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Faculteit Revalidatiewetenschappen

Master in de ergotherapeutische wetenschap

Masterthesis

Self-management interventions to promote participation in daily life for people with major depression: A systematic review

Ory Depuydt
Joy Vanantwerpen

Scriptie ingediend tot het behalen van de graad van Master in de ergotherapeutische wetenschap

PROMOTOR :
Prof. dr. Dominique VAN DE VELDE

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BEGELEIDER :
Mevr. Jolien BRAECKMAN

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Self-management interventions to promote participation in daily life for people with major depression:

A systematic review

Ory Depuydt (2470174) & Joy Vanantwerpen (2470452)

Masterproef ingediend tot het verkrijgen van de graad van
Master of Science in de ergotherapeutische wetenschap

Promotor: prof. dr. Van de Velde Dominique
Begeleider(s): Jolien Braeckman
Academiejaar 2024-2025

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Nederlands abstract

Introductie: Majeure depressieve stoornis (MDD) heeft een grote impact op het dagelijks functioneren en de levenskwaliteit van individuen. Hoewel er diverse behandelingen beschikbaar zijn, blijft de toegang tot gepaste zorg voor velen beperkt. Zelfmanagementinterventies worden steeds vaker erkend als een waardevolle aanvulling binnen de zorg voor personen met MDD, met het potentieel om de participatie in het dagelijks leven te bevorderen.

Methode: Een systematische literatuurstudie werd uitgevoerd volgens de PRISMA-richtlijnen. Er werd gezocht in drie databases (MEDLINE, PsycINFO en Embase) naar gerandomiseerde gecontroleerde studies gepubliceerd tussen 2012 en 2022. De geselecteerde studies werden beoordeeld met behulp van de Self-Management Analysis in Chronic Conditions (SMACC) checklist, een instrument ontwikkeld om zelfmanagementinterventies systematisch te analyseren op relevante attributen. Het wordt voornamelijk beschouwd als een waardevol hulpmiddel voor de ondersteuning van de ontwikkeling, vergelijking en evaluatie van zelfmanagementinterventies.

Resultaten: Zestien studies met in totaal 1821 deelnemers werden geïncludeerd. De onderzochte interventies verschilden sterk in inhoud, setting en leveringsvorm. Interventies zoals Cognitive Behavioral Analysis System of Psychotherapy (CBASP), Life Adaptation Skills Training (LAST) en psycho-educatie scoorden hoog op de SMACC-checklist en boden een breed scala aan zelfmanagementondersteuning. Andere interventies zoals mindfulness-gebaseerde therapieën (MBCT, MSC) en de Dejian Mind-Body Intervention (DMBI) vertoonden een beperkter profiel wat betreft ondersteuning van dagelijkse participatie. De meeste interventies richtten zich vooral op emotieregulatie en probleemoplossing, terwijl attributen zoals ‘levenslang leren’ en ‘medisch zelfbeheer’ weinig aan bod kwamen.

Conclusie: Hoewel verschillende zelfmanagementinterventies positieve effecten vertonen op symptoomvermindering bij MDD, is hun ondersteuning van participatie in het dagelijks leven vaak beperkt. Interventies met een brede, geïntegreerde aanpak, met aandacht voor rolmanagement, doelstelling en samenwerking, tonen het meeste potentieel om betekenisvolle participatie te ondersteunen. De SMACC-checklist blijkt een waardevol hulpmiddel om dergelijke interventies te evalueren en te ontwikkelen binnen een cliëntgerichte, herstelgerichte context.

Keywords: *Majeure depressieve stoornis, zelfmanagement, participatie, systematische review, SMACC*
Aantal woorden masterproef: 5850
Volgens de richtlijnen van de Journal of Affective Disorders

Engels abstract

Introduction: Major depressive disorder (MDD) significantly impacts individuals' daily functioning and quality of life. Although a wide range of treatments is available, access to appropriate care remains limited for many. Self-management interventions are increasingly recognized as valuable additions to the treatment of individuals with MDD, with the potential to enhance participation in daily life.

Method: A systematic literature review was conducted in accordance with PRISMA guidelines. Three databases (MEDLINE, PsycINFO, and Embase) were searched for randomized controlled trials (RCTs) published between 2012 and 2022. The included studies were assessed using the SMACC checklist, a tool developed to systematically analyze self-management interventions based on relevant attributes. It is mainly considered a valuable tool for supporting the development, comparison and evaluation of self-management interventions.

Results: Sixteen studies with a total of 1,821 participants were included. The interventions varied widely in content, setting, and mode of delivery. Interventions such as the Cognitive Behavioral Analysis System of Psychotherapy (CBASP), Life Adaptation Skills Training (LAST), and psychoeducation scored highly on the SMACC checklist and offered broad self-management support. Other interventions, such as mindfulness-based therapies (MBCT, MSC) and the Dejian Mind-Body Intervention (DMBI), showed more limited support for daily participation. Most interventions focused on emotional regulation and problem-solving, while attributes like 'lifelong task' and 'medical self-management' were rarely addressed.

Conclusion: Although various self-management interventions show positive effects on symptom reduction in MDD, their support for participation in daily life is often limited. Interventions that adopt a broad, integrated approach, addressing role management, goal-setting, and collaborative care, show the greatest potential to support meaningful participation. The SMACC checklist proved to be a valuable tool for evaluating and developing such interventions within a client-centered, recovery-oriented framework.

Keywords: *Major depressive disorder, self-management, participation, systematic review, SMACC*
Word count of the master thesis: 5850
By the guidelines of the Journal of Affective Disorders

Table of content

Voorwoord

Met dit voorwoord willen we kort stilstaan bij het traject dat voorafging aan deze masterproef en enkele mensen bedanken die hierbij een belangrijke rol hebben gespeeld. Deze masterproef is een resultaat van een intensieve samenwerking tussen (ondertussen) twee West-Vlaamse goede vrienden. We hebben dit onderwerp aangepakt met veel interesse en doorzettingsvermogen. We hebben twee complementaire delen van het onderzoek uitgewerkt, die samen een coherent geheel vormen. Deze masterproef was niet alleen een academische uitdaging, maar ook een leerproces op persoonlijk vlak. Het combineren van wetenschappelijke nauwkeurigheid met praktijkgerichte relevantie vergde veel inspanning, maar leverde ook veel voldoening op.

Met deze masterproef ronden we de opleiding Master of Science in Occupational Therapy af. Het was een uitdagend, maar verrijkend proces waar we onze vaardigheden, kennis, interesses, … verder hebben kunnen verdiepen. Midden in het proces hebben we *'het geweer van schouder moeten veranderen'*. We zijn geschakeld van een kwalitatief onderzoek naar een systematic review, wat veel flexibiliteit, doorzettingsvermogen en nauwe samenwerking nodig had. Deze omschakeling zorgde dus ook voor een nauwere samenwerking met onze promotor en begeleider.

Bij deze willen we ook Dominique Van de Velde, onze promotor, en Jolien Braeckman, onze begeleider, bedanken voor hun nauwe begeleiding, constructieve feedback, ondersteuning en aanmoedigingen tijdens dit gehele proces.

Daarnaast willen we ook onze familie, vrienden en medestudenten bedanken voor hun onvoorwaardelijke steun in dit proces. Door hen vonden we rust in de chaos, hun aanwezigheid zorgde ervoor dat ons hoofd koel bleef en dat we de zaken in perspectief bleven zien. We willen hier in het bijzonder onze ouders voor bedanken.

Ook willen we onze dankbaarheid uiten naar onze partners. Ze waren het stille kompas toen wij de richting even kwijt waren. Ze waren het luisterend oor en toonden heel veel begrip als we het zelf even moeilijk hadden in dit proces.

We sluiten hierbij een heel belangrijk hoofdstuk af in ons leven, maar dit opent wel deuren naar nieuwe ervaring die we kunnen opdoen in het werkveld.

We wensen jullie veel leesplezier toe!

Ory Depuydt & Joy Vanantwerpen– Hasselt, mei 2025

1. Situering

Deze masterproef is gesitueerd binnen het onderzoeksdomein van de ergotherapeutische wetenschappen en vormt onderdeel van de masteropleiding Ergotherapeutische Wetenschappen, met een specifieke focus op de majeure depressieve stoornis.

Deze masterproef draagt bij aan een lopend doctoraatsonderzoek dat tot doel heeft zelfmanagement, meer specifiek rolmanagement, bij personen met een majeure depressieve stoornis (MDD) in kaart te brengen. Het doctoraatsonderzoek bestudeert hoe personen met MDD hun dagelijkse rollen en verantwoordelijkheden navigeren, en identificeert ondersteunende interventies die dit proces kunnen faciliteren.

In de klinische praktijk bestaan verschillende interventies om zelfmanagement bij personen met MDD te bevorderen. Het vergelijken of evalueren van deze interventies brengt echter beduindende uitdagingen met zich mee. Een primaire belemmering vormt het ontbreken van consensus betreffende de precieze definitie van 'zelfmanagement'. Meerdere definities en interpretaties circuleren binnen de literatuur en klinische praktijk, wat resulteert in conceptuele verwarring en inconsistente toepassing.

Om deze problematiek aan te pakken werd een systematische review uitgevoerd. Deze systematische review beoogde een overzicht te bieden van de bestaande literatuur en de verschillende definities, doelstellingen en werkzame componenten van zelfmanagementinterventies voor MDD te karakteriseren. De bevindingen van deze review vormen de basis voor deze masterproef.

2. Introduction

2.1. Definition

Major depressive disorder (MDD) is a complex, heterogeneous, and potentially long-term mental illness affecting over 322 million people worldwide, with a lifetime prevalence of 20.6%[19]. It is one of the most prevalent psychiatric disorders globally and a leading contributor to the global burden of disease, associated with substantial personal, social, and economic costs[5, 21,58].

It not only influences the emotional state of individuals but also impacts their capacity to perform daily activities, including work responsibilities and social interactions[22]. This may result in diminished productivity and deterioration of social relationships, thereby negatively affecting overall quality of life[22, 58].

2.1.1. Social impact

MDD has substantial societal and economic consequences, affecting work productivity, interpersonal relationships, and overall quality of life. Evidence from various countries indicates that productivity losses due to depression far exceed the direct healthcare costs[5]. Notably, costs related to presenteeism, when employees are physically present at work but function at reduced productivity, are typically five to ten times higher than those associated with absenteeism[8, 58].

2.1.2. Personal impact

MDD significantly impairs cognitive function and daily functioning. Cognitive deficits, including difficulties in concentration, decision-making, and clear thinking, are prevalent in MDD patients and persist even during remission[10, 59]. These cognitive symptoms contribute to social and occupational impairments, affecting relationships, work productivity, and overall functioning[9,11, 58].

Caregivers often report a loss of control over their lives, feeling strained, and impaired self-perceived health[12]. The disorder affects the entire organism and manifests through emotional, cognitive, physiological, and behavioral symptoms[13]. Many patients prioritize cognitive symptoms in their treatment goals, recognizing their impact on recovery and return to normal functioning[59]. While full recovery from MDD typically occurs within four to six months, the course may be prolonged or include relapses[1,2, 58].

2.2. Treatment of major depressive disorder

Therapeutic approaches for MDD, including psychotherapy[22], cognitive therapy[23], pharmacotherapy[26], art and exercise-based interventions[24], primary care[25], and community support[27], have advanced significantly and are applied based on symptom severity and individual needs[28]. Despite this range of evidence-based options, only around 50% of individuals with depression seek treatment, and many fail to recognize their symptoms early[29]. Contributing factors such as limited mental health resources and reduced patient awareness have led to a significant treatment gap. In this context, self-management strategies are increasingly recognized as a promising means to enhance early recognition, promote engagement in care, and help bridge the divide in access to treatment[29, 58].

Self-management plays a crucial role in the recovery of individuals with MDD who are seeking to resume their life roles. The concept of self-management refers to an individual's ability to independently manage their health and well-being, take responsibility for their care, set personal goals, develop coping strategies, and take action to improve their health status[4]. Self-management interventions have shown promise in reducing depressive symptoms and improving outcomes for individuals with severe mental illness and chronic physical conditions. Meta-analyses have demonstrated small to medium effect sizes in reducing symptoms, improving functioning, and enhancing quality of life for people with severe mental illness[14]. For adults with chronic physical diseases and co-occurring depressive symptoms, self-management interventions have yielded significant reductions in depressive symptomatology and anxiety[15, 58].

In addition to self-management, role management (wich is a attribute of self-management) is an essential factor to consider in the resumption of meaningful life roles following residential treatment for depression[4]. This domain encompasses the individual's capacity to reclaim, sustain, or modify existing life roles and activities, while potentially exploring new ones in response to functional limitations imposed by their condition[6]. The individual demonstrates effective management of disease impact on meaningful daily activities. They demonstrate anticipatory coordination of necessary adaptations when routine activities can no longer be performed automatically (e.g., occupational responsibilities, recreational pursuits, household management)[6]. Research suggests that engaging in meaningful activities and diverse life roles contributes significantly to recovery processes for individuals with mental health and substance use disorders. Meaningful work, in particular, plays a central role in fostering a sense of purpose, self-worth, and social connectedness[16, 58].

2.2.1. Challenges in self-management

Individuals with MDD often face significant challenges in self-management due to symptoms such as fatigue, low motivation, and pervasive negative thinking. Cognitive impairments and diminished self-efficacy further hinder their ability to actively engage in treatment and selfmanagement activities[18]. Healthcare system barriers, including poor communication with providers and fragmented care, further complicate self-management efforts[30]. Encouraging patients and building their self-confidence can stimulate their inner strength and self-efficacy, thereby promoting their ability to self-manage[17]. However, current services often fail to adequately support self-management, with patients expressing a need for more individualized, holistic approaches and improved information about developing strategies and locating resources[17]. Self-management is seen as a promising strategy for identifying, treating, and managing depression, especially given the increasing prevalence of MDD and shortages of mental health professionals[17, 18, 58].

2.2.2. Facilitating factors for recovery.

In addition to obstacles, there are also facilitators that are essential for recovery and support the resumption of various life roles. A supportive social network is crucial as it provides emotional support and helps strengthen self-confidence[3]. Effective treatment and follow-up care are vital for reducing depressive symptoms and promoting recovery[17, 18]. Self-management skills play an important role in effectively coping with daily stressors and challenges[17, 18]. Finally, lifestyle changes, such as regular physical activity, healthy eating, and adequate sleep, are critical for improving both physical and mental health[18]. These facilitators are of great importance for successfully resuming personal, professional, and social roles[58].

2.3. Research goal

This study will contribute to the development of best practices and standardized protocols for healthcare workers working with individuals suffering from MDD. It will provide therapists with validated strategies to address cognitive impairments, skill development, and routine formation, all of which are essential for managing daily activities and improving overall well-being. The findings will also advocate for the inclusion of tailored, client-centered approaches in therapy, emphasizing the importance of personalized care plans that align with the unique needs and goals of each individual[58].

This leads us to the research question: *”Which self-management interventions are used for individuals with major depressive disorder (MDD)?”*. The objective is *"To systematically review and synthesize the evidence from randomized controlled trials on the effectiveness of self-management interventions in enhancing participation in daily life among individuals diagnosed with major depressive disorder"* .

3. Methods

We followed the PRISMA guidelines (Moher et al., 2009). Three reviewers (OD, JV and JB) conducted the review process, which comprised five steps, with each step involving two independent reviewers (appendix 9.8).

3.1. Search strategy and selection criteria

A comprehensive search was conducted in three databases. Our comprehensive search strategy, developed with two students (OD and JV) and one expert (JB), consisted of several combinations of the search terms: major depressive disorder AND Rehabilitation AND Self-management AND Clinical trial, and was performed in MEDLINE, PsycINFO and Embase (see Appendix 9.1-9.3 Final Search Strategy).

3.2. Study selection and eligibility criteria

Secondly, after deduplicating the search results using EndNote X9 using the method outlined by Bramer et al. (Bramer et al., 2016), we screened identified titles and abstracts and excluded irrelevant studies with Rayyan. One reviewer (JB) performed a first screening on title. Then two reviewers (OD and JV) independently performed the comprehensive screening process of both titles and abstracts, as well as full-text articles from the search results, to assess inclusion criteria. The inclusion criteria (Table 1) are based on self-management skills (SMACC)[6], in combination with recovery-focused outcomes, symptom-focused outcomes or daily functioning. To be eligible for inclusion, studies had to meet the following criteria: 1) reporting on adults aged 18 years and above with major depressive disorder; 2) published in English; 3) Included a self-management intervention designed to, at least in part, support the patient's ability to manage their everyday life; 4) reporting randomized controlled trials Details are provided in List of tables 10.1. One study included in our analysis was identified as a protocol for a randomized controlled trial. We attempted to contact the corresponding author to obtain complete intervention details and final results, but received no response despite our inquiries. Consequently, our assessment of this particular study was limited to the information available in the published protocol.

Studies that focused on comorbidities as well as other designs besides randomised controlled trials were excluded. The results of the search were limited to studies published between January 1, 2012 and February 1, 2022. We chose this timeframe for its feasibility, assuming that studies investigating previously published instruments would reappear in, for

example, reviews published from 2012 onwards. Both reviewers evaluated the eligibility of the studies.

Table 1: In- and Exclusioncriteria:

Inclusion	**Exclusion**
(a) Symptom-focused outcomes (b) Recovery-focused outcomes (c) Daily functioning (d) Self-management skills: Problem-solving; Decision making; Using Resources; Forming a patient-healthcare provider partnership; Goal-setting and evaluation A, B or C must always be combined with D (e) Dutch or English studies	(a) Comorbidities (b) Defined differently than RCT or CT

During the full-text screening phase, two authors independently screened an initial set of ten articles for inclusion or exclusion. This resulted in a Cohen's kappa coefficient of 0.48, indicating moderate agreement. Following a discussion to resolve discrepancies, an additional five articles were independently screened, after which inter-rater reliability improved to a kappa of 1.0, indicating perfect agreement (Appendix 9.4 - 9.5). Based on this outcome, the remaining articles were divided between the reviewers, with each author independently screening twelve articles. Discrepancies in study selection or full-text screening were resolved through discussion. If consensus could not be reached, the issue was referred to JB and DV for further deliberation. When information about self-management interventions was insufficient, the original documents detailing complete intervention protocols were consulted. This approach ensured comprehensive understanding of each intervention's methodology and components for thorough analysis[47, 57].

Following the data extraction, two authors (OD & JV) identified two additional studies that were excluded because MDD was not the sole condition investigated. Both studies included participants with schizophrenia and schizoaffective disorder in both the intervention and control groups. As a result, it is unclear whether the reported outcomes are specifically attributable to individuals with MDD, those with schizophrenia, or both. This ambiguity prompted the exclusion of these two studies from the final analysis[48, 49]. This screening proces is visualized in figure 2; the flowchart.

