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Research paper

Comparative efficacy of PsyPills and OCAT mobile psychological interventions in reducing depressive, anxiety and stress symptoms: A blinded randomized clinical trial

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ABSTRACT

Background: Digital applications, such as in smartphone apps format, have shown high suggestive evidence for their efficacy in reducing general distress, but rigorous studies of their efficacy in symptom change and the mechanisms involved are still needed.
Methods: In the current multi-arm parallel-group randomized trial, participants aged 18–65 with smartphone access were recruited through social media. They were randomly assigned to two app interventions (PsyPills and OCAT) or an active placebo group (shamOCAT). The primary outcome was psychological distress measured up to one month.
Results: A total of 229 participants from diverse regional and demographic groups of the general population of Romania were randomly allocated into the three groups (PsyPills $n = 80$; OCAT $n = 70$; shamOCAT $n = 79$) and included in intention-to-treat analyses. Both the PsyPills ($MD = -522$; 95%CI $= -10.00$ to -0.44; $d = 0.48$) and OCAT ($MD = -6.30$; 95%CI $= -11.39$ to -1.21; $d = 0.58$) reduced significantly, with medium effect sizes, the psychological distress levels compared with the control group at follow-up. For the separate outcomes, only PsyPills showed significant medium reduction effects for anxiety symptoms ($MD = -2.17$; 95%CI $= -3.83$ to -0.50; $d = -0.60$), while OCAT showed reduction effects of small size for depression ($MD = -1.50$ (95%CI $= -3.53$ to 0.54, $d = -0.34$), that was however statistically nonsignificant.
Limitations: We registered high attrition and low adherence rates. Also, lower-than-planned effects might have been statistically underpowered to detect.
Conclusion: The results support the high potential of both apps as scalable tools to provide low-intensity self-guided interventions for common psychological problems in the general population and expand opportunities for further research (e.g., confirm and capitulate on the differential effects).

1. Introduction

Stress-related disorders, including anxiety and depression, are prevalent in the general population (GBD 2019 Mental Disorders Collaborators, 2022; Santomauro et al., 2021), often resulting from prolonged maladaptive stress responses (Bystritsky and Kronemyer, 2014). Addressing this psychological distress is crucial to prevent clinical stress-related disorders, which entail significant individual and societal costs (OECD, 2018).

Digital interventions, particularly mobile-based formats (mHealth), are recognized as scalable and feasible low-intensity methods for tackling psychological distress, especially for the general population (Bakker and Rickard, 2018). Despite a recent comprehensive review finding limited evidence for their efficacy (Goldberg et al., 2022), the initial highly suggestive evidence in reducing common psychological problems (Goldberg et al., 2022), coupled with the cost-effective potential of these modalities, further support their future research. Specifically, we aimed to expand the mHealth psychological interventions literature on the

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impact of two promising different cognitive-based mobile applications (namely, PsyPills and OCAT) beyond their initial validation and proof-of-concept studies (Blanco et al., 2023; David and David, 2019).

PsyPills is the first mental health mobile application that integrates Rational Emotive Behavior Therapy strategies (REBT, Ellis, 2013), a distinct approach of Cognitive Behavioral Therapy (CBT). The REBT approach is mainly focused on challenging the irrational/dysfunctional beliefs (illogical, unrealistic, and contribute to emotional distress and maladaptive behavior) and strengthening the rational/functional ones (i.e., logical, flexible, and based on evidence and reason) to address mental disorders and promote emotional well-being (David et al., 2018). The app is based on the concept of 'Psychological Pills'©, originally developed by David (2016) and later adapted into an app format by David and David (2019) to reflect its evidence-based approach and alignment with a personalized medicine framework. In PsyPills, users track their emotional distress and identify the cognitive processes involved in it. Then, based on these inputs, the app prescribes a personalized reappraisal strategy called functional reappraisal, together with indications on how and when to use it, in order to change users' distressing emotions into functional ones. In the emotion regulation literature, functional reappraisal differentiates from other types of reappraisal strategies (e.g., positive, detached) in that the person is encouraged to engage even with a negative emotion but attempts to gain a more functional insight of its context (e.g., less catastrophization and accepting the situation, allowing for goal-directed behaviors) and shifting from a dysfunctional one (e.g., self-defeating beliefs and emotions; Cristea et al., 2012). A previous preliminary study using this strategy, delivered in the exercises format of the PsyPills app, has investigated the app's effectiveness over a 6-month period. Results showed that PsyPills' users significantly reduced the frequency of distressing emotions and reported more functional emotions after the use of the app (David and David, 2019). However, this initial real-life design did not allow for employing a control group and validated outcome measures, awaiting further studies to address these. Also, a considerable proportion of the users were from the psychology domain, limiting the large scale generalization of results.

Another promising and innovative smartphone app is OCAT. More specifically, OCAT is grounded in the cognitive bias modification paradigm (CBM; MacLeod et al., 2009). CBM posits that a core risk factor underlying the onset and further persistence of stress-related disorders is the presence of negative cognitive biases (i.e., preferential attention to negative information and tendencies to interpret ambiguous information negatively) in the information processing of relevant events (Martinelli et al., 2022). Bridging from the latest developments in eye-tracking assessment and training technologies of the cognitive-affective mechanisms of mental health (Sanchez-Lopez et al., 2019a, 2019b), OCAT has been developed by Blanco et al., 2023 as an innovative intervention that delivers the contents and tools used in previous forms of the training in an accessible app format. The app works through the same proofed principles of facilitating attentional disengagement from negative content and positive engagement of personally relevant information, providing instruction and performance feedback to facilitate top-down cognitive control and to improve the generation of adaptive interpretations. In these procedures, participants are presented with ambiguous sentences (e.g., "born loser am I winner a") that can be solved either positively or negatively (e.g., "I am a born winner" or "I am a born loser", respectively), and different techniques are used to train participants to shift and maintain their attention towards positive over negative information, to solve sentences more positively, thus training both attention and interpretation biases. In two recent proof-of-principle studies (Blanco et al., 2023), the OCAT has been found effective in modifying the cognitive processes of attention and interpretation, together with initial support for its transfer effects on anxiety and rumination, in two samples confronting with naturalistic stressful periods (i.e., undergraduates prior an exam, and a community sample during the lockdown restrictions at the beginning of COVID-19 pandemic, respectively). Although the results and the prospect of a training app capable of modifying cognitive processes underlying successful psychological adjustment are promising, there remains a need for proper randomized controlled trials to confirm its efficacy.

