)	0.456	0.05	
12 months	6.1 (5.1–7.0)	7.4 (6.6–8.3)	0.79 (0.01 to 1.57)	**0.047**	0.12	
Depression (HADS-D¶)						**0.022**
Baseline	7.0 (6.2–7.7)	7.1 (6.3–7.8)				
6 months	5.8 (5.1–6.6)	6.6 (4.9–7.2)	0.62 (−0.12 to 1.35)	0.100	0.10	
12 months	5.7 (4.8–6.5)	6.8 (6.0–7.6)	1.08 (0.35 to 1.82)	**0.004**	0.18	
Self-regulatory fatigue (SRF-18#)						**0.024**
Baseline	54.8 (52.6–57.0)	55.7 (53.6–57.8)				
6 months	53.3 (51.1–55.6)	55.1 (53.0–57.2)	0.80 (−1.25 to 2.84)	0.446	0.05	
12 months	51.9 (49.5–54.2)	55.1 (52.8–57.3)	2.42 (0.36 to 4.47)	**0.021**	0.14	
HRQoL (RAND-36)**						
Physical functioning						0.309
Baseline	52.7 (48.1–57.2)	49.6 (45.2–53.9)				
6 months	57.1 (52.3–62.0)	55.0 (50.4–59.6)	0.99 (−3.03 to 5.00)	0.630		
12 months	56.1 (51.3–61.0)	55.5 (51.0–60.1)	2.59 (−1.43 to 6.62)	0.207		
Role-physical						0.918
Baseline	16.4 (11.3–21.6)	8.40 (3.5–13.3)				
6 months	22.5 (15.7–29.2)	16.2 (10.0–22.4)	1.33 (−7.55 to 10.22)	0.768	0.02	
12 months	23.1 (16.3–30.0)	16.1 (9.7–22.5)	1.01 (−7.89 to 9.91)	0.824	0.01	
Bodily pain						0.918
Baseline	26.4 (23.4–29.4)	24.9 (22.1–27.8)				
6 months	31.6 (28.8–35.3)	28.6 ([25.2–32.0)	−1.47 (−5.96 to 3.02)	0.521	−0.04	
12 months	33.7 ([29.5–38.1	28.1 (24.1–32.1)	−4.17 (−8.67 to 0.32)	0.069	−0.11	
General health						0.234
Baseline	35.4 (31.5–39.4)	35.6 (31.9–39.3)				
6 months	39.3 (35.0–43.6)	36.9 (32.8–40.9)	−2.41 (−6.22 to 1.39)	0.214	−0.08	
12 months	39.8 (35.4–44.1)	38.8 (31.9–40.1)	−3.94 (−7.76 to −0.12)	**0.043**	−0.13	
Vitality						**0.016**
Baseline	26.0 (22.2–29.7)	24.6 (21.0–28.2)				
6 months	28.8 (24.6–33.0)	27.7 (23.8–31.7)	0.26 (−3.96 to 4.48)	0.905	0.01	
12 months	32.0 (27.7–36.4)	26.0 (21.6–29.8)	−4.97 (−9.20 to −0.74)	**0.021**	−0.14	
Social functioning						0.297
Baseline	45.5 (40.7–50.2)	44.3 (39.8–48.9)				
6 months	55.1 (49.8–60.4)	49.9 (44.9–54.8)	−4.02 (−10.17 to 2.12)	0.200	−0.08	
12 months	54.7 (49.4–59.9)	47.9 (43.0–52.7)	−5.66 (−11.82 to 0.50)	0.072	−0.11	
Role-emotional						0.210
Baseline	45.7 (37.1–54.4)	51.8 (43.5–60.1)				
6 months	50.2 (41.0–59.4)	48.9 (40.4–57.4)	−7.24 (−20.25 to 5.78)	0.276	−0.07	
12 months	59.4 (50.2–68.7)	50.6 (42.0–59.3)	−14.52 (−27.57 to −1.47)	**0.029**	−0.14	
Mental health						**0.047**
Baseline	65.2 (61.5–68.8)	64.7 (61.3–68.1)				
6 months	65.1 (61.0–69.1)	64.4 (60.7–68.2)	−0.05 (−3.81 to 3.71)	0.980	−0.00	
12 months	67.2 (63.1–71.3)	62.8 (58.9–66.7)	−4.05 (−7.82 to −0.28)	**0.035**	−0.13	
Pain catastrophizing (PCS††)						
Rumination						0.136
Baseline	7.4 (6.7–8.2)	8.2 (7.5–9.0)				
6 months	6.2 (5.4–7.0)	7.8 (7.0–8.6)	0.81 (−0.05 to 1.67)	0.064	0.12	
12 months	5.6 (4.7–6.4)	7.4 (6.6–8.2)	1.06 (0.20 to 1.92)	**0.016**	0.15	
Magnification						0.327
Baseline	3.5 (3.0–4.0)	3.8 (3.3–4.3)				
6 months	3.0 (2.5–3.5)	3.7 (3.2–4.2)	0.28 (−0.25 to 0.81)	0.303	0.06	
12 months	2.7 (2.2–3.2)	3.6 (3.1–4.1)	0.57 (0.04 to 1.10)	**0.035**	0.13	
Helplessness						0.407
Baseline	8.5 (7.5–9.5)	9.7 (8.8–10.7)				
6 months	7.6 (6.6–8.6)	9.4 (8.4–10.3)	0.49 (−0.54 to 1.52)	0.347	0.06	
12 months	7.0 (5.9–8.1)	9.2 (8.2–10.2)	1.01 (−0.03 to 2.04)	0.056	0.12	
PCS total						0.185
Baseline	19.5 (17.4–21.5)	21.9 (19.3–23.8)				
6 months	16.9 (14.8–19.0)	20.9 (19.0–22.9)	1.59 (−0.36 to 3.55)	0.111	0.10	
12 months	15.3 (13.1–17.6)	20.3 (18.1–22.4)	2.62 (0.66 to 4.58)	**0.009**	0.16	

