

ACTsmart: Guided Smartphone-Delivered Acceptance and Commitment Therapy for Chronic Pain—A Pilot Trial

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Abstract

Background. Acceptance and commitment therapy (ACT) is a behavioral health intervention with strong empirical support for chronic pain but, to date, widespread dissemination is limited. Digital solutions improve access to care and can be integrated into patients' everyday lives. **Objective.** ACTsmart, a guided smartphone-delivered ACT intervention, was developed to improve the accessibility of an evidence-based behavioral treatment for chronic pain. In the present study, we evaluated the preliminary efficacy of ACTsmart in adults with chronic pain. **Methods.** The study was an open-label pilot trial. The treatment lasted for 8 weeks, and participants completed all outcome measures at pretreatment and posttreatment and at 3-, 6-, and 12-month follow-ups, with weekly assessments of selected measures during treatment. The primary outcome was pain interference. The secondary outcomes were psychological flexibility, values, insomnia, anxiety, depressive symptoms, health-related quality of life, and pain intensity. All outcomes were analyzed using linear mixed-effects models. **Results.** The sample consisted of 34 adults (88% women) with long-standing chronic pain ($M=20.4$ years, $SD=11.7$). Compliance to treatment was high, and at the end of treatment, we observed a significant improvement in the primary outcome of pain interference ($d = -1.01$). All secondary outcomes significantly improved from pretreatment to posttreatment with small to large effect sizes. Improvements were maintained throughout 12 months of follow-up. **Conclusion.** The results of this pilot study provide preliminary support for ACTsmart as an accessible and effective behavioral health treatment for adults with chronic pain and warrant a randomized controlled trial to further evaluate the efficacy of the intervention.

Key Words: Acceptance and Commitment Therapy; Chronic Pain; mHealth; Psychological Inflexibility; Digital Behavioral Health Intervention

Introduction

Chronic pain is common and affects 20% of adults [1], often leading to reduced functioning in daily activities, in social situations, and at work [2]. Adults with chronic pain are at an elevated risk for insomnia, anxiety, depression, suicidality, and reduced quality of life (QoL) [3, 4]. Chronic pain is complex, and neither medical procedures nor pharmacological treatments are sufficiently effective at alleviating symptoms and pain-related functional impairments [4]. Behavioral health interventions are

often needed to meaningfully increase function and QoL [5–7].

Acceptance and commitment therapy (ACT) is a behavioral treatment approach developed from cognitive behavioral therapy (CBT). Although ACT was not originally developed to treat chronic pain, considerable evidence supports its use [8–11]. Many chronic pain patients focus on reducing or eliminating their pain and the associated emotional discomfort (e.g., by avoiding situations that might elicit pain). This is usually an effective strategy in the short term, as it is followed by

immediate reductions in pain or discomfort. In the long term, however, these avoidance behaviors commonly lead to a way of life that is governed by attempts to control the level of pain and discomfort at the cost of reducing engagement in important life activities. In ACT, this avoidant behavior pattern is called *psychological inflexibility* [12], and in the context of chronic pain these behaviors can lead to reduced pain tolerance as well as increased pain intensity [13, 14]. The objective of ACT is not to reduce pain but to increase an individual's psychological flexibility and hence reduce the dominance of pain and pain-related discomfort on a person's behavior as well as to increase value-driven behaviors. Multiple systematic and meta-analytic reviews have concluded that ACT for chronic pain is efficacious and effective in comparison with inactive control conditions or treatment as usual, with small to large effect sizes for measures of physical functioning, anxiety, depression, and psychological flexibility; medium to large effect sizes for measures of pain acceptance and psychological flexibility; medium effect sizes for pain interference; and small effect sizes for disability, pain intensity, and QoL [8–11, 15].

Unfortunately, access to ACT and other CBT programs for chronic pain treatment continues to be restricted due to health care system constraints such as long waiting lists and a shortage of trained health care professionals coupled with patient-derived challenges, such as physical and mobility limitations and patients residing far from a clinic. Altogether, limited access results in many patients with chronic pain either failing to receive or waiting very long for evidence-based care [16, 17].

One major breakthrough in improving access to behavioral health treatments is internet-based solutions [18, 19]. A recent systematic review on internet treatment for chronic pain based on CBT or ACT principles presented a number of beneficial effects [20]. For example, positive effects of small to moderate effect sizes were found for disability or pain interference outcomes, pain intensity, catastrophizing, depression, and anxiety. These results are in line with those of a previous systematic review on internet treatments for pain [21]. Beyond treatment effects, additional strengths of internet-delivered behavioral treatment include reduced cost and increased convenience for users, ability to reach isolated groups, continual access to treatment content, and reduced health care system costs [20]. All in all, six randomized controlled trials on digitally delivered ACT for patients with chronic pain have been conducted thus far; one was a noninferiority trial comparing video conferencing with in-person delivery [22–27].

One digital solution with increasing traction is delivering content via smartphone. Smartphones are portable, most often on, connected [28], and have exceeded desktop computers in terms of internet use [29]. Smartphones provide opportunities for real-time assessment and monitoring, dynamic adaptations and personalization of interventions, and context awareness to create opportunities

for ecological momentary assessments [28]. The use of smartphone-based treatment also increases a therapist's ability to react in real time to a patient's need for support during the intervention [30]. Prior research has demonstrated that smartphone applications that use reminders and instant feedback and that bring psychoeducation, assignments, and assessments closer to users' everyday lives increase the accessibility and reach of effective treatment [31]. The many easily accessible interactions with the treatment may also enhance treatment outcomes.

There are several smartphone applications available that are marketed to improve chronic pain, and attempts have been made to establish the quality of these [32–34]. Overall, the findings show that the majority of available applications do not follow evidence-based guidelines, do not involve health care providers or experts in the development process, and have not undergone any scientific studies of effect and/or validity. Thus, despite the wealth of pain applications, few have undergone efficacy testing.

In light of this, we developed ACTsmart, a stand-alone smartphone-delivered ACT treatment for adult patients with chronic pain developed by clinicians and researchers in collaboration with experienced end-user professionals, programmers, and potential end users. The aim of the present study was to evaluate the preliminary immediate and long-term effects of ACTsmart on pain interference, psychological flexibility, values, insomnia, depression, anxiety, pain intensity, and health-related QoL.

