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Feasibility and acceptability of a guided internet-based acceptance and commitment therapy intervention (MobACT) for adults with chronic pain in Italy: A pilot mixed-methods randomized controlled trial

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ABSTRACT

Background: Chronic pain (CP) is a leading cause of disability worldwide and is associated with substantial psychological, functional, and social burden. Acceptance and Commitment Therapy (ACT) has demonstrated efficacy in improving pain acceptance and functioning; however, access to psychological care remains limited. Internet-based interventions (IBIs) may help bridge this gap. To date, no ACT internet-based intervention has been developed and tested for individuals with CP in Italy. The present pilot randomized controlled trial (RCT) evaluated feasibility, acceptability, usability, and exploratory changes in pain acceptance of MobACT, a guided internet-based ACT intervention translated and adapted for the Italian context.

Methods: A two-arm pilot RCT with parallel groups (1:1 allocation) was conducted. Forty adults with CP were randomized to either the MobACT intervention ($n = 20$) or a waitlist control group (n = 20). The seven-week guided intervention was delivered via the *Iterapi* platform. Feasibility outcomes included recruitment, retention, usability, satisfaction, intervention experience, and participant feedback. The primary exploratory clinical outcome was pain acceptance, measured using the Chronic Pain Acceptance Questionnaire (CPAQ-20) at baseline (T0) and post-intervention (T1). Feasibility, usability, and participant experiences were explored through post-intervention questionnaires and semi-structured interviews analyzed using thematic analysis.

Results: Pain acceptance significantly improved over time across participants ($p < .001$), but the time × group interaction was not significant ($p = .978$), indicating no evidence of a differential change between MobACT and waitlist during the pilot period. Reliability of the CPAQ-20 was good at both time points ($\alpha = 0.802–0.842$). Qualitative findings indicated high usability, satisfaction, and perceived applicability of ACT strategies. Participants reported increased awareness, reduced rumination, improved emotional regulation, and greater engagement in valued activities, despite limited changes in pain intensity.

Conclusions: Findings support the feasibility, acceptability, and usability of MobACT as a culturally adapted internet-based ACT intervention for CP in Italy. Exploratory outcome findings should not be interpreted as evidence of efficacy; rather, they support further evaluation in a larger, fully powered RCT with more comprehensive engagement monitoring and longer follow-up.

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1. Introduction

Chronic pain (CP) represents one of the leading causes of disability worldwide (Dahlhamer, 2018; Smith et al., 2001), exerting a profound impact on individuals' psychological wellbeing, daily functioning, and overall quality of life (Rogers and Farris, 2022; Gureje et al., 1998; Tobin et al., 2026; Castelnuovo et al., 2015). In Italy, it is estimated that CP affects approximately 19.7% of the population, corresponding to nearly 9.8 million individuals (Marchesini et al., 2025). The burden associated with CP extends far beyond physical symptoms: over two-thirds of individuals report moderate to severe interference in everyday activities, while sleep disturbances affect approximately 50.5% of people (Violini et al., 2025). Emotional and psychosocial consequences are also highly prevalent, including emotional dysregulation, anxiety, and depressive symptoms (Aaron et al., 2025; Burke et al., 2015; Castelnuovo et al., 2016a; Tenti et al., 2025; Manna et al., 2025), often impacting family and social relationships (Suso-Ribera et al., 2020; Borthwick et al., 2024). Working life domain is similarly compromised, e.g., reduced working hours, modified job roles, or withdrawal from employment due to pain-related limitations (Hengstebeck et al., 2017; Yamada et al., 2016). These multidimensional consequences that characterize the CP condition reveal the need for interventions that move beyond symptom reduction alone and instead target psychological processes (Mellace et al., 2024; Castelnuovo et al., 2016b; Castelnuovo et al., 2016c; Giusti et al., 2017).

Acceptance and Commitment Therapy (ACT) has gained substantial empirical support as a psychological intervention for individuals living with CP. Indeed, evidence indicates that ACT can produce meaningful improvements in physical functioning, pain interference, emotional distress, and health-related quality of life (Ye et al., 2024; Cattivelli et al., 2018). Grounded in the psychological flexibility model, ACT aims to foster the capacity to engage in meaningful life activities while remaining open to pain-related experiences, rather than investing effort in unworkable attempts to avoid, suppress, or control pain-related thoughts, emotions, and bodily sensations. Through processes such as acceptance, cognitive defusion, present-moment awareness, and values-oriented action, ACT seeks to reduce the functional impact of pain and enhance overall well-being (Cattivelli et al., 2018; Liu et al., 2025; Landi et al., 2021; Castelnuovo et al., 2018; Spatola et al., 2024; Hayes et al., 2012). Despite these promising findings, access to psychological support remains challenging, both in terms of reaching care facilities and in ensuring sufficient availability of providers and treatment time to meet demand within an appropriate time frame (Bertuzzi et al., 2022; MacLean et al., 2025). Digital interventions have emerged as a promising response to this gap, offering an efficient, timely, and feasible approach to delivering psychological support within the CP context (Blake et al., 2024). Within this evolving digital landscape, internet-based interventions (IBIs) have gained increasing relevance as tools to expand access to psychological services (Semonella et al., 2022; Andersson and Titov, 2014; Castelnuovo et al., 2020; Simpson et al., 2021; Andersson, 2018), especially considering pain-related mobility limitations, fatigue, symptom flares, transport difficulties, work and caregiving constraints, and geographic or organizational barriers that can limit regular attendance at in-person care facilities (Vugts et al., 2018). Indeed, a growing body of evidence indicates that IBIs for CP are associated with significant improvements across multiple domains, including pain intensity, pain interference, psychological distress (e.g., anxiety and depression), physical functioning, and health-related quality of life (Tenti et al., 2025; Lin et al., 2017; Buhrman et al., 2016; Buhrman et al., 2013; Bendelin et al., 2020).

