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Facilitating Thought Progression Reduces Depressive Symptoms: A Randomized Controlled Trial

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Abstract

Background: The constant rise and the prevalence of Major Depressive Disorder call for new, effective, and accessible interventions. Recent digital health developments suggest that dedicated online platforms may successfully address this gap

Objective: We investigated the efficacy of a novel approach for treating depression by facilitating thought progression (FTP) through a gamified app.

Methods: A randomized control trial was conducted, comparing the improvement in depression symptoms between participants who played with the app in the intervention group (n=74) and waitlist controls (n=27) over the course of eight weeks.

Results: The results indicate that across multiple clinical measurements, app-playing participants showed greater and faster improvement in depressive symptoms compared with their waitlist control counterparts. Playing participants also showed high interest in continued post-trial engagement.

Conclusions: These results demonstrate that the implementation of FTP-based interventions in future therapeutic contexts may prove fruitful in providing novel, accessible and effective treatment for depression. Clinical Trial: Clinical Trial Registry Name Clinicaltrials.gov (http://www.clinicaltrials.gov)
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Facilitating Thought Progression Reduces Depressive Symptoms: A Randomized Controlled Trial

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Abstract

Background: The constant rise in prevalence of Major Depressive Disorder calls for new, effective, and accessible interventions that can rapidly and effectively reach a wide range of audiences. Recent developments in the digital health domain suggest that dedicated online platforms may potentially address this gap. Focusing on targeting ruminative thought, a major symptomatic hallmark of depression, here we hypothesized that delivering a digital-health based intervention designed to systematically facilitate thought progression would significantly alleviate depression.

Objective: The study aimed to investigate the efficacy of a novel digital intervention on the reduction of depressive symptoms. This intervention was designed as an easy-to-use, gamified app, specifically aimed to facilitate thought progression (FTP) through intense practicing of associative, semantically broad, fast, and creative thought patterns.

Methods: A randomized clinical trial was conducted, comparing changes in depression symptoms between participants who played the app in the intervention group (n=74) and waitlist controls (n=27) over the course of eight weeks. All participants filled out a battery of clinical questionnaires to assess the severity of depression at baseline and four and eight weeks after starting the study. These primarily included the MADRS (Montgomery–Åsberg Depression Rating Scale) and the PHQ-9 (Patient Health Questionnaire-9), as well as PANAS-NA (Positive Affect Negative Affect Scale- Negative Affect Score), RRS (Rumination Response Scale) and SDQ (Symptoms of Depression Questionnaire). Additional questionnaires were implemented to assess anxiety, positive affect, anhedonia and quality of life.

Results: The results indicate that across multiple clinical measurements, participants in the intervention group who played the app showed greater and faster improvement in depressive symptoms compared with their waitlist control counterparts. The difference between the groups in MADRS improvement was −7.01 points (95% confidence interval [CI], -10.72 to -3.29; p=0.0003, Cohen's *d*=0.67). Furthermore, difference in improvement between groups persisted up to four weeks post-trial (MADRS differences at week twelve: $F(49,2)= 6.62$, $p= 0.003$, $\eta p^2 =0.21$). At the end of the trial playing participants showed high interest in continuing using the app.

Conclusions: The results demonstrate that a gamified app designed to facilitate thought progression is associated with improvement in depressive symptoms. Given its innovative and accessibility features, this gamified method for facilitating thought progression may successfully complement traditional treatments for depression in the future, safely and effectively improving the lives of large populations suffering from depression and anxiety.

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Introduction

Depressive and anxiety disorders have been on a constant rise as major global disease burdens since 1990 and were among the ten most common non-communicable diseases in 2019, even among children as young as 10 years old [1]. Major depressive disorder (MDD), which is highly comorbid with anxiety, is characterized by persistent feelings of sadness, loss of interest or pleasure (i.e., anhedonia), changes in appetite or weight, disturbances in sleep patterns, fatigue, feelings of worthlessness or guilt, impaired cognitive and social function, and recurrent thoughts of death or suicide [2], altogether making it a highly complexed disease.

The global COVID-19 pandemic contributed significantly to the sharp increase in the already-high MDD and anxiety conditions; in 2020 the global number of mental health disorder cases rose significantly with an additional 76.2 million cases of MDD and 53.2 million cases of anxiety disorder [3]. The pandemic's associated lockdowns and social distancing have led patients to seek and successfully engage with remote psychotherapeutic options such as online sessions with their therapists, or digital health tools, such as mobile phone apps for the diagnosis and treatment of depression and anxiety [4]. A recent meta-analysis has demonstrated great efficacy for digital mental health interventions [5], despite their limited face-to-face component, and the constant technical support they require. In that manner, digital health has emerged as a promising avenue for addressing mental health challenges, in three critical aspects: accessibility, retention, and innovation.

Accessibility

Digital health has the clear benefit of allowing existing treatments a wider reach. For example, Telehealth and Internet-based approaches that translate existing treatments to online platforms have already been shown to be feasible and as effective as in-person care [5], [6], [7], [8], [9]. These remote evidence-based interventions utilize mobile phone apps as an additional platform for delivering care, encompassing clear advantages given their extensive accessibility, immediacy, low cost, and the ability for patients to use these tools at their convenience without having to wait for mental health professionals to be available [10], [11]. In particular, cognitive digital health interventions have attracted considerable attention because of their potential for targeting cognitive processes associated with depression more directly [5], [9], [12], [13], [14]. Digital mental health therapies can significantly elevate well-being, while potentially bypassing stigma-related obstacles in seeking treatment [15] and reaching a markedly wider population. All these while augmenting

existing treatments.

Retention

Digital health platforms can amplify retention in favor of mental health causes by harnessing and customizing online “gaming” features. A review of studies on digital health applications has found that gamification, the inclusion of game elements within non-game contexts, increased motivation and engagement, and resulted in improved outcomes [16]. Such interventions leverage the power of technology to deliver not only accessible and cost-effective support but also its power to sustain long-term motivation and engagement, for diverse mental health problems [17], [18], [19]. It has recently been found that online gaming platforms that utilize cognitive or behavioral techniques can be beneficial in mitigating depression [20], [21], [22], while showcasing how gaming can complement existing approaches and potentially enhance treatment outcome in several mental health issues [23], [24], [25].

Innovation

The success rate of traditional treatments for MDD, including psychotherapy and pharmacotherapy, remain unsatisfactory: approximately one-third of individuals with MDD do not respond to standard treatments, and high rates of relapse and residual symptoms further highlight the limitations of currently available therapies [26-32]. Furthermore, a significant portion (40-50%) of the population experiencing depression do not even seek treatment [33]. As such, there is a clear need for new and innovative solutions, which digital health solutions are well positioned to provide. A central problem with existing treatment options is their focus on symptoms rather than the underlying causes of depression [34], [35]. Therefore, although creating gamified online versions of existing treatments may improve accessibility, cost, and engagement, these developments have yet to solve the limited effectiveness of current therapeutic approaches. In other words, beyond successfully implementing remote versions of old treatments, there is an urgent need for remote and gamified solutions that implement innovative interventions and improve treatment outcomes, making life easier for those coping with depression.

Facilitating thought progression

The current study evaluated a new app-based intervention developed on the bases of a cognitive neuroscience framework for mood and depression which we termed ‘Facilitating Thought Progression’ (FTP) [36]. FTP is based on research showing that specific thought patterns are directly

and reciprocally connected with mood [37-41]. For example, narrow, slow, and repetitive thinking patterns have been associated with a more negative mood, whereas broad, rapid, and expanding thinking patterns are associated with a more positive mood. The FTP approach postulates that persistent rumination not only dampens mood but over time also leads to structural changes in critical brain areas such as the hippocampus and the prefrontal cortex [42-44]. Given the consistent findings linking depression and anxiety with ruminative thought patterns (repetitive, circular thinking, sluggish thinking, and narrow semantic representation), an FTP-based intervention would focus on reducing ruminative thought by broadening associative scope, reducing mental inhibition and increasing cognitive flexibility.

Additionally, it has been demonstrated that people with depression show a reduced ability for globalization - they exhibit a localized, detail-oriented perspective and are less able to develop a global one. This means that they are limited in their ability to think about things in global terms or in their holistic semantic representation [45], [46]. Given the bi-directional relationship between cognitive thought process and mood [35], [39], [40], [47], [48], individuals with depression may benefit from cognitive training to facilitate thought patterns that are more broadly associative, more global, and more rapid.

Consistently, our group developed a farm-like mobile phone app game called MoodVille, with the aim of providing this form of cognitive training. The app included five mini-games, and participants needed to complete levels in each of them to earn collectible rewards for their farm development. The therapeutic games were collectively aimed at facilitating thought progression, and specifically to enhance cognitive flexibility, associative breadth, creativity, rapid thinking, and globalization. Overview of the app and examples for level for each therapeutic game are portrayed in the supplementary materials (Fig. S1).

The study evaluated the efficacy of this FTP-based therapeutic intervention in improving symptoms among patients with MDD.

Methods

Participants

The study was a single-blind, randomized, controlled trial to test the efficacy of a newly developed FTP-based mobile phone application in alleviating symptoms of depression in individuals with MDD. Clinicians evaluating the participants were blinded to their trial condition. Overall, 117 participants aged 20-50 (mean age 32.43±8.5) were found eligible for the study. Of these, 16

participants from the intervention group and 3 from the WLC discontinued either due to technical and administrative reasons (n=5), personal reasons (n=1), or failure to meet minimum app playing requirements (n=10). Therefore, the results of the intervention group consisted of 74 participants and 27 participants in the WLC group.

Ethical considerations

The study was ethically approved by the IRB of MGH where the study was conducted. All participants provided informed consent prior to enrollment and were informed that they could opt-out at any time. Data files including participants' demographic information (e.g., age, gender), clinical measures and app usage data were kept separate from any identifying information, and all analyses were conducted using de-identified data. No deviations were made from the registered protocol. Participants were reimbursed via monthly payment card deposits or e-checks for the following components: Baseline visit (first month only): $25; Visits with a study clinician (once every 4 weeks): $10; Weekly questionnaires: $5. Participants in the intervention group received an additional $35 on the week they completed at least 75% of daily available game levels for four different games on at least four days of that week. Participants not meeting this weekly usage and those in the waitlist group received $9 per week. Data collection ended on July 26, 2023.

Study procedure

The study procedures were approved by the Mass General Brigham Institutional Review Board (MGB IRB).