Methods

Design and Procedure

The present study was a pilot trial with one intake conducted at a tertiary pain clinic. Participants were recruited through self-referral via links shared on social media and were considered eligible for participation if their pain had lasted for at least 6 months. For inclusion in the study, it was also required that participants 1) be between 18 and 70 years old; 2) be able to understand and communicate in Swedish; 3) have a smartphone or tablet connected to the internet; 4) not have a psychiatric comorbidity that required immediate attention (based on severity rather than specific psychiatric disorders); 5) not be acutely suicidal; 6) be stable on their pain medication for at least 2 months, with no planned changes in medication or other pain treatment; and 7) not have received treatment with CBT or ACT during the previous 3 months.

Individuals interested in participating completed an online registration, provided informed consent, and were thereafter contacted via telephone for a structured clinical interview. The interview consisted of assessments of eligibility, pain-related dysfunction, and psychiatric comorbidities assessed with sections A (Depressive Disorder), B (Suicidal Ideation), D (Panic Disorder), E (Agoraphobia), F (Social Anxiety), G (Obsessive

Compulsive Disorder), H (Posttraumatic Stress Disorder), I (Alcoholism), J (Substance-Related Disorders), L (Anorexia), M (Bulimia), and N (Generalized Anxiety Disorder) of version 7 of the Mini-International Neuropsychiatric Interview (MINI) [35, 36] corresponding to the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* [37]. The interviews were conducted by clinical psychologists. If diagnoses or other criteria were ambiguous, participant eligibility was discussed by a multiprofessional team of psychologists, a physician, and a physiotherapist who all specialized in pain. If a participant was considered to be in need of medical care, in need of other psychological treatment that was more relevant, or acutely suicidal, they were contacted by a psychologist or physician for immediate consultation.

Ethics

This study was approved by the regional ethics review board in Stockholm, Sweden, on November 3, 2015 (2015/1638–31/2) and registered at ClinicalTrials.gov on November 17, 2017, under registration number NCT03344926. Participants provided written informed consent prior to enrollment in the study.

ACTsmart Intervention

The treatment was an ACT-based intervention derived from a clinical model used at a tertiary pain clinic [38–41] that was then converted into a smartphone-delivered treatment using a process that followed the guidelines of the mHealth Agile Development & Evaluation Lifecycle [42]. Prior to the present study, ACTsmart underwent rigorous alpha testing, and the present efficacy testing was done using a beta testing sample, who also tested the solution with regard to feasibility (acceptability, usage, practicality), a procedure described in detail elsewhere [43].

Participants underwent the digital treatment program for 8 weeks and were prompted (in the eligibility interviews and by their therapist during treatment) to work with the treatment content for 20 minutes every weekday. The intervention consisted of four different sections—pain education, self-help texts, exercises, and values—and was delivered as text, audio, pictures, and animations. The treatment target was to decrease avoidant behaviors and to increase value-based behaviors and other psychologically flexible behaviors. Content was divided into six different themes intended to reflect the core processes of psychological flexibility—acceptance, distance to thoughts, distance to emotional and bodily experiences, noticing and changing behaviors, self-observation, and values [44]. All sections except the values section were accessible to the participants at all times, but participants were recommended to start with the educational sections, then move on to exercises and finally work with value formulation and exposure guided by

their own values. To obtain access to the values work section, participants had to receive psychoeducation on values and values formulation. All text-based content could be either read or listened to as a means to adapt to participants' different needs. After completion of an exercise, patients were asked to provide a written reflection that was visible from the therapist interface. An overview of the intervention sections and content is presented in Table 1. Screenshots of the patient interface are shown in Figure 1.

Therapists were instructed to log in to check on each participant every other day. Participants received feedback at least weekly from their therapist via a secure messaging function within the treatment platform. Feedback was also given automatically using checkboxes (for completed exercises), progress bars, thumbs-up (when participants reported taking a step toward a goal), and collection of achievement stars (when participants reported having reached a set goal). If a participant was inactive for 2 days, the therapist sent a chat message in the treatment platform to encourage the participant to engage with the treatment and offered help. If a participant did not log in for 4 days, the therapist sent a mobile text message notification, and if a participant was absent for a week or more, they received a phone call. If a participant did not respond to phone calls or still did not log in for 2 more weeks after contact attempts, the participant was regarded as a dropout.

Four therapists at the tertiary pain clinic participated in the study: one licensed psychologist with extensive knowledge of ACT and three intern psychologists who had had several months of training in ACT and treatment of adult pain patients. The intern psychologists received weekly supervision by a clinician with extensive training in ACT for chronic pain and ACTsmart. Participants were randomly allocated to a therapist by a randomizing algorithm in the digital platform.

Data Collection and Measures

Background variables (age, gender, education), including pain variables (intensity, type, duration, location, pain-related dysfunction, and additional symptoms [i.e., fatigue, stress sensitivity]) were collected at registration as self-report data. Efficacy data were self-reported and collected at pretreatment, posttreatment, and follow-up at 3, 6, and 12 months. Selected variables (pain interference, avoidance, value progress, and value obstruction) were also assessed weekly during treatment. The assessments were provided on a secure internet platform.

Primary Outcome

Pain interference was measured using the Pain Interference Index (PII) [45]. The PII is a six-item questionnaire measuring pain interference in adults in the last 2 weeks. The 6-point Likert scale ranges from “not at all” to “very much,” with lower scores indicating lower

Table 1. Treatment content

Section	Content	Primary Skill Taught
Why does it hurt?	Introduction to pain education, six educational chapters, one knowledge quiz	Knowledge about pain, how the pain system works, categories of pain, potential explanations for chronic pain, how and why the context affects pain experience, information about medication and why they do not always work, proposed focus shift from pain reduction to increased function and quality of life
Changing your behavior	Self-help texts, 15 educational chapters tagged with theme, links to related exercises	Introduction to ACT and own change process; divided into six themes
Exercises	Twenty-nine ACT-consistent exercises, graded and tagged with theme and with level of difficulty	Divided into six themes
Values	Introduction to values; exercises designed to start a thought process on life values; a short test to grade prioritized areas to work with during treatment and formulation of values, goals, and steps	Clarify and formulate life values, value-based exposure
Theme	Content	Primary Skill Taught
Acceptance	Education, exercises	Acceptance: Increase willingness and ability to let pain and other inner discomfort be, exactly as they are
Distance to thoughts	Education, exercises	Defusion: Taking perspective on thoughts, looking at them skeptically and making active choices when deciding if the thoughts are helpful for the current situation
Distance to experiences	Education, exercises	Defusion: Taking perspective on unpleasant inner experiences such as pain but also other internal discomfort such as anxiety, fatigue, or fear
Your behaviors	Education, exercises	Behavior analysis: Understanding and analyzing own adaptive or maladaptive behavior patterns, behavior in relation to context, antecedents and direct consequences of the behavior, and long-term consequences of maintaining or changing maladaptive behaviors
Self-observation	Education, exercises	Contact with present moment, observe in nonjudgmental way, acceptance, defusion
Values	Education, exercises	Clarify life values, valued action

ACT = acceptance and commitment therapy.

interference. In the original validation study [45], the instrument showed a one-factor structure and satisfactory internal consistency (Cronbach's $\alpha = 0.85$).