Recent systematic reviews and meta-analyses have further highlighted the capacity of digitally delivered psychological interventions to reduce the burden associated with chronic pain while simultaneously addressing structural barriers that often limit access to specialized psychological care (Blake et al., 2024; Vugts et al., 2018; Trindade et al., 2021; Rosser et al., 2023; Gandy et al., 2022; Moman et al., 2019; Pfeifer et al., 2020). Beyond clinical outcomes, digital interventions may promote continuity of care, support self-management, and facilitate the long-term application of adaptive coping strategies through flexible and patient-centered delivery models (MacLean et al., 2025; Trindade et al., 2021; Main et al., 2025; De la Vega et al., 2024). Several pilot, feasibility, and effectiveness studies published in Internet Interventions and related digital health journals have demonstrated the potential of guided and minimally guided digital psychological interventions for chronic pain (Buhrman et al., 2016; Bendelin, 2023; Reilly et al., 2024; Fioratti et al., 2022). In particular, guided internet-delivered ACT interventions have shown promising effects on pain acceptance, psychological flexibility, emotional functioning, pain-related disability, and valued activity engagement while maintaining high levels of treatment satisfaction, usability, and credibility among participants (Lin et al., 2017; Reilly et al., 2024; Rickardsson et al., 2020). Furthermore, qualitative investigations have reported that participants perceive online ACT programs as acceptable, empowering, and applicable to everyday pain management, particularly when interventions combine structured self-help content with therapist guidance, experiential exercises, and flexible access to materials (Bendelin et al., 2020; Main et al., 2025; Rickardsson et al., 2020).

Importantly, emerging evidence suggests that guidance may play a critical role in improving adherence, engagement, and treatment completion, which are increasingly recognized as key determinants of success in digital health interventions (MacLean et al., 2025; Trindade et al., 2021; De la Vega et al., 2024; Jones Berkeley et al., 2025; Ledel Solem et al., 2020). Consequently, recent research has emphasized the importance of evaluating implementation-related outcomes—including feasibility, acceptability, usability, engagement patterns, intervention adherence, therapeutic support intensity, and intervention exposure—in addition to traditional clinical endpoints (Trindade et al., 2021; Main et al., 2025; De la Vega et al., 2024; Jones Berkeley et al., 2025; Kassinopoulos et al., 2023). These outcomes are particularly relevant during the early phases of intervention development because they inform optimization strategies, identify barriers to uptake, and support the design of adequately powered efficacy trials (Main et al., 2025; De la Vega et al., 2024; Eldridge et al., 2016; Lackey and Wingate, 1986).

Collectively, these findings support the value of conducting pilot and feasibility studies before definitive efficacy testing and provide an important framework for interpreting the present MobACT study Evaluating usability, acceptability, participant engagement, guidance intensity, intervention exposure, and preliminary outcome signals is essential to determine whether a culturally adapted ACT-based intervention can be successfully implemented within the Italian healthcare context and warrant further investigation in a fully powered randomized controlled trial.

Notwithstanding strong evidence, ACT-based IBIs remain unexplored within the Italian CP context. MobACT is a translated and adapted internet-based ACT intervention tailored for individuals living with CP in Italy (Semonella et al., 2026). The program, delivered via the secure *Iterapi* platform (Vlaescu et al., 2026) integrates core ACT components within a structured online environment supported by therapist guidance and was culturally adapted from Swedish (Buhrman et al., 2013) for the Italian context to ensure linguistic appropriateness and contextual relevance. The adaptation process emphasized Italian-language clarity, examples and metaphors understandable to Italian users, compatibility with local chronic-pain care pathways, and accessibility for people who may need to engage with the material flexibly because of fluctuating symptoms. Before proceeding to a large-scale trial, a pilot evaluation represents a critical methodological step, enabling a preliminary examination of the program's feasibility in Italy. This includes assessing recruitment capability, intervention adherence, platform usability, and participant satisfaction and engagement-related indicators, while also identifying potential technical issues, navigation difficulties, and content-related barriers that may influence engagement and outcomes in subsequent RCTs.

Therefore, the present pilot RCT aimed to evaluate the feasibility acceptability, and usability of the MobACT program, an online ACT self-help intervention designed to increase CP acceptance in a sample of Italians with CP. Consistent with CONSORT recommendations for pilot and feasibility trials, clinical outcome analyses were treated as exploratory and were intended to inform the design of a future fully powered RCT rather than to establish efficacy.

2. Methods and materials

This present study used a pilot RCT design with 2 parallel groups, with equal allocation (1:1) to the intervention group and WL control group. The pilot was designed to examine the feasibility of recruitment, randomization, intervention delivery, follow-up assessment, platform use, and qualitative evaluation before a definitive efficacy and cost-effectiveness trial. Further details, such as themes of each session, topics covered, are detailed in the study protocol (Semonella et al., 2026) and the core intervention content is summarized below to make the present outcomes paper self-contained. This study is registered at ClinicalTrials.gov (NCT07270588) and received approval by the Ethics Committee of the Catholic University of Sacred Heart of Milan, Italy (Approval Number:146/24). The trial follows CONSORT reporting guidelines for randomized pilot and feasibility trials (Eldridge et al., 2016) (See supplementary material 1).