The study was pre-registered (Study IDs: 2022P002100). Participants were recruited between 17 October 2022, and 31 May 2023, from online channels including Craigslist, Facebook, Instagram, Reddit, ClinicalTrials.gov, and rally.massgeneralbrigham.org. Interested individuals were first screened over the phone by the study staff. Eligible participants were scheduled to complete a visit with clinical study personnel where they completed the consent procedure and were evaluated for inclusion and exclusion criteria. The inclusion criteria were meeting criteria for current major depressive disorder (MDD) per the Mini-International Neuropsychiatric Interview [49] (MINI) and having mild to moderate depression per the Montgomery Åsberg Depression Rating Scale [50] (MADRS, > =15 and < 35). The minimum score of 15 was chosen because a cutoff score of 15-16 has been shown in one study to be the most sensitive for MDD [51], as it falls between mild and moderate severity, suggesting that it is the ideal score to indicate the presence of Major Depressive disorders. The upper score of 35 was chosen because it indicates the presence of severe depression,

which was not identified by the authors as a treatment population and raised safety concerns about participation in a placebo-controlled trial in which the treatment intervention had not yet been validated. Exclusion criteria included: Meeting criteria for schizoaffective disorder, bipolar I/ II disorder, current posttraumatic stress disorder, panic disorder, obsessive-compulsive disorder that significantly impairs their functioning or lasts more than one hour per day, or personality disorder as long as their MDD diagnosis was primary; having treatment-resistant depression; planning to change treatment regimen (therapy or psychotropic medications) during the eight-week study period; having changed treatment regime (therapy or psychotropic medication) in the six weeks prior to the study initiation; using a computer, internet, or smartphone software-based application for mental health or depression treatment in the 6 weeks before the study; presence of neurodegenerative diseases or uncorrected visual or dominant-hand motor deficits. Eligible participants were then randomly assigned (3:1) to either the intervention group or the WLC group by a research coordinator. To control for sex at birth and gender-diverse status, blocks of randomized number sequences were used at randomization.

Following randomization, participants in the intervention group began playing the FTP-based mobile application, while WLC participants were informed that they would gain access to the app after an 8-week waiting period. Consistently, study staff contacted the WLC participants at their 8-week mark and offered them a link to download the FTP-based app. During the eight-week study period, participants from both groups were administered weekly online questionnaires on depression [52] (Patient Health Questionnaire, PHQ-9), anxiety [53] (General Anxiety Disorder, GAD-7), rumination [54] (Ruminative Response Scale, RRS), anhedonia [55] (Snaith-Hamilton Pleasure Scale, SHAPS), mood [56] (Positive and Negative Affect Schedule, PANAS), a monthly quality of life questionnaire [57] (World Health Organization Quality of Life- BREF) and the Symptoms of Depression Questionnaire [58] (SDQ). At the end of the study, the intervention group also received a user feedback questionnaire regarding the app itself. All online questionnaires were administered and stored via REDCap (Research Electronic Data Capture), a secure web application for online surveys and databases. MDD symptoms were evaluated monthly using the MADRS diagnostic questionnaire. MINI and MADRS assessments were conducted by Master-level, PhD or MD-level clinicians who were blind to group assignment and were extensively trained to administer the assessments.

Intervention

Intervention arm participants were instructed to play the FTP-based mobile app Mood Ville for at least four days per week and 15 minutes per day, for eight weeks. Participants who did not meet the play requirement for more than two weeks over the course of the eight-week trial (i.e., missing >25%

of minimum play requirements) were discontinued, as per the study's protocol and consent form. Study staff regularly monitored each participant's play rate and alerted participants who were close to not meeting their targets. 47 of the 87 participants in the intervention group were receiving either psychotherapy, medication, or a combination of both (5, 27, and 15, respectively). All participants were instructed not to change their treatment regimens during the 8-week study.

The intervention was a farm-like mobile phone app game called MoodVille, and it included five mini-games, each designed to train one of the following cognitive facets: associative breadth, cognitive flexibility, thinking speed, creativity and global attention (see Fig. S1).

Control group

The WLC allowed participants to continue their regular MDD treatment protocols, if such existed, and were instructed not to change them for the duration of the 8-week waiting period. 19 participants in the WLC group were receiving either psychotherapy, medication, or a combination of both (3, 8, and 8, respectively). Study coordinators contacted the WLC participants at their 8-week mark and offered them a link to download the FTP-based app.

Primary and Secondary outcomes

The primary outcomes of the clinical trial were changes in the clinical questionnaires. Questionnaires were filled out each week and changes were compared between the intervention and the control groups. The secondary outcomes of the clinical trial were post-intervention effects, measured through data collected on week 12 of the trial from participants from both groups who extended their engagement. Additional secondary outcomes were evaluated through participants' ratings of the app, contributing to assessment of the intervention's efficacy.

Data analytic strategy

The primary analysis of interest in this study was the effect of the FTP-based app on MDD severity. Our hypothesis was that clinical scores would be significantly improved for the intervention group, compared with WLC. Several analyses were conducted to test this hypothesis. First, a 2-way mixed repeated measures ANOVA was run, to assess differences between the two groups in their clinical scores, operationalized as the outcome variables. Here, the baseline, fourth, and eighth weeks of the clinical trial were used as the time points of reference for the within-subject independent variable, and group allocation was used as the between-subject independent variable. To address sample-size differences between the two groups, additional randomization analysis was conducted: the 2-way repeated measures ANOVA was performed in multiple iterations (n=1000) in which random data

sub-sampling of participants from the intervention group was performed so the sample size in each iteration was equal between intervention and WLC groups. The proportion of significant results out of the number of iterations is reported in the Results section. Second, t-test analyses tested whether the outcome variable of change in clinical scores from baseline was significantly enhanced for the intervention group compared with the WLC group after four weeks as well as after eight weeks (group and weeks operationalized as independent variables). Thirdly, the clinical benefit of the intervention was assessed by computing the standardized mean difference (SMD) for each assessment tool using Cohen's effect size. Lastly, to assess the rate of clinical improvement over time, a mixed linear regression analysis was run, estimating the change in each clinical questionnaire's score over the study's eight weeks for both groups. A linear model was built for each questionnaire, in which weeks (1-8) and group (intervention/WLC) were implemented as a fixed effect and participants were implemented as the random effect. Secondary analyses focused on post-intervention data. As participants could continue using the app for an additional 4 weeks, these analyses assessed the long-lasting effect of app use on clinical assessment. Here, the outcome variable of post-intervention clinical data was compared between groups on week 12, while dividing the intervention group into those maintaining high engagement post-intervention and those who maintained low engagement post-intervention (engagement as the independent variable). Additionally, analyses focused on participants' meta-experimental feedback, contributing to assessing the intervention's efficacy. Lastly, exploratory analyses were aimed at examining the intervention's effectiveness specifically on female players, as the intersection between their prevalence in depression diagnoses, and their prevalence in adopting online play-like apps, positions them to gain maximal benefit from the intervention. This is important amidst the growing interest in the intersection of mental health and gaming, a recent literary review has shed light on the potential positive impact of video games specifically on women in terms of enhancing cognitive, social, and physical abilities [59]. The latter results are reported in the supplementary materials.

Sample size and power

A sample size of 100 (75 intervention and 25 WLC) was calculated using the G*Power 3.1 software, under the assumption of power of 0.80, which a two-tailed t-test will be able to detect a large effect size (0.8) and a one-tailed t-test will be able to detect a moderate effect size of 0.57. Aiming to detect a moderated effect size was chosen based on recent findings in online depression treatment research, showing a 0.6 effect size in PHQ9 improvement in internet-based CBT interventions [60], and corresponding to a recent meta-analysis revealing a mean effect size of 0.67 across internet-based

studies [61]. The effect size of 0.57 was chosen to detect a slightly smaller effect within the same expected moderate range.

There was no use of generative AI in any portion of the study.

Results

Participants

348 eligible individuals underwent phone screening, 163 of which met the inclusion criteria for completing a clinical MDD assessment. Eventually, 117 individuals were found eligible for the study and underwent randomization; 87 were assigned to the intervention group and 30 to the WLC group. The mean age of the participants enrolled in the study was 32.43 years (min age= 20, max age=50), 91 (77.8%) were women and 61.5% were white. The study was conducted at Mass General Hospital. The primary diagnosis for all 117 participants was MDD and the mean MADRS score at baseline was 26.97(±4.65). There were no statistically significant differences between the two groups on any demographic or clinical variables. During the course of the study, participants were discontinued if they failed to reach the minimum app-use requirements for more than 2 weeks, missing 25% of minimal engagement requirements, as well as if they failed to complete their monthly clinical assessments. By the end of the study, 14 participants from the intervention group and 3 from the WLC ended up either discontinuing due to technical and administrative reasons (n=5), personal reasons (n=1), or failure to meet minimum app playing requirements (n=10). Therefore, the results of the intervention group consisted of 74 participants and 27 participants in the WLC group (Fig. 1). The demographic and clinical characteristics of the 101 participants from both groups who successfully completed the study were not statistically different at baseline from the original groups and are described in Tables 1 and S1.

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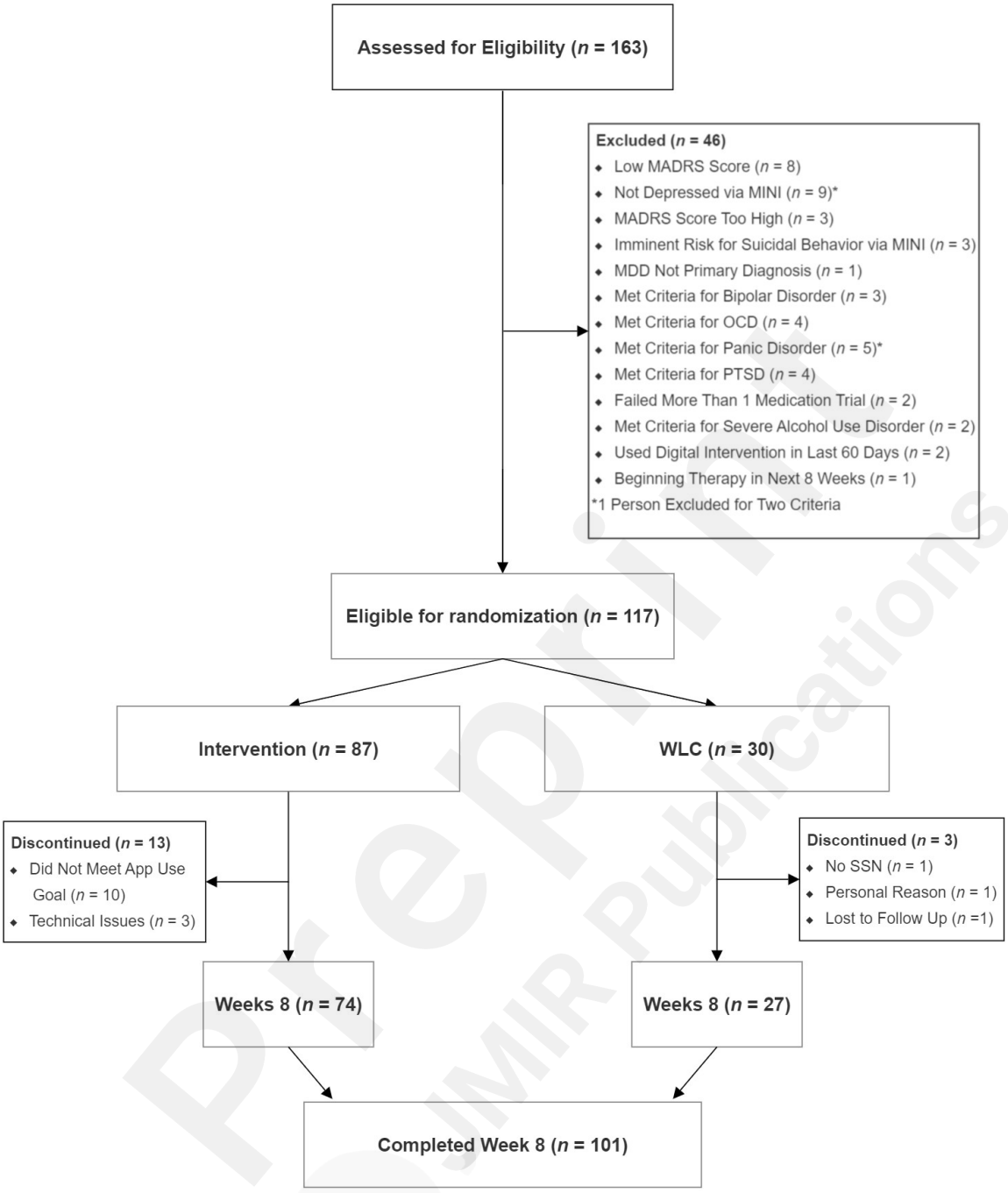