Overall, both PsyPills and OCAT have been previously validated as promising mobile-phone psychological interventions to reduce general distress in the general population, yet further steps are required to test their efficacy under rigorously controlled designs. In improving the literature's evidence-base quality on this issue, previous meta-analytic reviews on mobile phone psychological interventions have identified, among other important methodological aspects, the need to include an active control comparison (preventing confounding the intervention-specific effects from the effect of nonspecific factors of time, attention and expectation (Goldberg et al., 2023), the use of intention-to-treat analyses (reducing the risk of bias associated with incomplete outcome data) and preregistration of outcomes (preventing selective reporting bias). The investigation of the long-term effects, by including different follow-up time points, has also been a notable shortcoming of primary studies in this new field, repeatably pointed out in the mHealth literature in need of addressing. In addition, although meditation is one of the most widely used strategies in mHealth app interventions (Coulon et al., 2016; Gál et al., 2021) and has shown particularly promising efficacy, especially for reducing symptoms of depression (Gál et al., 2021; Goldberg et al., 2022), other evidence-based strategies remain underrepresented within the current mental health app landscape. This is the case with cognitive behavioral therapy (CBT) techniques (e.g., cognitive restructuring, emotion regulation, bias modification), which, although they have demonstrated efficacy (David et al., 2018; Martinelli et al., 2022), remain relatively underintegrated in current apps (Weisel et al., 2019). Thus, we aimed at incorporating all these components, while testing the efficacy of both PsyPills and OCAT in a community sample. This approach also allowed us to investigate the comparative efficacy of different, previously validated mHealth approaches (another common limitation in previous work; see Goldberg et al., 2023) and to disentangle the key active ingredients of each in a rigorously controlled design. Following such directions, the current study aims to contribute to the literature by comparing two psychological apps delivered in the general population against a placebo active control condition, at both ten days post-intervention and one-month follow-up and tested their effects on the reduction of psychological distress symptoms.

2. Methods

2.1. Study design

The research design of the present study is a multi-arm parallel-group randomized trial, with four waves of data collection (at baseline, mid, post, and follow-up), conducted following the extension of the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines for multi-arm parallel-group randomized trials (Juszczak et al., 2019) and focuses on the comparative hypotheses of the primary efficacy outcomes. A study protocol was registered on March 15th, 2022, at ClinicalTrials.gov, with the following ID: NCT05294809, before the participant recruitment was started. The statistical analyses plan, together with study hypotheses, and methods were preregistered on May 8, 2023, at the Open Science Foundation, prior to analysis of the data. A view-only link is available at: https://osf.io/6b2e7/?view_only=b4e17bf285ea405ca02f6a3a11e43ce7. For the present paper, we are focusing on the comparative hypotheses for the primary outcomes (i.e., stress, anxiety, and depression symptom levels).

The trial received approval from the Scientific Council of the Babeș-Bolyai University of Cluj-Napoca, having the approval number: 13.912/29.10.2021.

2.2. Procedure

Once consenting to participate and agreeing to the study's requirements, participants were randomly assigned to one of three conditions: two experimental conditions (PsyPills and OCAT) and an active placebo control group (sham version of OCAT). Measurements were collected before intervention allocation (baseline), five days during (mid), at the end of the ten-days intervention (post), and at one month after the intervention (follow-up). All measurement phases were collected online.

Immediately after completing the baseline questionnaire, the participants received an email with the download and access links and a PDF material with the usage and safety instructions for the allocated application (i.e., PsyPills, active OCAT, or sham-control OCAT). Participants were warned to take into account the fact that the application received is only intended for the management of mild and transient negative states and, therefore, is not intended to replace a psychological evaluation and appropriate treatment in case of persisting or worsening symptoms. Automated emails were sent with the follow-up questionnaires at five days (mid-intervention), ten days (post-intervention), and a month after the completion of the intervention. The app usage was self-guided with minimal contact with the study researchers, provided only at the request of technical support and/or study-related questions, by means of an email study contact and phone number provided in the instruction's material. Daily reminder emails for accessing the app in the ten days that each intervention period lasted were sent together with video demonstrations of the procedure.

2.3. Randomization and masking

Randomization was done automatically through the Qualtrics online questionnaire management platform, by equally randomly assigning participants to groups (1,1,1 randomization ratio) after completing the baseline questionnaire. Participants in all groups were informed that they would receive and use a mobile intervention for ten days, aimed at reducing general psychological distress, without knowing the rationale and specifics of each intervention. Outcomes were assessed only by online questionnaires, so no assessor was involved. The researcher team, including data manager and data analyst, were not blinded to the group allocation.

2.4. Participants

Participants included in the current study were recruited between June 2022 and May 2023 through social media posts from the general population of Romania. The eligibility criteria required participants to be be between 18 and 65 years old, and to have access to, and the ability to use a smartphone. The participants were rewarded by being provided a personalized report about their psychological profile recorded through the assessment used in this study.

2.5. Interventions

2.5.1. PsyPills

PsyPills is a freely available app on Google Play and the Apple App Store. Users start by monitoring their emotional state over recent weeks using the MoodWheel assessment module, a questionnaire app that integrates in a graphically intuitive way a dimensional circumplex model with a discrete emotions format. It employs discrete emotion terms to map the different qualities of emotions and incorporates a binary model of emotions by considering functional and dysfunctional dimensions for both positive and negative emotions alike (David, 2013; Tomoiagă et al., 2024). A graph is then generated showing functional and dysfunctional levels of positive and negative emotions. This self-monitoring module was complemented by a pulse measuring measure based on the photoplethysmogram technique by using the phone's camera. Next, users were instructed to select from a list a specific dysfunctional negative emotion to focus and work on. The Emotion tracking source module followed then with the assessment of three cognitive processes: (1) The domain of the emotion, where the participant can select from different options the life domain area (e.g., career, health, education) for which the above negative emotion state was concerned about; (2) Irrational processes, selecting from six processes representing: demandingness, awfulness, frustration intolerance, global evaluation of self, global evaluation of other, and global evaluation of life; and (3) Belief content, with four options representing: achievement, approval, comfort, and fairness. The above options were based on the relevant irrational processes and content areas in the REBT literature (David et al., 2018). Based on their responses, users receive personalized rational statements to help them change their negative dysfunctional emotions into functional ones. Video tutorials are available to aid understanding. After reflecting on the rational statement, users reassess their emotional state. The session ends with personalized recommendations for rational thinking. Users can save or share their "psychological prescription," set reminders, and review past prescriptions within the app. More details for the app description can be found in David and David (2019).