2.1. Participants and procedures

2.1.1. Participants

Participants were included in the MobACT pilot study, starting October 2025, if they provided informed consent online and fulfilled the following: 1) age 18 years or older, 2) verified medical diagnosis of chronic pain (duration $\geq$3 months, 3) access to internet, 4) Adequate computer and internet literacy to engage with the programme, 5) Fluent knowledge of the Italian language. Exclusion criteria included: 1) Current participation in psychological or psychotherapeutic treatment for chronic pain, 2) high suicide risk, 3) Diagnosed psychiatric conditions including: a) psychotic disorders (e.g., schizophrenia, schizoaffective disorders), b) bipolar disorder with unstable maniac/hypomanic episodes, c) severe depressive disorders (e.g., major depression with suicidal intent or recent suicide attempts), d) severe personality disorders affecting daily functioning (e.g., ability to work, self-care), e) cognitive or neurological impairments or disorder. Exclusion criteria were evaluated through the online screening questionnaires, including the WSQ, and a subsequent telephone interview conducted by a licensed psychologist; the interview clarified current psychiatric diagnoses, manic/hypomanic symptoms, suicide risk, psychological treatment for pain, cognitive or neurological impairment, and the degree to which personality-related difficulties interfered with daily functioning. Ambiguous cases were reviewed by the clinical team before randomization.

2.1.2. Procedure

Upon accessing the registration link for the MobACT project, potential participants were first presented with detailed information regarding the study aims, inclusion and exclusion criteria, registration procedures, and instructions for accessing the online platform. After providing informed consent, participants completed an initial online screening assessment using standardized questionnaires (e.g., Web Screening Questionnaire, WSQ) to determine preliminary eligibility. Individuals who met screening criteria were subsequently invited to participate in a telephone interview conducted by a licensed psychologist. Final eligibility was determined through a joint review by the clinicians, based on both quantitative screening data and qualitative interview content, and participants were informed of their inclusion or exclusion within a few days. Eligible participants were then randomly allocated to one of two study arms: an intervention group receiving immediate access to the MobACT program or a WL control group receiving access after a seven-week period. Participants received no financial or material incentives for completing questionnaires or interviews. The treatment program consisted of seven modules (one module per week), which covered the following topics: 1) introduction to the treatment, 2) willingness and acceptance of pain, 3) defusion from negative thoughts, 4) committed action and values, 5) values and goal setting, 6) willingness exercises, and 7) maintenance of learned strategies. All study procedures were delivered through a secure online platform (*Iterapi*), which was used for therapist–participant communication, intervention delivery, and outcome data collection. Personal data were anonymized through the assignment of unique identification codes (e.g., 1128sdfg), and at the start of the intervention, participants received login credentials via email, including a username and a personalized link to create their password.

The intervention followed a locked sequential structure, whereby each module became available only after completion of the previous one. As the post-treatment assessment was released only after completion of Module 7, completion of the post-treatment assessment served as an indicator of full intervention completion.

Throughout the intervention period, participants received automated weekly email notifications informing them when new content became available. Reminder emails were also sent to participants who had not accessed the materials or completed the assigned exercises, to promote adherence. Participants had the opportunity to contact the study therapist via the platform if needed; however, no scheduled therapist sessions were planned. The system informed users that messages would receive a response within three working days. Outcome assessments were administered at two time points: pre-intervention (T0), post-intervention (T1). Moreover, following program completion, participants from the intervention group were invited to participate in semi-structured interviews exploring their experiences with both the therapeutic content and the digital platform. Participation in the study was entirely voluntary, and participants could withdraw at any time. The intervention content and ACT processes are summarized in Table 1 below.

2.2. Randomization

Participants were randomly assigned in a 1:1 ratio into either the intervention or the WL control group through an automated, computer-generated randomization procedure implemented within the *Iterapi* platform. Randomization occurred only after eligibility confirmation and baseline assessment. The sequence was generated by the platform, which reduced the possibility that assessors could foresee the next assignment. No stratification was used in this pilot, and blinding of participants and the study therapist was not possible because of the nature of the intervention and waitlist condition (Fig. 1).

2.3. Measures

Participants were asked to self-report their demographic characteristics at baseline, including gender, age, employment status, and civil status. Baseline clinical descriptors included current medication use (drugs; yes/no), self-reported comorbidities (yes/no), perceived health rated on a 0–100 visual analogue scale, and perceived digital competence rated from 1 to 10, with higher scores indicating greater perceived competence.

The Brief Pain Inventory (BPI) (Cleeland, 1989; Caraceni et al., 1996). was used descriptively to characterize pain severity and pain interference/intensity. The BPI includes 11 items assessing two domains: pain severity (4 items evaluating current, worst, least, and average pain during the previous 24 h) and pain interference (7 items assessing the impact of pain on daily functioning and quality of life). Scores for each subscale are calculated as the means of the corresponding items.

Table 1
MobACT module content and ACT processes.