Figure 1: Consort table

	Intervention (n=74)	WLC (n=27)	P-value
Demographic Characteristics			
Mean Age (±SD)	33.22 (±8.6)	32.44 (±8.53)	0.69
Female (%)	57 (77)	21 (77.8)	0.83
Ethnicity (%)			0.56
American Indian or Alaska Native	2 (2.7)	0 (0)	
Asian	12 (16.2)	8 (29.6)	
Black or African American	8 (10.8)	2 (7.4)	
Native Hawaiian or Other Pacific Islander	0 (0)	0 (0)	
White	48 (64.9)	16 (59.3)	
Prefer Not to Answer	4 (5.4)	1 (3.7)	
University Level Education (%)	58 (78.4)	18 (66.7)	0.23
Married/Domestic Partners (%)	26 (35.1)	8 (29.6)	0.6
Employment Status (%)			0.25
Employed	52 (70.3)	16 (59.3)	
Unemployed	13 (17.6)	4 (14.8)	
Student	9 (12.2)	7 (25.9)	
Annual Household Income (%)			0.18
0 - 19,999	5 (6.8)	3 (11.1)	
20,000 - 39,999	13 (17.6)	9 (33.3)	
40,000 - 59,999	13 (17.6)	3 (11.1)	
60,000 - 79,999	7 (9.5)	5 (18.5)	
80,000 - 99,999	11 (14.9)	1 (3.7)	
100,000 or above	19 (25.7)	6 (22.2)	
Prefer Not to Answer	6 (8.1)	0 (0)	
English as Primary Language (%)	71 (95.9)	23 (85.2)	0.06
Clinical Characteristics			
MDD as Primary Diagnosis (%)	74 (100)	27 (100)	
Secondary Diagnosis (%)			0.40
Suicide Behavior Disorder	3 (4.1)	1 (3.7)	
Panic Disorder	5 (6.8)	2 (7.4)	
Social Anxiety Disorder	12 (16.4)	6 (22.2)	
Obsessive Compulsive Disorder	0 (0)	2 (7.4)	
Alcohol Use Disorder	2 (2.7)	0 (0)	
Generalized Anxiety Disorder	21 (28.4)	11 (40.7)	
Mean MADRS at Baseline (±SD)	27.53 (±4.71)	26.78 (±4.13)	0.47
Mean PHQ-9 at Baseline (±SD)	15.05 (±4.59)	15.70 (±3.48)	0.51
Mean GAD-7 at Baseline (±SD)	9.27 (±5.71)	10.52 (±5.73)	0.33

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Mean RRS at Baseline (±SD)	55.12 (±11.63)	58.96 (±7.99)	0.07
Mean SDQ at Baseline (±SD)	141.3 (±18.26)	146.7 (±14.68)	0.17
Mean PANAS-NA at Baseline (±SD)	23.72 (±7.63)	25.93 (±7.69)	0.19
Mean PANAS-PA at Baseline (±SD)	17.78 (±6.23)	20.15 (±8.11)	0.12
Mean WHO-QoL-BREF at Baseline (±SD)	77.86 (±10.05)	76.48 (±9.63)	0.54
Mean SHAPS at Baseline (±SD)	22.93 (±6.31)	22.48 (±6.30)	0.75
Receiving Psychotherapy and/or MDD Medication (%)	42 (56.8)	16 (59.3)	0.82

Table 1. Demographic and clinical characteristics at baseline. p = significance value, derived from either student's t-test or chi-square (χ^2) by comparing treatment conditions on binary variables. Note: data from the originally randomized 117 participants did not differ statistically and is presented in Table S1

In line with the minimum app playing requirements, which required participants to engage in the app for at least 15 minutes a day, 4 days a week, the mean weekly minutes played was 60.32 (SE=2), showing on-par compliance, and little variability across participants.

Playing FTP-based app leads to a significant reduction in negative clinical scores, compared with controls.

To assess the effectiveness of the intervention compared with the WLC, we conducted a mixed repeated measures ANOVA, separately for each questionnaire, implementing groups as the between-subject variable and timepoints (i.e., baseline, week 4, and week 8) as the within-subject variable. MADRS analysis shows a significant interaction between groups and time points ($F(97,2)= 7.79$, $p= 0.0005$), revealing that while there is no difference in MADRS scores between the groups at baseline (intervention: 27.52±0.54, WLC: 26.77±0.79, $t=0.77$,$p=0.44$), the intervention group shows significantly lower MADRS scores in the 4th and 8th weeks of the experiment compared with the WLC group (week 4; intervention: 18.64±0.94, WLC: 22.37±1.54, $t=-2.05$, $p= 0.04$, week 8; intervention: 15.7±1.07, WLC: 21.96±1.75, $t= -3.04$, $p= 0.004$). To account for group size differences, an additional permutation test of significance was carried out. For each questionnaire, the intervention group's participants' data were sub-sampled 1000 times, to fit the sampling size of the WLC group, and the statistical significance was re-calculated. This allowed us to conservatively estimate the proportion of permutations showing a significant interaction effect between groups and time points. In the MADRS analysis, this randomized permutation procedure resulted in a significant interaction in 90% of permutations. These results suggest that the FTB-based intervention effectively reduced clinical symptoms to a greater degree than the WLC. See Figure 2 for elaborated results.

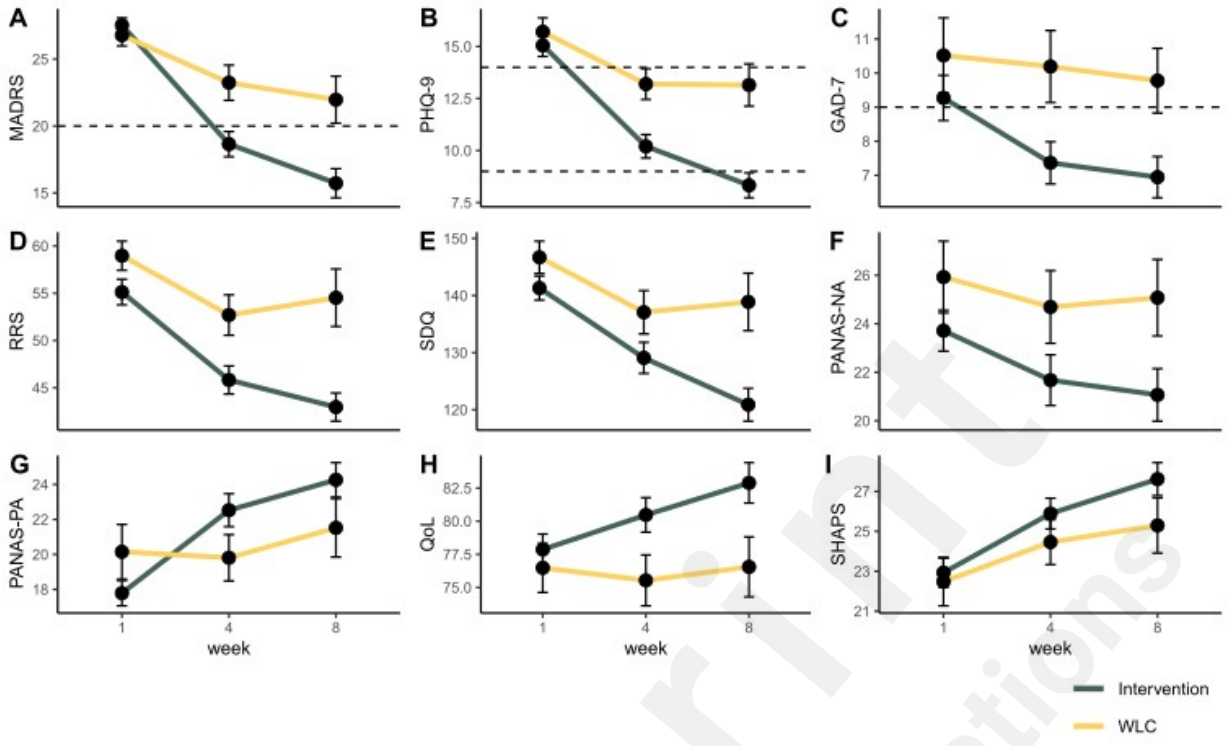

Figure 2: Greater improvement in clinical symptoms following FTP-based intervention compared with WLC. Clinical scores at the 1st, 4th, and 8th weeks in the intervention and WLC groups. The interaction results of a mixed-effects 3-way repeated measures ANOVA are reported. The proportion of significance in the randomized permutation procedure is indicated in parenthesis. A. MADRS: F(97,2)= 7.79, p= 2.49E-4 (90%); B: PHQ-9: F(95,2)= 7.17, p= 0.0009 (88%); C: GAD-7: F(95,2)= 1.75, p=0.17 (10%); D: RRS: F(97,2)= 5.67, p=0.004 (68%); E: SDQ: F(97,2)= 4.26, p=0.01 (57%); F: PANAS-NA: F(95,2)= 1.51, p=0.22 (6%); G: PANAS-PA: F(95,2)= 5.75, p=0.003 (73%); H: WHO-QoL-BREF:F(95,2)= 4.26, p=0.01 (29%); I: SHAPS: F(97,2)= 1.08, p=0.34 (1%). GAD-7= General Anxiety Disorder-7; MADRS= Montgomery–Åsberg Depression Rating Scale; PANAS-NA= Positive Affect Negative Affect Scale- Negative Affect Score; PANAS-PA= Positive Affect Negative Affect Scale- Positive Affect Score; PHQ-9= Patient Health Questionnaire-9; RRS= Rumination Response Scale; SHAPS= Snaith-Hamilton Pleasure Scale; SDQ= Symptoms of Depression Questionnaire; WHO-QoL-BREF= World Health Organization Quality of Life Brief Version; WLC= Waitlist Controls

Follow-up analyses examined the difference between the groups in their measured clinical change from baseline after four weeks as well as after eight weeks into the trial. The mean (±SE) change from baseline in the MADRS score after four weeks was −8.87±0.95 in the intervention group and -4.4±1.4 in the WLC group (difference, −4.47; 95% confidence interval [CI], -7.89 to -1.04; p=0.01), and after eight weeks was -11.82±1.12 in the intervention group and -4.81±1.47 in WLC group (difference, −7.01; 95% confidence interval [CI], -10.72 to -3.29; p=0.0003), indicating a significant difference between the groups in improvement in both time points. Of note, there was no significant difference in the MADRS score at baseline between the groups (0.74, p=0.46). Together, these findings suggest the rate of improvement is significantly faster in the intervention group (See Figure 3 and Table S2 for detailed results).