2.5.2. Active OCAT

OCAT is a web app accessible on mobile phones or computers via the *E*-motion online platform. Participants register and undergo a practice module of 10 trials, where they can exercise the main initial procedure. That is, a variant of the scrambled sentence task (SST), which prompts the user to order a series of 6 scrambled words to create one of two possible grammatically meaningful sentences using 5 words from that series (e.g., the following series: "her June in birthday July fall" could be unscrambled correctly either "her birthday falls in June" or "her birthday falls in July").

A reading phase hides words behind squares, revealing one at a time for reading. After a set time of 14 s, participants unscramble the sentence. In the daily training module for the following 48 training trials, disposed of in 8 training blocks of 6 trials each, neutral sentences are replaced with emotional ones. Participants aim to unscramble sentences with positive emotional meanings. Real-time feedback highlights positive and negative words, aiding attentional focus. Graphs track progress in attending to positive content and response times. These online contingent and real-time feedback procedures were used to increase the time to attentionally engage with the positive content and decrease the time to disengage attention from the negative one while trying to decrease the response times to form positive over negative interpretations as much as possible.

2.5.3. Sham OCAT

The sham version of OCAT presented the same accessibility and functionality principles as the active version, but participants did not receive online,real-time feedback and the explicit emphasis on manipulating emotional content, which are considered the action mechanisms behind the active version. Thus, in the 8-block training section of each online session, they were only asked to unscramble the sentences with the first grammatically correct solution that came to their mind, without explicitly instructing them to form positive meanings nor using online contingent and real-time feedback procedures to implement attention control in engagement with positive information and disengagement from negative information. Details of the entire OCAT procedure together with the sham version are available in Blanco et al. (2023).

2.6. Measures

In the questionnaire sent the following demographic questions was included concerning information about age, gender, education, occupancy, residency, psychological problems, psychological treatment, physiological problems, physiological treatment, operative system of the smartphone.

The primary outcome representing psychological distress was measured using the Depression Anxiety Stress Scale-21 Romanian version (DASS-21R, Lovibond and Lovibond, 1995) which is the abbreviated 21 items version of the original DASS questionnaire translated into Romanian, with only 7 items on the three scales assessed, depression, anxiety, and stress. Scores can be obtained for each of these scales as well as an aggregated score standing for general psychological distress, with higher ones meaning worse outcomes. Internal consistency for each subscale and the total questionnaire showed excellent reliability at each time point assessed (see Table S1 from the supplementary materials).

2.7. Statistical analysis

Before conducting the data analyses, we inspected the data graphically and checked for any outliers, using the outlier labeling rule with a 2.2 multiplier factor as recommended in the literature (Hoaglin and Iglewicz, 1987). After identifying the outliers, we applied the Winsorizing method, replacing the outlier values with the nearest non-outlier values.

The demographic and baseline variables were compared across groups to test if there was any difference between them and that the allocation was successful, with one-way ANOVA and chi square tests for continuous and categorical outcomes respectively. To test the differential attrition rate between groups as well as if any demographic and dependent variable can predict it, we used logistic regressions to model the probability of dropout as a function of group membership, demographic and baseline variables. We quantified the missingness in the data by creating a missingness variable that represented the presence or absence of missing values for each variable. This variable can take values of 1 or 0 to indicate the missingness or non-missingness, respectively.

For the main comparative hypotheses, linear multilevel models were used, estimated with the full information maximum likelihood method, which allows missing data to be a function of observed variables included in the statistical model and making possible for the usage of all available data based on a full-intention-to-treat analysis. An AR(1) correlation structure was applied between the time points, and the number of random effects as well as the type of between-subjects covariance structure was determined analytically by comparing different models looking at the fit assessment tests, such as the chi-square likelihood ratio test. Each model included a time variable as the within-subject factor (coded as 1, 2, 3, 4 for the baseline, mid, post, and follow-up time points respectively), a group variable as a between-subject factor (coded as 1, 2, 3 for PysPills, OCAT and shamOCAT respectively), and their interaction as fixed effects. Time was modeled as a categorical factor. Significant interactions were followed up with pairwise post-hoc tests between groups at different time points using the EMMEANS subcommand in SPSS via syntax. Cohen's *d* for the between-group effect sizes was calculated by the difference of the estimated marginal means at the different follow-up time points of interest divided by the polled baseline standard deviations of each two groups comparisons (Feingold, 2009). Based on power analysis for mixed-effects models with an AR(1) correlation structure using the WebPower online tool (Zhang and Yuan, 2018), an effect size of 0.5, and AR(1) correlation parameter of 0.8, retention rate in groups: 1, 0.9, 0.8, 0.7, $SD = 1$, allocation ratio of 1, number of observation times = 4, and a significance level of 0.05, a total N of 77 per group (for a three-arm RCT, a total N of 231) was estimated to give a sufficient power of 0.80.

Besides the main preregistered confirmatory analyses, we conducted further exploratory analyses. First, we examined if any demographic features (age, gender, education, occupancy, residency), clinical features (psychological and physiological problems, psychological and physiological treatment) and engagement with the app moderated the symptom change resulting from the interventions. To achieve this, we included in the mixed models a main effect of the moderator of interest and examined the three-way interaction between the moderator, group, and time for statistical significance. We further proceeded to examine simple interaction effects between group and time across various moderator levels in response to significant three-way interactions.

All the analyses were performed in SPSS 27.