Module	Topic	Main objectives	Exercises/metaphors
1	Introduction to Treatment	Introduce creative hopelessness and encourage reflection on previous unsuccessful pain-control strategies; foster openness to alternative approaches.	Man in the Hole metaphor
2	Willingness and acceptance of pain	Differentiate primary and secondary pain; introduce willingness and acceptance as alternatives to pain control strategies.	Shark Trap metaphor; Radio Metaphor
3	Defusion from negative thoughts	Develop mindfulness and cognitive defusion skills to reduce attachment to distressing thoughts and emotions	Bus Metaphor; mindfulness exercises
4	Committed action and values	Explore personal values and promote engagement in meaningful activities despite pain.	Chessboard Metaphor; mindfulness practices
5	Values and goal setting	Translate identified values into concrete goals and value-consistent actions.	Values Compass; The Skier Metaphor; My Party metaphor
6	Willingness exercises	Strengthening willingness to experience pain-related sensations and emotions without attempting to control or avoid them	My Party metaphor; experiential and mindfulness exercises
7	Maintenance of learned strategies	Consolidate treatment gains, review progress, and develop a long-term maintenance plan.	Maintenance planning; review exercises; mindfulness practices

Note: Each module was released weekly and could be revisited after release. Content combined psychoeducational text, metaphors, reflective writing, and experiential exercises; no scheduled synchronous sessions were included.

The Italian version of the Chronic Pain Acceptance Questionnaire (CPAQ-20) (Bernini et al., 2010), a widely used self-report measure designed to assess pain acceptance in individuals with CP, was also administered at the baseline (T0) and seven weeks after the intervention (T1). It is a 20-item self-report measure assessing pain acceptance in individuals with CP, grounded in the Acceptance and Commitment Therapy (ACT) framework. Items are rated on a 7-point Likert scale ranging from 0 (never true) to 6 (always true). The questionnaire comprises two subscales: Activity Engagement (AE, 11 items), reflecting participation in meaningful activities despite pain, and Pain Willingness (PW, 9 items), reflecting the absence of attempts to control or avoid pain. Subscale scores are calculated by summing item responses, with PW items reverse-scored prior to computation (reversed score = 6 – original score). A total score is obtained by summing the two subscales (range 0–120), with higher scores indicating greater levels of pain acceptance and psychological flexibility. Reliability analyses provided evidence of the internal consistency of the Italian version of the CPAQ-20: alpha coefficients were good (>0.80) for the AE and total score, and acceptable (> 0.70) for the PW domain. In the present study the measure showed good internal consistency at both baseline ($\alpha = 0.802$) and post-intervention ($\alpha = 0.842$).

To collect more insights regarding participants' experience of the MobACT program and intervention platform, a structured post-intervention interview was conducted for the experimental group participants. The interview comprised both multiple-choice and open-ended questions and was designed to explore the following key domains: 1) usefulness and usability of the MobACT program and intervention platform, 2) feasibility of the intervention and interaction with the therapist, 3) further suggestions and improvements for the present intervention and future development (e.g., "How would you describe your experience interacting with the online platform and your reference therapist?" or "To what extent do you feel able to apply the strategies learned during the program in your daily life, on a scale from 1 to 10? In what way?" or "Is there anything you would have liked to change or improve in the modules or in the structure of the program?"). Acceptability indicators included perceived ease of use, understanding of module content, negative experiences with the platform or therapist, whether the program met initial expectations, perceived ability to apply strategies, overall satisfaction, and open-ended suggestions for improvement.

2.4. Sample size calculation

An a priori power analysis (F tests) conducted with G*Power 3.1.9.2 (Cattivelli et al., 2018; Pietrabissa et al., 2019) indicated that 116 participants (58 per group) were required to achieve 95% power ($\alpha = 0.05$, two-sided) to detect an interaction effect size = 0.15 (Semonella et al., 2026). The present study was not powered to test intervention efficacy. The pilot sample was set pragmatically to evaluate recruitment, randomization, intervention delivery, retention, outcome-measure completion, usability, acceptability, and qualitative feasibility, and it exceeded the commonly cited minimum of 12 participants per group for pilot studies (Eldridge et al., 2016; Julious, 2005). With 20 participants per arm, statistical analyses were interpreted descriptively and used to estimate feasibility parameters and outcome variability for future trial planning.

2.5. Statistical analysis

Preliminary analyses examined univariate and multivariate normality, revealing no major violations of assumptions. Continuous variables were reported as means and standard deviations, while categorical variables were summarized using frequencies and percentages. Consistent with CONSORT guidance for randomized trials, baseline characteristics were interpreted descriptively rather than through null-hypothesis testing of baseline imbalance.

Given the pilot nature of the trial and the limited sample size, analyses focused primarily on pre–post changes in the primary outcome (CPAQ-20), in line with methodological recommendations for early-phase feasibility studies. Although the registered protocol includes a broader set of secondary clinical and process outcomes, these outcomes were not included in the present analyses because the pilot was not powered to support robust inferential evaluation across multiple endpoints. This analytic strategy was established a priori and should not be interpreted as selective outcome reporting. All protocol-specified secondary outcomes will be assessed in the future fully powered RCT.

Analyses were conducted according to the intention-to-treat (ITT) principle, with a significance level set at 0.05. Exploratory changes in CPAQ-20 were analyzed using a linear mixed-effects model with fixed effects for group, time, and the group × time interaction, and a participant-level random intercept to account for repeated measurements. The interaction term was treated as the primary exploratory estimate of differential change between conditions. Pairwise comparisons were not interpreted when the interaction was non-significant. Partial η^2 values were interpreted descriptively using conventional benchmarks of 0.01 (small), 0.06 (medium), and 0.14 (large) (Cohen, 2013).