(continued on next page)

Table 2 (continued)

Effects of EPIO at 6 and 12 months.*

	Intervention group n = 125	Control group n = 134	Between-group differences			Time-trend
	M (95% CI)	M (95% CI)	MD (95% CI)	P	Effect size β†	P
Chronic pain acceptance (CPAQ‡‡)						
Willingness						0.704
Baseline	13.7 (13.1–14.2)	13.8 (13.3–14.3)				
6 months	13.7 (13.1–14.2)	13.8 (13.2–14.3)	−0.05 (−0.81 to 0.72)	0.908	0.01	
12 months	13.9 (13.3–14.5)	13.6 (13.1–14.2)	−0.42 (−1.19 to 0.35)	0.288	0.07	
Activity engagement						0.086
Baseline	13.5 (12.8–14.2)	13.8 (13.1–14.5)				
6 months	13.8 (13.1–14.5)	14.1 (13.5–14.8)	0.12 (−0.67 to 0.92)	0.770	0.02	
12 months	14.4 (13.7–15.1)	14.3 (13.7–15.0)	−0.43 (−1.23 to 0.37)	0.293	−0.07	
CPAQ total						0.225
Baseline	27.2 (26.1–28.3)	27.6 (26.6–28.7)				
6 months	27.5 (26.4–28.6)	27.9 (26.9–29.0)	0.07 (−1.20 to 1.34)	0.913	0.01	
12 months	28.3 (27.3–29.4)	28.0 (26.9–29.0)	−0.83 (−2.11 to 0.44)	0.201	0.08	

Estimated means from generalized linear mixed models.
* Three-months findings reported elsewhere.[9]
† Effect size β study-specific interpretations: small = 0.10 to 0.29, medium = 0.30 to 0.49, and large ≥0.5.[50]
‡ Subscale of the Brief Pain Inventory (score range 0–10; a higher score indicates higher interference in life).
§ Subscale of the Brief Pain Inventory (score range 0–10; a higher score indicates higher severity).
‖ HADS-A: Hospital Anxiety and Depression Scale-Anxiety subscale (score range 0–21; a higher score indicates a higher degree of anxiety).
¶ HADS-D: Hospital Anxiety and Depression Scale-Depression subscale (score range 0–21; a higher score indicates a higher degree of depression).
# SRF-18: Self-regulatory Fatigue 18 scale (score range 18–90; a higher score indicates higher self-regulatory fatigue).
** RAND-36: RAND 36-Item scale (score range 0–100; a higher score indicates higher emotional well-being).
†† PCS: Pain Catastrophizing Scale (score range 0–52; a higher score indicates higher catastrophizing).
‡‡ CPAQ: Chronic Pain Acceptance Questionnaire (score range 0–52; a higher score indicates a higher acceptance of pain).
BPI: Brief Pain Inventory; CI, confidence interval; HRQoL, health-related quality of life; MD, mean difference; β, standardized coefficients beta.
The statistical significance for the bold entries is listed under P and Time-trend P.