3. Results

A total of 493 participants completed the eligibility questionnaire, of which 229 were randomly allocated into the three groups (PsyPills $n = 80$; OCAT $n = 70$; shamOCAT $n = 79$) and included in the intention-to-treat analyses (see Fig. 1). Sample demographic and clinical characteristics at baseline can be consulted in Table 1. Most participants had a female gender (73.8 %), a higher education level (undergraduate and/or post-/graduate, 76.8 %), were living in an urban area (66.4 %), and were fully active workers (59.0 %). Regarding the clinical status, the majority had not or been previously confronted with a significant psychological or physiological problem (52.4 % and 65.9 %, respectively). The groups did not significantly differ on any of these baseline features or outcome values, as all p values of F and $\chi 2$ tests were above 0.05 (Table 1 and Table 2).

3.1. Attrition and adherence

The missing data rates registered at the follow-up assessment points (e.g., attrition) were 47 % at mid, 59.83 % at post, and 71.18 % at one-month follow-up across the whole sample. No significant predictor of differential attrition rates was found, whether it was the allocation in the study groups or baseline demographic and clinical characteristics that were investigated, as obtained from the logistic regression analysis (see Table S2 from the supplementary materials). For the adherence with the app interventions, the mean number of days of engaging with the prescribed ten days of usage was 3.03 ($SD = 3.56$), with a median of 1 day. No significant difference was observed between the three groups (see Table S3 from the supplementary materials for the separate adherence rates for the three groups).

3.2. General psychological distress

A random intercept model was chosen as the final model for the best fit for all the outcomes. Estimated means (*EMM*) and associated standard errors (*SE*) and 95 % confidence intervals (CI) from the linear mixed models by group and time points are displayed in Table 2.

For the general psychological distress outcome, we obtained a significant Group x Time interaction, $F(6, 225.65) = 225.65$, $p < 0.05$. Thus, there was a change in the participants' psychological distress symptoms across the four time points, different for the three intervention groups (as illustrated in Fig. 2). Following pairwise tests (as shown in Table 3), participants in both the PsyPills ($MD = -5.22$; 95%CI = −10.00 to −0.44; adjusted $p = 0.03$) and active OCAT ($MD = -6.30$; 95%CI = −11.39 to −1.21; adjusted $p = 0.02$) conditions showed a significantly greater reduction in the psychological distress levels compared with the control group at the follow-up. Although the second Sidak adjusted p-value was marginally non-significant for the PsyPills condition ($p = 0.09$), both interventions effects were of medium size (PsyPills, $d = -0.48$; OCAT, $d = -0.58$).

3.3. Depression, anxiety, and stress

For the separate depression outcome, we did not obtain a significant Group x Time interaction, $F(6, 184.253) = 1.20$, $p > 0.05$ (Fig. 2), although the active OCAT intervention demonstrated a small effect size ($d = -0.34$). Further examining changes within each group, there was also a significant decrease in depression for those in the active OCAT condition ($MD = -2.98$; 95%CI = −4.31 to −1.66; adjusted $p < 0.001$) across time, which was not found in either of the other two groups

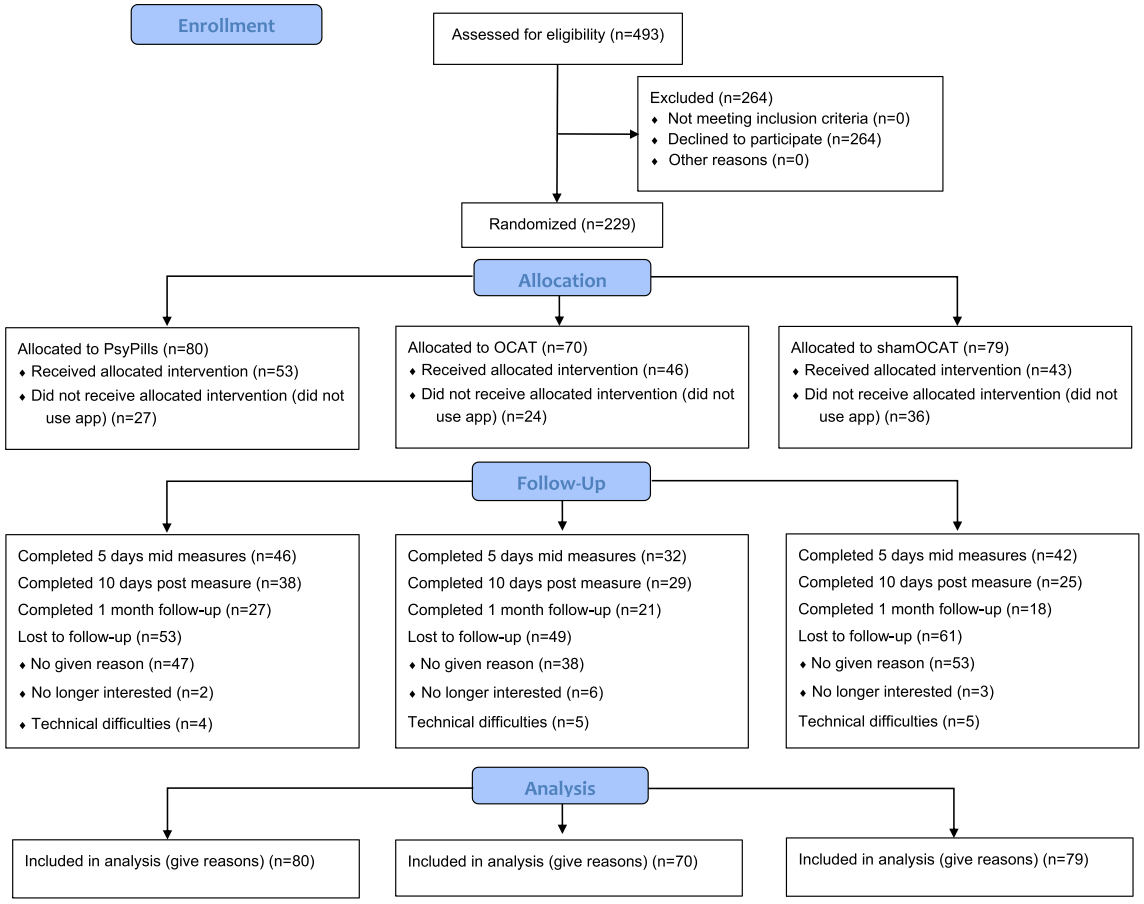

Fig. 1. CONSORT flow diagram.