Data were analyzed with SPSS version. 24.0 (IBM Corp., 2016). Moreover, a qualitative thematic analysis was conducted on data collected through structured interviews at the end of the MobACT program. An inductive approach was used to identify recurring patterns and themes grounded in participants' narratives on both psychological and social changes after participating in the program, with illustrative quotations selected to reflect their personal experiences (Braun and Clarke, 2019). The interviews also included open-ended questions exploring participants' satisfaction with the program, as well as perceived strengths, limitations, and areas for improvement.

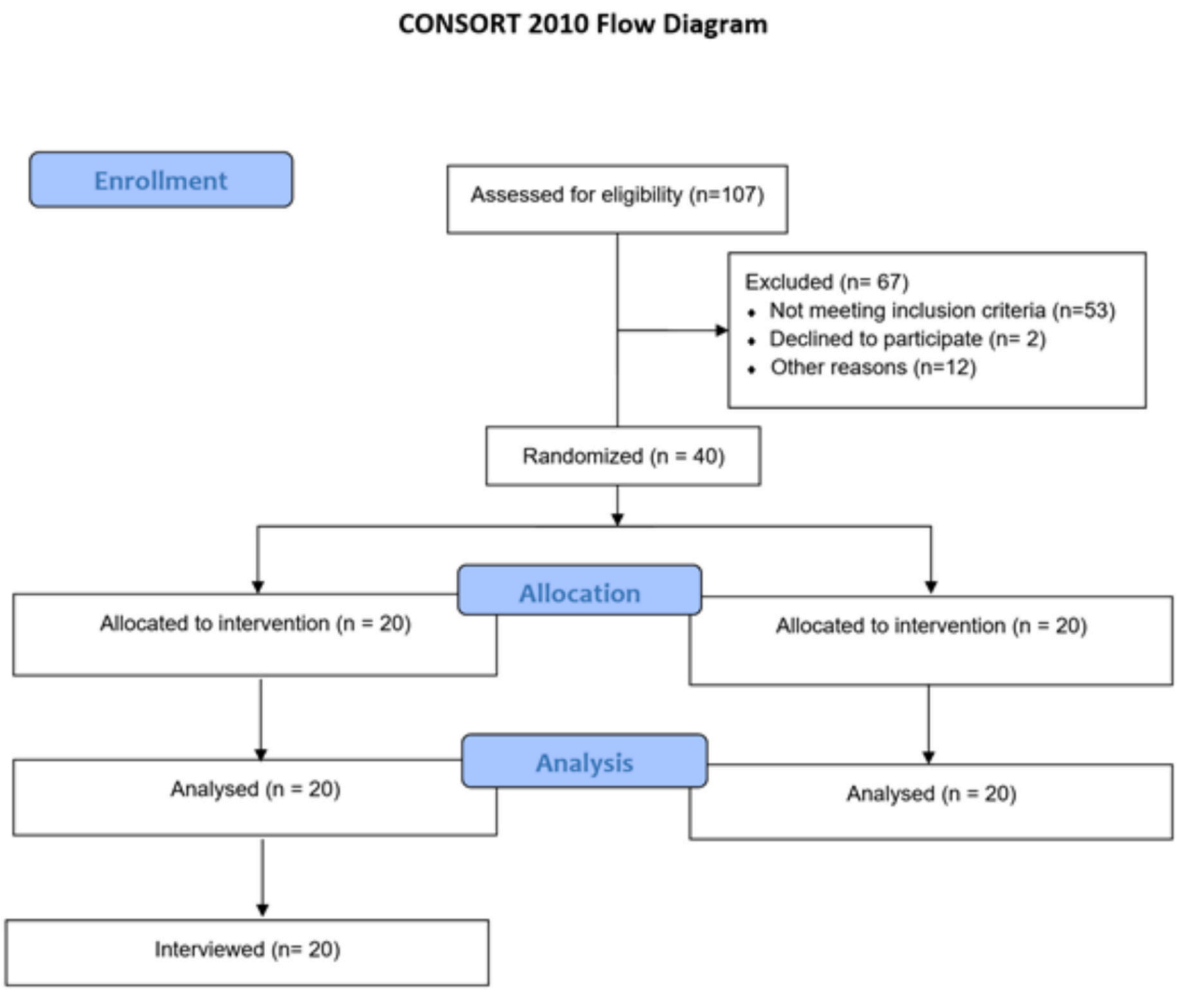

Fig. 1. CONSORT frow diagram of the MobACT pilot study.

3. Results

3.1. Characteristics of the sample

A total of 40 participants were included in the study (MobACT: n = 20; WL: n = 20). The sample's mean age was 53.75 years (SD = 13.56). The overall gender distribution was 92.5% female and 7.5% male, with similar proportions across groups (MobACT: 90% female; WL: 95% female).