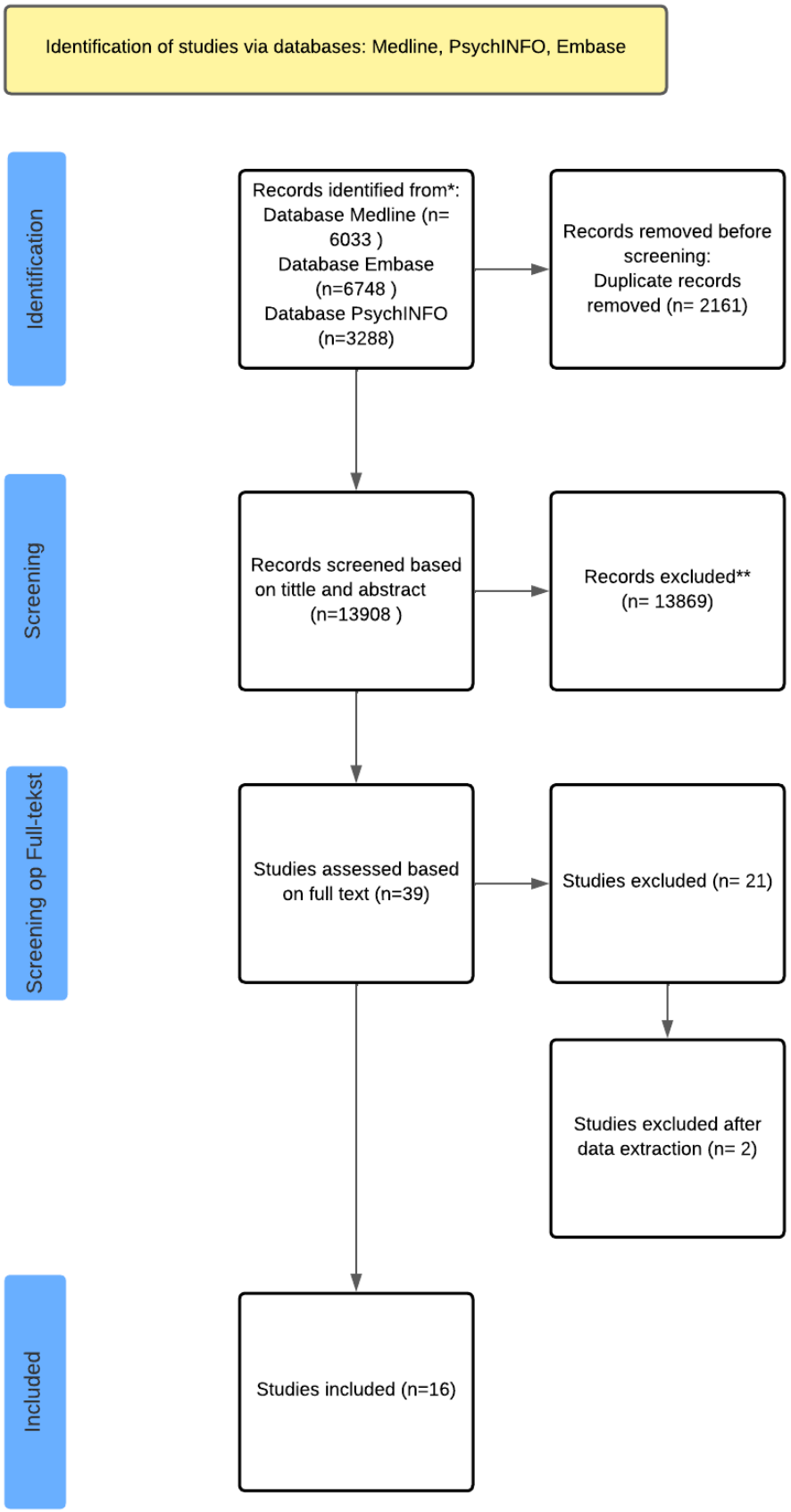

Fig 1: Flowchart

3.3. Data extraction

The articles were evaluated based on the self-management interventions they described, using the Self-Management Analysis in Chronic Conditions (SMACC) checklist as the assessment tool[6]. Two authors each independently assessed nine interventions using this checklist. The SMACC checklist was developed as a validated instrument to address the inherent ambiguity surrounding self-management interventions and their content[6]. The content validity of the checklist was investigated through an international Delphi study involving healthcare professionals with expertise in self-management and chronic conditions, from both research and clinical practice perspectives[6].

The SMACC checklist is primarily considered a valuable tool to support the development, comparison, and evaluation of self-management programs. A key characteristic of the SMACC checklist is that it was predominantly developed for the support and evaluation of guided self-management interventions, as opposed to unguided interventions[6].

In cases where limited information was provided about the intervention itself, the reviewers sought additional details by contacting the original authors, consulting the referenced primary descriptions of the interventions, or examining supplementary materials such as appendices or online supplement files. Discrepancies in scoring were resolved through discussion, with input from the other authors when necessary.

In addition, administrative data were independently extracted by OD and JV for nine included studies each respectively. Extracted information included: (1) study identification details (first author, year of publication, title, and country); (2) general study characteristics (study design, target population, baseline sample size, outcomes, and outcome measures); and (3) intervention characteristics (mode of delivery, setting, providers, detailed intervention description and components, and timing of the intervention).

3.4. Data synthesis

Descriptive data were organized and summarized in tabular format (list of tables 11.9).

A qualitative meta-synthesis was conducted following the guidelines proposed by Sandelowski and Barroso[7]. Initially, extracted data on self-management attributes, intervention formats and components, and outcome measures were categorized into domains and subdomains based on descriptive similarities, with domain size determined by the frequency of content occurrence. To evaluate the overall representation of these domains across the studies, their relative occurrence was calculated. A sunburst chart was created to provide a visual representation of these domains. The sunburst chart is a hierarchical visualization technique utilizing concentric circles to display multi-level categorical data structures. In this visual representation, the central circle depicts the

primary category or parent node, while the outer rings illustrate subcategories or subordinate levels within the hierarchical framework.

The authors further analyzed the identified interventions by extracting their p-values and ranking these for each assessment from most to least statistically significant. All findings were triangulated, and any discrepancies or interpretations were discussed and resolved in meetings involving two of the authors.

3.5. Risk of bias

Risk of bias was independently assessed by two authors, OD and JV using the Cochrane Risk of Bias 2 (RoB 2) tool for randomized studies. Details are provided in appendix 9.7. Any disagreements between reviewers were resolved through consultation with the other authors.

4. Results

4.1. Study Characteristics

Table 2: Study charachteristics

Characteristics	No. of studies (%)
Design - Randomised controlled trial	16 (100)
No. of participants - 1-25 - 26-50 - 51-75 - 76-100 - 100+	 - 2 (13) - 2 (13) - 7 (44) - 2 (13) - 3 (19)
Country - United States - Thailand - Turkey - Switzerland - Taiwan - United Kingdom - Greece - Japan - Germany - China - Norway - Iran	 - 3 (19) - 1 (6) - 1 (6) - 1 (6) - 2 (13) - 1 (6) - 1 (6) - 1 (6) - 2 (13) - 1 (6) - 1 (6) - 1 (6)

The included studies comprised a total of 1.821 individuals diagnosed with major depressive disorder (median = 71.5 participants; range = 21–523). Across these studies, a variety of interventions were employed. Control interventions included treatment as usual (n = 153), cognitive behavioral therapy (n = 172), wait-list control (n = 83), phone contact as intervention (n = 45), group psychoeducation (n = 19), medication (n = 111), standardized guided exercise therapy (GET; n = 36), Common Factor Treatment-Control (CFT-C; n = 40).

In terms of self-management interventions, participants received the Pythagorean Self-Awareness Intervention (PSAI; n = 30), the Dejian mind-body intervention (DMBI; n = 25), self-organized activity (SOA; n = 40), the Coping With Depression Program (CWDP) based on the Neuman Systems Model using CBT techniques (n = 36), Deprexis (n = 51), Goal Management Training (GMT; n = 35), computerized cognitive training (CCT; n = 28), Mindful

Awareness Practices (MAPs; n = 39), supportive-expressive dynamic psychotherapy (n = 54), Life Adaptation Skills Training (LAST; n = 33), the Quality of Life Enhancement Programme (QOLEP; n = 11), Affect Regulation Training (ART; n = 40), Cognitive Behavioral Analysis System of Psychotherapy (CBASP) combined with medication (n = 200), Brief Supportive Psychotherapy (BSP) combined with medication (n = 195), mindfulness-based cognitive therapy (n = 15) and a combined mindfulness and self-compassion intervention (n = 33).

The studies were published between 2004 and 2021 and were primarily conducted in the United States, Taiwan, and Germany (see Table 2).

4.2. Intervention Characteristics

Self-management interventions were delivered in various formats: individually (n = 4), in a group setting (n = 11), in a mixed format combining individual sessions with an online module (n = 1), and entirely through an online platform (n = 1).

Regarding the setting, fifteen studies were conducted in a hospital environment. One study was delivered exclusively online. The healthcare professionals delivering the interventions were most commonly trained clinicians specialized in the respective interventions (n = 4). Other providers included clinical psychologists, psychotherapists, psychiatrists, and neuropsychologists (n = 7), exercise therapists (n = 1), occupational therapists (n = 2), and in one case, a clerk (n = 1). In six studies, the professional background of the intervention provider was not specified.

4.3. Primary Outcomes, Assessment Frequency, and Intervention-Specific Effects

Across the reviewed intervention studies, six distinct primary outcomes were identified, each assessed with varying frequency. The most frequently measured outcome was the reduction of depressive symptoms, which was evaluated in ten assessments. Other outcomes, daily executive functioning, perceived stress, quality of life, mood, and problem-solving ability, were assessed once or twice[58]. Details are provided in list of tables 11.5.

4.3.1. Reduction of Depressive Symptoms

Depressive symptoms were evaluated using four validated instruments: the Beck Depression Inventory-II (BDI-II), the Hamilton Depression Rating Scale (HDRS), the Center for Epidemiologic Studies Depression Scale (CES-D), and the Montgomery-Åsberg Depression Rating Scale (MADRS). A range of interventions demonstrated statistically significant effects on depressive symptoms[58].

When measured using the BDI-II, significant reductions were observed for several interventions. Coping With Depression Program (CWDP) ($p < .001$), Dejian mind-body intervention (DMBI; $p < .001$), Mindfulness-Based Cognitive Therapy (MBCT; $p = .001$), and Pythagorean Self-Awareness Intervention (PSAI; $p = .001$) all demonstrated robust effects.

Additional interventions including Deprexis ($p < .05$) and Group Psychoeducation ($p = .008$) also produced statistically significant outcomes[58].

On the HDRS, the most significant effect across all assessments was observed for Self-Organized Activity (SOA) intervention ($p < .0005$), making it the most effective intervention for reducing depressive symptoms overall. Other significant results were found for MBCT ($p = .001$), DMBI ($p = .002$), and Group Psychoeducation ($p = .002$). In contrast, Supportive-expressive dynamic psychotherapy (SE) did not demonstrate a significant effect ($p = .88$)[58].

Using the CES-D, the Mindful Awareness Practices (MAP) was assessed with various mediators. The most significant effects were observed for MAP with self-kindness as mediator ($p < .001$), followed by MAP with rumination ($p = .002$), and MAP with mindfulness ($p = .01$)[58].

Lastly, the MADRS assessment revealed a statistically significant reduction in depressive symptoms for participants in the Mindfulness and Self-Compassion (MSC) intervention group ($p = .003$)[58].

4.3.2. Daily Executive Functioning

Daily executive functioning was evaluated once using the Behavior Rating Inventory of Executive Function–Adult version (BRIEF-A). The intervention Goal Management Training (GMT) did not yield a statistically significant result ($p = .127$)[58].

4.3.3. Perceived Stress

Perceived stress was assessed using the Perceived Stress Scale (PSS) in studies involving the MAP intervention with different mediators. The strongest effect was observed for MAP with self-kindness ($p = .002$), followed by MAP with rumination ($p = .02$). MAP with mindfulness did not reach statistical significance ($p = .09$)[58].

4.3.4. Quality of Life

Quality of life was measured using the World Health Organization Quality of Life–BREF (Taiwan version). Life Adaptation Skills Training (LAST) and Quality of Life Enhancement Programme (QOLEP) intervention produced a statistically significant improvement ($p < .05$)[58].

4.3.5. Mood

Mood was evaluated using the Mood Rating Scale, with two cognitive strategies compared: distraction and rumination induction. Both interventions led to statistically significant improvements in mood, with distraction induction showing slightly greater efficacy ($p = .001$) compared to rumination induction ($p = .002$)[58].

4.3.6. Problem-Solving Ability

Problem-solving was assessed using the Means-Ends Problem-Solving (MEPS) task and the Social Problem-Solving Inventory–Revised (SPSI-R). The MEPS task demonstrated a highly significant effect for rumination induction ($p < .0005$), whereas distraction induction did not yield a statistically significant effect ($p = .28$). The SPSI-R showed a moderate but significant improvement following the Cognitive Behavioral Analysis System of Psychotherapy (CBASP) intervention ($p = .03$)[58].

4.3.7. Comparative Summary

When interventions are ranked by statistical significance within each outcome domain, several patterns emerge. The most statistically significant effect across all studies was observed for the Self-Organized Activity (SOA) intervention on depressive symptoms ($p < .0005$). Other highly effective treatments for depression included CWDP, DMBI, MAP with self-kindness, MBCT, and PSAI (all $p \leq .001$). In the domain of perceived stress, MAP with self-kindness showed the strongest effect ($p = .002$). For mood, distraction induction was marginally more effective than rumination induction. In terms of problem-solving, rumination induction yielded the most significant result ($p < .0005$), while CBASP also had a noteworthy but smaller effect ($p = .03$). Quality of life improved significantly with LAST and QOLEP ($p < .05$), whereas GMT did not produce a significant improvement in executive functioning ($p = .127$)[58].

4.4. Systematic Analysis of Self-Management Intervention Components Using the SMACC checklist

The self-management interventions identified in the articles were evaluated using the SMACC checklist, analyzing the frequency of different attributes across the studies. Each self-management attribution was subdivided into various domains to elucidate distinctions between interventions. Only attributes (7) openness to social support, (8) lifelong task, (10) decision making, and (14) medical management were not further subdivided[58]. Details are provided in List of tables 11.3.

The remaining attributes were categorized into subdomains as follows: (1) active participation (self-reflection/self-evaluation; self-analyses), (2) personal responsibility in self-management (self-observation and early recognition of signals; self-control & behavioral regulation), (3) coping with setbacks in self-management (acceptance and non-judgmental attitude; normalization of relapse and setbacks; learning coping strategies and resilience), (4) the person is informed about their condition, illness and treatment by the self-management intervention (psychoeducation), (5) expression of the person's needs and priorities (personal needs and strengths; daily functioning; personal characteristics), (6) collaborative care partnerships (shared decision-making; open dialogue), (9) problem-solving (training; daily problems), (11) use resources (internal resources; external resources), (12) ability to work in partnership with healthcare professional (translating therapy into real-life context;

community integration and social participation), (13) setting and evaluating goals (goals for emotional and interpersonal coping), (15) emotional management (cognitive restructuring; interpersonal insight and awareness), and (16) role management (role planning and routine building)[58].

Following the meta-synthesis, one article was excluded from the sunburst chart visualization as its intervention failed to meet any attributes outlined in the SMACC checklist. This particular study employed rumination induction or distraction induction as the intervention methodology for participants with Major Depressive Disorder[50].

Figure 2 provides a visual summary of these attributes, Table 3 demonstrates their presence across studies, List of tables 11.9 details the content per study, and List of tables 11.3 presents the complete coding tree.

Fig 2: Sunburst chart

Table 3: Presence of reported self-management attributes across the studies

Self-management attributes	**Reported in No. Studies (%)**
• **Active Participation** ○ Self-reflection/ Self-evaluation ○ Self-analyses	6 (37,5) 1 (6,25) 2 (12,5)
• **Personal responsibility in self-management**	6 (37,5)

○ Self-observation and early recognition of signals ○ Self-control & behavioral regulation	3 (18,75) 2 (12,5)
● **Coping with setbacks in self-management** ○ Acceptance and non-judgmental attitude ○ Normalization of relapse and setbacks ○ Learning coping strategies and resilience	8 (50) 1 (6,25) 1 (6,25) 4 (25)
● **The person is informed about their condition, illness and treatment by the self-management intervention** ○ Psychoeducation	8 (50) 7 (43,75)
● **Expression of the person's needs and priorities** ○ Personal needs and strengths ○ Daily functioning ○ Personal characteristics	10 (62,5) 3 (18,75) 2 (12,5) 3 (18,75)
● **collaborative care partnerships** ○ Shared decision-making ○ Open dialogue	6 (37,5) 1 (6,25) 3 (18,75)
● **Openness to social support**	5 (31,25)
● **Lifelong Task**	1 (6,25)

● **Problem-solving** ○ Training ○ Daily problems	10 (62,5) 4 (25) 1 (6,25)
● **Decision making**	4 (25)
● **Use resources** ○ Internal resources ○ External resources	5 (31,25) 2 (12,5) 1 (6,25)
● **Ability to work in partnership with healthcare professional** ○ Translating therapy into real-life context ○ Community integration and social participation	4 (25) 1 (6,25) 1 (6,25)
● **Setting and evaluating goals** ○ Goals for emotional and interpersonal coping	8 (50) 2 (12,5)
● **medical management**	2 (12,5)
● **Emotional management** ○ Cognitive restructuring ○ Interpersonal insight and awareness	13 (81,25) 2 (12,5) 2 (12,5)
● **Role management** ○ Role planning and routine building	4 (25) 2 (12,5)

4.5. Frequency of selfmanagement-attributes

This section analyzes the distribution and prevalence of SMACC checklist components across the evaluated interventions. The analysis categorizes interventions based on their alignment with SMACC attributes, highlighting those with high, moderate, and low presence of self-management attributes[58]. Details are provided in List of figures 10.3 & 10.4 and list of tables 11.6 & 11.7.

4.5.1. Interventions with the highest presence of SMACC attributes

Across the evaluated interventions, the Cognitive Behavioral Analysis System of Psychotherapy (CBASP) demonstrated a strong alignment with the SMACC attributes, with nine criteria fully present, one partially present, and six not present. This reflects a particular emphasis on problem-solving, behavioral regulation, and the development of interpersonal skills[58].

Similarly, Group Psychoeducation, which is patient-focused, achieved high scores, with eight criteria fully present, five partially present, and three not present. These results suggest that this intervention provides a comprehensive approach to self-management support[58].