(PysPills, $MD = -1.06$; 95%CI = −2.23 to 0.11; adjusted $p = 0.07$; control group, $MD = -1.20$; 95%CI = −2.55 to 0.14; adjusted $p = 0.08$).

For the anxiety outcome, there was a significant Group x Time interaction, $F(6, 227.45) = 2.41$, $p = 0.03$ (Fig. 2), and following pairwise comparisons, only participants in the PsyPills group significantly decreased their anxiety symptoms, with a medium effect size at follow-up in comparison with the control group ($MD = -2.17$; 95%CI = −3.83 to −0.50; adjusted $p = 0.01$; $d = -0.60$).

As for the stress outcome, analyses also supported a significant Group x Time interaction, $F(6, 186.45) = 2.42$, $p = 0.03$ (Fig. 2). Looking at the pairwise comparisons, both PsyPills and active OCAT apps significantly decreased the stress symptoms with medium effects size at the follow-up period (PsyPills, $MD = -2.64$; 95%CI = −4.72 to −0.56; adjusted $p = 0.01$; $d = -0.59$; and OCAT, $MD = -2.62$; 95%CI = −4.83 to −0.41; adjusted $p = 0.02$; $d = -0.58$).

3.4. Moderation effects

From the mixed models including a three-way interaction factor investigating the moderation effect of various demographic, clinical and app characteristics, only the education, $F(12, 187.13) = 2.42$, $p = 0.03$, and place of residency, $F(11, 216.25) = 3.15$, $p < 0.01$, reached a significant result. As such, only in the case of the active OCAT app, compared with the control group, showed a significant reduction in psychological distress at follow-up for participants with an undergraduate level of education ($MD = -8.44$; 95%CI = −16.83 to −0.51, $p < 0.05$), but not for those with a high school or graduate level of education. As for the place of residency, it was observed that only in the case of the PsyPills app, on this occasion, there was a significant reduction of psychological distress at follow-up for participants who lived in rural areas, compared with the sham OCAT ($MD = -15.28$; 95%CI = −29.64 to −0.91, $p < 0.04$).

Age, gender, occupancy, app engagement, psychological problems, psychological treatment, physical problems, and physical treatment did not moderate the symptom change from pre-intervention to follow-up (see Table S4 from the supplementary material).

4. Discussion

As expected according to our hypothesis, both apps obtained significant results for their reduction effect of general psychological distress levels compared with the placebo group, with small to medium effect sizes (PsyPills, $d = -0.48$; OCAT, $d = -0.58$). After adjusted for the multiple pairwise comparison, PsyPills obtained only a marginal significant effect ($p = 0.09$). Although this result is, strictly speaking, not statistically significant, this could rather point to potential limitations in statistical power, given the effect was medium and practically meaningful. Moreover, when analyzed separately for each specific symptomatic outcomes, specific effects for each intervention were observed. As for anxiety, PsyPills had a sole significant result, reducing the outcome with a medium effect size ($d = -0.60$), while for stress, both apps performed significantly better than the control condition (PsyPills, $d = -0.59$; OCAT, $d = -0.58$). In the case of depression, although no significant effects were supported, the trend was still in the expected direction, with an effect size of $d = -0.34$ obtained for the active OCAT app intervention. To note, all the above significant findings were obtained only at the end of the follow-up time of a month, but not at immediate post-training assessment. These suggest that the effects of these interventions may require some time to consolidate, as users implement the trained strategies and processing modes beyond the training when

Table 1
Sample demographic and clinical characteristics.

Variable	Overall	Study group			*P* value[a]
		PsyPills	OCAT	ShamOCAT	
Age (years) Mean (*SD*)	30.00 (10.70)	33.61 (10.81)	32.10 (10.74)	33.56 (10.66)	0.650
Gender, *n* (%)					0.731
Female	169 (73.8)	55 (68.8)	58 (82.9)	56 (70.9)	
Male	31 (13.5)	8 (10.0)	11 (15.7)	12 (15.2)	
Education, *n* (%)					0.652
High School	24 (10.5)	5 (6.3)	9 (12.9)	10 (12.7)	
Undergraduate	72 (31.4)	24 (30.0)	27 (38.6)	21 (26.6)	
Post-/graduate	104 (45.4)	34 (42.5)	33 (47.1)	37 (46.8)	
Occupancy, *n* (%)					0.191
Worker	135 (59.0)	49 (61.3)	42 (60.0)	44 (55.7)	
Student	36 (15.7)	9 (11.3)	15 (21.4)	12 (15.2)	
Unemployed	2 (0.9)	0 (0)	2 (2.9)	0 (0)	
Other	27 (11.8)	5 (6.3)	10 (14.3)	12 (15.2)	
Residency, *n* (%)					0.132
Rural	27 (11.8)	7 (8.8)	11 (15.7)	9 (11.4)	
Suburb	21 (9.2)	6 (7.5)	3 (4.3)	12 (15.2)	
Urban	152 (66.4)	50 (62.5)	55 (78.6)	47 (59.5)	
Psychological problems, *n* (%)					0.767
No	120 (52.4)	39 (48.8)	39 (55.7)	42 (53.2)	
Yes	80 (34.9)	24 (30.0)	30 (42.9)	26 (32.9)	
Psychological treatment, *n* (%)					0.349
No treatment	46 (20.1)	13 (16.3)	14 (20.0)	19 (24.1)	
Counselling/ Psychotherapy	23 (10.0)	8 (10.0)	11 (15.7)	4 (5.1)	
Pharmaceutic	4 (1.7)	1 (1.3)	2 (2.9)	1 (1.3)	
Physiological problems, *n* (%)					0.987
No	151 (65.9)	48 (60.0)	52 (74.3)	51 (64.6)	
Yes	49 (21.4)	15 (18.8)	17 (24.3)	17 (21.5)	
Physiological treatment, *n* (%)					0.774
No	13 (5.7)	5 (6.3)	4 (5.7)	4 (5.1)	
Yes	36 (15.7)	10 (12.5)	13 (18.6)	13 (16.5)	
Operative System, *n* (%)					0.451
Android	130 (56.8)	37 (46.3)	47 (67.1)	46 (58.2)	
iOS	70 (30.6)	26 (32.5)	22 (31.4)	22 (27.8)	

[a] The statistical significance *p* value from several tests (*F* test for continuous variables and $\chi 2$ for categorical ones) comparing demographic characteristics between study goups.

encountering distressing situations in their daily life function. Regarding further exploratory hypotheses, no demographic (age, gender, occupancy, residency), app (engagement), or clinical features (psychological problems, psychological treatment, physical problems, physical treatment) moderated the main symptom change effects observed from pre-intervention to follow-up for any of the interventions, except the education level. Here, the benefits of the active OCAT app compared with the control group were significantly greater in terms of general psychological distress for participants with an undergraduate level of education, but not in the case of participants with a high school or graduate level of education.