Civil status varied, with 52.5% married and 30% single. Most participants were employed (42.5%) and retired (25%), with a smaller proportion of students (5%), unemployed (15%), and self-employed individuals (12.5%). Fifty-five percent of the total sample (n = 22) reported perceived social support. Medication use was reported by 29 participants (72.5%), including 15 (75%) in the MobACT group and 14 (70%) in the control condition (p = .493). Most of the participants (n = 31, 77.5%) presented comorbidities (MobACT: n = 17; WL: n = 14). Baseline variables are presented descriptively in Table 2; inferential p values were not reported because baseline significance testing is not recommended for randomized trial reporting and had generated avoidable inconsistencies in the previous version. Users reported generally low perceived health (M = 47.75, SD = 20.47) and high perceived digital competence (M = 8.60, SD = 1.17). At baseline, participants reported a mean perceived pain severity of 5.72 (SD = 1.81) and a mean pain intensity of 6.22 (SD = 1.93). Chronic pain acceptance (CPAQ-20) averaged 10.43 (SD = 4.21) in the total sample, with MobACT (M = 11.28, SD = 4.38) and WL (M = 9.73, SD = 4.03; p = .323) showing comparable descriptive values. Data are reported in Table 2 below.

3.2. Exploratory analysis of pain acceptance (CPAQ-20)

At baseline, the MobACT group showed a mean CPAQ-20 score of 39.35 (SD = 14.96), increasing to 51.80 (SD = 14.16) post-intervention. The waitlist (WL) group presented a baseline mean of 42.25 (SD = 13.03) and a post-intervention mean of 54.85 (SD = 16.18). Both groups therefore exhibited comparable descriptive improvements over time (MobACT: +12.45 points; WL: +12.60 points).

Exploratory changes in pain acceptance were analyzed using a linear mixed-effects model including fixed effects for group, time, and the group × time interaction, with a participant-level random intercept. Results indicated a significant main effect of time, reflecting an overall increase in CPAQ-20 scores across participants, $F(1, 38) = 20.84$, $p < .001$, partial $\eta^2 = 0.354$ (large effect). In contrast, the group × time interaction was not significant, $F(1, 38) = 0.001$, $p = .978$, partial $\eta^2 < 0.001$, indicating no evidence of differential change between the MobACT and WL conditions. The estimated between-group difference in change was −0.15 points (95% CI −10.90 to 10.60). The main effect of group was also not significant, $F(1, 38) = 0.64$, $p = .429$, partial $\eta^2 = 0.017$ (small effect).

Given the absence of significant interaction effects and the pilot nature of the study, no post hoc pairwise comparisons were conducted. All findings should therefore be interpreted as exploratory. Results are reported in Table 3.

Table 2
Group comparison of sample characteristics.

	Total sample (n = 40)		MobACT (n = 20)		WL (n = 20)	
	n	%	n	%	n	%
Gender						
Male	3	7.5	2	10.0	1	5.0
Female	37	92.5	18	90.0	19	95.0
Civil status						
Single	12	30.0	9	45.0	3	15.0
Married	21	52.5	8	40.0	13	65.0
Widowed	1	2.5	1	5.0	0	0
Divorced	6	15.0	2	10.0	4	20.0
Occupation						
Employee	17	42.5	11	55.0	6	30.0
Employer	5	12.5	1	5.0	4	20.0
Unemployed	6	15.0	1	5.0	5	25.0
Student	2	5.0	2	10.0	5	25.0
Retired	10	25.0	5	25.0	6	30.0
HelpHome (Support)						
Yes	22	55.0	11	55.0	11	55.0
No	18	45.0	9	45.0	9	45.0
Drugs						
Yes	29	72.5	15	75.0	14	70.0
No	11	27.5	5	25.0	6	30.0
Comorbidities						
Yes	31	77.5	17	85.0	14	70.0
No	9	22.5	3	15.0	6	30.0
	M	SD	M	SD	M	SD
Age	53.75	13.56	53.60	13.87	53.90	13.59
Perceived_Health	47.75	20.47	45.50	20.77	50.00	20.45
Perceived digital competence	8.60	1.17	8.30	2.27	8.55	2.48
BPI_Severity	5.72	1.81	5.45	1.77	5.98	1.85
BPI_Intensity	6.22	1.93	5.54	2.28	6.90	1.33
CPAQ-20_SUM	10.43	4.21	11.28	4.38	9.73	4.03
CPAQ-20_Willingness	14.28	7.16	14.60	7.13	13.95	7.36
CPAQ-20_Engagement	26.53	9.67	24.75	9.83	28.30	9.32

Legend: CPAQ-20 = Chronic Pain Acceptance Questionnaire, BPI = Brief Pain Inventory, M = Mean, SD = standard deviations, WL = Waitlist. Note: baseline p values are not reported because baseline significance testing is discouraged for randomized trials and can be misleading in small pilot samples.

3.3. Feasibility, engagement, and acceptability indicators

All MobACT participants completed the post-intervention interview (20/20), indicating excellent short-term retention and feasibility of follow-up assessment in this pilot.

The intervention consisted of seven weekly modules delivered asynchronously. Participants received automatic weekly notifications when new materials were released and reminder emails when they had not accessed materials or completed assigned exercises. Detailed time-on-task data, module-by-module completion timestamps, number of participant-initiated therapist messages, and therapist minutes per participant were not prospectively extracted in a standardized log for this pilot; this limitation has been addressed in the planned full trial by adding prospective engagement and therapist-time monitoring. The available feasibility data nevertheless indicated high perceived usability: all interviewed participants reported that the platform was easy to use and that they had no negative experiences with the platform or therapist, 17/20 (85.0%) reported understanding module content, and mean satisfaction with the program was 9.11/10. See Table 4 for details.