Secondary Outcomes

Psychological inflexibility was measured using the Psychological Inflexibility in Pain Scale (PIPS) [46]. The PIPS assesses self-rated psychological inflexibility related to pain. It is a 12-item questionnaire that consists of two subscales: Avoidance (eight items) and Cognitive Fusion (four items). It is rated on a 7-point Likert scale that ranges from 1 ("never true") to 7 ("always true"). Higher scores indicate higher levels of psychological inflexibility. The PIPS has shown satisfactory internal consistency, with Cronbach's $\alpha = 0.87$ for the total scale, Cronbach's $\alpha = 0.89$ for the Avoidance subscale, and Cronbach's $\alpha = 0.66$ for the Cognitive Fusion subscale [47, 48].

Values were assessed using the Valuing Questionnaire (VQ) [49]. The VQ is a 10-item questionnaire with two subscales: Progress (VQ-p) and Obstruction (VQ-o). Items are rated on a 7-point Likert scale ranging from 0 ("not at all true") to 6 ("completely true"). Higher scores on the Progress subscale indicate greater progress toward values, whereas higher scores on the Obstruction subscale indicate greater obstruction to values. The two-factor solution has shown excellent model fit and satisfactory internal consistency (Cronbach's $\alpha = 0.87$) for both the Progress and Obstruction subscales [49]. The VQ has been translated into Swedish and validated in a Swedish chronic pain sample with adequate psychometric properties [50].

Insomnia was assessed using the Insomnia Severity Index (ISI) [51]. The ISI is a seven-item questionnaire that evaluates sleep onset, sleep latency, early awakening, the feeling of being rested, how sleep problems affect

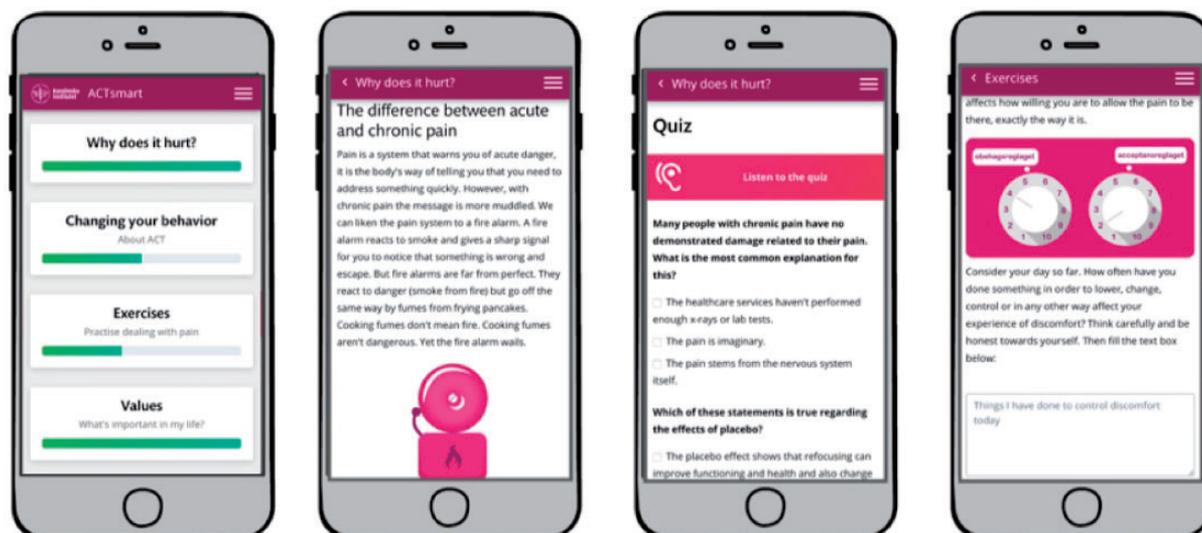


Figure 1. Screenshots of the patient interface in ACTsmart (translated from Swedish to English).

daily life, and how concerned the individual is with their sleep pattern. The 5-point scale ranges from 0 (“not at all”) to 4 (“very much”), and a higher score indicates more symptoms of insomnia. The ISI has shown satisfactory internal consistency (Cronbach’s $\alpha = 0.74$) [52] and has been validated in a Swedish chronic pain sample [53].

Depressive symptoms were assessed using the Nine-Item Patient Health Questionnaire (PHQ-9) [54]. Patients rate the frequency of depressive symptoms on a 4-point Likert scale ranging from 0 (“not at all”) to 3 (“almost every day”), where higher scores indicate more symptoms of depression. The PHQ-9 has been found to be reliable and valid with satisfactory internal consistency (Cronbach’s $\alpha = 0.86$) [54]. The PHQ-9 has been validated for migraine patients [55] as well as chronically ill patients [56].

Anxiety was assessed using the Seven-Item Generalized Anxiety Disorder Scale (GAD-7) [57]. The GAD-7 assesses the frequency of anxiety symptoms during the last 2 weeks on a 4-point Likert scale ranging from 0 (“not at all”) to 3 (“nearly every day”), with higher scores indicating higher levels of distress. The GAD-7 has shown strong internal consistency (Cronbach’s $\alpha = 0.92$) [57] and is validated for chronic pain patients with migraine [58].