Life Adaptation Skills Training (LAST) also showed comparable outcomes, with eight criteria fully present, five partially present, and three not present. This intervention primarily focuses on lifestyle restructuring, enhancing emotional awareness, and skill-building to support patient adaptation[58].

4.5.2. Interventions with moderate presence of SMACC attributes

The Coping With Depression Program (CWDP) demonstrated a solid presence across the SMACC attributes, with seven criteria fully present, four partially present, and five not present. This suggests a balanced approach, although certain elements remain less addressed. Deprexis, a web-based intervention, showed seven criteria fully present, one partially present, and eight not present, indicating a selective focus within its digital framework, with particular areas requiring further integration[58].

The Pythagorean Self-Awareness Intervention (PSAI) achieved similar results, with seven criteria fully present, three partially present, and six not present, highlighting its strengths in fostering self-awareness while leaving some domains less covered. The Quality of Life Enhancement Programme (QOLEP) presented six criteria fully present, three partially present, and seven not present, reflecting a moderate alignment with the SMACC checklist. Supportive-Expressive Psychotherapy (SE) scored five criteria fully present, three partially present, and eight not present, indicating a more limited scope in relation to the criteria evaluated[58].

Finally, Goal Management Training (GMT) showed five criteria fully present, two partially present, and nine not present, suggesting a primary focus on goal-directed behavior, with considerable areas of the SMACC attributes remaining unaddressed[58].

4.5.3. Interventions with low presence of SMACC attributes

Mindfulness and Self-Compassion (MSC) exhibited limited alignment with the SMACC attributes, with only three criteria fully present, two partially present, and eleven not present. This indicates a focused yet narrow emphasis within the intervention's scope. Similarly, the Dejian Mind-Body Intervention (DMBI) showed minimal engagement across the evaluated domains, with three criteria fully present, none partially present, and thirteen not present[58].

Both Mindfulness-Based Cognitive Therapy (MBCT) and Guided Exercise Therapy (GET) demonstrated comparable patterns, with one criterion fully present, three partially present, and twelve not present, reflecting a selective focus on specific aspects of self-management support[58].

The Psychological Experiment focusing on rumination and distraction did not demonstrate alignment with any of the SMACC attributes, as all sixteen were rated as not present. This reflects the highly controlled and experimental nature of the intervention, which does not aim to provide comprehensive self-management support[58].

4.6. Risk of bias analysis

Appendix 9.7 summarizes the risk of bias assessments of the individual studies, and only one study reported a low risk of bias across all measurement domains. Overall risk of bias was moderate to high.

5. Discussion

With this systematic review, we aimed to provide an overview and synthesis of existing self-management interventions designed, at least in part, to support life participation for persons with major depressive disorder. The SMACC checklist played a significant role in this review by objectively structuring the evaluation of self-management interventions. Through systematic assessment against sixteen concrete attributes, the instrument facilitated identification of programmatic nuances and differentiation between interventions with comprehensive versus limited self-management approaches[58].

Various self-management interventions exist for individuals with major depressive disorder. These interventions include psychoeducation, mindfulness practices, online platforms, psychotherapy, and cognitive skills training designed to enhance life management capabilities. When evaluating interventions using the SMACC checklist, approaches grounded in structured psychotherapy and psychoeducation appear to have the highest SMACC score. in contrast, digital self-help platforms and cognitive training methods show more moderate alignment with the SMACC components. Notably, mindfulness-based interventions yield the lowest SMACC scores, indicating minimal support for daily life participation.

CBASP, LAST, and psychoeducation prioritize individualized needs assessment and resource utilization, encompassing both external resources (collaboration with healthcare professionals, family and social support integration) and internal resources (cognitive capabilities). Furthermore, LAST represents one of the few interventions incorporating role management, a critical component of daily life participation. Nevertheless, mindfulness-based interventions do address significant elements including problem-solving strategies, setback management, articulation of personal needs and values, and emotional regulation. While these components are undoubtedly valuable, they are also typically incorporated within other intervention approaches. This suggests that mindfulness-based interventions establish a fundamental foundation for self-management and daily life participation but may not extend beyond these foundational elements[58].

As indicated, cognitive training (CT) and psychoeducation have high SMACC scores, these interventions also have high effectiveness according to recent Systematic review. This research suggests that CT and psychoeducation may be effective interventions for treating MDD and improving daily functioning. Woolf et al, (2020) found that CT led to significant improvements in cognitive and affective outcomes for adults with MDD, with moderate to large effect sizes[31]. Another study proposed an integrated approach combining functional remediation and computerized cognitive training to enhance cognitive performance and psychosocial functioning in MDD patients[32]. Mindfulness-based interventions (MBIs) have shown effectiveness in reducing depressive symptoms for individuals with MDD, despite still scoring low on the SMACC checklist. Meta-analyses indicate that MBIs, particularly Mindfulness-Based Cognitive Therapy (MBCT), can significantly decrease depressive symptom severity compared to control conditions[33]. However, the long-term benefits of MBIs remain uncertain, as improvements may not persist at follow-up[33]. This contradicts the

hypothesis that high SMACC scores correspond to high effectiveness, demonstrating that low SMACC scores can also be associated with high intervention efficacy[58].

A notable finding within this review is the limited presence of the SMACC attributes 'lifelong task' and 'medical management' across the analyzed interventions. This suggests insufficient recognition of self-management for individuals with major depressive disorder as an ongoing learning and adaptation process, despite the chronic and recurrent nature of the condition. Similarly, targeted support for clients in independently managing medication regimens and navigating medical information receives minimal attention. Conversely, most interventions emphasize 'emotional management' and 'problem-solving' components, indicating a predominant focus on addressing acute symptoms and enhancing coping strategies. While these components are essential for recovery, a more balanced approach is warranted, one that explicitly incorporates long-term self-care and medical self-management support[58].

Most studies primarily focus on depressive symptoms as their principal outcome measure. Only two studies, evaluating the QOLEP and LAST interventions, designate quality of life as their primary outcome. Notably, these occupational therapy-based interventions score moderately and highly, respectively, on the SMACC checklist. Occupational therapists prioritize improving clients' quality of life and participation rather than symptom reduction alone. They emphasize engagement in meaningful activities and collaborate with clients to facilitate participation following illness or injury[34]. This client-centered approach aims to enhance social participation and inclusion, particularly for individuals in institutional settings[34]. Occupational therapy practice is founded on occupation-centered, client-centered, and evidence-based principles[35]. It is therefore significant that interventions primarily targeting depressive symptoms, particularly mindfulness-based interventions, consistently demonstrate the lowest scores on the SMACC checklist[58].

Generally, self-management interventions demonstrate significant efficacy for their designated primary outcomes. This pattern extends to the online intervention 'Deprexis,' which focuses on depressive symptoms as its primary outcome measure. Recent meta-analyses corroborate this finding, establishing that web-based self-management interventions significantly reduce depressive symptomatology compared to control conditions[15,36]. These digital therapeutic approaches have demonstrated additional benefits beyond symptom reduction, including enhanced functional capacity, improved quality of life, and positive effects on recovery-oriented outcomes such as hope and empowerment[14, 58].

The SMACC checklist played a significant role in this review by objectively structuring the evaluation of self-management interventions. Through systematic assessment against 16 concrete attributes, the instrument facilitated identification of programmatic nuances and differentiation between interventions with comprehensive versus limited self-management approaches. This methodological approach revealed that certain programs, such as CBASP and LAST, encompass multiple relevant domains, while others focus predominantly on singular aspects like emotional management[58].

Nevertheless, the SMACC checklist exhibits certain limitations. Developed originally for chronic conditions broadly rather than specifically for psychiatric disorders such as MDD, the framework includes attributes like 'medical management' or 'lifelong task' that may appear

with less frequency in mental health interventions, suggesting context-dependent relevance[37]. Additionally, the instrument provides limited capacity for incorporating user perspectives or contextual determinants within the evaluation framework[58].

5.1. Strengths and Limitations

A key strength lies in the transparent and systematic methodology, including adherence to PRISMA guidelines and the use of a validated tool (SMACC) to evaluate intervention content. This enabled a nuanced assessment of intervention components, beyond symptom reduction alone, by focusing on attributes relevant to daily life participation[58].

However, several limitations must be acknowledged. First, the limited reporting of intervention content in the included studies restricted the ability to fully apply the SMACC-checklist, as crucial details on the presence or absence of certain self-management attributes were often missing. This limitation was exemplified in the study by Haussleiter et al. (2020), which employed Self-Organized Activity as an intervention but provided insufficient methodological detail. Despite attempts to contact the authors for clarification, no response was received, precluding SMACC checklist scoring. This represents a significant limitation, as the intervention demonstrated considerable efficacy for the study's primary outcome measure.

Also, the SMACC checklist exhibits certain limitations. Developed originally for chronic conditions broadly rather than specifically for psychiatric disorders such as MDD, the framework includes attributes like 'medical management' or 'lifelong task' that may appear with less frequency in mental health interventions, suggesting context-dependent relevance[37]. Additionally, the instrument provides limited capacity for incorporating user perspectives or contextual determinants within the evaluation framework[58].

Secondly, the heterogeneity in definitions of self-management and outcome constructs across studies introduced variability, complicating direct comparisons. This was further exacerbated by the use of different measurement tools, which assess varying aspects of mental health and well-being. For instance, a 10-point reduction on the Beck Depression Inventory (BDI) is not equivalent to a 10-point change on the Montgomery–Åsberg Depression Rating Scale (MADRS), making cross-study interpretation challenging. Similarly, quality of life outcomes assessed with WHOQOL differ conceptually from depression symptom scales, even when both show statistically significant results. A meta-analysis could address this issue in future research by synthesizing standardized effect sizes, means, and standard deviations[58].

The review’s exclusive focus on randomized controlled trials (RCTs), while methodologically robust, may have excluded valuable insights from high-quality quasi-experimental or qualitative studies. Additionally, the selected timeframe (2012–2022) may have excluded more recent developments in digital or personalized self-management interventions. Another notable limitation is the lack of long-term follow-up data in many studies. Only a few interventions assessed outcomes beyond two or three months, and those that did[51, 53]

provided limited evidence of sustained behavioral or functional change. This absence limits conclusions about the durability of intervention effects, which is particularly important in the context of a relapsing-remitting condition like MDD[58].

Lastly, no GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach was applied in this review, as the intention was not to develop practice recommendations. However, the results of this synthesis could inform future guideline development, where a formal assessment of evidence certainty would be warranted[58].

5.2. Implications for clinical practice

The findings of this review highlight the importance of implementing integrated and multidimensional interventions for individuals with MDD. Interventions such as Cognitive Behavioral Analysis System of Psychotherapy (CBASP) and Group Psychoeducation demonstrated broad coverage across key self-management attributes, particularly in areas such as problem-solving, goal-setting, and emotional regulation. These components appear to be especially relevant in supporting clients to manage their condition autonomously and to reintegrate into everyday life roles[58].

The application of the SMACC-checklist proved to be a valuable tool for identifying the presence and depth of self-management components within interventions. In clinical settings, this checklist can serve as a practical framework for both the selection and development of tailored interventions, ensuring that essential elements of self-management, such as personal responsibility, active coping, and collaborative care, are adequately addressed[58].

Finally, the review underscores the need for practitioners to prioritize participation in meaningful activities as a central outcome in recovery-oriented care. Beyond symptom reduction, fostering engagement in personally valued roles and routines is crucial for sustainable recovery and improved quality of life. Occupational therapists and other mental health professionals should be encouraged to integrate this functional perspective into intervention planning, aligning therapeutic goals with the client's lived experience and individual aspirations[58].

6. Conclusion

This systematic review examined self-management interventions for major depressive disorder (MDD) with focus on daily life participation support. Findings revealed intervention heterogeneity, with few programs (CBASP, Group Psychoeducation) offering comprehensive approaches aligned with the SMACC checklist. Most interventions emphasized emotional regulation and problem-solving while neglecting long-term self-management (Life-long task) and medical management.

The review highlights the need for integrated interventions promoting meaningful engagement beyond symptom reduction. The SMACC checklist effectively evaluated self-management support scope and can guide development of client-centered interventions.

Future research priorities include longitudinal studies assessing sustained intervention impact and meta-analyses using standardized effect sizes to compare self-management intervention effectiveness. These findings highlight the importance of including a broad range of self-management attributes when developing interventions to support both symptom reduction and meaningful participation in daily life.

7. Disclosure

All authors have nothing to disclose.

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9. Appendix

9.1. Search string Medline

(("depressive disorder"[MeSH] OR "depressive disorder, major"[MeSH] OR depress*[tiab] OR“central depression”[tiab] OR “clinical depression”[tiab] OR “depressive disease”[tiab] OR “depressive illness”[tiab] OR “depressive state”[tiab] OR “depressive syndrome”[tiab] OR “mental depression”[tiab] OR “depression, unipolar”[tiab]) NOT (“Depression, Postpartum”[MeSH] OR “Premenstrual Dysphoric Disorder”[MeSH] OR (“postnatal depression”[tiab] OR “depression, puerperium”[tiab] OR “maternal depression”[tiab] OR “post partum depression”[tiab] OR “post-natal depression”[tiab] OR “puerperal depression”[tiab] OR “premenstrual dysphoric disorder”[tiab]))

(“Rehabilitation”[Mesh] OR “Rehabilit*”[tiab] OR “Psychotherapy”[Mesh] OR “Psychotherap*”[tiab] OR “functional readaptation”[tiab] OR “rehabilitation concept”[tiab] OR “rehabilitation engineering”[tiab] OR “rehabilitation potential”[tiab] OR “rehabilitation process”[tiab] OR “rehabilitation program”[tiab] OR “rehabilitation, medical”[tiab] OR “rehabilitative treatment”[tiab] OR “resocialization”[tiab] OR “resocialisation therapy”[tiab] OR “revalidation”[tiab] OR “holistic psychotherapy”[tiab] OR “multiple psychotherapy”[tiab] OR “psychotherapeutic processes”[tiab] OR “psychotherapeutic training”[tiab] OR “socioenvironmental therapy”[tiab])

(“Self-management”[MeSH Terms] OR Self*[tiab] OR “Self-management behaviours”[tiab] OR “Patient participation”[MeSH Terms] OR “Patient Empowerment”[tiab] OR “Patient Activation”[tiab] OR “Patient Engagement”[tiab] OR “Social Participation”[MeSH Terms] OR “Social Participation”[tiab] OR “Social Engagement”[tiab] OR “Social Citizenship”[tiab] OR “Community Participation”[MeSH Terms] OR “Community Participation”[tiab] OR “Community involvement*”[tiab] OR “Public Participation”[tiab] OR “Community Action”[tiab] OR “Activity participation”[tiab] OR “Personal autonomy”[MeSH Terms] OR “Autonom*” [tiab] OR “Self Determination”[tiab] OR “Self Care”[MeSH Terms] OR “Self Care”[tiab] OR “Self-Care”[tiab] OR “Self Care Skills”[tiab] OR “Self Monitoring”[tiab] OR “Self Regulation”[tiab] OR “Self Regulation”[tiab] OR “Self Efficacy”[MeSH Terms] OR “Self Efficacy”[tiab] OR “Self-confidence”[tiab] OR “Self-governance”[tiab] OR “Adaptation, Psychological”[Mesh Terms] OR “Adaptation, Psycho*”[tiab] OR “Adjustment”[tiab] OR “Coping Behavior”[tiab] OR “Coping Skill*”[tiab] OR “Coping strateg*”[tiab] OR “Adaptive Behavior*”[tiab] OR “Functional capacit*”[tiab] OR “Activities of daily living”[MeSH] OR “Activity of daily living”[tiab] OR “ADL”[tiab] OR “Daily routine*”[tiab] OR “Illness cognition”[tiab] OR “Decision making”[MeSH] OR “Decision making”[tiab] OR “Problem solving”[MeSH] OR “Problem solving”[tiab] OR “Goal-setting”[tiab])

(“Clinical trial”[MeSH] OR “Clinical trial*”[tiab] OR “Randomized Controlled Trial”[MeSH] OR “Randomized Controlled Trial”[MeSH] OR “Controlled Clinical Trial”[MeSH] OR “Controlled Clinical Trial”[tiab] OR “Random Allocation”[MeSH] OR “Random Allocation”[tiab] OR “Randomization”[tiab] OR “Double-blind Method”[MeSH] OR “Double-blind Method”[tiab] OR “Single-blind Method”[MeSH] OR “Single-blind Method”[tiab] OR “Random*”[tiab] OR “Cross-over Studies”[MeSH] OR “Cross-over”[tiab] OR “Masked”[tiab])

(("Adolescent"[Mesh] OR "Child"[Mesh] OR "Infant"[Mesh] OR adolescen*[tiab] OR child*[tiab] OR schoolchild*[tiab] OR infant*[tiab] OR girl*[tiab] OR boy[tiab] OR boys[tiab] OR boyhood[tiab] OR teen[tiab] OR teens[tiab] OR teenager*[tiab] OR youth*[tiab] OR pediatr*[tiab] OR paediatr*[tiab] OR puber*[tiab]) NOT ("Adult"[Mesh] OR adult*[tiab] OR man[tiab] OR men[tiab] OR woman[tiab] OR women[tiab]))

9.2. Search string PsychINFO

((MAINSUBJECT.EXACT("Depression (Emotion)") OR tiab(Depress*) OR MAINSUBJECT.EXACT("Major Depression")) NOT (tiab(Postpartum OR Premenstrual OR Dysphoric)))

tiab(“rehabilit*”) OR tiab(“psychotherapy*”) OR tiab(“functional readaptation”) OR tiab(“rehabilitation concept”) OR tiab(“rehabilitation engineering”) OR tiab(“rehabilitation potential”) Or tiab(“rehabilitation process”) OR tiab(“rehabilitation program”) OR tiab(“rehabilitative treatment”) OR tiab(“resocialization”) OR tiab(“resocialization therap*”) OR tiab(“revalidation”) OR tiab(“holistic psychotherapy*”) OR tiab(“multiple psychotherapy*”) OR tiab(“socioenvironmental therap*”)