3.4. Qualitative findings and perceived impact of the MobACT intervention

Qualitative analysis of post-intervention responses indicated that MobACT was generally perceived as clear, usable, and relevant. Participants most often described the platform as "easy," "useful," and "clear," and they particularly valued experiential ACT exercises that could be remembered and applied outside the platform. The most salient themes are summarized below to avoid overemphasizing individual comments while preserving the main feasibility and acceptability lessons.

First, participants described a shift from pain-focused rumination toward present-moment awareness: "The pain hasn't gone away, but the perspective has changed." Second, acceptance was described as an active change in perspective rather than resignation, as reflected in the statement: "Accepting pain is not giving up, but being willing to change perspective." Third, several participants reported improved emotional regulation and reduced automatic negative thinking, for example: "I take my time, I stop and reflect." Fourth, participants valued practical strategies, including breathing exercises, mindfulness practices, values clarification, and metaphors, because these techniques could be used during daily activities and symptom flares.

Several ACT exercises were specifically mentioned. The "Bus

Table 4
Feasibility and acceptability feedback for MobACT participants.

Indicator	n/ Mean	%/Scale
Platform was easy to use	20	100%
Understood the content presented in the modules	17	85.0%
Reported no negative experience with the MobACT platform	20	100%
Reported no negative experience with the therapist	20	100%
Program met initial expectations	18	90.0%
Program partially/not at all met expectations	2	10.0%
Perceived ability to apply ACT strategies	7.45	0–10
Overall satisfaction	9.11	0–10
Completed post-intervention interview	20	100%
Randomized participants retained to T1	40	100%
Modules delivered	7	1 per week
Scheduled therapist contact	0	Asynchronous guidance
Standardized therapist-time log available	No	Future-trial metric

Note: Percentages for acceptability indicators are calculated among intervention participants who completed post-intervention interviews (n = 20). Access to the post-treatment assessment was granted only upon completion of all seven intervention modules.

Table 3
Descriptive CPAQ-20 scores and mixed-model effects.

CPAQ-20 total score	MobACT (n = 20)	WL (n = 20)	Test statistic	*p* value	Partial η^2	Interpretation
Baseline, M ± SD	39.35 ± 14.96	42.25 ± 13.03	–	–	–	Descriptive
Post-intervention, ± SD	51.80 ± 14.16	54.85 ± 16.18	–	–	–	Descriptive
Mean Diff.	12.45	12.60	–	–	–	
95% CI	3.98, 20.93	4.85, 20.35	–	–	–	
Time	–	–	$F(1,38) = 20.84$	<0.001	0.354	Large
Group × time	–	–	$F(1,38) = 0.001$	0.978	<0.001	Negligible
Group	–	–	$F(1,38) = 0.64$	0.429	0.017	Small

Legend: CPAQ-20 = Chronic Pain Acceptance Questionnaire; M = mean; SD = standard deviation; WL = waitlist; η^2 = partial eta squared. *Note*: Partial η^2 values were interpreted descriptively using conventional benchmarks of 0.01 (small), 0.06 (medium), and 0.14 (large).

Metaphor" invited participants to notice thoughts and emotions as passengers while continuing to steer behavior toward valued directions; the "Gardening Metaphor" supported values-based cultivation of meaningful activities; the "Pool with Sharks" metaphor illustrated avoidance and willingness; and defusion exercises such as "I am not my pain, I feel pain" helped some participants distinguish themselves from pain-related thoughts. At the same time, feedback identified areas for refinement: shorter modules or shorter content segments to support concentration, more flexible timelines, greater therapist or peer interaction, improved accessibility options such as printable material for users who experience headaches with screen use, and clearer guidance for maintaining practice after the intervention.

4. Discussion

The present pilot RCT sought to examine the feasibility, acceptability, usability, and exploratory outcome signals of the MobACT intervention. Overall, the findings offer encouraging support for the feasibility, usability, and acceptability of the program, while also providing early indications of its potential clinical value and directions for further optimization before large-scale testing. Accordingly, clinical outcome findings should be interpreted as exploratory signals rather than estimates of intervention efficacy.

The exploratory quantitative findings showed that pain acceptance increased over time across both conditions, but the time × group interaction was essentially null. This parallel change is important: it may reflect measurement reactivity, expectancy effects associated with being enrolled in a chronic-pain intervention study, increased reflection prompted by repeated assessment, regression to the mean, or the natural fluctuation of chronic pain and pain-related coping over a seven-week period. Therefore, the within-group increases should not be interpreted as evidence that MobACT was superior to the waitlist condition. Future trials would be strengthened by a larger sample, longer follow-up, and consideration of an active or attention-matched comparator to help distinguish ACT-specific effects from non-specific study participation effects. The qualitative data nevertheless provides useful process information: participants described changes in how they related to pain, including present-moment awareness, defusion from pain-related thoughts, reduced rumination, and engagement in valued activities. These experiences are theoretically coherent with ACT, which conceptualizes improvement primarily as enhanced psychological flexibility rather than pain elimination (Cattivelli et al., 2018; Spatola et al., 2024; Hayes et al., 2012).

In this scenario, metaphors, mindfulness exercises, and acceptance-based practices were frequently identified as catalysts for perspective transformation, suggesting that the intervention's experiential design successfully operationalized core ACT mechanisms.