Health-related QoL was assessed using the European Quality of Life Questionnaire (EQ-5D-3L [59, 60]). The EQ-5D-3L has five dimensions—mobility, self-care, usual activities, pain, and anxiety or depression—and three levels: 1) no problems; 2) moderate problems; and 3) severe problems. In this study, items were summarized to a total score without the use of index scores, a procedure proposed by Parkin et al. [61]. As proposed by the EuroQol Group, the scale was reversed, with higher scores indicating better health, and the total score ranged from 5 to 15. The EQ-5D-3L has been validated in chronic pain samples [62], and the Swedish version of the

EQ-5D-3L has been validated in several Swedish samples [63–65].

Pain intensity was assessed using a numeric rating scale from 0 (“no pain”) to 10 (“worst imaginable pain”). At baseline, participants were asked to assess their current pain intensity as well as their average pain intensity during the last 2 weeks. At posttreatment and at follow-up, participants only rated their current pain intensity. Analyses of pain intensity were therefore performed using patients’ current pain intensity.

Data Analysis

Preliminary Comparisons and Descriptive Analyses

Statistical analyses were performed using SPSS version 26.0 (IBM SPSS Statistics for Macintosh, version 26.0, Armonk, NY). Figures 3–6 were created using Stata version 15 (StataCorp., College Station, TX). Descriptive statistics were used to calculate participant characteristics at baseline, attrition, and therapist time, as well as weekly means for pain interference, avoidance, value progress, and value obstruction. Independent-sample *t* tests were conducted for all treatment variables at posttreatment to determine whether treatment results varied with the therapist’s level of training (intern psychologist or licensed psychologist). Frequency distributions were plotted using histograms and Q-Q plots, and tests of normality, skewness, and kurtosis were performed. Outliers were detected using the outlier labeling test as described by Hoaglin et al. [66].

Analyses of Primary and Secondary Outcomes

All outcomes from the included participants were analyzed with an intent-to-treat approach, with full-information maximum-likelihood estimation for model fit using linear mixed-effects models. Prior to running the analyses, the assumptions of the modeling approach were

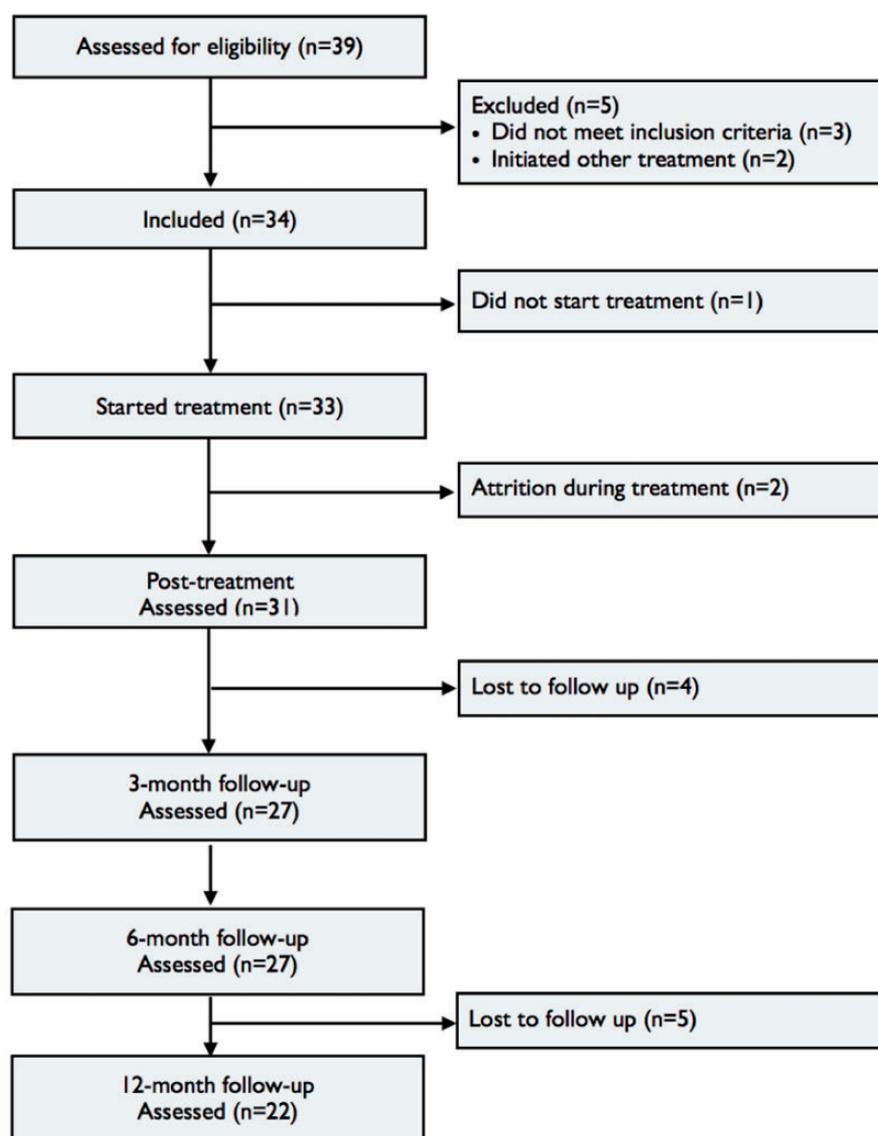


Figure 2. Participant flow throughout treatment.

tested, the amount and pattern of missing data were analyzed, and Little's missing completely at random (MCAR) test was performed to ensure that data were missing at random. Linear mixed-effects models for repeated measures were fit to model longitudinal change. Random effects were included based on their contribution to the model fit. Pretreatment to posttreatment assessments were analyzed for detection of immediate treatment effects, and posttreatment to 12-month follow-up assessments were analyzed for detection of maintained or prolonged treatment effects. This piecewise approach was used to model change with how likely it is to occur in a trial that includes follow-up assessments [67]. For all outcomes, the same model was used for both piece 1 and piece 2. For the weekly assessed variables (avoidance, pain interference, value progress, and value obstruction), 10 time points (pretreatment, eight weekly time points, and posttreatment) were entered to calculate changes from pretreatment to posttreatment, and four

time points (at posttreatment and at the 3-, 6-, and 12-month follow-ups) were entered to calculate changes from posttreatment through follow-up. For all other variables, pretreatment to posttreatment calculations consisted of two time points (pretreatment, posttreatment), and posttreatment to follow-up consisted of four time points (at posttreatment and at the 3-, 6-, and 12-month follow-ups). For all variables with weekly assessments during treatment, the model showing the best model fit included the fixed effect of time, random intercepts, and random slopes, where covariance between random effects was constrained to be zero. For all other variables, best model fit was found using the fixed effect of time and the random intercepts.