The results confirm the similar effectiveness of both interventions to target the symptomatology of psychological distress, with a medium effect size, and indices of specificity in the mechanisms involved (PsyPills with a larger effect size on Anxiety, and OCAT in Depression, although with a non-significant difference). The present findings are congruent with those observed in the meta-analytical literature (Goldberg et al., 2022), where small to medium magnitude effects (ds = 0.32 to 0.47) were obtained for smartphone interventions compared to inactive controls on the reduction of common psychological symptoms (anxiety, depression, stress) in the general population. The control group in our study can be categorized as a placebo active control, which allow to control for potential confounding nonspecific factors and assures a superior strength of evidence compared with inactive control groups used in other studies (Goldberg et al., 2023). Thus, although there is a known tendency for the effect sizes in these studies to weaken as comparisons become more rigorous (Goldberg et al., 2022), the present findings still indicate valid effect sizes. For that matter, other large effects for CBT based apps were found in the literature (e.g., Levin et al., 2019) while in a recent meta-analysis (see Linardon et al., 2019), smartphone interventions with a CBT orientation were significantly associated with larger effect sizes in anxiety, and stress, effect sizes which are similar to ours (ds = 0.42, and 0.61, respectively). The small-to-medium effects observed in the present study, when active interventions are compared to an active control, can thus be more representative of the efficacy of CBT apps beyond the effect of time and expectancy. The present study can thus contribute to broadening the scope of future meta-analyses, which should consider not only pooled effect sizes for different control conditions, but also different types of apps within each control category.

The finding that PsyPills was the only effective specifically for anxiety symptoms, might suggest a predilection usage and a particularly efficient way of targeting anxious symptoms, by addressing the irrational beliefs that sustain them, in an easy and interactive format. Indeed, in the original study of the preliminary effectiveness of Psypills (David and David, 2019), the authors observed that among user, the most frequent reason for accessing the apps was the need for anxiety relief.

Compared with the results from the two proof-of-concept studies (Blanco et al., 2023), the OCAT did not result in significant reduction for anxiety compared with the control, although there was a significant reduction from pre to follow-up within the group while the same had not been obtained for the control group. This non-significant result for the between-group comparison could be related to the particularity of the sample, as in the second validation study, in a community sample similar to ours, there were no significant results for anxiety either, compared with the first study, where an undergraduate sample was used. Indeed, the moderation results, showing an effect of OCAT against the control, only in the case of undergraduate education level, seem to indicate a particularly higher effect for this population type. In this sense, given the type of instructions and usage principles of OCAT, which may require a relatively higher level of technical proficiency and time, it is conceivable that a younger, more available, and more tech-savvy population could find more value in a self-guided training format like this.

The other significant moderator found seem to converge to a similar interpretation. The residency area of the participant influenced the comparative efficacy of the intervention apps, in that only the PsyPills was efficient, and this finding was conditional of the participants living in a rural area. The ease of access and interactive app format might be what allow the PsyPills distress reducing content to be available even for participants in a rural area of Romania, where access to internet and technical abilities are expected to be more limited in such contexts. These moderation analyses were exploratory and should be interpreted with caution as there was no statistical power planned for them and no controlling methods. But they seem to indicate a specificity in the application depending on the demographic characteristics of the target

Table 2
Descriptive statistics for repeated measures by group and time point.

Group and outcome	Pretest	Mid treatment	Posttest	Follow up	*P* value[a]
	EMM[b] (*SE*; 95 % CI)	*EMM* (*SE*; 95 % CI)	*EMM* (*SE*; 95 % CI)	*EMM* (*SE*; 95 % CI)	
PsyPills					
DASS	13.89 (1.16; 11.61–16.167)	12.60 (1.30; 10.04–15.16)	10.57 (1.40; 7.82–13.33)	9.61 (1.62; 6.43–12.780)	0.18
Depression	4.31 (0.46; 3.40–5.22)	3.33 (0.52; 2.31–4.35)	2.98 (0.56; 1.88–4.09)	3.25 (0.65; 1.97–4.53)	0.29
Anxiety	3.40 (0.38; 2.65–4.16)	3.28 (0.45; 2.39–4.16)	2.07 (0.48; 1.12–3.02)	1.56 (0.56; 0.45–2.67)	0.34
Stress	6.18 (0.49; 5.22–7.14)	5.98 (0.56; 4.89–7.07)	5.36 (0.60; 4.18–6.55)	4.66 (0.70; 3.30–6.03)	0.18
OCAT					
DASS	17.21 (1.24; 14.77–19.65)	13.99 (1.48; 11.06–16.91)	12.53 (1.59; 9.40–15.65)	8.53 (1.84; 4.91–12.14)	N/A[c]
Depression	5.41 (0.50; 4.43–6.38)	4.38 (0.59; 3.21–5.54)	3.46 (0.64; 2.21–4.72)	2.42 (0.73; 0.99–3.859)	N/A
Anxiety	4.23 (0.41; 3.42–5.04)	3.14 (0.52; 2.12–4.17)	3.34 (0.55; 2.26–4.42)	2.17 (0.63; 0.93–3.41)	N/A
Stress	7.58 (0.52; 6.55–8.61)	6.42 (0.64; 5.17–7.68)	5.89 (0.69; 4.54–7.24)	4.69 (0.79; 3.13–6.24)	N/A
shamOCAT					
DASS	15.60 (1.16; 13.31–17.88)	13.77 (1.34; 11.13–16.41)	11.77 (1.60; 8.63–14.91)	14.82 (1.82; 11.25–18.40)	N/A
Depression	5.13 (0.46; 4.21–6.04)	4.13 (0.54; 3.08–5.18)	3.19 (0.64; 1.93–4.44)	3.92 (0.73; 2.48–5.37)	N/A
Anxiety	3.53 (0.39; 2.78–4.29)	3.01 (0.47; 2.09–3.93)	2.87 (0.56; 1.77–3.97)	3.72 (0.64; 2.47–4.97)	N/A
Stress	6.94 (0.49; 5.97–7.90)	6.43 (0.57; 5.31–7.56)	5.53 (0.69; 4.16–6.89)	7.30 (0.90; 5.73–8.87)	N/A