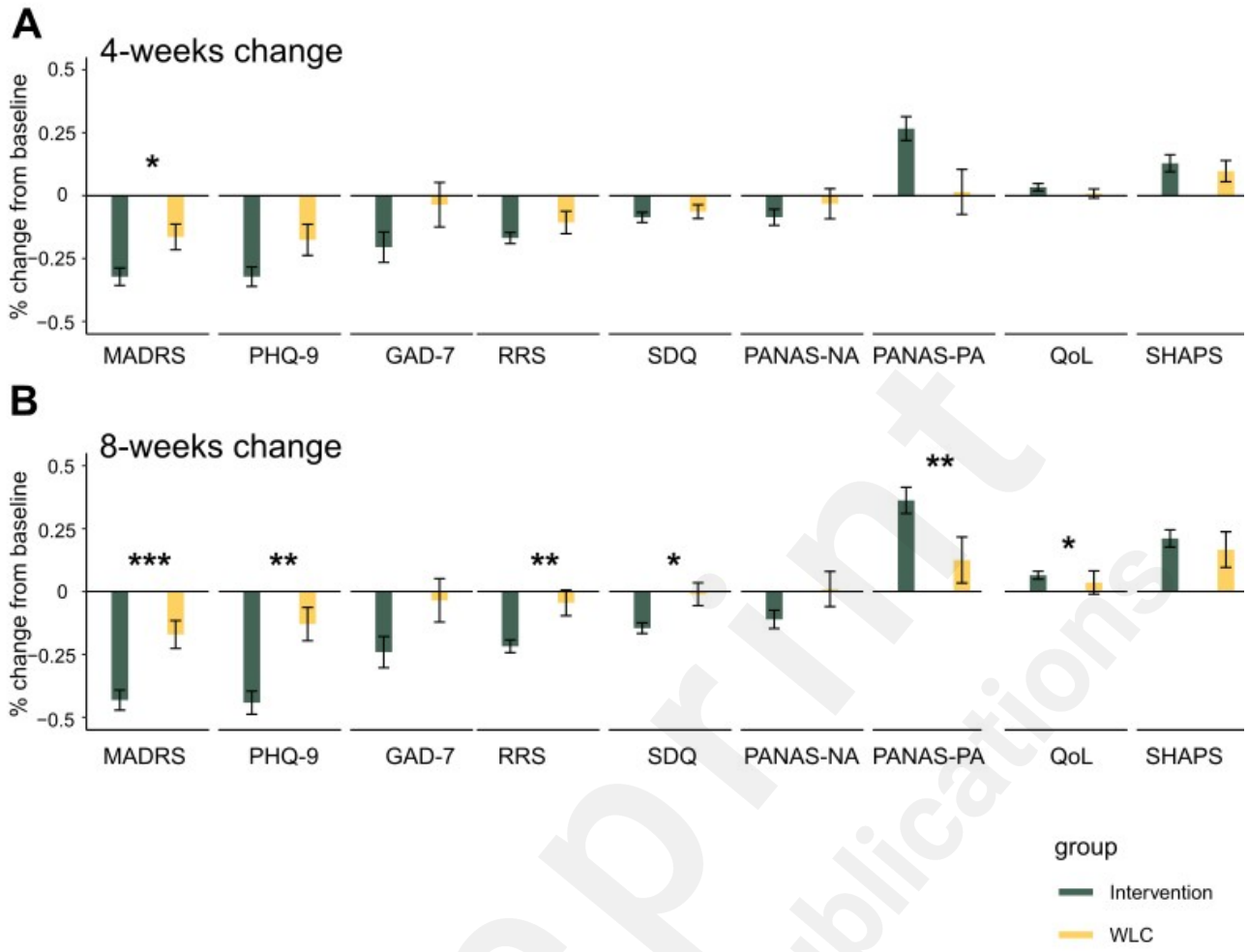

Figure 3: Enhanced Improvement in clinical symptoms following FTP-based intervention compared with WLC. The figure depicts the percent change from baseline after 4 weeks (A), as well as after 8 weeks (B) of enrolling in the clinical trial to either the FTP-based intervention or the WLC groups. Asterisks denote significant differences in percent change from baseline between the intervention and the WLC groups. *=<0.01, **=<0.05, ***=<0.001. Error bars denote S.E.M. Results are in a normalized format. GAD-7= General Anxiety Disorder-7; MADRS= Montgomery–Åsberg Depression Rating Scale; PANAS-NA= Positive Affect Negative Affect Scale- Negative Affect Score; PANAS-PA= Positive Affect Negative Affect Scale- Positive Affect Score; PHQ-9= Patient Health Questionnaire-9; RRS= Rumination Response Scale; SHAPS= Snaith-Hamilton Pleasure Scale; SDQ= Symptoms of Depression Questionnaire; WHO-QoL-BREF= World Health Organization Quality of Life Brief Version; WLC= Waitlist Controls

Further evaluation of the clinical benefit of the intervention was done by computing the standardized mean difference (SMD) for each assessment tool. This calculation was based on Cohen's effect size estimating the difference between the groups at the end of the study (week 8), in line with past studies evaluating the SMD of MDD improvement in mental health digital therapy apps [9]. The results of this analysis support the intervention's effectiveness over WLC in all assessment questionnaires, with the exception of the SHAPS questionnaire (Figure 4). The mean effect size across all questionnaires was -0.51, with larger effect sizes of -0.67 in the MADRS and- 0.92 in the PHQ-9 questionnaires.

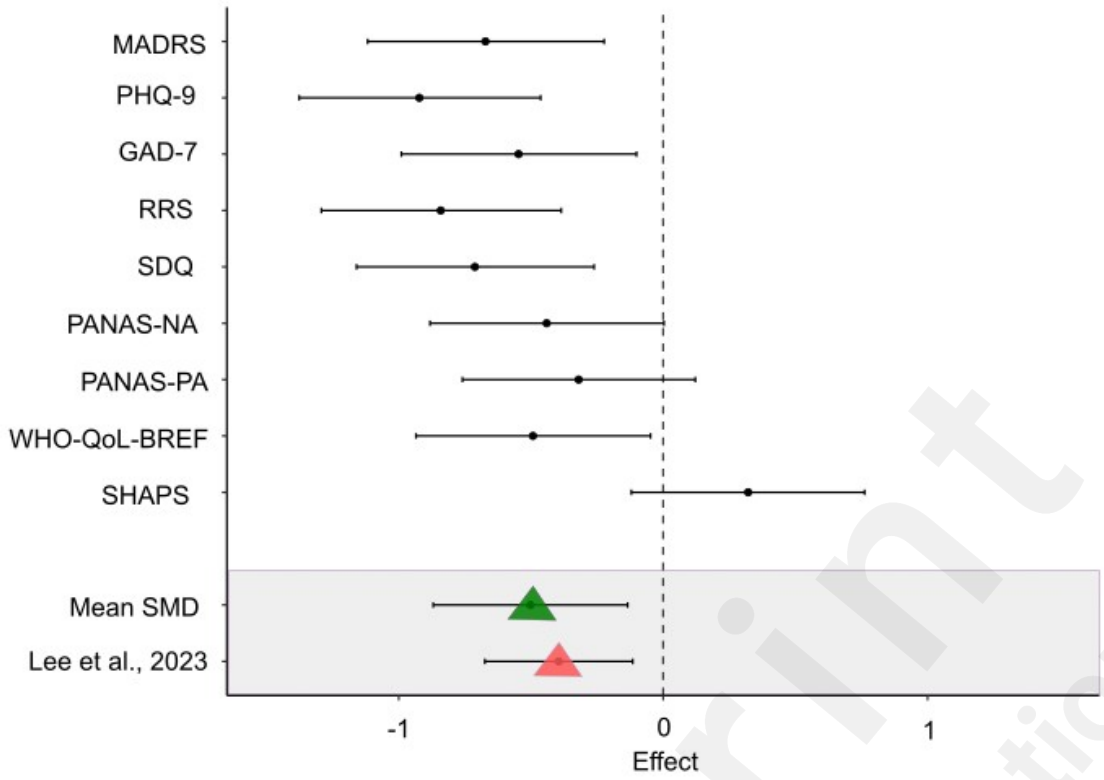

Figure 4: The effect of FTP-based app intervention on depression. Dots denote Cohen's d effect size. Negative values provide evidence in support of the intervention's efficiency, while positive values provide evidence in support of waitlist efficiency. Horizontal lines denote confidence intervals. Mean effect sizes for each questionnaire are as follows: MADRS= -0.67, PHQ-9=- 0.92, GAD-7= -0.54, RRS= -0.84, SDQ=- 0.71, PANAS-NA= -0.44, PANAS-PA= -0.31, WHO-QoL-BREF= -0.49, SHAPS= 0.32. The green triangle denotes the mean effect size across all questionnaires. The pink triangle denotes the mean effect size across all studies reported in Lee et al., 2023.

Playing an FTP-based app leads to a significantly faster reduction in negative clinical scores, compared with controls.

To assess the rate of week-by-week clinical improvement, mixed-effects linear models were composed for each clinical questionnaire. These models included all weeks as well as group as fixed effects, and participants as a random effect, and were found statistically significant for all nine questionnaires. A significant group effect was found for six out of nine questionnaires, suggesting that the rates of clinical improvement across these assessments were faster for playing participants compared with WLC (Table 2).