Effect sizes for the within-group effect were calculated using model-implied estimates of standard deviations and mean differences [68, 69]. Effect sizes were calculated separately for pretreatment to posttreatment and posttreatment to follow-up.

Deterioration

Negative outcomes were evaluated as a feasibility aspect using a deterioration criterion of $\geq 30\%$ from the participant's own baseline [70].

Results

Sample Characteristics

In total, 34 participants were enrolled in the study. One participant (3%) withdrew before the start of treatment, and two participants (6%) never started working with the treatment content and were considered dropouts. Figure 2 presents the flowchart of the study.

The sample was predominantly female (88%), with a mean age of 44.4 years (SD = 8.59). The mean pain duration at baseline was 20.4 years (SD = 11.67) with an average of 5.8 pain locations (SD = 2.78). Eighteen participants (53%) fulfilled the criteria for one or more psychiatric diagnoses, with depression being the most common (24%). All participants (100%) suffered one or more additional symptoms in addition to pain; sensitivity to stress (88%) and fatigue (85%) were the most common concerns. Twenty-three (68%) participants were unable to work or study full time due to their pain. Further sample characteristics at baseline are listed in Table 2.

Compliance and Practicality

Of the remaining 31 participants, 28 (90%) completed treatment according to the predefined criteria of completion of at least eight exercises and reported behavior changes toward at least one value. On average, participants completed 84% of the treatment content (SD=17.81; range, 26.5–100), divided over pain education (97%, SD=17.96), self-help texts (93%, SD=21.55), preparations for values work (89%, SD=26.43), and exercises (16.24 of 29; 56%, SD=33.08). Twenty-six participants (84%) formulated values, goals, and steps, and the average number of formulated values was 3.85 (SD=1.99) among those participants who formulated one or more values (3.23 [SD=2.32] in total).

Therapists spent, on average, 16 minutes (range, 2–32) per patient per week and sent, on average, 15.6 (SD = 4.9) chat messages throughout the course of the treatment. Participants sent, on average, 7.1 (SD = 6.4; range, 0–24) chat messages to their therapist during the treatment.

Analysis of Primary and Secondary Outcomes

Missing Data and Assumptions of Linear Mixed-Effects Model

At baseline, there were no missing values. At posttreatment, there was 8.8% missing data in total on all variables. The missing data were due to the three participants who chose to not start or discontinued treatment. Due to how the questionnaire platform worked, it was

Table 2. Participant characteristics at baseline

Participant Characteristic	n=34		
	Percentage	n	M (SD)
Sex			
Female	88%	30	—
Male	12%	4	—
Age	—	—	44.3 (8.59)
Pain duration, y	—	—	20.4 (11.7)
No. of pain locations	—	—	5.9 (2.8)
Education			
Up to 12 y	41%	14	—
12–15 y	21%	7	—
15+y	38%	13	—
Occupational status (multiple options possible)			
Working, studying, or on parental leave full time	32%	11	—
Working or studying part time	21%	7	—
Sick leave, temporary	29%	10	—
Sick leave, permanent	24%	8	—
Pain diagnosis type			
Nociceptive (spinal disc hernia, rheumatic diseases, endometriosis, whiplash)	35%	12	—
Neuropathic (MS, nerve damage)	3%	1	—
Nociplastic (fibromyalgia, CRPS)	29%	10	—
Headaches (migraine)	3%	1	—
Other or unclear	9%	3	—
Unspecified diagnosis	21%	7	—
Pain medications (multiple options possible)			
Opioids	47%	16	—
Antiepileptics	15%	5	—
NSAIDs	29%	10	—
Antidepressants	29%	10	—
Sedatives or relaxants	9%	3	—
Other analgesics	68%	22	—
Ataractics	6%	2	—
Migraine medication	3%	1	—
None	3%	1	—
No. of medications	—	—	3.5 (2.5)
Additional symptom burden (multiple options possible)			
Recurring fever	15%	5	—
Sickness feeling	50%	17	—
Fatigue	85%	29	—
Concentration difficulties	77%	27	—
Memory deficits	77%	26	—
Sensitive to stress	88%	30	—
Other nonspecified symptom	21%	6	—
None	0%	0	—
Psychiatric diagnoses (multiple diagnoses possible)			
Depression	24%	8	—
Moderately suicidal	21%	7	—
Panic disorder	3%	1	—
Social phobia	3%	1	—
Posttraumatic stress disorder (PTSD)	6%	2	—
General anxiety disorder (GAD)	21%	7	—
Specific phobia	3%	1	—
None	47%	16	—

SD = standard deviation; MS = multiple sclerosis; CRPS = complex regional pain syndrome; NSAID = nonsteroidal anti-inflammatory drug.

Table 3. Observed means and standard deviations at pretreatment and posttreatment and at 3-, 6-, and 12-month follow-up

	Pretreatment	Posttreatment	Three-Month Follow-Up	Six-Month Follow-Up	Twelve-Month Follow-Up
Pain interference	25.62 (6.03)	19.03 (8.55)	17.41 (8.70)	17.41 (9.56)	19.18 (9.81)
Avoidance	37.47 (7.84)	28.87 (9.62)	28.11 (11.85)	28.59 (12.66)	26.82 (10.79)
Value progress	13.82 (7.80)	17.71 (6.79)	18.07 (7.47)	17.56 (7.39)	18.86 (7.62)
Value obstruction	15.18 (7.33)	10.61 (7.13)	10.67 (7.81)	12.44 (8.02)	12.36 (8.26)
Insomnia	16.42 (6.33)	14.06 (7.50)	12.81 (7.73)	12.35 (7.60)	13.27 (8.21)
Anxiety	8.68 (5.39)	6.06 (4.60)	6.59 (5.43)	7.54 (6.17)	7.05 (6.32)
Depression	12.45 (5.56)	9.55 (6.23)	9.15 (6.53)	10.46 (7.62)	10.64 (7.72)
Health-related quality of life	5.58 (1.77)	6.10 (1.70)	6.07 (1.96)	6.00 (1.86)	5.82 (1.97)
Fusion	22.09 (4.39)	18.52 (5.14)	19.33 (4.91)	18.15 (5.99)	17.50 (6.26)
Pain intensity	6.52 (1.55)	5.35 (2.03)	4.74 (2.07)	4.56 (1.91)	5.18 (1.76)

impossible for participants to refrain from answering single items or questionnaires—either they answered all items on all questionnaires or completely refrained from responding. At the 3- and 6-month follow-ups, 20.6% of the sample did not complete assessments. At the 12-month follow-up, 35.3% of the sample did not complete assessments. Little's MCAR test [71] showed that data were MCAR ($\chi^2 = 724.170$, $df = 1,647$, $P = 1.000$). Residuals on all outcome variables were normally distributed.