(MAINSUBJECT.EXACT.EXPLODE("Self-Management") OR TI ((self OR oneself OR personal) N/3 manag*) OR AB ((self OR oneself OR personal) N/3 manag*) OR MAINSUBJECT.EXACT("Involvement") OR MAINSUBJECT.EXACT("Participation") OR MAINSUBJECT.EXACT("Client Participation") OR tiab("Involvement") OR tiab("Participation") OR tiab("Client participation") OR tiab("Client involvement") OR tiab("client empowerment") OR tiab("client activation") OR tiab("client engagement") OR tiab("social participation") OR tiab("social engagement") OR tiab("Social citizenship") OR tiab("Community participation") OR tiab("Community involvement") OR tiab("Public participation") OR tiab("community action") OR MAINSUBJECT.EXACT("Autonomy") OR MAINSUBJECT.EXACT("Resistance") OR MAINSUBJECT.EXACT("Self-Determination") OR MAINSUBJECT.EXACT("Empowerment") OR MAINSUBJECT.EXACT("Independence (Personality)") OR tiab("Autonomy") OR tiab("Resistance") OR tiab("Self-determination") OR tiab("Empowerment") OR tiab("Independence") OR MAINSUBJECT.EXACT("Health Related Quality of Life") OR tiab("Health related quality of life") OR MAINSUBJECT.EXACT("Self-Care Skills") OR MAINSUBJECT.EXACT("Functional Status") OR MAINSUBJECT.EXACT("Adaptive Behavior") OR MAINSUBJECT.EXACT("Rehabilitation") OR MAINSUBJECT.EXACT("Life Skills") OR MAINSUBJECT.EXACT("Daily Activities") OR tiab("Self-care Skills") OR tiab("Functional status") OR tiab("adaptive behavior") OR tiab("Rehabilitation") OR tiab("Life skills") OR tiab("Daily activit*") OR MAINSUBJECT.EXACT("Coping Style") OR MAINSUBJECT.EXACT("Illness

Behavior") OR MAINSUBJECT.EXACT("Adaptability (Personality)”) OR MAINSUBJECT.EXACT("Coping Behavior")) OR MAINSUBJECT.EXACT("Decision Making”) OR tiab(“decision making”) OR tiab(“problem solving”) OR MAINSUBJECT.EXACT("Goal-setting”) OR tiab(“goal-setting”)

(MAINSUBJECT.EXACT.EXPLODE("Clinical Trials") OR MAINSUBJECT.EXACT.EXPLODE("Randomized Clinical Trials") OR tiab("Clinical trial") OR tiab("Randomized controlled trial") OR tiab("Randomized clinical trial") OR tiab("controlled clinical trial") OR MAINSUBJECT.EXACT.EXPLODE("Random Sampling") OR tiab("Random sampling") OR tiab("Random allocation") OR tiab("randomization") OR tiab("double-blind") OR tiab("double-blind method") OR tiab("single-blind") OR tiab("single-blind method") OR tiab("random") OR tiab("cross-over stud*") OR tiab("masked"))

9.3. Search string Embase

('depression'/exp OR 'central depression':ti,ab OR 'clinical depression':ti,ab OR 'depression':ti,ab OR 'depressive disease':ti,ab OR 'depressive disorder':ti,ab OR 'depressive illness':ti,ab OR 'depressive state':ti,ab OR 'depressive syndrome':ti,ab OR 'mental depression':ti,ab OR 'major depression'/exp OR 'depression, major':ti,ab OR 'depression, unipolar':ti,ab OR 'depressive disorder, major':ti,ab OR 'major depression':ti,ab OR 'major depressive disorder':ti,ab OR 'major depressive episode':ti,ab OR 'unipolar depression':ti,ab OR 'unipolar disorder':ti,ab) NOT ('postnatal depression'/exp OR 'depression, postpartum':ti,ab OR 'depression, puerperium':ti,ab OR 'maternal depression':ti,ab OR 'post partum depression':ti,ab OR 'post-natal depression':ti,ab OR 'postnatal depression':ti,ab OR 'postpartum depression':ti,ab OR 'puerperal depression':ti,ab OR 'puerperium depression':ti,ab OR 'premenstrual dysphoric disorder'/exp OR 'premenstrual dysphoric disorder':ti,ab)

('rehabilitation'/exp OR 'functional readaptation':ti,ab OR 'readaption':ti,ab OR 'readjustment':ti,ab OR 'rehabilitation':ti,ab OR 'rehabilitation concept':ti,ab OR 'rehabilitation engineering':ti,ab OR 'rehabilitation potential':ti,ab OR 'rehabilitation process':ti,ab OR 'rehabilitation program':ti,ab OR 'rehabilitation programme':ti,ab OR 'rehabilitation, medical':ti,ab OR 'rehabilitative treatment':ti,ab OR 'resocialisation':ti,ab OR 'resocialisation therapy':ti,ab OR 'resocialization':ti,ab OR 'resocialization therapy':ti,ab OR 'revalidation':ti,ab OR 'psychotherapy'/exp OR 'holistic psychotherapy':ti,ab OR 'multiple psychotherapy':ti,ab OR 'psychotherapeutic processes':ti,ab OR 'psychotherapeutic training':ti,ab OR 'psychotherapy':ti,ab OR 'psychotherapy, multiple':ti,ab OR 'socioenvironmental therapy':ti,ab)

('self care'/exp OR 'self care':ti,ab OR 'self management':ti,ab OR 'self treatment':ti,ab OR 'self-management':ti,ab OR 'self-nurturance':ti,ab OR 'selfcare':ti,ab OR 'selfmanagement':ti,ab OR 'selftreatment':ti,ab OR 'self concept'/exp/mj OR 'concept, self':ti,ab OR 'self':ti,ab OR 'self awareness':ti,ab OR 'self concept':ti,ab OR 'self confrontation':ti,ab OR 'self efficacy':ti,ab OR 'self image':ti,ab OR 'self perception':ti,ab OR 'self rating':ti,ab OR 'self representation':ti,ab OR 'selfconcept':ti,ab OR 'self-management behavio?r*':ti,ab OR 'patient participation'/exp OR 'patient involvement':ti,ab OR 'patient

participation':ti,ab OR 'patient participation rate':ti,ab OR 'patient empowerment'/exp OR 'patient empowerment':ti,ab OR 'patient activation'/exp OR 'patient engagement'/exp OR 'patient engagement':ti,ab OR 'social participation'/exp OR 'social participation':ti,ab OR 'social engagement'/exp OR 'social citizenship':ti,ab OR 'community participation'/exp OR 'community participation':ti,ab OR 'community involvement':ti,ab OR 'public participation'/exp OR 'community action':ti,ab OR 'activity participation':ti,ab OR 'personal autonomy'/exp/mj OR 'personal autonomy':ti,ab OR 'self determination'/exp OR 'self-care skill*':ti,ab OR 'self monitoring'/exp OR 'self confidence'/exp OR 'psychological adjustment'/exp OR 'adaptation, psychological':ti,ab OR 'emotional adaptation':ti,ab OR 'emotional adjustment':ti,ab OR 'emotional equilibrium':ti,ab OR 'personal adjustment':ti,ab OR 'psychologic adaptation':ti,ab OR 'psychological adaptation':ti,ab OR 'psychological adjustment':ti,ab OR 'coping behavior'/exp OR 'behavior, coping':ti,ab OR 'behaviour, coping':ti,ab OR 'coping':ti,ab OR 'coping ability':ti,ab OR 'coping behavior':ti,ab OR 'coping behaviour':ti,ab OR 'coping mechanism':ti,ab OR 'coping strategy':ti,ab OR 'coping skill*':ti,ab OR 'coping strateg*':ti,ab OR 'adaptive behavior'/exp/mj OR 'adaptive behavior':ti,ab OR 'adaptive behaviour':ti,ab OR 'behavior, adaptive':ti,ab OR 'behaviour, adaptive':ti,ab OR 'codependency (psychology)':ti,ab OR 'codependency, psychological':ti,ab OR 'states of change':ti,ab OR 'functional status'/exp/mj OR 'capacity, functional':ti,ab OR 'functional capacity':ti,ab OR 'functional status':ti,ab OR 'daily life activity'/exp OR 'adl (activities of daily living)':ti,ab OR 'activities of daily living':ti,ab OR 'activity, daily living':ti,ab OR 'daily life activity':ti,ab OR 'daily living activity':ti,ab OR adl:ti,ab OR 'daily routine':ti,ab OR 'illness cognition':ti,ab OR 'decision making'/exp/mj OR 'arbitration':ti,ab OR 'career choice':ti,ab OR 'choice behavior':ti,ab OR 'choice behaviour':ti,ab OR 'choice making':ti,ab OR 'decision making':ti,ab OR 'decision process':ti,ab OR 'decisionmaking':ti,ab OR 'judgement':ti,ab OR 'judgment':ti,ab OR 'problem solving'/exp/mj OR 'problem solving':ti,ab OR 'goal setting'/exp)

('clinical trial'/exp OR 'clinical drug trial':ti,ab OR 'clinical trial':ti,ab OR 'major clinical trial':ti,ab OR 'trial, clinical':ti,ab OR 'randomized controlled trial'/exp OR 'controlled trial, randomized':ti,ab OR 'randomised controlled study':ti,ab OR 'randomised controlled trial':ti,ab OR 'randomized controlled study':ti,ab OR 'randomized controlled trial':ti,ab OR 'trial, randomized controlled':ti,ab OR 'controlled clinical trial'/exp OR 'clinical trial, controlled':ti,ab OR 'controlled clinical comparison':ti,ab OR 'controlled clinical drug trial':ti,ab OR 'controlled clinical experiment':ti,ab OR 'controlled clinical study':ti,ab OR 'controlled clinical test':ti,ab OR 'controlled clinical trial':ti,ab OR 'randomization'/exp OR 'random allocation':ti,ab OR 'randomisation':ti,ab OR 'randomization':ti,ab OR 'double blind procedure'/exp OR 'double blind clinical trial':ti,ab OR 'double blind comparison':ti,ab OR 'double blind design':ti,ab OR 'double blind procedure':ti,ab OR 'double blind studies':ti,ab OR 'double blind study':ti,ab OR 'double blind test':ti,ab OR 'double blind trial':ti,ab OR 'double masked clinical study':ti,ab OR 'double masked clinical trial':ti,ab OR 'double masked comparison':ti,ab OR 'double masked design':ti,ab OR 'double masked method':ti,ab OR 'double masked procedure':ti,ab OR 'double masked study':ti,ab OR 'double masked test':ti,ab OR 'double masked trial':ti,ab OR 'double-blind clinical study':ti,ab OR 'double-blind method':ti,ab OR 'single blind procedure'/exp OR 'procedure, single blind':ti,ab OR 'single blind clinical study':ti,ab OR 'single blind clinical trial':ti,ab OR 'single blind comparison':ti,ab OR 'single blind design':ti,ab OR 'single blind procedure':ti,ab OR 'single blind studies':ti,ab OR 'single blind study':ti,ab OR 'single blind trial':ti,ab OR 'single masked clinical study':ti,ab OR 'single masked clinical trial':ti,ab OR 'single masked comparison':ti,ab OR 'single masked design':ti,ab OR 'single masked method':ti,ab OR 'single masked procedure':ti,ab OR 'single masked study':ti,ab

OR 'single masked test':ti,ab OR 'single masked trial':ti,ab OR 'single-blind method':ti,ab OR 'study, single blind':ti,ab OR 'crossover procedure'/exp OR 'cross over clinical study':ti,ab OR 'cross over clinical trial':ti,ab OR 'cross over comparison':ti,ab OR 'cross over design':ti,ab OR 'cross over method':ti,ab OR 'cross over procedure':ti,ab OR 'cross over study':ti,ab OR 'cross over test':ti,ab OR 'cross over trial':ti,ab OR 'cross-over studies':ti,ab OR 'crossover clinical study':ti,ab OR 'crossover clinical trial':ti,ab OR 'crossover comparison':ti,ab OR 'crossover design':ti,ab OR 'crossover method':ti,ab OR 'crossover procedure':ti,ab OR 'crossover study':ti,ab OR 'crossover test':ti,ab OR 'crossover trial':ti,ab OR 'double blind cross over study':ti,ab OR 'double blind crossover study':ti,ab OR 'procedure, crossover':ti,ab)

9.4. First Kappa calculation (10 studies)

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Eerste beoordelaar_ory * Tweede _Joy	10	100.0%	0	0.0%	10	100.0%

Eerste beoordelaar_ory * Tweede _Joy Crosstabulation

			Tweede _Joy		
			Exclusie	Inclusie	Total
Eerste beoordelaar_ory	exclusie	Count	1	2	3
		% within Eerste beoordelaar_ory	33.3%	66.7%	100.0%
		% within Tweede _Joy	33.3%	28.6%	30.0%
		% of Total	10.0%	20.0%	30.0%
	Inclusie	Count	2	5	7
		% within Eerste beoordelaar_ory	28.6%	71.4%	100.0%
		% within Tweede _Joy	66.7%	71.4%	70.0%
		% of Total	20.0%	50.0%	70.0%
Total		Count	3	7	10
		% within Eerste beoordelaar_ory	30.0%	70.0%	100.0%
		% within Tweede _Joy	100.0%	100.0%	100.0%
		% of Total	30.0%	70.0%	100.0%

Symmetric Measures

		Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Measure of Agreement	Kappa	.048	.321	.151	.880
N of Valid Cases		10			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

9.5. Second Kappa calculation (15 studies)

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Eerste beoordelaar_ory * Tweede _Joy	15	100.0%	0	0.0%	15	100.0%

Eerste beoordelaar_ory * Tweede _Joy Crosstabulation

			Tweede _Joy		
			Exclusie	Inclusie	Total
Eerste beoordelaar_ory	exclusie	Count	8	0	8
		% within Eerste beoordelaar_ory	100.0%	0.0%	100.0%
		% within Tweede _Joy	100.0%	0.0%	53.3%
	Inclusie	Count	0	7	7
		% within Eerste beoordelaar_ory	0.0%	100.0%	100.0%
		% within Tweede _Joy	0.0%	100.0%	46.7%
Total		Count	8	7	15
		% within Eerste beoordelaar_ory	53.3%	46.7%	100.0%
		% within Tweede _Joy	100.0%	100.0%	100.0%

Symmetric Measures

		Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Measure of Agreement	Kappa	1.000	.000	3.873	<.001
N of Valid Cases		15			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

9.6. Use of Generative AI

Use of ChatGPT (or any other AI writing assistance tool)

Form to be completed

Student name: Ory Depuydt & Joy Vanantwerpen

Student number: 2470174 & 2470452

Please indicate with "X" whether it relates to a course assignment or to the master thesis:

O This form is related to a **course assignment**.

Course name:

Course number:

O This form is related to **my Master thesis**.

Title Master thesis: Self-management interventions to promote participation in daily life for people with major depression: A systematic review

Promotor: Prof. dr. Dominique Van de Velde

Please indicate with "X":

O **I did not use** ChatGPT or any other AI writing assistance tool.

O **I did use** AI Writing Assistance. In this case **specify which one** (e.g. ChatGPT/GPT4/...):

ChatGPT/ Atlas.org/ Claude.ai

Please indicate with "X" (possibly multiple times) in which way you were using it:

O **Assistance purely with the language of the paper**

- ☐ *Code of conduct*: This use is similar to using a spelling checker

O **As a search engine to learn on a particular topic**

- ☐ *Code of conduct*: This use is similar to e.g. a google search or checking Wikipedia. Be aware that the output of Chatbot evolves and may change over time.

O **For literature search**

- ☐ *Code of conduct*: This use is comparable to e.g. a google scholar search. However, be aware that some AI writing assistance tools like ChatGPT may output no or wrong references. As a student you are responsible for further checking and verifying the absence or correctness of references.

O **For short-form input assistance**

- ☐ *Code of conduct*: This use is similar to e.g. google docs powered by generative language models

O **To let generate programming code**

- *Code of conduct*: Correctly mention the use of ChatGPT (or other AI writing assistance tool) and cite it. You can also ask ChatGPT how to cite it.

O **To let generate new research ideas**

- *Code of conduct*: Further verify in this case whether the idea is novel or not. It is likely that it is related to existing work, which should be referenced then.

O **To let generate blocks of text**

- *Code of conduct*: Inserting blocks of text without quotes from ChatGPT (or other AI writing assistance tool) to your report or thesis is not allowed. According to Article 84 of the exam regulations in evaluating your work one should be able to correctly judge on your own knowledge. In case it is really needed to insert a block of text from ChatGPT (or other AI writing assistance tool), mention it as a citation by using quotes. But this should be kept to an absolute minimum.

O **Other**

- *Code of conduct*: Contact the professor of the course or the promotor of the thesis. Inform also the program director. Motivate how you comply with Article 84 of the exam regulations. Explain the use and the added value of ChatGPT or other AI tool: ….

Further important guidelines and remarks

- ChatGPT cannot be used related **to data or subjects under NDA agreement.**
- ChatGPT cannot be used related **to sensitive or personal data due to privacy issues**.
- **Take a scientific and critical attitude** when interacting with ChatGPT (or other AI writing assistance tool)and interpreting its output. Don’t become emotionally connected to AI tools.

- As a student you are responsible to comply with Article 84 of the exam regulations: your report or thesis should reflect your own knowledge. Be aware that plagiarism rules also apply to the use of ChatGPT or any other AI tools.
- **Exam regulations Article 84**: “Every conduct individual students display with which they (partially) inhibit or attempt to inhibit a correct judgement of their own knowledge, understanding and/or skills or those of other students, is considered an irregularity which may result in a suitable penalty. A special type of irregularity is plagiarism, i.e. copying the work (ideas, texts, structures, designs, images, plans, codes , ...) of others or prior personal work in an exact or slightly modified way without adequately acknowledging the sources. Every possession of prohibited resources during an examination (see article 65) is considered an irregularity.”
- **ChatGPT suggestion about citation**: Citing and referencing ChatGPT output is essential to maintain academic integrity and avoid plagiarism.

  Here are some guidelines on how to correctly cite and reference ChatGPT in your Master's thesis: 1. Citing ChatGPT: Whenever you use a direct quote or paraphrase from ChatGPT, you should include an in-text citation that indicates the source. For example: (ChatGPT, 2023). 2. Referencing ChatGPT: In the reference list at the end of your thesis, you should include a full citation for ChatGPT. This should include the title of the AI language model, the year it was published or trained, the name of the institution or organization that developed it, and the URL or DOI (if available). For example: OpenAI. (2021). GPT-3 Language Model. https://openai.com/blog/gpt-3-apps/ 3. Describing the use of ChatGPT: You may also want to describe how you used ChatGPT in your research methodology section. This could include details on how you accessed ChatGPT, the specific parameters you used, and any other relevant information related to your use of the AI language model. Remember, it is important to adhere to your institution's specific guidelines for citing and referencing sources in your Master's thesis. If you are unsure about how to correctly cite and reference ChatGPT or any other source, consult with your thesis advisor or a librarian for guidance.”