[a] *p* value from one-way analyses of variance predicting baseline values for outcome measures by group status.
[b] *EMM*: estimated marginal means from linear mixed-effects models at each of the 3 study time points shown for each intervention arm and each outcome measure.
[c] N/A: not applicable.

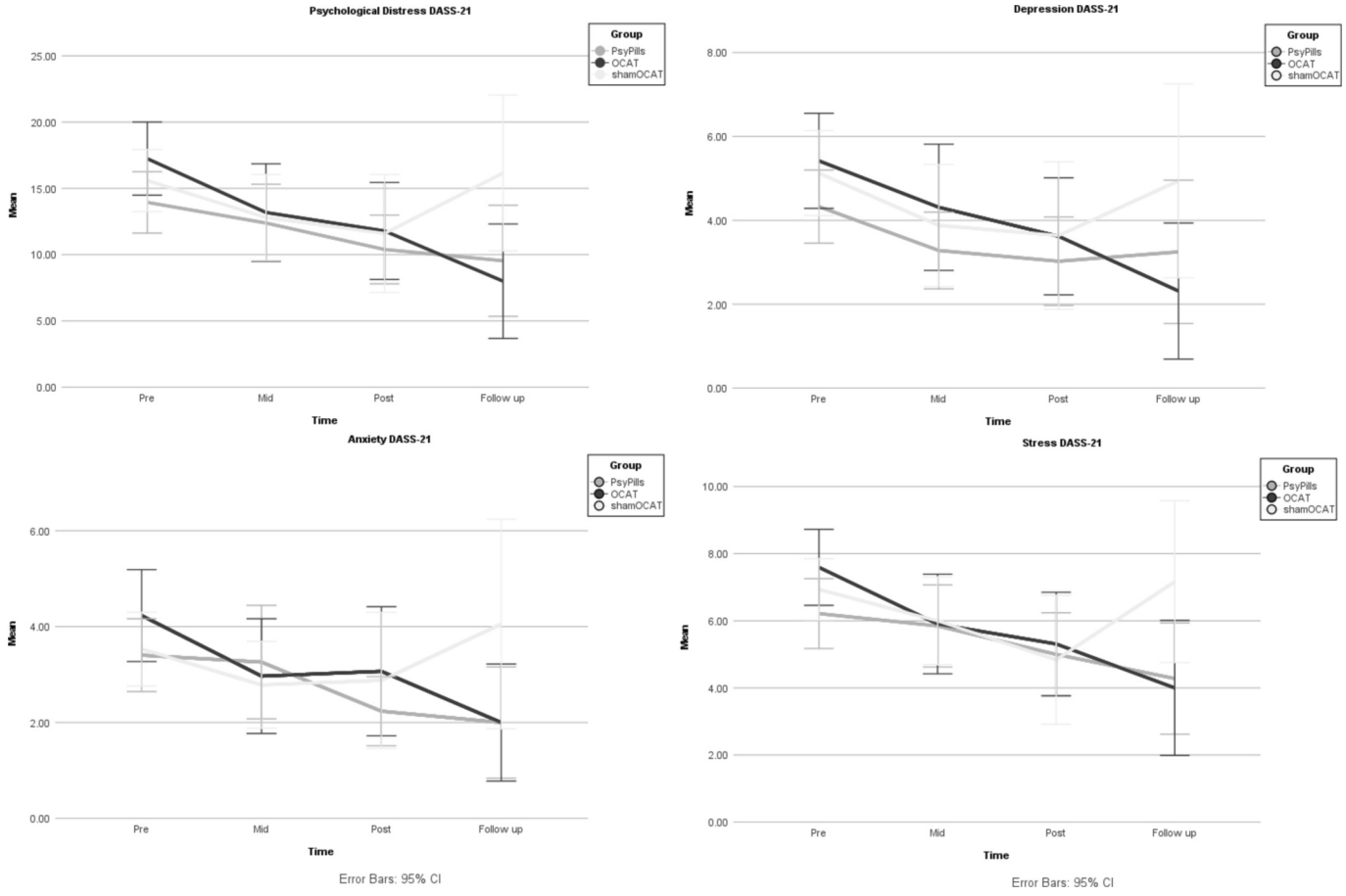

Fig. 2. Scores on the pyschological distress, depression, anxiety, and stress during the study.

population too.

The reduction in depression, although non-significant for the between comparisons, but with a small effect, and significant within reduction trends from pre to both post, and follow-up in active OCAT users is a promising finding too. This non-significant result for the between-group comparisons in the intervention groups could be an artifact of the error II type, as the power was calculated for at least a medium size. However, the self-referential negative content of the OCAT derived from the SST task, particularly relevant for core depressive cognitions, along with the explicit top-down feedback on regulating

Table 3
Contrasts and between-group effect size calculations from LMMs[a].