3.5. Follow-up phone calls—qualitative analyses

Notes from follow-up phone calls were analyzed into 4 themes as follows: (1) raising awareness, (2) a useful toolbox, (3) use, and (4) barriers for use. Participants described EPIO as particularly *raising awareness* about the connection between thoughts and feelings, motivation for change, and need for activity pacing, planning, and self-care. EPIO was described as *a useful toolbox*, providing coping strategies and helping participants deal with the pain, even if the pain did not go away. Some described *using* EPIO with others (eg, partner/health care provider) as beneficial and suggested incorporating EPIO in, and after, pain rehabilitation care. Participants reported implementing simple exercises (eg, diaphragmatic breathing) into daily life, without the app, and described practicing breathing exercises as contributing to helpful distraction, relaxation, calmness, and pain reduction. Struggling to prioritize use was described as the most frequent *barrier for use*.

4. Discussion

4.1. Principal findings

Considering all timepoints over the course of 12 months in a linear mixed model revealed no statistically significant between-group differences for the primary outcome of pain interference on function. Participants having access to EPIO did however report significantly lower symptoms of depression and self-regulatory fatigue as well as improved HRQoL vitality and mental health, compared with the control group. The largest between-group changes were observed from baseline to 12 months, with statistically significant findings in favor of the intervention group for symptoms of anxiety, depression, self-regulatory fatigue, HRQoL (ie, general health, vitality, role-emotional, and mental health), and pain catastrophizing.

Taking all findings into account, the EPIO intervention was associated with significant changes for psychological variables, yet nonsignificant changes for pain-related variables including physical components (ie, pain intensity, pain interference, and physical HRQoL scales). This might partly be explained by the fact the EPIO program is built to increase agency, raise awareness about psychosocial components, provide knowledge, and foster engagement in helpful strategies. As such, EPIO does not encourage people to think life can be pain free. Rather, EPIO seeks to show how pain is just a part of life, but that living well with pain is possible, a fact also reflected upon by participants in the follow-up phone calls.

Effects of existing pain self-management interventions seem to fade after 3 months.[72] This study, with significant changes in psychological domains after 12 months in favor of the intervention group, even stronger than 3-month findings,[9] therefore provides a major contribution to the pain literature. The nature of the EPIO intervention, with participants having access anywhere and anytime for 12 months, may explain these long-term effects, perhaps together with the fact that learning takes time, particularly when aiming for change after having lived with pain for years.

4.2. Mental health, quality of life, and self-regulation

The statistically significant psychological findings in favor of the intervention group indicate that using EPIO can strengthen mental health and quality of life for people suffering from chronic pain. Seeking to meet current recommendations for digital health solutions,[10,11,29,36,37,41,60,66] including evidence-based content and user involvement in design and development processes, likely contributed to these improvements. This is also consistent with research showing potential positive impact of CBT and ACT for people living with chronic pain.[22, 64,72]

Psychological distress and unexplained bodily symptoms are part of the ICD-11 diagnostic criteria for "primary musculoskeletal pain," which includes fibromyalgia,[49,73] conditions reported by 64% of participants in this study. The positive psychological impact for people receiving EPIO could hence indicate contribution to improved health above and beyond pain-related outcomes.