Treatment Outcome

The means and standard deviations of the pretreatment, posttreatment, and follow-up assessments for all outcome variables are listed in Table 3. The means for the weekly measured variables of pain interference, avoidance, value progress, and value obstruction during treatment are shown in Figures 3–6. The results from linear mixed-effects analyses for primary and secondary outcome measures are listed in Table 4. There were no significant differences on any study variable at posttreatment between participants receiving treatment from an intern psychologist or a licensed psychologist (all P values were greater than 0.05).

Primary Treatment Outcome

For pain interference, there was a significant linear effect of time from pretreatment to posttreatment, indicating improvement with a large effect size ($d = -1.01$). There were no significant changes in pain interference in the follow-up phase (posttreatment to 12-month follow-up), illustrating stability in improvement from posttreatment to follow-up.

Secondary Treatment Outcomes

For the secondary treatment outcomes of avoidance, fusion, value progress, value obstruction, insomnia, anxiety, depression, health-related QoL, and pain intensity, improvement was seen in all study variables, illustrated by a significant linear effect of time from pretreatment to posttreatment. There were no changes in any of the

variables from posttreatment through the follow-up phase, illustrating stability in improvements. Effect sizes in the secondary outcome variables varied, with health-related QoL presenting the smallest effect size ($d = 0.16$) and avoidance presenting the largest ($d = -1.34$) effect size.

Deterioration

No serious adverse events (psychiatric hospitalization, self-harm, suicidal behaviors) were reported during the study. However, a clinically significant deterioration (>30%) was reported by 11 participants (35%) at posttreatment; five participants deteriorated on one variable, four participants deteriorated on two variables, and two participants deteriorated on three variables. Five participants were improved at follow-up and ended up with no change or a minor improvement. For three participants, deterioration took place during treatment and was not improved during follow-up. The variables concerned were value progress, value obstruction, and anxiety. For another three participants, deterioration took place during treatment, and the participants were then lost to follow-up. The variables concerned were pain interference, value progress, value obstruction, and two cases of health-related QoL. Thus, at the end of the follow-up period, deterioration was still present in six participants (19%).

Discussion

This pilot study provides the first evaluation of treatment effects for ACTsmart, a smartphone-delivered ACT treatment for adult patients with chronic pain. There were significant improvements from pretreatment to posttreatment on all variables. Large effect sizes were seen in the primary outcome of pain interference and in the secondary outcomes of avoidance, value obstruction, and anxiety. Significant medium effect sizes were found for the secondary outcomes of value progress, depressive symptoms, fusion, and insomnia; small effect sizes were seen for the secondary outcomes of pain intensity and health-

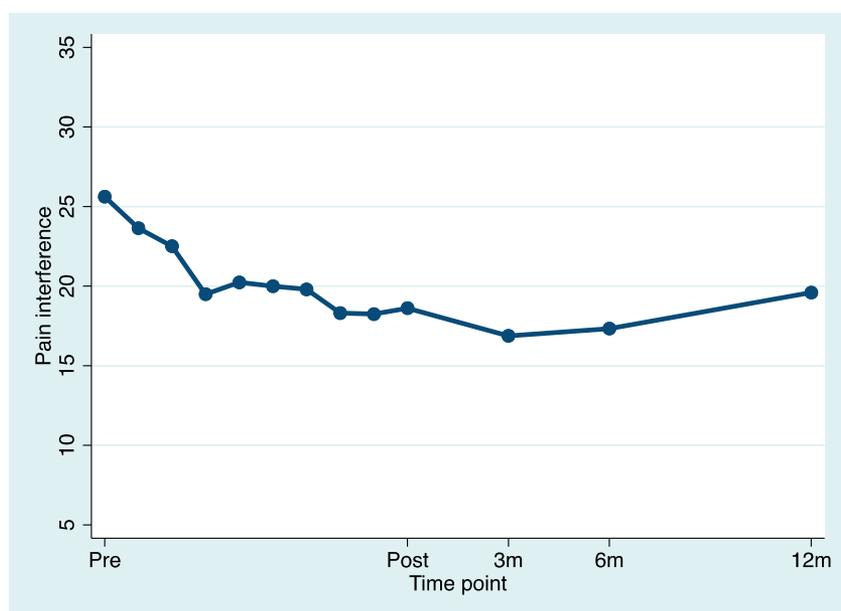


Figure 3. Estimated means for pain interference for pretreatment, during treatment, and posttreatment (pretreatment to posttreatment $d = -1.01$). For illustrative purposes, time was used as a discrete variable to model weekly estimates to the mean.

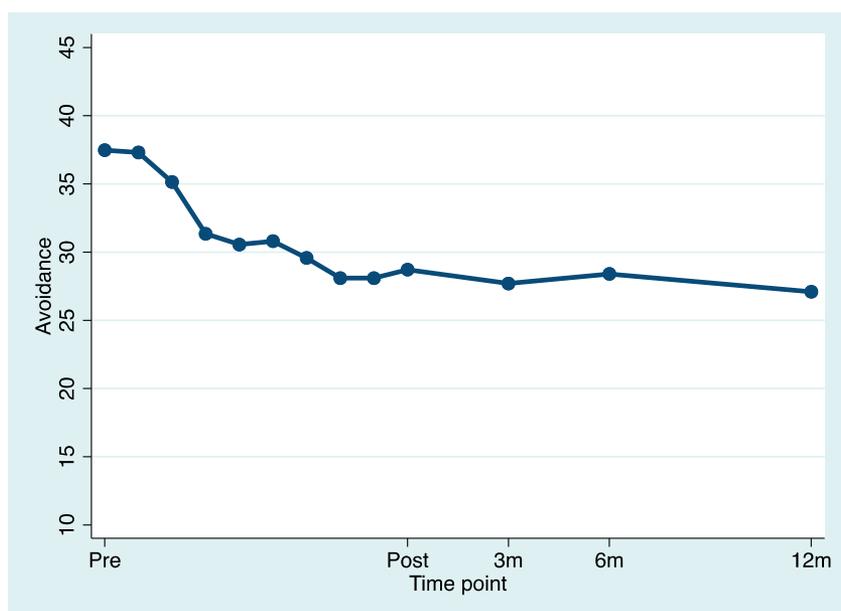


Figure 4. Estimated means for avoidance for pretreatment, during treatment, and posttreatment (pretreatment to posttreatment $d = -1.34$). For illustrative purposes, time was used as a discrete variable to model weekly estimates to the mean.

related QoL. All results were maintained for 12 months following the end of treatment.