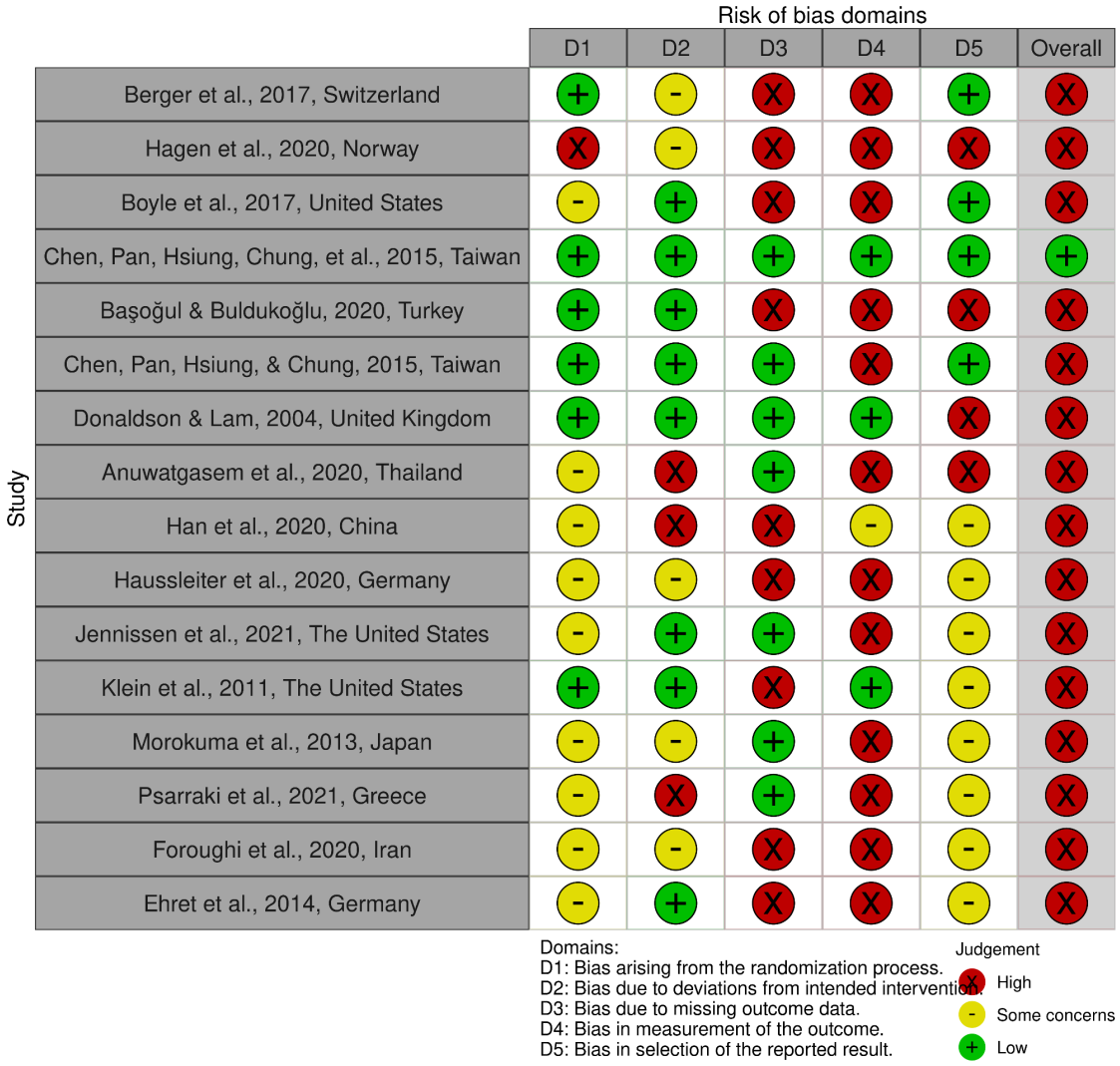
Additional reading

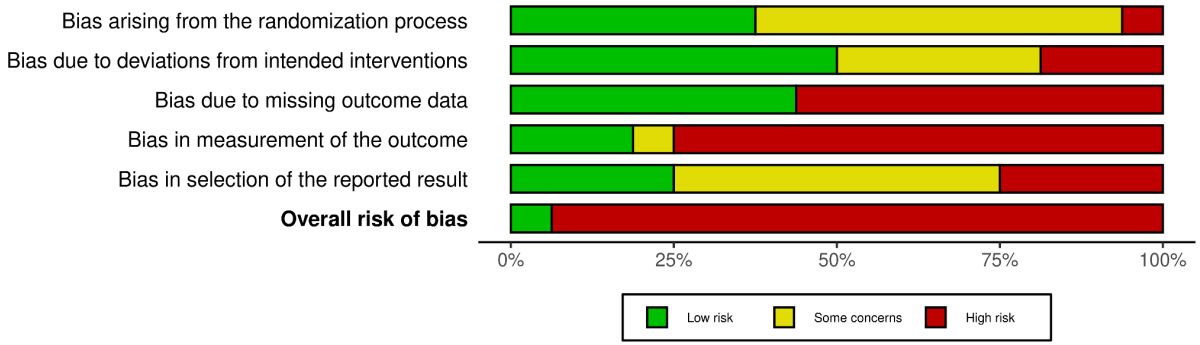
ACL 2023 Policy on AI Writing Assistance: https://2023.aclweb.org/blog/ACL-2023-policy/

KU Leuven guidelines on citing and referencing Generative AI tools, and other information:

https://www.kuleuven.be/english/education/student/educational-tools/generative-artificial-intelligence

9.7. Risk of bias





1.

Study details	
Reference	Han, Y. M. Y., Sze, S. L., Wong, Q. Y., & Chan, A. S. (2020). A mind-body lifestyle intervention enhances emotional control in patients with major depressive disorder: a randomized, controlled study. Cognitive Affective & Behavioral Neuroscience, 20(5), 1056–1069. https://doi.org/10.3758/s13415-020-00819-z

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Comparator:
Dejian Mind-Body Intervention (DMBI)	Cognitive Behavioral Therapy (CBT)

Specify which outcome is being assessed for risk of bias	Depressive symptoms

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

HRSD Total Score:

- DMBI group: Mean reduction = 5.44 (p = .002, d = 0.96)
- CBT group: Mean reduction = 6.06 (p < .001, d = 1.29)
- Control group: Non-significant change (p = .20)

BDI-II Total Score:

- DMBI group: Mean reduction **=** 10.35 (p < .001, d = 1.10)
- CBT group: Mean reduction **=** 12.33 (p = .001, d = 1.10)
- Control group**:** Small reduction = 4.43 (p = .045, d = 0.59)

Is the review team's aim for this result…?

☒ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ x Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The interventions were not blinded. The DMBI, CBT, and control conditions are clearly distinct and delivered in very different formats (e.g., group sessions vs. no additional intervention), making it very likely that participants knew which group they were in. The interventions involved active delivery by therapists or instructors (especially in the DMBI and CBT groups), and there is no indication of blinding for facilitators or care providers.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	The exclusion of participants based on session attendance could systematically bias the results by removing those who were less motivated or had more severe symptoms, potentially inflating the observed treatment effects	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	It is plausible that participants who attended fewer than 70% of sessions or dropped out were less engaged or had worse depressive symptoms, suggesting their missingness could depend on the true outcome value. he study only analyzed data from participants who adhered to the intervention, and there is no evidence that reasons for dropout were unrelated to depressive outcomes. Given the nature of depression studies, it's **likely** that more symptomatic individuals were less engaged, making outcome-dependent missingness likely.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The article does not report blinding of outcome assessors.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Both self-report (BDI-II) and clinician-rated (HRSD) measures involve subjective judgement and could plausibly be influenced by expectations or beliefs about the assigned intervention. Participants may have expected improvement from DMBI or CBT, and assessors (if not blinded) may have been influenced during HRSD evaluations. This risk is particularly relevant given that no masking procedures are described and the study focused on psychological outcomes that are susceptible to expectancy effects.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns

Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The study measured depressive symptoms using both HRSD and BDI-II, and it reported both, but without clarification on whether these were pre-specified primary or secondary outcomes. It is possible that other time points or metrics were measured but not reported. However, both measures are standard and were reported at a consistent time point post-treatment.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	The paper reports only pre-post change scores with effect sizes and p-values, without details on adjusted models, alternative analyses (e.g. ANCOVA), or handling of missing data. Without an analysis plan, selective reporting is possible.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

2.

Study details	
Reference	Haussleiter, I. S., Bolsinger, B., Assion, H., & Juckel, G. (2020). Adjuvant Guided Exercise therapy versus Self-Organized Activity in patients with Major Depression. *The Journal Of Nervous And Mental Disease*, *208*(12), 982–988. https://doi.org/10.1097/nmd.0000000000001240

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial
☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Experimental: Standardized Guided Exercise Therapy (GET) an intervention involving therapist-led sessions with mixed exercise modalities

Comparator: Comparator: Self-Organized Activity (SOA) unsupervised physical activity, encouraged but not guided.

Specify which outcome is being assessed for risk of bias

Depressive symptoms

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

p = 0.017 (partial $\eta^2 = 0.12$), indicating a statistically significant superiority of GET over SOA in reducing depressive symptoms over time.

No significant interaction between group and time (p = 0.091), but both groups improved (main effect of time: *p < 0.0005*, partial $\eta^2 = 0.66$).

Is the review team's aim for this result…?

☒ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The study explicitly reports that participants were randomly assigned using a block random method**.** This method includes a random component in sequence generation and is a commonly accepted approach in randomized controlled trials. Therefore, the allocation sequence can be considered genuinely random.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There were no meaningful baseline imbalances between the groups in terms of size or key prognostic variables. All differences appear small and statistically non-significant, consistent with what would be expected under a valid randomization process. Thus, there is no indication of a problem with the randomization.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants were aware of their assigned intervention because the two conditions were behaviorally and procedurally distinct, and there was no blinding**.** The design made it impossible to mask the assignment. The carers (i.e., therapists delivering or supporting the intervention) were aware of group assignment because they were directly involved in either delivering structured GET or advising participants in the SOA condition. Blinding was not applied**,** and the nature of the interventions makes blinding infeasible.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	There is no indication that deviations from the assigned interventions were caused by the trial context. Both groups followed their respective protocols as intended: GET participants attended supervised sessions, while SOA participants exercised independently with support. Dropouts were due to hospital discharge after symptom improvement, which is common in clinical settings and not linked to the trial design. There is no evidence that participants switched groups or that study personnel undermined the protocol. Therefore, deviations arising specifically because of the trial context are unlikely.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study reports that an intention-to-treat (ITT) analysis was used. Participants were analyzed in the groups to which they were originally randomized, regardless of adherence. This is considered an appropriate method to estimate the effect of assignment to intervention.	Y / PY / PN / N / NI

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Data were not available for all or nearly all randomized participants. With around one-third of participants missing from the per-protocol analysis, the amount of missing data exceeds the threshold for "nearly all," especially for a continuous outcome like depression severity. These missing data could potentially influence the estimated treatment effect.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	The study does not provide sufficient detail about whether missing outcome data were handled in a way that would protect against bias**.** No sensitivity analyses or bias-correction methods were reported. Therefore, it cannot be determined whether the missing data introduced bias or not.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Missingness in outcome data could plausibly depend on the participants' true depression status. Participants were discharged due to symptom improvement, meaning their outcomes (if measured) would likely show greater improvement. This creates a risk that the missing data were not missing at random**,** potentially biasing the results. It is likely that missingness in the outcome depended on its true value. Participants with improved depressive symptoms were discharged early, which directly links dropout to better outcomes. This could bias the results if not properly addressed, and the study did not adjust for this source of bias in its analysis.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The method of measuring the outcome was appropriate. The HAMD is a validated and sensitive instrument for detecting changes in depression severity and is commonly used in clinical trials. There is no indication that the tools used were invalid or poorly suited to the outcomes measured.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	The outcome measurements were collected using identical instruments **at** identical time points across both groups. There is no evidence that the method of outcome assessment differed in any way between intervention groups. Therefore, differential measurement or ascertainment is unlikely.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Outcome assessors were not blinded to intervention assignment. The study explicitly states that the randomization method prevented blinded psychiatric assessment, meaning assessors likely knew which intervention participants received.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	The outcome (HAMD) involves subjective clinical judgment and was assessed by personnel who were not blinded to intervention allocation. This makes it likely that knowledge of the assigned intervention could have influenced outcome assessment. Given the use of a subjective outcome measure (HAMD), lack of blinding, and potential expectations of benefit from the more structured GET intervention, it is **likely** that outcome assessment was influenced by knowledge of group assignment. These factors collectively raise a high risk that assessor bias affected the measurement.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

3.

Study details

Reference	Berger, T., Krieger, T., Sude, K., Meyer, B., & Maercker, A. (2017). Evaluating an e-mental health program ("deprexis") as adjunctive treatment tool in psychotherapy for depression: Results of a pragmatic randomized controlled trial. *Journal of Affective Disorders*, *227*, 455–462. https://doi.org/10.1016/j.jad.2017.11.021

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	deprexis, a web-based self-help program designed to support the treatment of depression.	Comparator:	regular face-to-face psychotherapy

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	

Is the review team's aim for this result…?

- ☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
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Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The study utilized an automated computer-generated random numbers table placed in a secured web-based database, which was concealed from both the investigators and the therapists involved in the enrollment process.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study reported that baseline characteristics were comparable between the intervention groups, with no statistically significant differences observed in key demographic variables, clinical characteristics, or outcome measures at baseline.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Probably yes, participants were aware of their assigned intervention during the trial. The study involved a web-based program called "deprexis" that was introduced to participants in the intervention group by their therapists. Since the therapists provided information about the program and its use, it is likely that participants were aware of their assignment to the intervention group.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	Probably yes, there were deviations from the intended intervention that arose because of the trial context. The study indicates that the process of securing informed consent and the nature of the trial may have influenced participants' perceptions and behaviors regarding their assigned interventions. For instance, participants assigned to the control group may have felt disadvantaged and sought out the experimental intervention, which could lead to inconsistencies in the implementation of the trial protocol.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	The study indicates that the lack of blinding for both participants and therapists may have led to biases in the implementation of the interventions.	NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	Yes, the deviations from the intended intervention were not balanced between the groups, which could impact the intervention effect estimate. The study indicates that the therapists were instructed to use their clinical judgment when integrating the online program into their face-to-face sessions, which could lead to variations in how the intervention was implemented across different participants. Specifically, it states that "therapists were free to support participants following their own clinical judgment, without any specific guidelines or constraints".	NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, an appropriate analysis was used to estimate the effect of assignment to intervention in the study. The analysis employed both intention-to-treat (ITT) and modified intention-to-treat (mITT) approaches, which are considered appropriate methods for evaluating the effectiveness of interventions.	Y / PY / PN / N / NI

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes, participants were aware of their assigned intervention during the trial. The study indicates that "participants randomized into the intervention group received access to the deprexis intervention" and that "the therapists informed their self-referred patients about the study".	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	The study did not specifically address whether important non-protocol interventions were balanced across the intervention groups	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	The study indicates that the therapists were trained and instructed to use their clinical judgment when integrating the web-based program (deprexis) into their treatment, which suggests a degree of flexibility in implementation.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	The study had a notable dropout rate, which is a form of non-adherence. Specifically, 28% of participants dropped out during the treatment phase, and this increased to 43% by the 6-month follow-up assessment.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	while the study utilized a valid analytical approach in terms of ITT, it did not adequately address adherence to the intervention, which is crucial for estimating the per-protocol effect. Therefore, the analysis may not have fully captured the impact of adherence on outcomes.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	the availability of data for the primary outcome was limited, and the dropout rate suggests that the analysis may not fully reflect the intended intention-to-treat effect.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	The study did not explicitly mention the use of analysis methods that correct for bias due to missing data, such as instrumental variable analyses or inverse probability weighting.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	the potential for bias due to missing outcome data in this study is a concern. The high dropout rate and lack of detailed information on the reasons for missing data suggest that the missingness could indeed depend on the true value of the outcome	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	the BDI-II was an appropriate choice for measuring the primary outcome in this study, as it effectively captured the intended effects of the intervention on depressive symptoms, supported by its strong psychometric properties and the significant results observed in the intervention group	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	while the study used comparable methods of outcome measurement, the additional engagement with the "deprexis" program and potential differences in therapist interactions could have led to differences in how outcomes were ascertained between the intervention and control groups.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	while the study does not provide explicit details about the timing of the finalization of the analysis plan relative to the unblinded data availability, it appears that the data were analyzed in accordance with a pre-specified analysis plan.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Based on the information provided, it appears that the study did assess multiple eligible outcome measurements and reported results for both primary and secondary outcomes without evidence of selective reporting based on results.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	it appears that the study did assess multiple eligible analyses of the data, but it does not provide evidence that the results were selectively reported based on the outcomes.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

4.

Study details	
Reference	Hagen, B. I., Lau, B., Joormann, J., Småstuen, M. C., Landrø, N. I., & Stubberud, J. (2020). Goal management training as a cognitive remediation intervention in depression: A randomized controlled trial. *Journal of Affective Disorders*, *275*, 268–277. https://doi.org/10.1016/j.jad.2020.07.015

Study design

X Individually-randomized parallel-group trial

Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Goal management training

Comparator: Computerized Cognitive Training (CCT)

Specify which outcome is being assessed for risk of bias: Everyday executive functioning

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The participants were randomized using computer-generated simple randomization, which is a method that incorporates a random component in the sequence generation process.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	The study states that "the person responsible for data collection (author B.H) was not blinded to group allocation and acted as therapist in both interventions" which indicates that the enrolling investigator had knowledge of the allocation process.	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study found that "no statistically significant difference between the groups emerged for any baseline variable in the randomized sample", indicating that the randomization process was effective and that any observed imbalances were compatible with chance.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The lack of blinding means that any side effects or specific experiences related to the interventions could influence their perceptions and behaviors during the trial.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	The study adhered to its protocol without evidence of deviations that would indicate a failure to implement the interventions as planned.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study utilized ITT analyses, which are considered appropriate for estimating the effect of the intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	There is no evidence to suggest that such interventions were inconsistent with the trial protocol or that they created a risk of bias between the groups.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	The implementation of GMT was successful for the majority of participants, and the study maintained a high standard of intervention delivery.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	The dropout rate and variations in attendance suggest that non-adherence was present and could have influenced the results of the study.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	The reliance on ITT analysis without the incorporation of methods that specifically address adherence issues limits the ability to accurately assess the impact of the intervention on participants who adhered to the treatment regimen.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The lack of specific details regarding missing data limits the ability to assess the risk of bias due to missing outcome data.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	The absence of detailed reporting on missing data and the lack of advanced analytical methods limit the ability to conclude that the results were unbiased.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	The study lacks detailed information on the reasons for missing data and their potential relationship to participants' health status or the true value of the outcomes the evidence suggests that it is likely that missingness in the outcome depended on its true value. The lack of detailed reporting on missing data and the potential influence of participants' health status on dropout rates contribute to this assessment.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The chosen measurement method is suitable for evaluating the intended outcomes in the context of the study.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	the measurement and ascertainment of outcomes in this study were conducted using comparable methods across both intervention groups, with no evidence of diagnostic detection bias or differences in opportunities for identifying outcome events.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The outcome assessors had knowledge of the intervention status, which could influence the assessment of outcomes.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	The assessment of outcomes in this study could have been influenced by the knowledge of the intervention received, particularly for participant-reported and observer-reported outcomes that involve judgment.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	It is likely that the assessment of outcomes in this study was influenced by the knowledge of the intervention received, particularly for participant-reported outcomes.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	the data from the study were analyzed in accordance with a pre-specified analysis plan that was finalized before the unblinded outcome data were available.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There is clear evidence that the domain was measured in multiple ways, and the results reported may have been selectively chosen based on their significance.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	There is clear evidence that the domain was measured in multiple ways, and the results reported may have been selectively chosen based on their significance.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The study does not report whether the analysis was conducted according to a pre-specified plan finalized before unblinded outcome data were available. Without a trial registry entry, protocol reference, or analysis plan timestamp, there is insufficient information to assess whether selective reporting could have occurred.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There is no accessible trial protocol or pre-specified analysis plan to verify whether all measured outcomes were reported or whether certain scales or time points were selectively presented. Given the presence of multiple eligible outcome measurements in the same domain and no clear documentation of pre-specified reporting intentions, the potential for selective reporting cannot be ruled out.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	Although some analytic methods are described (e.g., ANCOVA, ITT), there is no available protocol or pre-specified analysis plan to confirm whether these were the only planned analyses. Because the outcome could be analyzed in multiple legitimate ways and only one set of results is reported without confirmation of pre-specification, there is insufficient information to judge the risk of selective reporting.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

5.