Assessment	Time					Group						Models' P value
	β	SE	t	p-value	CI	β	SE	t	p-value	CI	Effect favors intervention significantly	
MADRS	-1.24	0.1	-11.74	1.9e-26	[-1.45,-1.03]	3.07	1.33	2.3	0.02	[0.45, 5.7]	yes	3.63e-

												26
PHQ-9	-0.64	0.04	-16.2	6.48e-52	[-0.72,-0.56]	3.13	0.85	3.65	0.0002	[1.45, 4.81]	yes	6.86e-53
GAD-7	-0.29	0.03	-7.69	3.7e-14	[-0.36,-0.21]	2.07	1.03	1.99	0.04	[0.03, 4.1]	yes	8.1e-14
RRS	-1.32	0.9	-14.55	3.68e-43	[-1.5,-1.14]	8.03	2.41	3/32	0.0009	[3.29, -12.76]	yes	3.15e-43
SDQ	-2.13	0.28	-7.35	1.83e-12	[-2.7,-1.56]	10.41	3.88	2.68	0.007	[2.76, 18.05]	yes	1.04e-12
PANAS-NA	-0.35	0.05	-6.27	5.63e-10	[-0.51,-0.27]	3.46	1.64	2.11	0.03	[0.24, 6.68]	yes	5.92e-10
PANAS-PA	0.56	0.06	9.09	5.97e-19	[0.44, 0.68]	-0.99	1.4	-0.71	0.47	[-3.74, 1.75]	No	1.18e-17
WHO-QoL-BREF	0.46	0.11	4.03	6.83e-06	[0.23,0.68]	-4.08	2.21	-1.84	0.06	[-8.44, 0.27]	no	7.2e-05
SHAPS	0.46	0.05	8.61	3.11e-17	[0.36,0.57]	-1.03	1.27	-0.81	0.41	[-3.53, 1.46]	no	4.32e-16

Table 2: Rate of improvement in clinical symptoms following FTP-based intervention compared with WLC. Mixed-effects general linear models were conducted for each clinical measurement, assessing the rate of clinical symptom change as a function of time (weeks into the clinical trial) and group (playing participants vs. WLC). Participants were included in the models as a random variable. Each model's parameters are reported for the different time and group effects. All significant group effects favor the intervention group (second to right column). Each models' p values (right column) are FDR-corrected for multiple comparisons. GAD-7= General Anxiety Disorder-7; MADRS= Montgomery–Åsberg Depression Rating Scale; PANAS-NA= Positive Affect Negative Affect Scale- Negative Affect Score; PANAS-PA= Positive Affect Negative Affect Scale- Positive Affect Score; PHQ-9= Patient Health Questionnaire-9; RRS= Rumination Response Scale; SHAPS= Snaith-Hamilton Pleasure Scale; SDQ= Symptoms of Depression Questionnaire; WHO-QoL-BREF= World Health Organization Quality of Life Brief Version; WLC= Waitlist Controls

Secondary outcomes:

Post-trial follow-up in week 12.

While the study required 8 weeks engagement, participants could choose to continue for an additional 4 weeks. During this additional phase, participants were compensated for completing the assessment but not for engaging with the app. 90% (n=58 of 64) of participants who were offered the option choose to continue and completed 12 weeks of app use. Though the intervention group contained 74 participants who reached the end of week 8, only participants who were recruited before May 2023 were offered to continue playing for another 4 weeks, due to time limitations. 43 participants from the intervention group and 15 from the WLC group completed a MADRS assessment and filled out self-assessment questionnaires at week 12. 12 participants from the intervention group maintained the high playing regiment of at least four days a week (henceforth 'high engagement', or HE group), 31 participants kept playing but did not maintain regiment-level engagement (i.e., missed at least one week of playing). These players used the app for a total of 8 minutes (SD± 7) throughout the post-intervention period, henceforth 'low engagement', or LE group). 15 participants from the WLC group underwent MADRS assessment at week 12, out of which 6 chose to also play the app. These participants played a total of 24 minutes (SD± 10) throughout the 4 weeks (range 12-37), notably below the minimum 60-minutes per week engagement criteria. The remaining 6 participants did not play the app at all. Analysis shows that although similar in their baseline MADRS score, participants in the HE group differed from the LE and WLC groups in their clinical scores at week 8, such that the HE group exhibited the lowest negative MADRS scores at week 8, compared to their LE and WLC group counterparts ($F(49,2)=7.14$, $p=0.002$; Figure 5A, colored lines). This difference between the groups was preserved at week 12 ($F(49,2)= 6.62$, $p= 0.003$; Figure 5A, colored bars), as each group maintained an equivalent level to the scores obtained at week 8, suggesting a possible long-lasting effect for the LE group. Similar results were found for the PHQ-9 questionnaire (week 8: $F(52,2)=8.48$, $p=0.0006$; week 12: $F(52,2)=8.57$, $p= 0.0006$; Figure 5B). These results point to the intervention's possible long-lasting effect, as well as suggest that participants for which the intervention was most effective, voluntarily continued considerable app-playing engagement.

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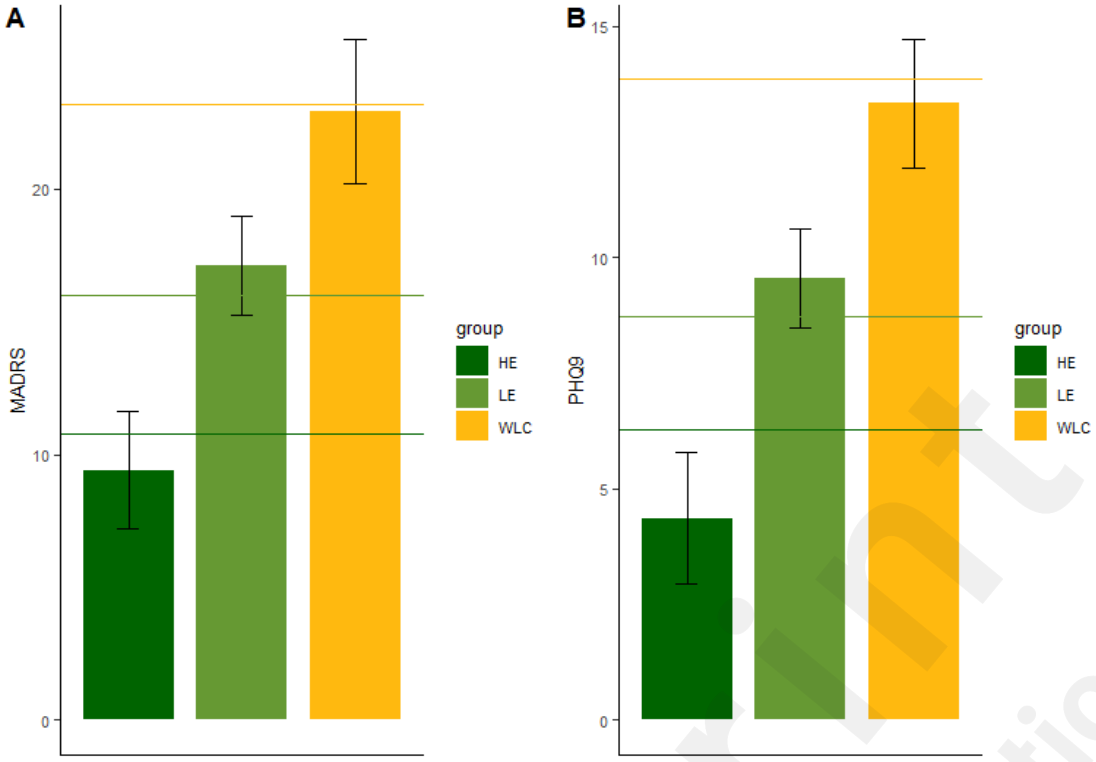

Figure 5: Group differences one-month post-intervention. A. MADRS scores of participants in week 12. **B.** PHQ-9 scores of participants at week 12. Bars depict week 12 scores of high-engagement participants (HE, dark-green bar), low-engagement participants (LE, light-green bar), and WLC participants (yellow bar). Horizontal lines depict individual groups' mean scores at week 8 for reference.

Subjective engagement and benefits

With respect to participant feedback, 47.9% reported that they saw themselves using the app at least once a week if the app was to be made publicly available. Additionally, a high percentage of the participants in the intervention group reported either "agree" or "strongly agree" to the following statements: "*Use of this app is likely to decrease low mood and sadness*" (46.5%), "*The app was easy to use*" (94.4%), "*Playing this app was fun*" (74.6%), as well as "*This app is likely to increase awareness of the importance of addressing low mood and sadness*" (43.7%) and "*This app is likely to increase intentions or motivation to address low mood and sadness*" (50.7%), suggesting high subjective perceived benefits. 53.5% gave the app either 4 or 5 ratings on a 1-5 scale, 1 being very negative and 5 being very positive views of the app. The mean score was 3.59, and the median score was 4.

Discussion

Principal Findings

This randomized controlled trial aimed to test the efficacy of a digital health intervention, which was

designed to facilitate thought progression, on alleviating symptoms of depression over the course of eight weeks. This intervention stems from the theoretical grounds showing that flexible, fast, broad, creative and global thinking patterns are bi-directionally tied with mood. On the one hand they are dampened among people experiencing negative mood disorders, but on the other hand, practicing and instigating these patterns may improve negative mood [38].

The primary outcomes in this trial show that the rate of clinical improvement in the intervention group was faster, and its overall magnitude was significantly larger compared with that of the WLC. This was true both for several main gold-standard measurements for depression, importantly MADRS and PHQ-9, as well as for GAD-7 which assessed the improvement in anxiety symptoms. The effect size of the results was on-par with previous results found in other existing online apps for depression. Secondary outcomes showed that the positive clinical effect persisted to at least one-month post-trial and that the intervention was perceived as fun, engaging, and beneficial. Overall, these findings demonstrate the efficacy of an FTP-based app in the long-term reduction of depressive symptoms.

Of note, other existing treatments have focused on the existence of maladaptive thought in depression. For example, Cognitive behavioral therapy (CBT) focuses on identifying negative, irrational or distorted thoughts and encourages patients to assess their validity and replace them with more beneficial alternatives [62], [63]. However, while CBT intervention aims at teaching strategies to change the content of thought [64], [65], the FTP-based approach focuses on changing thoughts structure and pattern by having patients engage in cognitive exercises that are independent from thought content. Therefore, FTP is agnostic to the content of the thought, or to the level to which one's thought content corresponds with realistic truth, and rather focuses on the structure of thought patterns, and how they progress. Therefore, it is likely that an intervention based on the FTP framework could be a complement to CBT.

Beyond its relation to CBT, the current study aligns well with the accumulating literature showing sustained beneficial effects of online digital interventions in mental health [11-14]. These found that mobile apps may have the greatest impact on people with mild to moderate depression, which is the audience targeted in the current study. These studies also show that video games facilitate cognitive control and multitasking, accompanied by attention-related neural changes, which suggest that digital interventions may lead not only to externally-measured improvement, but to changes in the underlying mechanisms as well. While the effect of the FTP-based intervention on neural processes

remains to be tested, the significant findings here corroborate this literature by showing significant improvement in depressive and anxiety symptoms following consistent, cognitive training that aims to sustain healthy thinking patterns.