Studies have shown capacity for self-regulation to be a limited source that can be fatigued,[4,5,55] and the complexity of chronic pain likely negatively affects ability to self-regulate.[46,48,58,69] The improvement in self-regulatory capacity seen in this study might therefore be explained through the primarily CBT-based EPIO content,[36] targeting cognitive, emotional, and behavioral factors necessary for self-regulation.[9,43] Self-regulatory capacity could also be associated with the current improvement seen in pain catastrophizing (ie, exaggerating, ruminating on, and feeling helpless about the pain).[65]

4.3. Pain and pain interference

The change of focus from pain intensity to also capturing interference of pain has supported a broader understanding of individual pain impact.[21,63] This was also why this study chose interference on function[34,35] as a primary outcome. Measuring pain interference is nevertheless complicated because it depends on how pain affects a person's willingness to experience pain, their acceptance of living with pain, and their values and activities. Pain's impact on daily life therefore varies depending on the individual, and the same pain intensity score can be associated with large individual differences in pain interference.

Living with pain for many years, as was the case for most participants in this study, likely also makes changes in pain and pain interference challenging, perhaps even unlikely. The heterogeneous sample and large data variability may also have contributed to the rather small study effect sizes ($\beta < 0.2$), although not uncommon for psychosocial interventions in chronic pain.[72]

4.4. System use

At the end of the 12-month study, 66% of participants in the intervention group were considered completers, an accomplishment given the substantial adherence/attrition challenges for digital interventions.[33,56] This is also an increase from the 50% completion seen at 3 months,[9] indicating EPIO fostered continued program engagement over the year, and more than 3 months might be needed for people with chronic pain to engage in pain self-management interventions.

4.5. Study limitations and strengths

This study has some limitations. First, participants volunteered for study participation, which indicates high motivation. Most participants were also female, Anglo-American, and with higher education, all potential limitations for generalizability. Second, high heterogeneity (eg, pain conditions) could mean limited statistical power to explore subgroup comparisons. Future studies may therefore increase study sample and/or homogeneity to enhance chance of detecting change, for whom and when. Third, performing multiple statistical tests may inflate significance level (ie, type I error). Analyses therefore focused on confidence interval's, effect sizes and their interpretations and are described in detail in section 2.7 for transparency.[77] Fourth, because the study did not monitor whether the control group engaged in any types of self-management training during the study period, analyses could not control for this aspect. Finally, most participants had lived with pain for many years and were on sick leave/receiving disability benefits. Being approved for disability is an arduous process and describing improvement in pain-related outcomes could potentially interfere with identity for some.

This study also has several strengths. The EPIO intervention program is designed and developed with sound theoretical foundation, stakeholder involvement and testing, qualitative and quantitative feasibility explorations, implementation planning, and taking adherence/attrition challenges into account[10,11,36,37,66] before RCT. The blended care delivery method used may also have contributed to program engagement and completion, and the RCT allowed for thorough examination of system use and self-reported outcome measures over an entire year.

4.6. Future directions

Digital intervention programs such as EPIO may improve outreach of evidence-based pain self-management treatment. The therapeutic relationship from face-to-face interventions likely contributes to engagement, however, and to ensure impact, digital interventions must incorporate ways to encourage engagement, for example through blended care delivery.[1,11,51,60] Study participants recommended incorporating EPIO into pain rehabilitation programs and including EPIO in a multidisciplinary setting (eg, combined with physical therapy[24]), might enhance impact, particularly where fear of pain and movement are impediments for physical improvement.[17,18,68]

Pain is a subjective phenomenon that can only be assessed through self-report, and a combination of quantitative and qualitative measures might therefore enable more in-depth explorations, as seen through the EPIO feasibility pilot.[10,11] Digital wearables could also complement self-report measures, for example to gauge factors such as physical activity and sleep. Digital pain self-management might not be for everyone though, and future research should explore who would benefit from purely in-person treatment, blended care hybrid models, or simply access to digital treatment.

5. Conclusion

The EPIO project seeks to improve outreach of evidence-informed pain self-management interventions. Pain is challenging, sometimes impossible, to treat. However, this 12-month RCT shows how EPIO can contribute to psychological well-being and quality of life, even if living *with* pain. As most existing pain self-management interventions struggle to show effect beyond 3 months, these 12-month findings represent a major contribution to pain research. Complicated concepts such as how to live well *with* pain might not easily be solved or made sense of without considering psychosocial factors, as seen impacted in this study.

Disclosures

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Article history:

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