Study details	
Reference	Boyle, C. C., Stanton, A. L., Ganz, P. A., Crespi, C. M., & Bower, J. E. (2017). Improvements in emotion regulation following mindfulness meditation: Effects on depressive symptoms and perceived stress in younger breast cancer survivors. *Journal of Consulting and Clinical Psychology*, *85*(4), 397–402. https://doi.org/10.1037/ccp0000186

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Comparator:
mindfulness-based program known as Mindful Awareness Practices (MAPs)	wait-list control group, which received no intervention

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Yes, a random component was used in the sequence generation process	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	No, the document does not provide sufficient information to confirm that the allocation sequence was concealed.	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No, the baseline differences between intervention groups do not suggest a problem with the randomization process. The groups appear to be well-balanced at baseline, with no significant differences reported in demographic variables or baseline measures.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes, participants were likely aware of their assigned intervention during the trial. The design of the mindfulness intervention and the absence of a placebo or sham intervention suggest that participants could identify their group assignment. Yes, it is likely that carers and people delivering the interventions were aware of participants' assigned intervention during the trial. The design of the mindfulness intervention and the absence of blinding measures suggest that those administering the interventions could identify the group assignments	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	Probably no, there were no significant deviations from the intended intervention that arose because of the trial context. The changes that occurred were consistent with what could happen outside the trial context, and there is no strong evidence to suggest otherwise	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, appropriate analyses such as intention-to-treat (ITT) and modified intention-to-treat (mITT) analyses were used to estimate the effect of assignment to intervention, while per-protocol and as treated analyses were deemed inappropriate.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns

Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	Probably no, important non-protocol interventions were balanced across intervention groups, as there is no strong evidence indicating significant imbalances that could affect the outcomes.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	No, there were no significant failures in implementing the intervention that could have affected the outcome, as the implementation was largely successful for most participants.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	Probably no, as the structured nature of the intervention and participant engagement likely minimized significant non-adherence that could have affected outcomes.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	Yes, an appropriate analysis was used to estimate the effect of adhering to the intervention, focusing on mediation analyses and employing bootstrapping for significance testing.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	No, data for the primary outcome were not available for all participants, as approximately 16.9% of participants had missing outcome data, which could impact the estimated effect of the intervention.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No, there is insufficient evidence that the result was not biased by missing outcome data, as the study did not employ robust analysis methods or sensitivity analyses to address potential biases.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Yes, missingness in the outcome could depend on its true value, especially if loss to follow-up is related to participants' health status. If missing data are due to unrelated reasons, the risk of bias is lower.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	Yes, it is likely that missingness in the outcome depended on its true value, especially if there are differences in missing data between intervention groups or if reasons for missing data relate to health status.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	"No," the method of measuring the primary outcome was not inappropriate.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Yes, the measurement or ascertainment of the primary outcome could have differed between intervention groups.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Yes, the data that produced the results were analyzed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The study focused on specific mediators (self-kindness, rumination, and mindfulness) and their effects on depressive symptoms and perceived stress, with results indicating that self-kindness played a significant role in mediating these effects. Given this information, if the analysis intentions were clearly defined and adhered to, and if all eligible results were reported without selective reporting, the appropriate answer would likely be 'Probably no'.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

6.

Study details	
Reference	Jennissen, S., Gibbons, M. B. C., Crits-Christoph, P., Schauenburg, H., & Dinger, U. (2021). Insight as a mechanism of change in dynamic therapy for major depressive disorder. *Journal Of Counseling Psychology*, *68*(4), 435–445. https://doi.org/10.1037/cou0000554

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Comparator:
Experimental: Supportive-Expressive (SE) Dynamic Psychotherapy, focusing on gaining insight into maladaptive interpersonal patterns.	Comparator: Cognitive Therapy (CT), focusing on cognitive restructuring and behavioral activation

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Change in insight from baseline to month 2 significantly predicted change in depression symptoms from month 2 to month 5 for the SE group (b = -5.57, *p* = .035; partial r = -0.21). No significant effect in the CT group. The interaction between treatment and insight change was not statistically significant, but conditional effects were significant in SE only.

Is the review team's aim for this result…?

☐ x to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ x Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The study used computerized urn randomization, which is a recognized method involving randomness to allocate participants. This satisfies the requirement for a truly random allocation sequence.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Although a computerized urn randomization method was used, the study does not provide any information about whether the allocation sequence was concealed from those enrolling participants. Without this detail, we cannot determine whether allocation concealment was maintained.	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Baseline characteristics between the intervention groups appear similar and balanced. There is no indication of substantial differences in group sizes or key prognostic variables that would suggest a problem with the randomization process. All observed differences are consistent with chance.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants would have been aware of their assigned intervention due to the distinct nature of the therapies and the lack of any blinding procedures. This awareness is unavoidable in psychotherapy trials and can influence behavior and expectations Therapists delivering the interventions were necessarily aware of which treatment each participant received. In psychotherapy research, blinding of intervention providers is typically not feasible due to the inherent differences in therapeutic models and required expertise.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	There is no evidence that deviations from the intended interventions were caused by the trial context. Dropouts or partial adherence appear consistent with real-world therapy settings, not driven by participant expectations or study design influences. Therefore, deviations due to trial context are unlikely.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study used an intention-to-treat (ITT) analysis, including all randomized participants in the groups to which they were originally assigned. This is an appropriate method for estimating the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Outcome data were available for 95% of participants, which meets the typical threshold for "nearly all" in continuous outcomes. The small amount of missing data is unlikely to have meaningfully affected the estimate of the treatment effect.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The study used well-validated and widely accepted outcome measures for depression, such as the Hamilton Depression Rating Scale (HAM-D) and Beck Depression Inventory (BDI)**.** These are appropriate, sensitive, and valid instruments for detecting changes in depression severity.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Both groups (CT and PDT) were assessed using **the** same instruments at the same time points. There is no indication of systematic differences in how outcomes were measured between groups.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	There is no indication that outcome assessors were blinded. Given that this is a psychotherapy trial, blinding is typically not applied and the study does not report any measures to blind assessors	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	The primary outcome (HAM-D) is a clinician-rated scale involving judgment. If the assessor knows which therapy was given, their expectations may influence their scoring, especially in a psychological context.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The article does not mention a pre-registered protocol, nor is there any reference to a pre-specified statistical analysis plan. Therefore, it is unclear whether the reported analyses were defined before outcome data were available.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The study used multiple instruments to assess depression (HAM-D, BDI), insight, and functioning, but there is no documentation of a pre-specified plan stating which measurement would be primary. This opens up the possibility of selective reporting based on favorable results.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	Different analytical approaches (e.g., mixed-effects models, mediation analyses) were applied, but there is no clear indication that all were pre-specified or whether alternatives were tried and not reported. Thus, we cannot rule out selective reporting of analyses.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

7.

Study details	
Reference	Chen, Y., Pan, A., Hsiung, P., Chung, L., Lai, J., Gau, S. S., & Chen, T. (2015). Life Adaptation Skills Training (LAST) for persons with depression: A randomized controlled study. *Journal of Affective Disorders*, *185*, 108–114. https://doi.org/10.1016/j.jad.2015.06.022
Study design	
X Individually-randomized parallel-group trial	

☐ Cluster-randomized parallel-group trial
☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Life Adaptation Skills Training (LAST)

Comparator: Treatment as usual (TAU)

Specify which outcome is being assessed for risk of bias

Quality of life

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The participants were randomly assigned to either the intervention group or the control group based on numbers placed in sealed envelopes.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Yes, the allocation sequence was concealed until participants were enrolled and assigned to interventions in the study "Efficacy of Life Adaptation Skills Training (LAST) for Persons with Depression."	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	there were no baseline differences between intervention groups that would suggest a problem with the randomization process.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	participants were aware of their assigned intervention during the trial. This awareness could potentially influence their health-related behaviors and outcomes. it was indicated that the randomization process was not fully concealed.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	there is no explicit evidence or strong reason to believe that the trial context led to failure to implement the protocol interventions or to the implementation of interventions not allowed by the protocol.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	An appropriate analysis was used to estimate the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	there is no indication that important non-protocol interventions were balanced across the intervention groups.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	while the intervention was successful for many, the high dropout rate and variability in participation indicate that there were indeed failures in implementing the intervention that could have affected the overall outcomes	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	Yes, there was non-adherence to the assigned intervention regimen that could have affected participants' outcomes.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	Yes, an appropriate analysis was used to estimate the effect of adhering to the intervention, as the study employed a mixed-effects model and adhered to the intent-to-treat principle, which are both suitable for addressing the complexities of adherence in randomized trials.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Data for this outcome were available for all, or nearly all, participants randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	the method of measuring the primary outcome was not inappropriate. The chosen instruments were suitable for evaluating the intended outcomes and were sensitive to the effects of the intervention.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	measurement or ascertainment of the outcome did not differ between intervention groups. The methods of outcome measurement were comparable, and there was no indication of diagnostic detection bias or additional opportunities for outcome events to be identified due to the intervention.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	the outcome assessors were not aware of the intervention received by study participants, as they were blinded to the treatment group assignments throughout the assessment process. This methodological rigor enhances the reliability of the study's findings.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The data that produced the results were analyzed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	there is no clear evidence that the numerical result was selected from multiple eligible outcome measurements based on the results. The study appears to have followed a pre-specified analysis plan and reported all intended outcome measurements.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	The study clearly outlines its analysis intentions and methodology, indicating that all eligible reported results for the outcome measurements correspond to the intended analyses.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

8.

Study details	
Reference	Başoğul, C., & Buldukoğlu, K. (2020). Neuman Systems Model with Depressed Patients: a randomized controlled trial. *Nursing Science Quarterly*, *33*(2), 148–158. https://doi.org/10.1177/0894318419898172

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	The intervention applied in this study was the Coping With Depression Program (CWDP), developed based on the Neuman Systems Model (NSM) and incorporating techniques from Cognitive Behavioral Therapy (CBT).	Comparator:	Standard treatment

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	

Is the review team's aim for this result…?

- ☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	"The participants were randomly placed in a consecutive manner to either the intervention or the control group according to the order of their arrival"	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	the allocation sequence was concealed until participants were enrolled and assigned to interventions. This was achieved by randomly assigning participants to either the intervention or control group as they arrived.	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study reported that there were "no statistically significant differences between the groups in terms of sociodemographic characteristics, which were determined before the study" .	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	Based on the information provided in the study, there is no strong evidence to suggest that deviations from the intended intervention arose specifically because of the trial context. The researchers focused on maintaining adherence to the protocol, and any changes that occurred were likely consistent with typical participant behavior in non-trial settings.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study utilized a two-factor variance analysis for mixed patterns to evaluate the effect of the intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	the study's design and execution suggest that important non-protocol interventions were indeed balanced across the intervention groups, allowing for a clearer assessment of the intervention's effectiveness.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	While the study demonstrated significant improvements in depression levels and self-esteem among participants in the intervention group, the aforementioned factors indicate potential failures in the implementation of the intervention that could have affected the outcomes.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	The study acknowledged the issue of non-adherence and took steps to exclude participants who did not meet the adherence criteria. However, the presence of non-adherence suggests that the outcomes may have been influenced by participants' engagement with the intervention.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	the analysis used in the study was appropriate for estimating the effect of adhering to the intervention.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	while the study began with 72 randomized participants, the data for the outcomes were not available for all or nearly all participants due to dropouts and exclusions related to non-adherence. Only 62 participants completed the posttest, and 43 completed the follow-up, indicating that a significant number of randomized participants did not have data available for the outcome measures	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Based on the information provided, there is insufficient evidence that the results of the study were not biased by missing outcome data.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	The study indicates that if participants withdrew from the study or were lost to follow-up due to their health status, it is plausible that the missing outcome data could be related to the true value of the outcome.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	While the BDI is a valid tool for measuring depression, the concerns regarding missing data and the potential influence of participants' health status on the outcome measurements suggest that the method of measuring the primary outcome may not be entirely appropriate.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	the measurement or ascertainment of the primary outcome could indeed have differed between intervention groups due to the structured nature of the intervention, the context of the assessments, potential biases related to participant health status, and differences in retention and engagement with the program.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	the numerical result being assessed was likely selected from multiple eligible outcome measurements, including various scales and time points, within the outcome domain.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	the numerical result being assessed was likely selected from multiple eligible analyses of the data, given the variety of outcome measurements used, the statistical methods employed, and the significant findings reported in the study	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

9.

Study details	
Reference	Morokuma, I., Shimodera, S., Fujita, H., Hashizume, H., Kamimura, N., Kawamura, A., Nishida, A., Furukawa, T. A., & Inoue, S. (2013). Psychoeducation for major depressive disorders: A randomised controlled trial. *Psychiatry Research*, *210*(1), 134–139. https://doi.org/10.1016/j.psychres.2013.05.018

Study design

X Individually-randomized parallel-group trial

⬜ Cluster-randomized parallel-group trial

⬜ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Experimental: Six sessions of group psychoeducation focused on coping with family and workplace interactions (didactic + problem-solving).	Comparator:	Comparator: Treatment As Usual (TAU) standard outpatient psychiatric care with antidepressants.

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Relapse rate by 9 months: • Intervention: 1/17 (6%) • Control: 5/14 (36%) • Risk Ratio (RR): 0.12 (95% CI: 0.02–0.87), *p* = 0.015 Time to relapse: Significantly longer in intervention group (Kaplan–Meier log-rank *p* = 0.011). HR for relapse: 0.091 (95% CI: 0.01–0.87), *p* = 0.038 (Cox regression)

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☒ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants in the intervention group received psychoeducation sessions, while the control group did not receive any intervention. Given the nature of the intervention and the lack of blinding, participants were certainly aware of their group assignment. The psychoeducational program was delivered by trained mental health staff. It is clear that those delivering the intervention were aware of the assignment, as blinding was not feasible in this behavioral trial.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	There is no indication in the article of protocol deviations due to the trial context. While adherence to the intervention is not described in detail, the absence of reported deviations or contamination between groups suggests that deviations were minimal and not caused by the study setting.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The article reports that all 60 participants (30 in the intervention group and 30 in the control group) **completed** the pre- and post-intervention assessments. There is no mention of dropouts or missing outcome data, which supports a low risk of bias due to missing data.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	The HRSD is an interviewer-rated tool that involves clinical judgment. If assessors were not blinded (which is likely), their ratings could have been influenced by expectations about the effect of psychoeducation, even unintentionally. The lack of assessor blinding, combined with the subjective nature of the outcome (depression severity) and small sample size, increases the likelihood that ratings were influenced by knowledge of group assignment.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There were multiple instruments used to assess depressive symptoms and functioning (e.g., HRSD-17, BDI-II, CGI, GAF), measured at different time points. However, it is **u**nclear whether the reported outcomes were selected based on favorable results, and there is no clear pre-specified plan stating which specific outcome measures and time points would be used. This suggests probable selective reporting	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	Although the article reports intention-to-treat analysis and sensitivity analyses (e.g., imputing missing 9-month follow-up data using baseline values), it does not clarify whether multiple analysis strategies were considered and only favorable ones reported. Given the absence of a pre-specified statistical analysis plan, there is **a** probable risk that the reported results were selectively chosen from among several possible analyses	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

10.

Study details	
Reference	Chen, Y., Pan, A., Hsiung, P., & Chung, L. (2015). Quality of Life Enhancement Programme for Individuals with Mood Disorder: A Randomized Controlled Pilot Study. *Hong Kong Journal of Occupational Therapy*, *25*(1), 23–31. https://doi.org/10.1016/j.hkjot.2015.04.001

Study design

X Individually-randomized parallel-group trial

Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Quality of Life Enhancement Programme (QOLEP)

Comparator: treatment as usual (TAU)

Specify which outcome is being assessed for risk of bias: Quality of Life

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The researchers used a method of random allocation to assign participants to either the treatment group or the control group. Specifically, participants were randomly assigned using random numbers in sealed envelopes after baseline measures were taken.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study reported baseline characteristics for both the treatment and control groups, and these characteristics were generally well-balanced between the groups.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants were not aware of their assigned intervention during the trial. The study employed a randomized controlled trial design, which typically includes measures to ensure that participants remain unaware of their group assignments to minimize bias. Yes, carers and people delivering the interventions were likely aware of participants' assigned intervention during the trial. The study indicated that the randomization process may not have been adequately concealed, which could lead to awareness among those administering the interventions.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	The study did not report any deviations from the intended intervention that arose specifically because of the trial context.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes, an appropriate analysis was used to estimate the effect of assignment to intervention in the study. The analysis employed both intention-to-treat (ITT) and modified intention-to-treat (mITT) approaches, which are considered appropriate methods for handling missing outcome data.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	The successful delivery of the QOLEP and the high participant satisfaction rates indicate that the intervention was carried out effectively, minimizing the risk of bias related to implementation failures.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	the evidence suggests that there was no significant non-adherence to the assigned intervention regimen, as all participants completed the intervention and reported satisfaction with the program. Therefore, the risk of bias related to non-adherence is minimal in this study.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The study included 21 individuals with mood disorders, all of whom completed the intervention, resulting in a dropout rate of 0%. This indicates that the data for the outcome measure were available for all randomized participants.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The method of measuring the primary outcome was appropriate and suitable for evaluating the intended outcome.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	the ascertainment of outcomes was designed to be uniform across groups, but the nature of the interventions could lead to differences in how outcomes were identified and reported.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The data analysis in the study was conducted in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There is clear evidence that all reported results correspond to the intended outcome measurements, and there was no opportunity for selective reporting based on the results.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	There is clear evidence that all reported results correspond to the intended analyses, and there was no opportunity for selective reporting based on the results.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

11.