Theoretical implications and future directions

The main results indicated that participants in the intervention group showed faster and greater clinical improvement compared with waitlist controls. This improvement was further sustained for four weeks after the critical trial period and overall high compliance was assessed, supporting the efficacy of the intervention and its potential to engage other clinical populations in need. This is the first study showing that an app based on the idea of the FTP framework is associated with improvement of depression. Therefore, altering thought structure may be as important as changing the content of thought. The findings support the notion that practicing faster, broader and more associative thought patterns may alleviate depression. Future studies may examine whether applying this intervention in parallel to other psychotherapeutic intervention such as CBT, as suggested above, or even classical psychotherapy, boosts their anticipated effect. It is possible that engaging in CBT-like treatments, which focus on re-routing the content of negative thought, conjointly with engaging with the FTP-based digital intervention which focuses on the structural (e.g., breadth) and dynamic-related (e.g., pace) aspects of thought, described and tested here, may show promising results in targeting depression.

The intervention discussed here provides proof-of-concept for the feasibility of an FTP-based digital intervention to clinically aid depressive populations. Future studies are required to understand how each specific component within the FTP approach impacts depression. For example, fostering broad associative thoughts may have a specific positive effect on rumination reduction, while fast thinking may instate a needed sense of progress. The combination between these elements may also lead to a unique effect on depressive symptoms. Given that the current trial evaluated engagement of all five therapeutic ‘mini-game’, studies that will further dissociate the FTP approach to its individual therapeutic elements may provide insight into whether different FTP configurations can be tailored to different depressive patients for maximal clinical improvement.

Limitations

The current research includes two limitations that would require future work to mitigate. First, the experimental design does not allow us to discern whether increased app engagement accelerates the reduction in depressive symptoms. The study required all participants in the intervention group to engage in the FTP-based app for a minimum of 15 minutes daily for 8 weeks, and the majority of

participants requested to continue playing 4 weeks more. Nevertheless, little variability was observed with regards to the overall duration of engagement, so whether more extensive engagement would prove even more beneficial remains an open question. Future studies in which participants are free to play as much or as little as they like would help fine-tune the parameters of optimal engagement (e.g., daily duration, number of levels solved, etc.) that will maximize efficacy in alleviating depression symptoms.

Second, another possible limitation is the cohort's low ethnic and socioeconomic diversity. Future research should involve better diversifying strategies to improve the ability to conclude efficacy for the broader MDD population.

Third, the study lacks a sham-app control group, to control for possible placebo effects. For example, while the reported significant changes in MADRS scores in both the intervention and the WLC groups may have resulted from the placebo effects related to being assessed by professional clinicians, the boosted improvement in MADRS in the intervention group may have resulted from an additional placebo effect caused by mere app-engagement. A sham app would have controlled for this potential placebo effect, making the study a complete double-blind. Considering this limitation, follow-up examinations evaluated the possibility that our findings were driven by placebo effects, revealing several key insights into why a mere placebo account is unlikely. First, improvement was not observed on all assessment tools, as SHAPS scores did not improve for either group. Second, in an exploratory analysis it was found that for women, the intervention was more effective as age increased, (see Supplementary Material). Together, these add further support for the specificity in app efficacy for most clinical measurements, but not all, and to a greater extent for some populations over others. Third, a concern for a placebo effect is generally attributed, in major part, to the possible worsening of symptoms among the WLC, which may eventually account for misattributed beneficial intervention results. Here, however, the WLC showcased improvement in symptoms yet was outperformed by the intervention group, which further supports the app's effectiveness. Lastly, while the RCT did not involve a sham app, the SMD score of all nine clinical measurements, and specifically the SMD of MADRS, fall well on the high end of effective measures, compared with other digital therapeutics RCTs. This analysis suggests that the intervention method developed and studied here is comparable in its magnitude of depressive symptoms reduction to other recently developed online treatments, making a pure placebo account highly unlikely.

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Conclusion

Within the global context of the rising need for innovative solutions that effectively alleviate depression and anxiety, a digital intervention that was designed to facilitate thought progression (FTP) was found here to effectively reduce depressive symptoms across multiple measurements. It was also found appealing for MDD patients showing interest in further engagement. These findings support the implementation of FTP-based interventions in future therapeutic efforts or along with other forms of therapeutic intervention, serving the effective facilitation of widely accessible mental-health solutions, and further bolster the promising potential of digital-health solutions to bridge the increasing gap in access to effective treatments for depression and anxiety.

Funding statement

The study was funded by Hedonia Ltd.

Conflict of Interest

S-L.Y, S.B., N.S., B.S. and M.B also work at Hedonia.ltd

Author contribution

M.B and S-L.Y designed the clinical trial. P.P, H.C and J.C oversaw participant recruitment and acquired clinical data at MGH. S-L.Y, S.B., N.S and B.S conducted data analyses. S-L.Y, S.B and M.B wrote the initial drafts of the paper. All authors approve the final version of the paper.

Data availability

The data reported in this manuscript as well as all analysis scripts are available from the corresponding author to facilitate replication. The up-to-date app version can be accessed via the MoodBloom app, available at the app store (https://apps.apple.com/us/app/mood-bloom-therapeutic-game/id6449717065) or Google Play store (https://play.google.com/store/apps/details?id=hedonia.bloom.mood&hl=en_US)

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Supplementary Material

Figure S1

Figure S1. App illustration and screenshots. The intervention included five mini-games aimed for facilitating thought progression. **A**. general layout of the game, presenting the five mini-games to play. Participants navigate app-engagement, decide the order of mini-game played, and the number of levels played within each mini-game. **B.** The 'word-chains' mini-game. Players are requested to arrange the words in a chained manner, such that each word is associated with the word preceding it and the word following it. This game is aimed to facilitate broad associative thought. **C.** The 'zoom-out' game. Players are shown a large letter composed of small letters, and are asked to indicate what the big letter is. This game is aimed to facilitate global attention. **D.** The 'belong' mini-game. Players are shown an image of a scene and are asked to choose two words depicting something that could have appeared in the scene, or is semantically related to the scene. This game is aimed to facilitate associative thought. **E.** The 'clouds' mini-game. Players are asked to choose the most creative interpretation for the meaning of a given abstract 'cloud'. This game is aimed to facilitate creative thought. **F.** The 'speed-read' mini-game. Players see a short text, which is rapidly presented on screen, and answer a question related to the text. This game is aimed to facilitate fast thinking. Games were implemented within a broader 'farm' like game, and collectible points earned at each therapeutic mini-game were used for building and designing the farm.

Table S1

	Intervention (n=87)	WLC (n=30)	P-value
Demographic Characteristics			
Mean Age (±SD)	32.62 (±8.61)	31.87 (±8.33)	0.68
Female (%)	68 (78.2)	23 (76.7)	0.81
Ethnicity (%)			0.37
American Indian or Alaska Native	3 (3.4)	0 (0)	
Asian	14 (16.1)	9 (30)	
Black or African American	12 (13.8)	2 (6.7)	
Native Hawaiian or Other Pacific Islander	0 (0)	0 (0)	
White	54 (62.1)	18 (60)	
Prefer Not to Answer	4 (4.6)	1 (3.3)	
University Level Education (%)	67 (77)	21 (70)	0.44
Married/Domestic Partners (%)	28 (32.2)	9 (30)	0.82
Employment Status (%)			0.57
Employed	60 (69)	19 (63.3)	
Unemployed	14 (16.1)	4 (13.3)	
Student	13 (14.9)	7 (23.3)	
Annual Household Income (%)			0.21
0 - 19,999	7 (8)	3 (10)	
20,000 - 39,999	15 (17.2)	10 (33.3)	
40,000 - 59,999	16 (18.4)	5 (16.7)	
60,000 - 79,999	9 (10.3)	5 (16.7)	
80,000 - 99,999	11 (12.6)	1 (3.3)	
100,000 or above	21 (24.1)	6 (20)	
Prefer Not to Answer	8 (9.2)	0 (0)	
English as Primary Language (%)	82 (94.3)	26 (86.7)	0.18
Clinical Characteristics			
MDD as Primary Diagnosis (%)	87 (100)	30 (100)	
Secondary Diagnosis (%)			0.38
Suicide Behavior Disorder	3 (3.4)	2 (6.7)	
Panic Disorder	5 (5.7)	3 (10)	
Social Anxiety Disorder	15 (17.2)	6 (20)	
Obsessive Compulsive Disorder	0 (0)	2 (6.7)	
Alcohol Use Disorder	3 (3.4)	0 (0)	
Binge-Eating Disorder	1 (1.1)	0 (0)	
Generalized Anxiety Disorder	25 (±28.7)	13 (±43.3)	
Mean MADRS at Baseline (±SD)	27.29 (±4.64)	26.03 (±4.63)	0.20

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Mean PHQ-9 at Baseline (±SD)	14.79 (±4.52)	15.41 (±3.82)	0.51
Mean GAD-7 at Baseline (±SD)	9.44 (±5.54)	10.62 (±5.56)	0.32
Mean RRS at Baseline (±SD)	55.54 (±11.71)	58.03 (±8.46)	0.22
Mean SDQ at Baseline (±SD)	141.15 (±18.4)	145.48 (±14.87)	0.25
Mean PANAS-NA at Baseline (±SD)	23.93 (±7.06)	25.76 (±7.44)	0.24
Mean PANAS-PA at Baseline (±SD)	18.43 (±6.45)	20.21 (±7.89)	0.23
Mean WHO-QoL-BREF at Baseline (±SD)	77.95 (±9.93)	77.14 (±9.83)	0.70
Mean SHAPS at Baseline (±SD)	23.60 (±6.39)	22.03 (±7.38)	0.27
Receiving Psychotherapy and/or MDD Medication (%)	47 (54)	18 (60)	0.57

Table S1. Demographic and clinical characteristics at baseline. p = significance value, derived from either student's t-test or chi-square ($\chi 2$) by comparing treatment conditions on binary variables. Note: the final analysis was conducted on 73 and 27 completers from the intervention and WLC groups, accordingly.