The preliminary efficacy results of the present study support previous findings on internet-delivered (primarily using a desktop computer) ACT for chronic pain patients [22–26, 72], but our results also extend these findings, with promising effects on insomnia, values, and QoL. Sleep disorders are among the most common concerns related to pain [73]. Sleep-related variables have

been shown to predict pain-related outcomes such as disability [74], and sleep disruption is related to increased pain sensitivity and lowered pain thresholds [75]. Randomized controlled studies concerning internet-delivered ACT for chronic pain have so far either failed to show improvements in insomnia [26] or have not used it as a measure of outcome, which implies that the moderate improvement shown in this study is promising and warrants future studies.

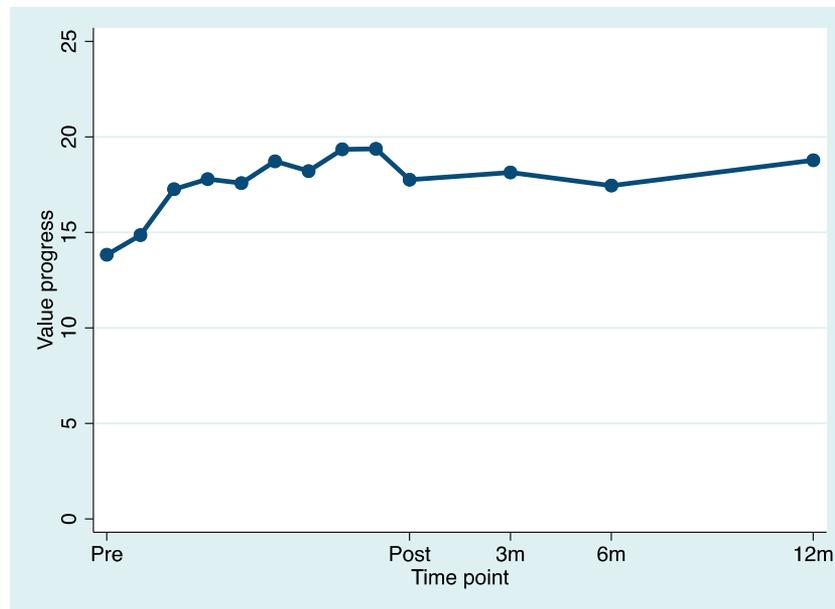


Figure 5. Estimated means for value progress for pretreatment, during treatment, and posttreatment (pretreatment to posttreatment $d = 0.78$). For illustrative purposes, time was used as a discrete variable to model weekly estimates to the mean.

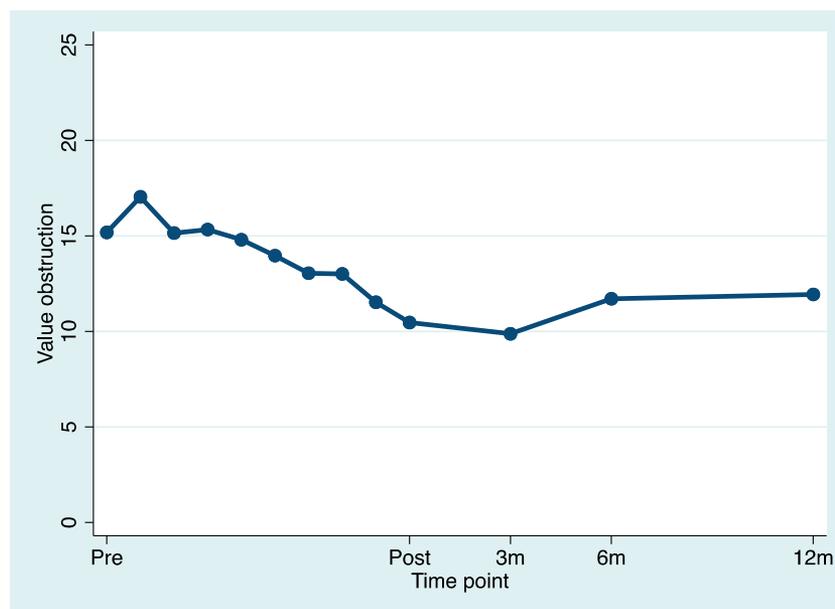


Figure 6. Estimated means for value obstruction for pretreatment, during treatment, and posttreatment (pretreatment to posttreatment $d = -1.02$). For illustrative purposes, time was used as a discrete variable to model weekly estimates to the mean.

The obtained results are also comparable with those of clinical studies of face-to-face interventions of ACT for adults with chronic pain in which significant small to medium effect sizes have been found for pain, depression, anxiety, physical well-being, and QoL [9, 11, 15]. This is promising, as it provides the opportunity to offer a treatment with similar effects as face-to-face treatment with less therapist time spent per patient. This can increase

availability, reach, and accessibility, as each therapist can treat more patients and patients can access treatment regardless if they live far away from a treatment facility, have mobility issues, or have difficulty getting away from work. Another interesting research objective would be to examine the combination of face-to-face and smartphone-delivered treatment (e.g., in a blended care approach). The addition of smartphone support

Table 4. Results from piecewise linear mixed-effects models for primary and secondary outcome variables