Study details	
Reference	Ehret, A. M., Kowalsky, J., Rief, W., Hiller, W., & Berking, M. (2014b). Reducing symptoms of major depressive disorder through a systematic training of general emotion regulation skills: protocol of a randomized controlled trial. *BMC Psychiatry*, *14*(1). https://doi.org/10.1186/1471-244x-14-20

Study design

X Individually-randomized parallel-group trial

⬜ Cluster-randomized parallel-group trial

⬜ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Affect Regulation Training (ART) an 8-week group intervention focused exclusively on enhancing general emotion regulation (ER) skills.	Comparator:	Common Factor Treatment-Control (CFT-C) designed to account for non-specific therapeutic effects (e.g., therapeutic alliance, goal setting). Waitlist Control (WL) participants receive no immediate intervention, but access ART after the study.

Specify which outcome is being assessed for risk of bias

Depressive symptoms

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result…?

- [x] to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- [ ] to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ x Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The protocol states that "participants will be assigned using a computerized randomization tool." The method of computerized randomization suggests that allocation was concealed.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The protocol clearly describes the training conditions (ART, CBT, waitlist) and intervention specifics. As this was a behavioral intervention with group training sessions and explicit instruction, participants would inevitably be aware of their assigned intervention group. The interventions involved training sessions and instructions delivered by clinicians or facilitators. Therefore, those delivering the intervention were necessarily aware of group allocations.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	The protocol does not report any deviations from the intended intervention caused by the trial context. Interventions were structured and standardized. Deviations, if any, would likely fall within what could happen outside the trial context (e.g., missed sessions, standard dropout).	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The protocol explicitly states that the analysis will be performed according to the intention-to-treat principle and that mixed-effect modeling will be the main analytical strategy. This is appropriate for estimating the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	In clinical trials involving mental health interventions, especially for depression, it is common for participants who experience less benefit (or worsening symptoms) to drop out. This introduces the possibility that missingness is related to unobserved outcomes. While explicit reasons for dropout are not discussed, the context of depression and the anticipated use of imputation suggest a non-random missingness mechanism is likely. Also, given the nature of the disorder and intervention, it is reasonable to suspect that those who did poorly may be more likely to drop out.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Since the outcomes are self-reported and participants were not blinded, the assessors (i.e., the participants themselves) were aware of their group allocation.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Because participants were aware of the intervention and the outcomes are subjective (e.g., mood, emotional state), their responses could be influenced by their expectations or beliefs about the intervention. Given the nature of the intervention (emotion regulation training) and the self-report format, there is a considerable chance that participants' beliefs about the efficacy of the program may have influenced how they reported their symptoms.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

12.

Study details	
Reference	Donaldson, C., & Lam, D. (2004). Rumination, mood and social problem-solving in major depression. *Psychological Medicine*, *34*(7), 1309–1318. https://doi.org/10.1017/s0033291704001904

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Rumination induction Comparator: Distraction induction

Specify which outcome is being assessed for risk of bias Mood and problem-solving

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result…?

- ☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The researchers utilized a randomized controlled design, where participants were randomly allocated to either a rumination or distraction induction condition.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study appears to have properly randomized participants between the rumination and distraction conditions.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The study involved participants being assigned to either a rumination or distraction condition, and the nature of these interventions (focusing on thoughts related to emotions and behaviors versus playing a board game) would have made it apparent to participants which intervention they were receiving. The study does not mention any blinding procedures for the carers or those administering the interventions, which suggests that they were likely aware of the assigned interventions. Furthermore, the lack of mention regarding the concealment of randomized allocation indicates that it is probable that the carers and intervention deliverers were aware of the participants' assigned interventions during the trial.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	there is no strong evidence or reason to believe that deviations from the intended intervention arose because of the trial context.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study used an appropriate analysis to estimate the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns

Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	There is no evidence to suggest that participants experienced side effects or toxicities that would lead to differences in health-related behaviors between the intervention groups.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	There is no indication of significant implementation failures that would introduce bias or affect the study's results.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	There is no evidence to suggest that non-adherence was a concern in this study.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	The analysis used was appropriate for the study design and intervention type.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	the availability of data from all participants supports the integrity of the analysis and minimizes the risk of bias due to missing outcome data.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The measurement methods were suitable for evaluating the intended outcomes of the study.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	There was no indication of diagnostic detection bias or additional opportunities for outcome events to be identified due to the nature of the interventions.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The blinding of outcome assessors to intervention status supports the integrity of the study's findings.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The study adhered to rigorous standards for analysis, ensuring that the results were derived from a well-defined and transparent process.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The study involved multiple eligible outcome measurements, and without explicit justification for the selection of reported results, there is a likelihood that the results were chosen based on their favorability or significance.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	The study involved multiple eligible analyses, and without explicit justification for the selection of reported results, there is a likelihood that the results were chosen based on their favorability or significance.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

13.

Study details	
Reference	Klein, D. N., Leon, A. C., Li, C., D'Zurilla, T. J., Black, S. R., Vivian, D., Dowling, F., Arnow, B. A., Manber, R., Markowitz, J. C., & Kocsis, J. H. (2011). Social problem solving and depressive symptoms over time: A randomized clinical trial of cognitive-behavioral analysis system of psychotherapy, brief supportive psychotherapy, and pharmacotherapy. *Journal Of Consulting And Clinical Psychology*, *79*(3), 342–352. https://doi.org/10.1037/a0023208

Study design

X Individually-randomized parallel-group trial

⬜ Cluster-randomized parallel-group trial

⬜ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Experimental: Cognitive-Behavioral Analysis System of Psychotherapy (CBASP) plus pharmacotherapy	Comparator:	Brief Supportive Psychotherapy (BSP) plus pharmacotherapy Pharmacotherapy alone

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Change in depressive symptoms over time, as predicted by changes in social problem solving. Key result: "As social problem solving increased over time, depressive symptoms at the next visit declined" (*coefficient* = -0.3136, $p < .001$ for total SPSI-R predicting lagged HAM-D). However, the interaction of treatment condition with the association between social problem solving and lagged depression scores was not statistically significant (e.g., $p = .94$ for interaction with SPSI-R Total)

Is the review team's aim for this result…?

- [ ] to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- [x] to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ x Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ x Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The study explicitly states that randomization was conducted by the University of Pittsburgh Epidemiology Data Center using a computer-generated randomization procedure**.** This involves a random component and satisfies the criteria for a truly random allocation sequence. The allocation was managed by an independent data coordinating center, which suggests that the allocation sequence was concealed from those enrolling participants. This meets the criteria for proper allocation concealment.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Baseline characteristics were generally well balanced across treatment groups. A small difference in ethnicity was noted, but it was minor and plausibly due to chance. No meaningful imbalance in key prognostic variables was observed.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	This was a psychotherapy study, so participants would necessarily know the type of therapy they were receiving (CBASP, BSP, or medication only). Therapists delivered specific treatments (CBASP or BSP) and were trained and certified for their respective modalities, so they clearly knew what they were delivering	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	There is no evidence or suggestion that participants received non-protocol interventions due to the trial context. The study maintained treatment fidelity with protocol adherence checks	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The study used mixed-effects linear regression models, which is appropriate, and analyzed based on treatment assignment	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Given the population was patients with chronic depression and treatment dropouts are common due to symptom severity, it is plausible that missingness was related to depression severity**,** i.e., to the true outcome values The trial design and patient population (chronically depressed individuals receiving therapy over 12 weeks) suggest that those with worse outcomes were more likely to drop out. This, combined with the absence of methods to account for missingness, implies likely bias due to missing outcome data	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The study used the Hamilton Depression Rating Scale (HAM-D) and the QIDS-SR. The HAM-D was administered by trained clinical evaluators and has good validity and reliability, and QIDS-SR has demonstrated good convergent validity with HAM-D	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	The study used complex analyses (e.g., mixed effects linear regression models with different covariate adjustments), and the report lacks detail on whether these were pre-specified. This suggests the possibility that among several possible analyses, those showing significant or desired results may have been preferentially reported	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

14.

Study details	
Reference	Foroughi, A., Sadeghi, K., Parvizifard, A., Moghadam, A. P., Davarinejad, O., Farnia, V., & Azar, G. (2020). The effectiveness of mindfulness-based cognitive therapy for reducing rumination and improving mindfulness and self-compassion in patients with treatment-resistant depression. *Trends in Psychiatry And Psychotherapy*, *42*(2), 138–146. https://doi.org/10.1590/2237-6089-2019-0016

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Mindfulness-Based Cognitive Therapy (MBCT) combined with antidepressants

Comparator: Antidepressant treatment only (Treatment As Usual, TAU)

Specify which outcome is being assessed for risk of bias	Depressive symptoms

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	• BDI score reductions (Experimental group):
	  ○ Pre: 33.78 ± 9.41 → Post: 6.11 ± 1.45 → Follow-up: 7.11 ± 2.93
	  ○ $p < 0.001$ (Bonferroni comparisons show significant pre-post and pre-follow-up reductions)
	  ○ Effect size (η^2) from repeated measures ANOVA: 0.90 (within subjects), 0.51 (between groups)
	• HDRS score reductions (Experimental group):
	  ○ Pre: 20.77 ± 3.92 → Post: 5.11 ± 1.26 → Follow-up: 4.44 ± 1.13
	  ○ $p < 0.001$, $\eta^2 = 0.84$ for time × group interaction

Is the review team's aim for this result…?

- [ ] to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- [x] to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- [ ] occurrence of non-protocol interventions
- [ ] failures in implementing the intervention that could have affected the outcome
- [ ] non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- [x] Journal article(s) with results of the trial
- [ ] Trial protocol
- [ ] Statistical analysis plan (SAP)
- [x] Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- [ ] Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- [ ] "Grey literature" (e.g. unpublished thesis)
- [ ] Conference abstract(s) about the trial
- [ ] Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- [ ] Research ethics application
- [ ] Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- [ ] Personal communication with trialist
- [ ] Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The study states participants were randomly assigned to intervention and control groups. However, it does not specify the exact method (e.g., computer-generated sequence, random number table). Because the trial appears to be conducted rigorously and clearly describes random assignment (without indications of predictability), "Probably yes" is appropriate.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	This was a psychological intervention involving active participation in mindfulness training. The nature of the intervention makes blinding of participants impractical, and the article does not mention any attempt to blind them. As with most psychological interventions, therapists delivering MBCT would necessarily be aware of the treatment being delivered. The article confirms this by describing the nature and delivery of MBCT sessions.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The article specifies that data were analyzed using an intention-to-treat (ITT) approach, which is appropriate for estimating the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The article mentions that 20 participants were randomized**, but only** 18 completed the post-intervention assessments**,** indicating that some outcome data are missing (10% dropout). This is close to the 95% threshold, but not sufficient to confidently say "Yes." Therefore, "Probably no" is most appropriate.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Participants who dropped out might have done so due to lack of perceived benefit or worsening symptoms, especially in a mental health trial where depression severity could influence continued participation. Therefore, it's plausible that missingness depended on the true outcome values. The paper does not explain the reasons for dropout in detail, but given the nature of treatment-resistant depression and the fact that the intervention involves ongoing active participation, it is likely that those who were not benefiting (or worsened) were more likely to discontinue.	NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The outcomes were self-reported by participants. Since the intervention (mindfulness-based cognitive therapy) is not blinded, participants were aware of their group assignment. Therefore, they were also the assessors of the outcome, and not blinded.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Because the outcomes are subjective and participants knew their treatment group, their expectations or experiences could have influenced how they rated their symptoms and mindfulness/self-compassion.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	Given the nature of psychological interventions and participant-reported outcomes (e.g., mindfulness, self-compassion), it is likely that beliefs about the intervention or perceived benefit influenced how participants rated their own changes. The risk of expectation bias is high in unblinded self-assessments.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Multiple validated psychological instruments were used (e.g., RRS, MAAS, SCS), and while all were reported, there is no documentation confirming that all outcome measures and time points were pre-specified. This opens up the possibility that selective reporting occurred based on the results.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	The article lacks detail on the statistical analysis plan, including whether analyses (e.g., adjusted vs. unadjusted, per-protocol vs. ITT) were pre-specified. Without this information and given the multiple potential analytic strategies available, there is a reasonable chance that only favorable results were reported.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

15.

Study details	
Reference	Anuwatgasem, C., Awirutworakul, T., Vallibhakara, S. A.-O., Kaisa-ard, P., Yamnim, T., Phadermphol, K., Pranudta, P., Wisajun, P., & Jullagate, S. (2020). The Effects of Mindfulness and Self-Compassion-Based Group Therapy for Major Depressive Disorder: A Randomized Controlled Trial. *Journal Of The Medical Association Of Thailand*, *103*(9), 856–863. https://doi.org/10.35755/jmedassocthai.2020.09.12020

Study design

X Individually-randomized parallel-group trial

☐ Cluster-randomized parallel-group trial

☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: mindfulness and self-compassion-based group therapy (MSC) program

Comparator: Standard treatment

Specify which outcome is being assessed for risk of bias

Depressive symptoms

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

(p<0.001)

Is the review team's aim for this result…?

☐ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses <u>underlined in green</u> are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options

1.1 Was the allocation sequence random?	The study utilized a computer-generated block randomization method to create the two treatment groups, which included mindfulness and self-compassion-based therapy (experimental group) and standard psychotherapy (control group) .	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	The study reported that there were no significant differences in demographic characteristics or baseline measurements of depression-related parameters between the mindfulness and self-compassion group and the control group.	Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The study mentions that "the participants were aware of their assigned intervention," which implies that the therapists and carers would also have knowledge of which intervention each participant was receiving.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	The document notes that some participants experienced discontinuation from the study, which was attributed to various factors such as "lacking time, workload, personal issues, and no desire for treatment" . Additionally, the study highlighted that the dropout rate was higher in the control group compared to the mindfulness and self-compassion (MSC) group, with 42.11% of participants in the control group discontinuing versus 18.18% in the MSC group .	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	the deviations from the intended intervention, including participant dropout rates, awareness of treatment assignments, variability in treatment delivery, and contextual factors, were likely to have affected the study's outcomes. These elements can introduce biases that complicate the interpretation of the effectiveness of the mindfulness and self-compassion therapy compared to standard treatment	NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	Specifically, the MSC group had a dropout rate of 18.18%, while the control group had a dropout rate of 42.11%.	NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	the study appropriately used ITT and mITT analyses to estimate the effect of assignment to intervention, adhering to best practices in clinical trial methodology.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns

Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	while the study effectively randomized participants and balanced key characteristics at baseline, it did not provide detailed information on the balance of important non-protocol interventions across the intervention groups, which could potentially introduce bias if imbalances existed.	NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	based on the available information, it can be inferred that there were no significant failures in implementing the MSC intervention that could have adversely affected the outcomes for most participants. The successful delivery and positive results suggest that the intervention was effective and adhered to the intended protocol.	NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	there was non-adherence to the assigned intervention regimen that could have affected participants' outcomes, particularly due to the dropout rates and the reasons for discontinuation among participants.	NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	while the study employed a recognized analysis method (ITT), it did not utilize more sophisticated approaches to specifically estimate the effect of adherence to the intervention.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	while there were some participants who did not complete the study, the data for the primary outcome were available for a substantial number of participants, allowing for meaningful analysis of the intervention's effects.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	the methods used to measure the outcomes in this study were appropriate, utilizing validated instruments and comprehensive assessment strategies to evaluate the effects of mindfulness and self-compassion-based group therapy on major depressive disorder.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	while the study aimed to use standardized measurement methods, the potential for diagnostic detection bias and differences in the frequency of healthcare provider interactions could lead to variations in how outcomes are measured or ascertained between the intervention groups	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The text states that "All these data were collected by trained staff who did not know about each group's assignment".	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	the numerical results assessed in the study were likely selected from multiple eligible outcome measurements within the outcome domain. The study utilized various validated scales to evaluate different aspects of the participants' mental health and well-being.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

16.

Study details	
Reference	Psarraki, E. E., Bacopoulou, F., Panagoulias, E., Michou, M., Pelekasis, P., Artemiadis, A., Chrousos, G. P., & Darviri, C. (2021). The effects of Pythagorean Self-Awareness Intervention on patients with major depressive disorder: A pilot randomized controlled trial. *Journal Of Psychiatric Research*, *138*, 326–334. https://doi.org/10.1016/j.jpsychires.2021.03.067

Study design

X Individually-randomized parallel-group trial

⬜ Cluster-randomized parallel-group trial

⬜ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:	Pythagorean Self-Awareness Intervention (PSAI) an 8-week holistic stress management program including relaxation techniques, cognitive restructuring, and healthy lifestyle coaching.	Comparator:	Treatment As Usual (TAU) standard psychiatric outpatient care, including medication and monthly psychiatric counseling.

Specify which outcome is being assessed for risk of bias	Depressive symptoms
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Change in BDI scores (ΔDepression): • Intervention group: Mean Δ = -6.10 (SD = 8.39) • Control group: Mean Δ = -0.69 (SD = 5.32) • p = 0.001, Effect size r = 0.41 (moderate)

Is the review team's aim for this result…?