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Table S2

Assessment	Mean change- intervention		Mean change- WLC	
MADRS	0-4	-8.87±0.95^{***ǂ}	0-4	-4.4±1.4**
	0-8	-11.82±1.12^{***ǂ}	0-8	-4.81±1.47**
PHQ-9	0-4	-4.85±0.58***	0-4	-2.76±0.93**
	0-8	-6.68±0.71^{***ǂ}	0-8	-2.55±1.03*
GAD-7	0-4	-1.90±0.56**	0-4	-0.38±0.82$^{n.s}$
	0-8	-2.21±0.59***	0-8	-0.74±0.86$^{n.s}$
RRS	0-4	-9.29±1.22***	0-4	-6.3±2.46*
	0-8	-12.04±1.43^{***ǂ}	0-8	-4.44±2.55$^{n.s}$
SDQ	0-4	-12.24±2.85***	0-4	-9.34±3.86*
	0-8	-20.56±3.06^{***ǂ}	0-8	-7.81±5.02$^{n.s}$
PANAS-NA	0-4	-2.04±0.76**	0-4	-0.84±1.42$^{n.s}$
	0-8	-2.61±0.88**	0-8	-0.85±1.65$^{n.s}$
PANAS-PA	0-4	4.74±0.84^{***ǂ}	0-4	0.3±1.59
	0-8	6.47±0.95^{***ǂ}	0-8	1.37±1.53$^{n.s}$
WHO-QoL-BREF	0-4	2.6±1.11*	0-4	-0.61±1.43$^{n.s}$
	0-8	5.01±1.27^{***ǂ}	0-8	0.07±2.04$^{n.s}$
SHAPS	0-4	2.95±0.78***	0-4	2.19±0.97*
	0-8	4.73±0.8***	0-8	2.81±1.29*

Table S2: Improved clinical symptoms following FTP-based intervention compared with WLC. The table depicts for each assessment its mean change from baseline after 4 weeks, as well as after 8 weeks of enrolling in the clinical trial to either the FTP-based intervention or the WLC groups. Asterisks denote significant changes from baseline. ǂ= significant differences in mean change from baseline between the intervention and the WLC groups. GAD-7= General Anxiety Disorder-7; MADRS= Montgomery–Åsberg Depression Rating Scale; PANAS-NA= Positive Affect Negative Affect Scale- Negative Affect Score; PANAS-PA= Positive Affect Negative Affect Scale- Positive Affect Score; PHQ-9= Patient Health Questionnaire-9; RRS= Rumination Response Scale; SHAPS= Snaith-Hamilton Pleasure Scale; SDQ= Symptoms of Depression Questionnaire; WHO-QoL-BREF= World Health Organization Quality of Life Brief Version; WLC= Waitlist Controls

Female Spotlight

In addition to our main findings, we were interested in assessing whether FTP-based app use was more effective given specific demographic conditions. Considering that females compose a larger

proportion of humans experiencing depression and anxiety [66], [67], [68], and are also more likely to seek help [69], [70], it was important to understand the relation between their demographic attributes and the intervention. Indeed, selectively for female players, we find a significant correlation between age and clinical improvement, such that the older the player was, there was a greater reduction in MADRS and PHQ-9 scores between baseline and week 8 (MADRS: r= -0.33, p=0.01; PHQ-9: r= -0.33, p=0.01). These correlations did not emerge for male participants, nor did they emerge in the WLC.

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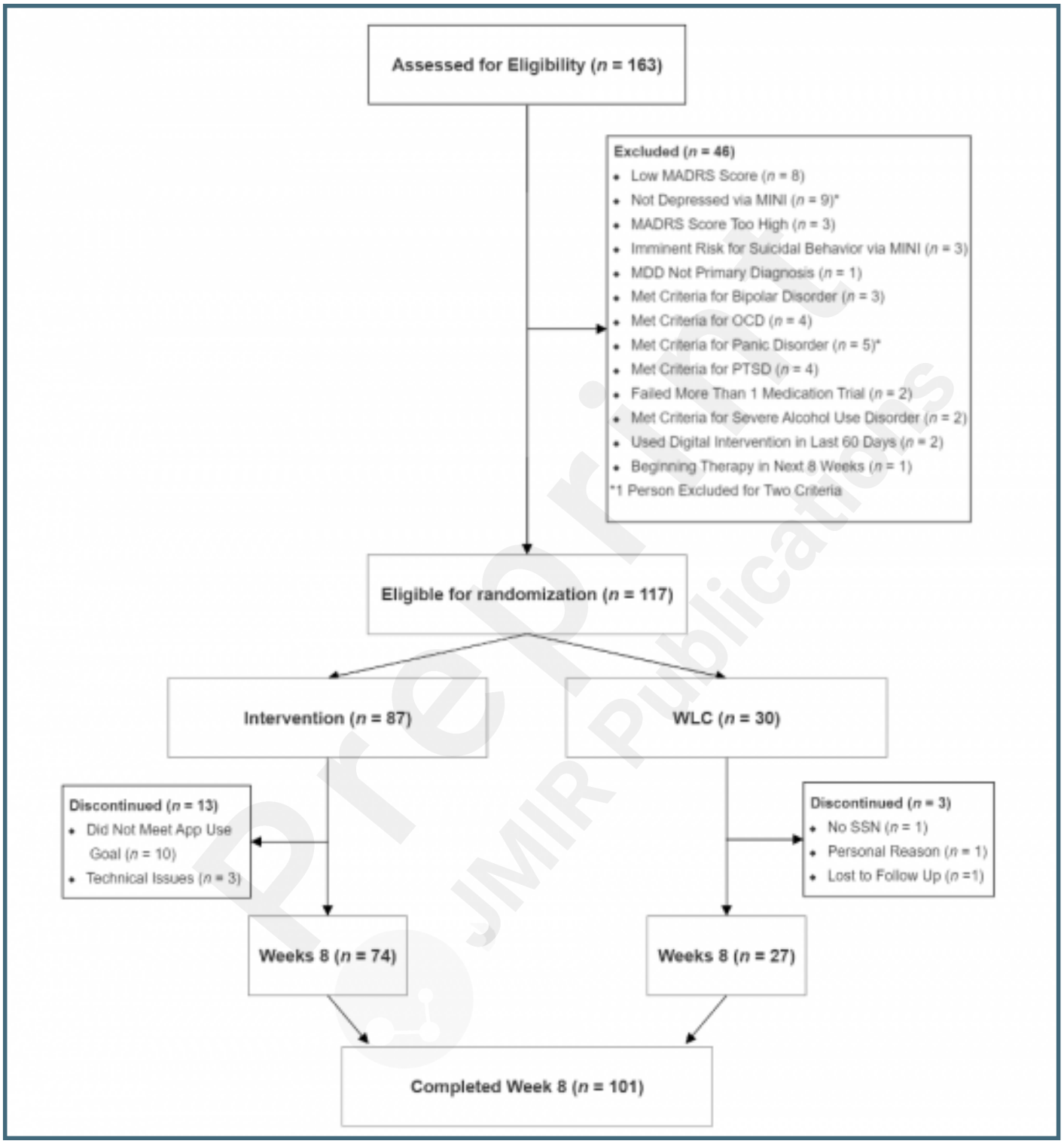
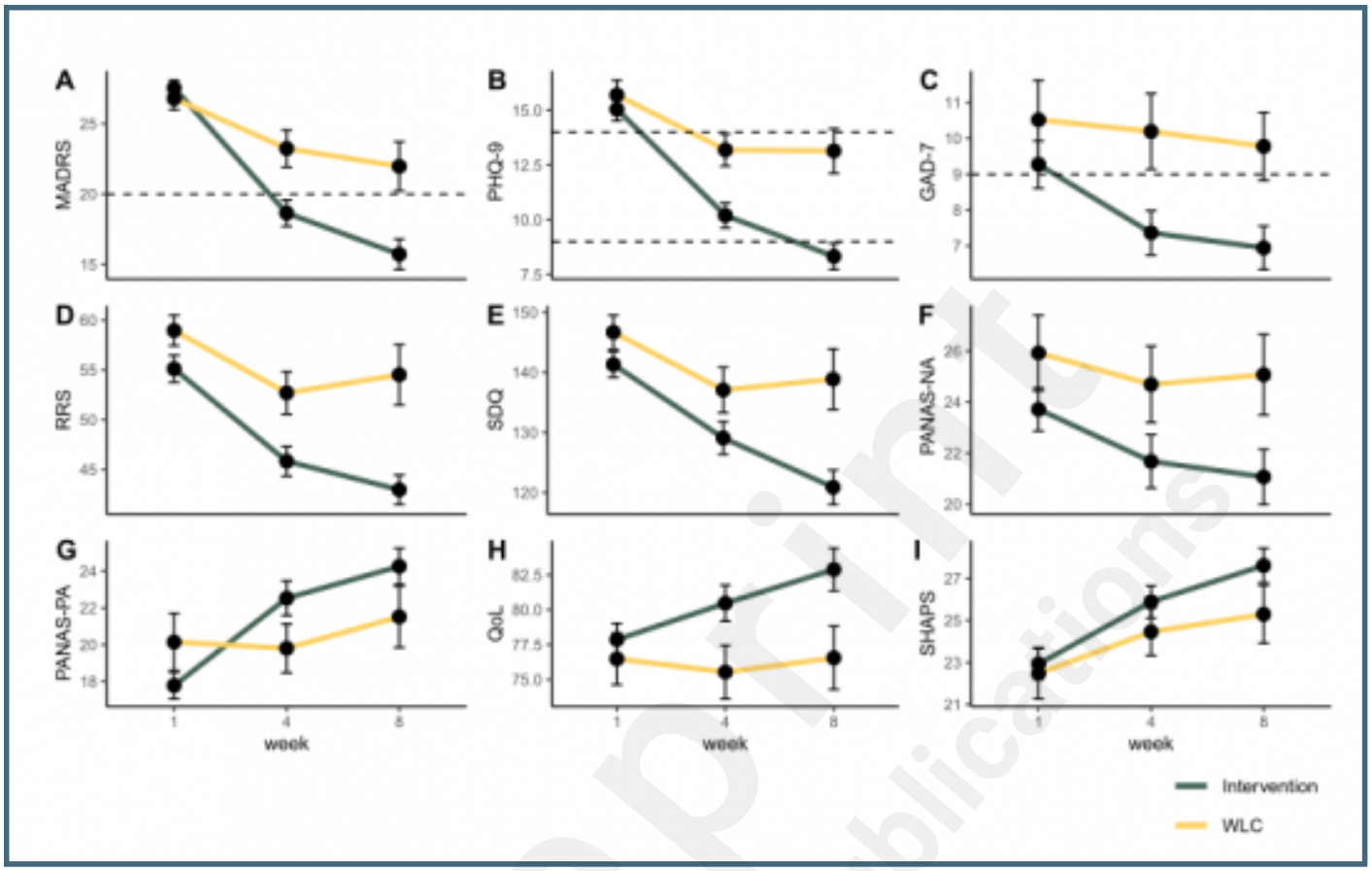


Greater improvement in clinical symptoms following FTP-based intervention compared with WLC.