Outcome	Estimate (SE)	95% CI		P	d	95% CI	
		Lower Limit	Upper Limit			Lower Limit	Upper Limit
Pain interference							
Pretreatment to posttreatment	-6.54 (1.18)	-8.94	-4.15	0.000*	-1.01	1.38	-0.64
Posttreatment to 12-mo follow-up	1.17 (1.36)	-1.62	3.97	0.395	0.19	-0.26	0.63
Avoidance							
Pretreatment to posttreatment	-9.81 (1.58)	-13.02	-6.61	0.000*	-1.34	-1.78	-0.90
Posttreatment to 12-mo follow-up	1.56 (1.16)	-3.87	0.76	0.185	0.23	-0.57	0.11
Fusion							
Pretreatment to posttreatment	-3.64 (0.70)	-5.06	-2.22	0.000*	-0.67	-0.93	-0.41
Posttreatment to 12-mo follow-up	-1.33 (0.69)	-0.05	0.04	0.057	-0.27	-0.01	0.01
Value progress							
Pretreatment to posttreatment	4.21 (1.03)	2.11	6.31	0.000*	0.78	0.39	1.17
Posttreatment to 12-mo follow-up	0.62 (1.09)	-1.63	2.86	0.576	0.12	-0.31	0.54
Value obstruction							
Pretreatment to posttreatment	-5.32 (1.08)	-7.53	-3.12	0.000*	-1.02	-1.44	-0.60
Posttreatment to 12-mo follow-up	2.18 (1.12)	-0.05	4.41	0.055	0.42	-0.01	0.85
Insomnia							
Pretreatment to posttreatment	-2.40 (0.77)	-3.97	-0.82	0.004*	-0.47	-0.78	-0.16
Posttreatment to 12-mo follow-up	-0.05 (0.82)	-1.69	1.59	0.955	-0.01	-0.36	0.34
Anxiety							
Pretreatment to posttreatment	-2.57 (0.62)	-3.83	-1.31	0.000*	-0.67	-1.01	-0.34
Posttreatment to 12-mo follow-up	0.85 (0.68)	-0.51	2.20	0.217	0.25	-0.15	0.64
Depressive symptoms							
Pretreatment to posttreatment	-2.89 (0.74)	-4.39	-1.39	0.000*	-0.63	-0.96	-0.30
Posttreatment to 12-mo follow-up	1.30 (0.86)	-0.39	3.03	0.129	0.30	-0.09	0.70
Health-related quality of life							
Pretreatment to posttreatment	0.52 (0.19)	0.90	0.13	0.010*	0.16	0.28	0.04
Posttreatment to 12-mo follow-up	-0.05 (0.07)	-1.57	-4.55	0.444	-0.02	-0.51	-1.48
Pain intensity							
Pretreatment to posttreatment	-1.16 (0.30)	-1.76	-0.56	0.000 [†]	-0.44	-0.66	-0.21
Posttreatment to 12-mo follow-up	-0.017 (0.31)	-0.63	0.60	0.955	-0.01	-0.25	0.24

SE = standard error; CI = confidence interval; * = $P < 0.05$.

reminding patients to practice daily and facilitating therapist support between sessions could potentially increase compliance and enhance treatment effects.

As previously described, the treatment target in the present study was to decrease avoidance behaviors, increase psychological flexibility, increase value-based behavior, and thereby decrease pain interference. Future studies should expand on the theoretical and empirically supported notion that psychological flexibility may function as a vehicle for changes in the other outcomes.

The aim of the intervention in the present study was not explicitly to reduce pain intensity. A small but significant improvement in pain intensity was, however, seen at posttreatment and remained at the 12-month follow-up. Although small, the improvement is encouraging, especially as the study group showed a mean pain duration of >20 years. As encouraging as it is that the present study showed significant effects despite the long pain duration, several studies instead point to the importance of early interventions in order to prevent the pain from becoming chronic [76, 77]. Smartphone-delivered treatment may be a way to enable early intervention, with its promise of increased availability, reach, and accessibility.

In comparison with previous research on internet-delivered (via a desktop computer) ACT treatment for chronic pain patients [20, 23–25], the compliance rate in the present study was high (90%). This might, of course, be due to differences in requirements for completion and adherence, but this might also be due to differences in the design and structure of the intervention. In the present study, the requirements for treatment completion were completion of at least eight exercises or formulation of and reported behavior changes toward at least one value. By fulfilling these requirements, a participant was considered to have undergone a sufficient proportion of active treatment. In the study conducted by Trompetter et al. [23], completion and sufficient dose of active treatment required the participants to complete the first six modules of the intervention, and adherence was defined as both completing the intervention and engaging with the treatment for at least 3 hours per week. As attention, sitting still, and processing large amounts of information are tasks that are known to be difficult for chronic pain patients [3, 4, 78], perhaps the microinteractions possible with smartphone-delivered treatment better suit the needs of the chronic pain population. In addition, the present intervention underwent rigorous alpha testing

focused on user friendliness and comprehensibility based on user feedback before this study started.

The therapists in the present study were all trained in ACT and chronic pain, which may have influenced the magnitude of the effects observed. Further efficacy testing is needed with less experienced therapists or with therapists who do not specialize in chronic pain, such as primary care clinicians. The structure and content of ACTsmart (and many other internet-delivered treatments) limit the risk of therapist drift, but the level of training that is required remains an empirical question. Moreover, there is a need to further investigate dose-response relationships (e.g., varying levels of therapist support, varying treatment lengths, and whether the treatment is delivered as a stand-alone treatment or in combination with face-to-face treatment).

Limitations to this pilot study that should be considered when interpreting the results include the lack of a control condition, the small sample size, the predominance of female participants, and the proportion of missing data at the 12-month follow-up. Also, the sample is self-referred, which may reduce the external validity of the findings, as self-referred patients may possibly be more healthy, better educated, and more motivated than clinical patients. However, baseline characteristics in the present study such as pain intensity and pain duration correspond with those of previous research using participants recruited from pain clinics [38, 45, 48]. The sample is also representative of the chronic pain population with regard to psychiatric comorbidities [22] as well as additional symptom burden. Furthermore, a recent direct comparison between clinical and self-referred pain patients showed similar effects and similar degrees of feasibility for both groups when receiving a therapist-guided ACT protocol through the internet [79].

The promising results of the present study warrant further research, primarily randomized controlled trials with larger sample sizes, but also studies on cost-effectiveness and dose-response relationships, as well as implementation studies in various care settings with varying levels of clinical expertise. Also, as some participants deteriorated during treatment, a high-priority research objective is to find models to predict who will likely be a treatment responder or nonresponder.

Conclusion

In conclusion, the present study provides preliminary support for the usefulness of ACTsmart as a digital behavioral intervention to improve functioning in individuals with chronic pain. Larger clinical trials with an active control condition and studies using patients recruited from tertiary care pain units are warranted to validate these findings.

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