Outcome	*MD*[b] (*SE*; 95 % CI)	*P* value		Cohen's *d*
		LSD[c]	Sidak[d]	
DASS-21[e]				
Follow up				
PsyPills	−5.22 (2.43; −10.00 to −0.44)	**0.03***	0.09	−0.48
OCAT	−6.30 (2.59; −11.39 to −1.21)	**0.02***	**0.04***	−0.58
Post				
Psypills	−1.20 (2.13; −5.38 to 2.98)	0.57	0.92	−0.11
OCAT	0.76 (2.25; −3.68 to 5.19)	0.74	0.98	0.07
Mid				
PsyPills	−1.17 (1.87; −4.85 to 2.51)	0.53	0.90	−0.11
OCAT	0.22 (2.01; −3.73 to 4.16)	0.91	0.99	0.02
Depression				
Follow up				
PsyPills	−0.67 (0.98; −2.60 to 1.26)	0.49	0.87	−0.15
OCAT	−1.50 (1.03; −3.53 to 0.54)	0.15	0.38	−0.34
Post				
Psypills	−0.21 (0.85; −1.88 to 1.47)	0.81	0.99	−0.04
OCAT	0.27 (0.90; −1.50 to 2.05)	0.76	0.99	0.06
Mid				
PsyPills	−0.80 (0.75; −2.26 to 0.67)	0.29	0.63	−0.18
OCAT	0.24 (0.80; −1.32 to 1.81)	0.76	0.99	0.05
Anxiety				
Follow up				
PsyPills	−2.17 (0.85; −3.83 to −0.50)	**0.01***	**0.03***	−0.60
OCAT	−1.55 (0.90; −3.31 to 0.212)	0.085	0.23	−0.43
Post				
Psypills	−0.80 (0.74; −2.25 to 0.66)	0.28	0.63	−0.22
OCAT	0.46 (0.79; −1.08 to 2.01)	0.56	0.91	0.13
Mid				
PsyPills	0.27 (0.65; −1.01 to 1.54)	0.68	0.97	0.07
OCAT	0.13 (0.70; −1.25 to 1.51)	0.85	0.99	0.04
Stress				
Follow up				
PsyPills	−2.64 (1.06; −4.72 to −0.56)	**0.01***	**0.04***	−0.59
OCAT	−2.62 (1.12; −4.83 to −0.41)	**0.02***	0.06	−0.58
Post				
Psypills	−0.16 (0.92; −1.97 to 1.65)	0.86	0.99	−0.04
OCAT	0.36 (0.98; −1.55 to 2.28)	0.71	0.98	0.08
Mid				
PsyPills	−0.45 (0.80; −2.02 to 1.12)	0.57	0.92	−0.10
OCAT	−0.01 (0.86; −1.70 to 1.68)	0.98	0.99	0.00

Note: significant results are bolded and superscripted with *.
[a] Linear mixed-effects models.
[b] Pairwise mean differences from LMMs.
[c] *P* value following least significant difference (LSD) adjustment for all pairwise comparisons.
[d] *P* value following Sidak adjustment for all pairwise comparisons.
[e] DASS-21: Depression, Anxiety, and Stress Scale - 21 items form.

cognitive biases and the observed positive impact on depressive symptoms within the general population in the present study, collectively suggest promising attributes for applying this type of training in clinically depressed samples.

Despite the rigorous design of this RCT, and the novelty of the online interventions and supporting results, some limitations should be considered when interpreting the current findings. Firstly, we registered high attrition rates at post (59.83 %) and follow-up (71.18 %), together with low adherence rates, which is also a common outcome in the mHealth literature, especially in the case of self-guided interventions for general community adults with an enrollment process carried out entirely online (i.e., no telephone or in-person enrollment; Linardon and Fuller-Tyszkiewicz, 2020). While we did not obtain significant differential attrition or adherence rates between the groups and did not find any baseline variable to be a significant predictor of attrition (probably given that our control group was a placebo sham condition, matching in expectancy and engagement levels with the active interventions), future studies are needed to address this compliance issue, as it continues to threaten the validity of the majority of mHealth RCTs (Linardon and Fuller-Tyszkiewicz, 2020). For example, influence tactics known from the social psychology research to be efficient at obtaining high compliance (e.g., active, voluntary, and communicated to other persons commitments obtained at the beginning of the study; e.g., Cialdini, 2009) and persuasive and engagement app features (e.g., gamification and personalization; e.g., Weisel et al., 2019) represent viable solutions in need of future implementations.

Another limitation of the present study is the statistical power that this study's hypotheses were planned for, given that most of our results were below this a priori estimated threshold. Failing to detect a true effect (type II error) due to insufficient statistical power might have been a particular problem in identifying a significant benefit of PsyPills on general distress after adjusting for multiple comparisons (limiting the statistical power). This limitation in statistical power, compounded by the adjustment, is notable given the medium effect size observed, as well as the significant results in the expected direction for the individual anxiety dimension of distress. Finally, although the current findings might suggest a differential effect of the two interventions across specific general distress symptom outcomes, questions regarding whether these outcomes have different average rates of change or whether change in one symptom outcome is related to change in another one between different interventions, require further statistical tests for confirming the primary results (Baldwin et al., 2014). Further analysis contrasts for differential treatment effects or mediation analyses for estimating the relations between variables are future endeavors to pursue in this type of research.

In conclusion, the significant effects of a ten-days format of online psychological interventions such as PsyPills and OCAT to target general psychological distress and specific psychological problems, separately confirm the positive impact of these novel smartphone mental health apps to improve mental health in the general population. This opens the venue for further developments (procedures reducing attrition, gamification components that facilitate user's engagement) as a mean to provide a full-scale implementation of these interventions to assist individuals in the general populations suffering from low-to-mid levels of general psychological distress.

CRediT authorship contribution statement

Vasile Sîrbu: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Oana Alexandra David:** Writing – review & editing, Supervision, Software, Investigation, Funding acquisition, Data curation, Conceptualization. **Alvaro Sanchez-Lopez:** Writing – review & editing, Software, Resources, Funding acquisition, Conceptualization. **Ivan Blanco:** Writing – review & editing, Software, Resources, Conceptualization.

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

During the preparation of this work, the author(s) used ChatGPT 3.5 in order to improve readability and language. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jad.2024.10.052.

Data availability

The underlying custom code used for this study is available in the supplementary material that can be accessed online. Deidentified individual participant data will be available. Data will be available immediately after publication for a period of 5 years. Data will be shared with researchers who provide a methodologically sound proposal to achieve aims related to outcomes. Proposals should be sent to vasile.sirbu@ubbcluj.ro. To gain access, data requestors will need to sign a data access agreement.

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