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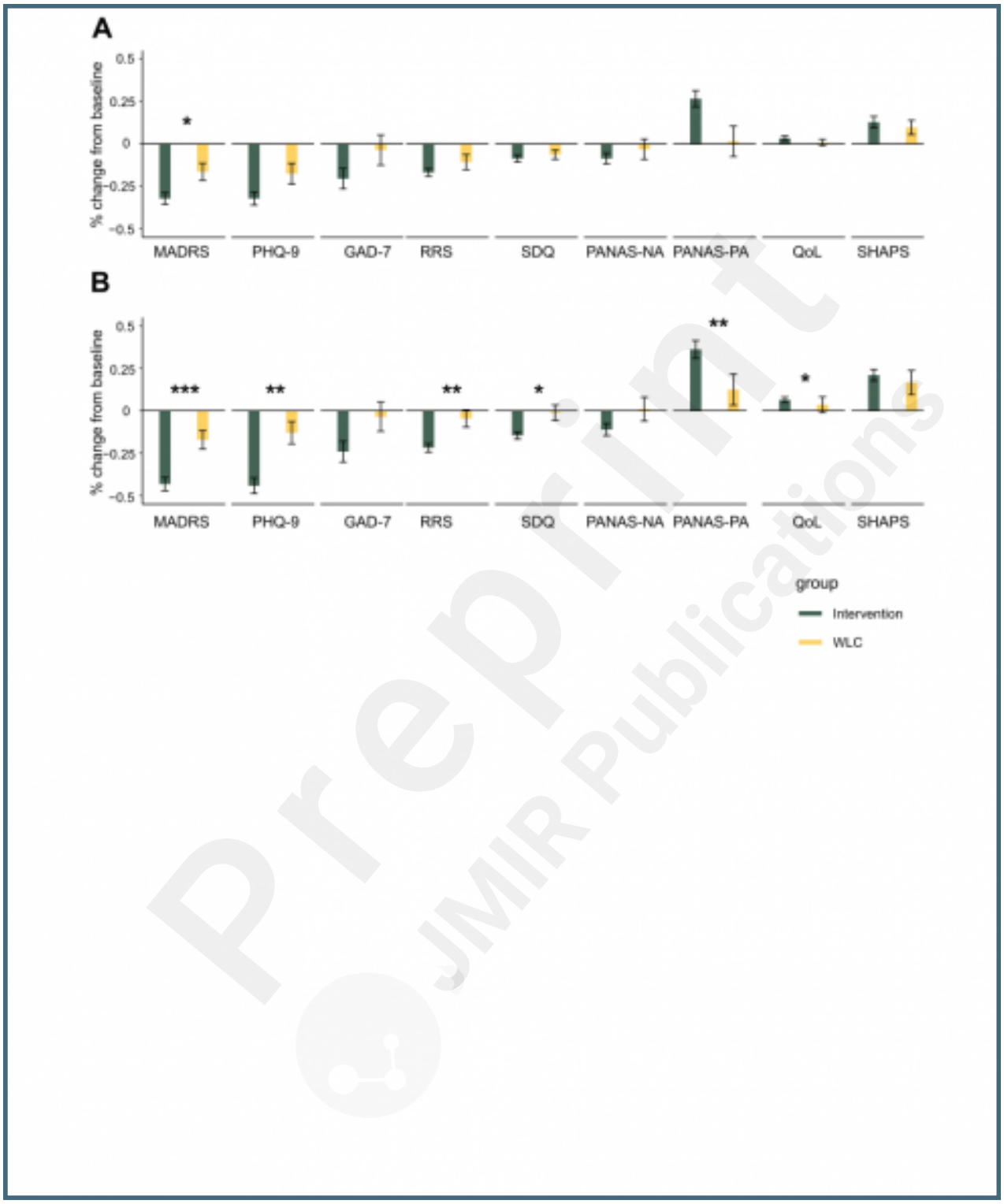

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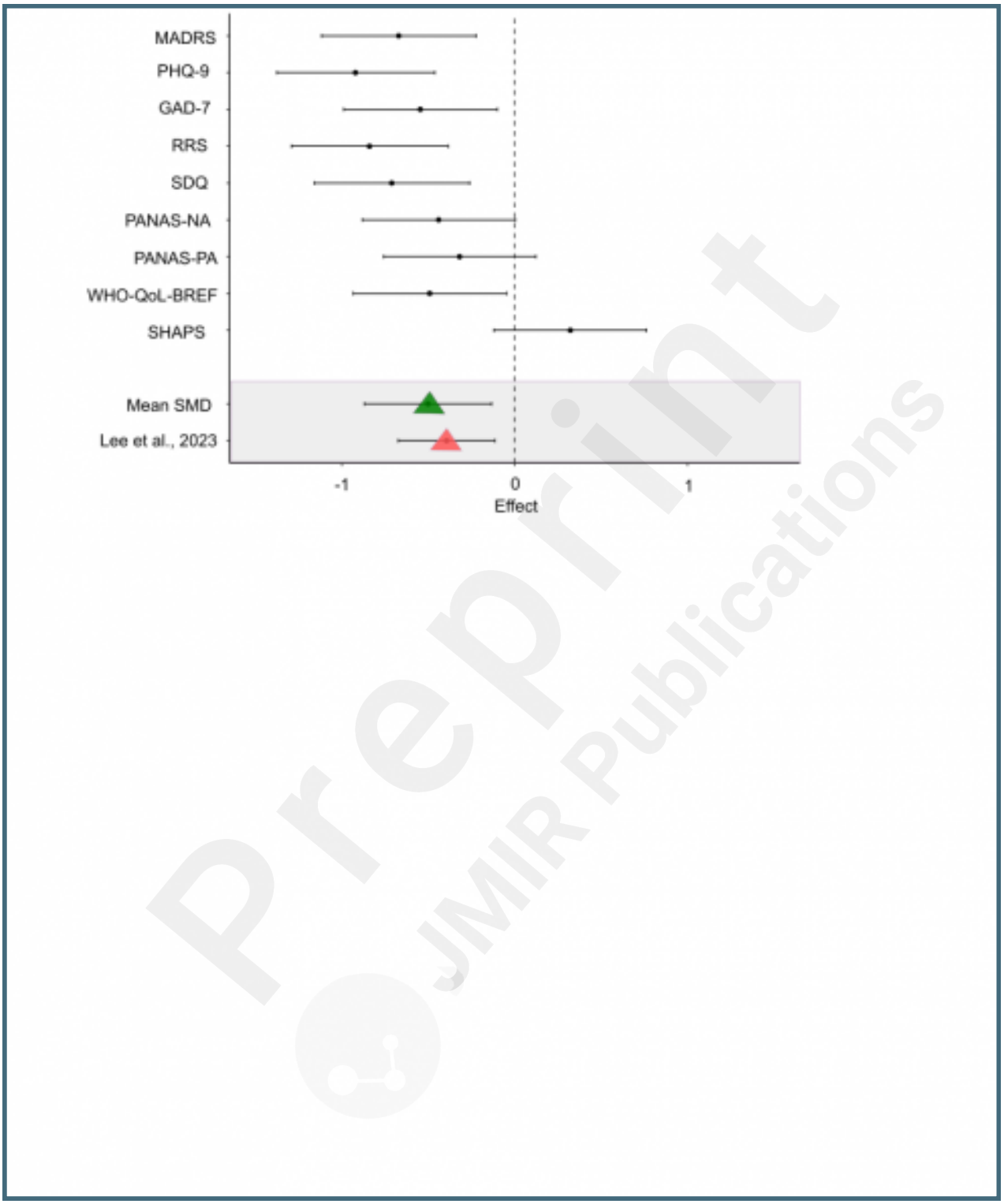

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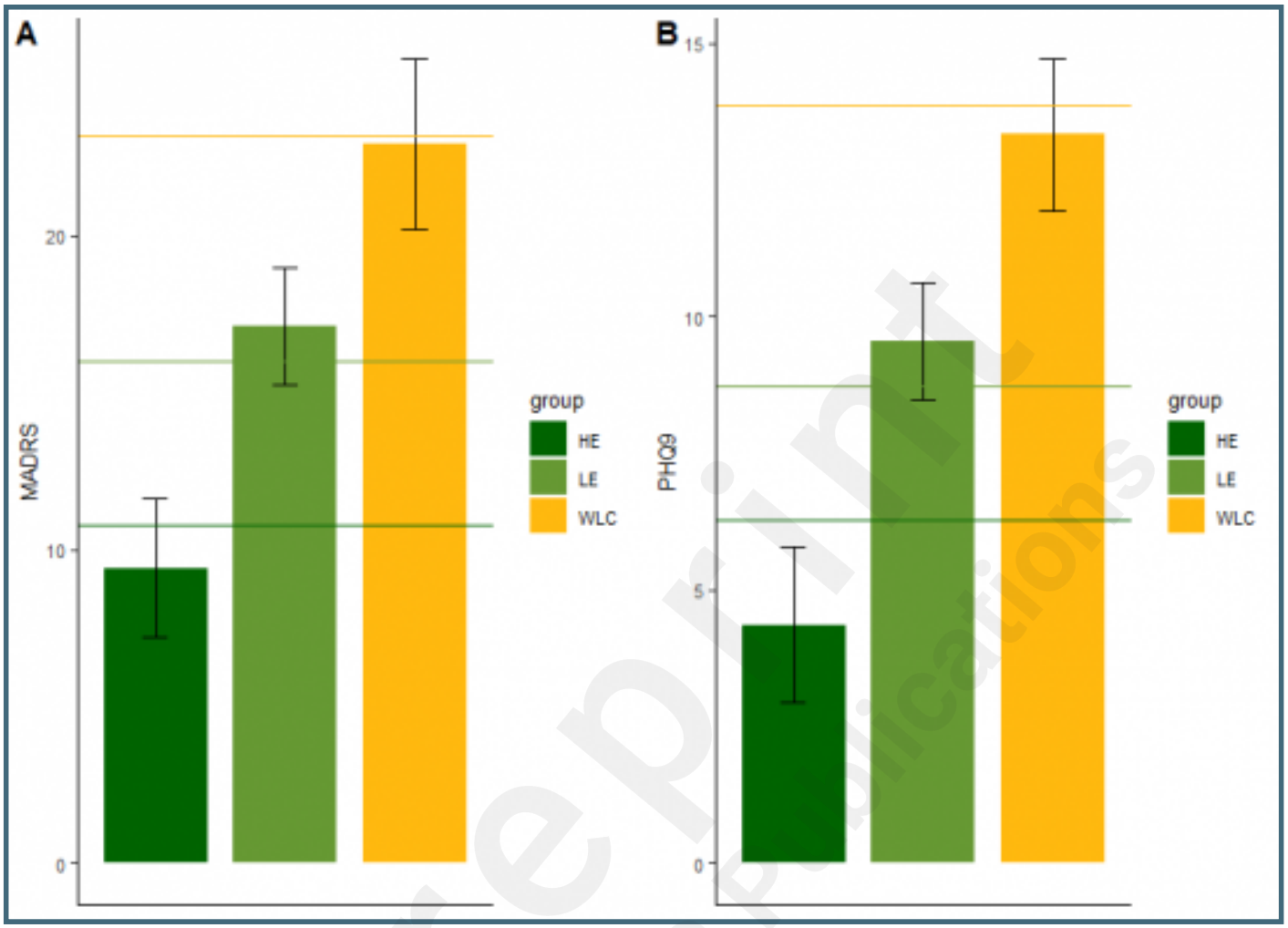
Group differences one-month post-intervention.



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