The *Iterapi* platform was perceived as accessible and user-friendly, and the program structure was generally experienced as compatible with daily routines. However, the absence of standardized time-on-task and therapist-contact logs limits conclusions about engagement and guidance intensity. The asynchronous guidance format appeared acceptable for most participants, yet requests for enhanced therapist interaction, peer contact, printable materials, and more flexible pacing indicate that the optimal balance between scalability and relational support remains an important area for refinement.

Overall, the results supported MobACT as an acceptable digital ACT program focused on changing how individuals relate to pain rather than on reducing pain intensity itself. This interpretation is consistent with the qualitative finding that several participants felt more capable of engaging in valued activities despite ongoing symptoms, but it must remain tentative until tested in a fully powered RCT with complete secondary outcome reporting and prospectively captured engagement metrics.

Based on participant feedback, the next version of MobACT should include shorter and more modular content segments, clearer instructions for long-term independent practice, optional printable materials, improved accessibility features, and structured opportunities for therapist feedback or peer support while preserving the scalability of asynchronous delivery. The fully powered trial should also prospectively log module completion, time spent on each module, number and type of therapist contacts, and therapist minutes per participant.

4.1. Strengths and limitations

The present study presents several methodological and clinical strengths alongside important limitations. The mixed-methods design enabled the integration of quantitative outcomes with qualitative data, providing a more comprehensive understanding of the intervention's impact and allowing psychological and behavioral changes to emerge beyond quantitative measures alone. In addition, this study represents the first pilot RCT evaluating a culturally adapted internet-based ACT intervention for adults with CP in Italy, addressing a relevant gap in the national digital mental health landscape and enhancing ecological validity for Italian users. The randomized design, even within a pilot framework, further strengthened the assessment of procedural feasibility by demonstrating the ability to implement controlled recruitment, allocation, outcome assessment, and post-intervention interviews. In addition, the high levels of usability and acceptability support the potential scalability of the MobACT program. However, findings must be interpreted cautiously because the sample was small, not powered for efficacy, and highly imbalanced by gender. The high self-rated digital competence of participants suggests possible selection bias toward individuals already comfortable with digital tools, which may inflate usability and satisfaction estimates and limit generalizability to people with lower digital literacy. The waitlist control condition did not control attention, expectancy, or repeated-assessment effects, and both arms improved similarly on the CPAQ-20. The reliance on self-report measures may introduce response bias, and the short follow-up prevents conclusions about maintenance. In addition, module-level time-on-task, module completion, and therapist-contact minutes were not systematically extracted, limiting interpretation of adherence and guidance intensity. Finally, the broader protocol-specified secondary outcomes were not analyzed inferentially in this pilot report; these outcomes should be reported descriptively or comprehensively in the definitive trial to prevent concerns about selective outcome reporting.

4.2. Future development of MobACT

The findings of this pilot study informed several planned refinements for the next version of MobACT and for the forthcoming fully powered RCTS. Future iterations of the platform will include prospective automated logging of module completion, time spent on each module, total platform use, participant-initiated therapist contacts, and therapist time dedicated to each participant. In the definitive trial, additional monitoring procedures will be implemented to systematically track participant attrition, dropout patterns, and therapist contact intensity over time. These indicators will provide a direct assessment of the capacity of the asynchronous guided intervention model to sustain participant engagement throughout treatment.

Recruitment procedures will also be expanded to achieve a more balanced sample composition, including greater representation of men and participants with lower levels of confidence in using digital technologies. These groups are often underrepresented in digital mental health research despite frequently facing substantial barriers to accessing traditional psychological services. Evaluating feasibility and engagement across a broader range of users will improve the external validity and implementation potential of MobACT within routine chronic pain care.

5. Conclusion

In conclusion, the present pilot RCT provides preliminary support for the feasibility, acceptability, and usability of MobACT as a guided internet-based ACT intervention for individuals living with CP in Italy. Still, no differential improvement in pain acceptance was observed between MobACT and the waitlist condition; therefore, efficacy conclusions are not warranted from this pilot sample.

Qualitative findings suggest that participants perceived the program as useful for present-moment awareness, defusion from pain-related thoughts, emotion regulation, and engagement in valued activities. These findings justify progression to a larger, fully powered RCT that includes longer follow-up, comprehensive secondary outcome reporting, prospective engagement metrics, and consideration of a more active comparator.

Ethical approval

This study has been conducted in compliance with the Declaration of Helsinki and with all relevant national regulations governing research involving human participants. Ethical approval has been obtained from the Ethics Committee of Università Cattolica del Sacro Cuore, Milan (Approval Number:146/24).

Trial registration

The trial has been registered on ClinicalTrials.gov under Identifier NCT07270588.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, the authors used ChatGPT to assist with paraphrasing and language editing. Following the use of this tool, the authors carefully reviewed and revised the content as necessary and take full responsibility for the final version of the manuscript and its content.

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Safety procedure

A trained clinician was available to promptly contact any participant who reported suicidal ideation or significant psychological distress during the study. The clinician conducted an initial risk assessment and provided appropriate guidance regarding available mental health services. When clinically indicated, participants were advised to seek timely support from their general practitioner, the local Mental Health Centre, or emergency services.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors report no conflicts of interest related to the development, evaluation, or dissemination of the intervention described in this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2026.100972.

Data availability

This set of raw data is accessible upon request because it includes sensitive information. Please write your request to g.pietrabissa@auxologico.it.

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