- [x] to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- [ ] to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ x Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ x Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	The article clearly states that the study was non-blinded: "This study was non-blinded, as patients and researchers were aware of the group assignment" .Therefore, participants were aware of their intervention group. Because the study was explicitly described as non-blinded, those delivering the intervention were also aware of participants' group assignment.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The analysis was not conducted using an intention-to-treat (ITT) approach. The authors state that only participants who completed the final measurement were analyzed: "30 patients of the intervention group and 32 patients of the control group participated in the final measurements and were analyzed." This suggests a per-protocol analysis, which is inappropriate when estimating the effect of assignment to intervention.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Seven out of the 69 randomized participants were excluded from the analysis. This represents approximately 10% of the sample. There is no information about whether these exclusions were related to outcomes, meaning they could have potentially influenced the trial results.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / Y / PY / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / PN / N / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Out of 69 participants randomized, 62 completed the study and were analyzed (30 in the intervention group and 32 in the control group), with only 7 dropouts. This represents approximately 90% data availability, which is close to the generally acceptable 95% for continuous outcomes and appears adequate given the moderate outcome effects reported	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The study used validated instruments such as the Beck Depression Inventory (BDI), the Positive and Negative Affect Schedule (PANAS), the Depression Anxiety Stress Scales (DASS), and the Pittsburgh Sleep Quality Index (PSQI), all of which are standard, reliable tools in clinical psychology and psychiatry.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	There is no indication in the study that different tools or timing were used across the groups. All participants were assessed with the same battery of tests.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The study does not mention blinding of assessors, and because self-report tools were used, the participants (as assessors of their own outcomes) were aware of their intervention allocation	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Self-reported outcomes such as mood, affect, and sleep quality are subjective and can be influenced by participants' expectations or beliefs about the intervention. Given that participants were not blinded, and the outcomes were based on subjective self-assessment (e.g., BDI, PANAS), it is likely that their responses were influenced by their knowledge of receiving the intervention.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

9.8. PRISMA-checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	pg 1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	pg 2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	7-9
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review	9

Section and Topic	Item #	Checklist item	Location where item is reported
		addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	10-11
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	10
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	10, Appendix 9.1-9.3
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	12
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	13
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	13
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	13

Section and Topic	Item #	Checklist item	Location where item is reported
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	14, Appendix 9.7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	13
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	13-14
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	13-14
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	13-14
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	13-14
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	20-22
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	14, Appendix 9.7
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	20-22
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	14-15
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	14-15
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	22
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	20-22
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	14, 16, 22, appendix
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Appendix
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	20-22

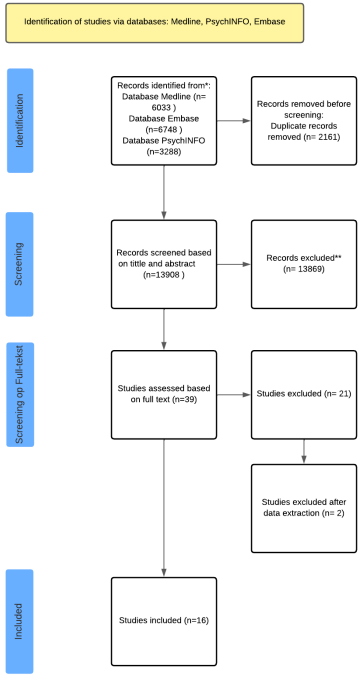
Section and Topic	Item #	Checklist item	Location where item is reported
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	22
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	20-22
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	22-24
	23b	Discuss any limitations of the evidence included in the review.	24
	23c	Discuss any limitations of the review processes used.	24
	23d	Discuss implications of the results for practice, policy, and future research.	25
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	N/A
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	26
Availability of data, code and other materials	27	Report which of the following are publicly	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
		available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

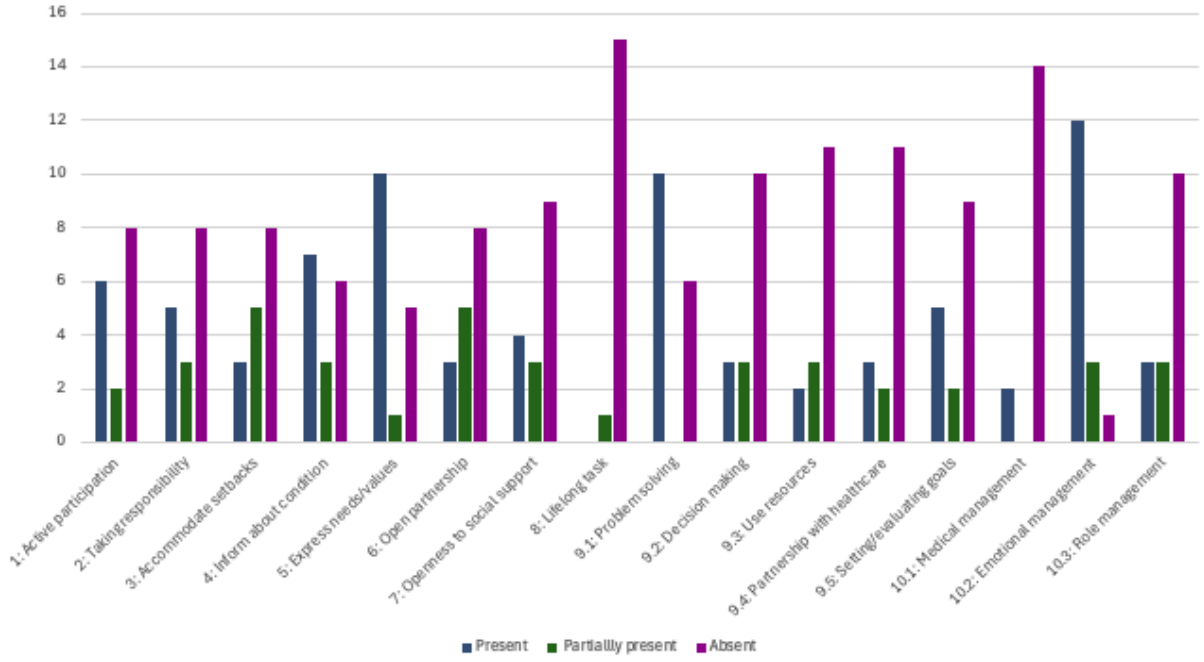
10. List of figures

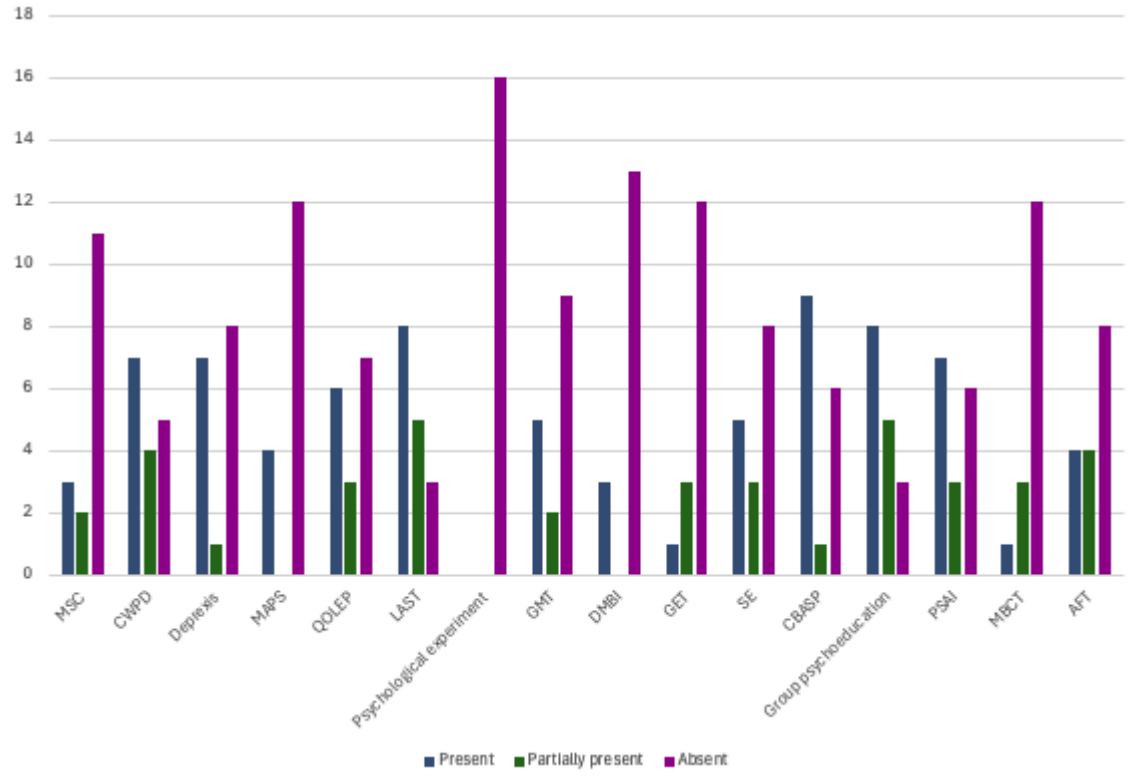
10.1. Figure 1: Flowchart of inclusion and exclusion



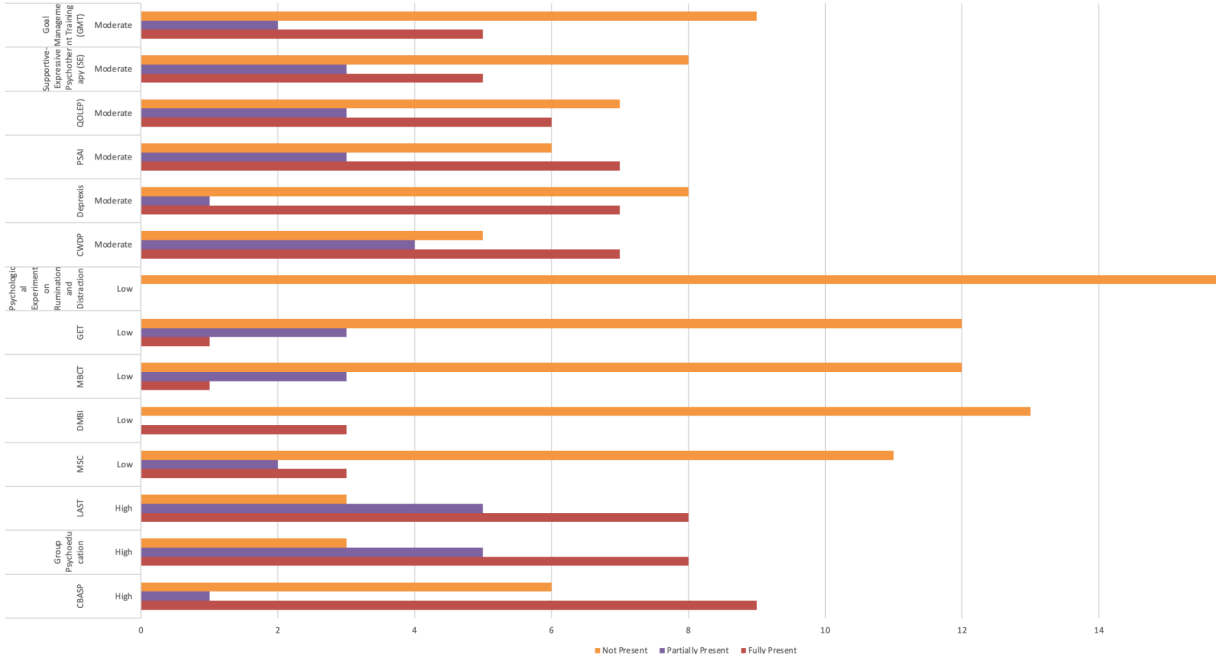
10.2. Figure 2: Sunburst Chart

10.3. Figure 3: Frequency SMACC-attributes (Self-management interventions)




18
16
14
12
10
8
6
4
2
0
MSC
CWPD
Depnexis
MAPS
QOLEP
LAST
Psychological experiment
GMT
DMBI
GET
SE
CBASP
Group psychoeducation
PSAI
MBCT
AFT
Present
Partially present
Absent

10.4. Figure 4: Scores (high, moderate, low)



11. List of tables

11.1. Table 1: PICO & inclusion & exclusion criteria

	Hyperoniem	Hyponiem
P	- Depressive disorder	- Major Depressive Disorder - Dysthemic disorder - Affective disorder
I	- Psychotherapy - Rehabilitation	
C	/	/
O	- Self-management - Participation - Personal autonomy - Quality of life	- Self-care, self- esteem - Patient participation - Community participation - Social participation - Disease management
Filter	- Adult - Randomized controlled trial - Clinical trial	

Inclusie	Exclusie
(a) Symptom-focused outcomes. (b) Recovery-focused outcomes such as self-efficacy, self-esteem, self-care and participation. (c) Daily functioning. (d) Self-management skills: Problem solving, Decision-making, Using resources, Forming a patient-healthcare provider partnership, Goal setting and evaluation → A,B of C moet steeds gecombineerd worden met D - Engels- en Nederlandstalige articels	- Comorbiditeiten - Anders gedefinieerd design dan RCT en CT

11.2. Table 2: Study Characteristics

Charachteristics	**No. of studies (%)**
Design - Randomised controlled trial	16 (100)
No. of participants - 1-25 - 26-50	 - 2 (13) - 2 (13)

- 51-75 - 76-100 - 100+	- 7 (44) - 2 (13) - 3 (19)
Country - United States - Thailand - Turkey - Zwitserland - Taiwan - United Kingdom - Greece - Japan - Germany - China - Norway - Spain	 - 3 (19) - 1 (6) - 1 (6) - 1 (6) - 2 (13) - 1 (6) - 1 (6) - 1 (6) - 2 (13) - 1 (6) - 1 (6) - 1 (6)

11.3. Table 3: Thematic analysis self-management interventions

Reported items in the self-management program	Summary
• Participants are asked to do 40 minutes of self-compassion practice each day, which can be a combination of formal and informal practices. (MSC) (Anuwatgasem et al., 2020) • Participants were instructed to practice formal mindfulness exercises at home, beginning with 5 minutes and increasing to 20 minutes daily, and completed weekly logs documenting home practice. (MAPs) (Boyle et al., 2017) • Time management in daily life; self-awareness of lifestyle re-design; Planning to participate in a new activity (QOLEP) (Y. Chen et al., 2015)	1.Active participation in care process
• They had to pose to themselves three questions: “What have I done wrong? What have I done right? What have I omitted that I ought to have done?“. (PSAI) (Psarraki et al., 2021)	**Self-reflection/ Self-evaluation**

• Participants were encouraged to raise questions of any kind that they wanted to know or solve (Group psychoeducation) (Morokuma et al., 2013) • Patients identify a recent distressing interpersonal situation and examine it with the therapist. (CBASP) (Klein et al., 2011)	**Self-analyses**
• Participants were encouraged to take responsibility for their progress by completing modules independently and applying learned strategies in daily life. (Deprexis) (Berger et al., 2017)	2.Does your self-management programme allow the person to take responsibility in the care process? - **personal responsibility in self management**
• Taking care of oneself in the face of lowering mood, responding to one's own pattern of early warning signs of depression, taking wise and skillful action (MBCT) (Foroughi et al., 2020) • The individuals had to recall and evaluate all the actions and discussions of the day concerning issues, such as diet, physical exercise, human relationships and emotions. (PSAI) (Psarraki et al., 2021) • With this workbook, the clients were able to review the contents of the sessions in advance, make revisions after the sessions, do the homework given in the sessions, and evaluate themselves. (CWDP) (Başoğul	**Self-observation and early recognition of signals**

& Buldukoğlu, 2020). ● The strategies consist of a self-instruction to stop ("STOP!") ongoing behavior (GMT) (Hagen et al., 2020) ● Responsibility was fostered by encouraging daily mindfulness practice and personal reflection outside of group sessions. (MAPs) (Boyle et al., 2017)	**Self-control & behavioural regulation**
● It is designed to prevent relapse in individuals with a history of recurrent major depressive disorder (MBCT) (Foroughi et al., 2020) ● Addressing the thought-feeling connection by identifying nonhelpful automatic thoughts (“Why can’t I ever succeed?” “Nothing feels good anymore”) and using communication skills by sharing them. (CWDP) (Başoğul & Buldukoğlu, 2020). ● The ability to accept and tolerate negative affective states when necessary and the ability to have compassionate self-support (ART) (Ehret et al., 2014)	3.Does the self-management programme provide scope to accommodate setbacks the person faces? - **coping with setbacks in self management** **Acceptance and non-judgmental attitude** **Normalisation of relapse and setbacks**

• Conditions for, and consequences of, absentminded slips discussed."The automatic pilot", and how it may lead to inappropriate responding. (GMT) (Hagen et al., 2020)	**Learning coping strategies and resilience**
• Teaches coping strategies for setbacks, but lacks individual tailoring during or after difficulties (Başoğul & Buldukoğlu, 2020). • Coping and stress management sessions helped participants recognize challenges and develop adaptive responses to setbacks. (QOLEP) (Y. Chen et al., 2015) • The stress coping strategies (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015) • The MSC program focuses primarily on building the capacity to tolerate and transform difficult emotions (MSC) (Anuwatgasem et al., 2020)	
• Introducing “automatic pilot” and how it contributes to depression. Attending to direct experience through the five senses and body (MBCT) (Foroughi et al., 2020)	4.Does the self-management programme inform the person about their condition, illness and treatment? - **The person is informed about their condition, illness and treatment by the self-management intervention** **Psychoeducation**

• Participants receive psychoeducation (ART) (Ehret et al., 2014) • The topics of the didactic parts included 'Patient recognition of depression and its consequences' (Group psychoeducation) (Morokuma et al., 2013) • Provides psychoeducation on depression and CBT principles, ensuring understanding of symptoms and thought–emotion–behavior links; complements but does not focus on medical treatment. (CWDP) (Başoğul & Buldukoğlu, 2020). • Users received evidence-based psychoeducation about depression, its symptoms, causes, and treatment options in the initial modules. (Deprexis) (Berger et al., 2017) • The intervention included psychoeducation about emotional stress responses and the role of mindfulness in recovery after cancer. (MAPs) (Boyle et al., 2017) • Psychoeducational sessions provided information about mood disorders, their effects on daily life, and the importance of balanced occupation. (QOLEP) (Y. Chen et al., 2015) • The course of depressive disorder and its impact on personal daily life (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	
• Week 5 emphasizes the importance of living in accordance with core values (MSC) (Anuwatgasem et al., 2020) • clarifying personal values and building commitment to pursue value-consistent goals even in the presence of distressing thoughts or feelings. (Deprexis) (Berger et al., 2017)	5.Can the person in the self-management programme express their needs, set values and priorities? - **Expression of the persons needs and priorities.** **Personal needs and strengths**

• Participants reflected on personal roles, needs, and life priorities while redesigning daily routines and planning meaningful activities. (QOLEP) (Y. Chen et al., 2015) • Lifestyle checking. (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015) • Selecting and deciding which activity and reward provide the opportunity to determine what is meaningful (CWDP) (Başoğul & Buldukoğlu, 2020).	**Daily functioning**
• It should be stressed that participants were not required to abstain from these foods, but advised to cut down their intake according to their own lifestyles and plans. (DMBI) (Han et al., 2020) • Applying learned strategies in an everyday environment. (GMT) (Hagen et al., 2020)	**Personal charachteristics**
• The evaluation was based on the lifestyle and moral framework (PSAI) (Psarraki et al., 2021) • In situational analysis (SA), patients identify a recent distressing interpersonal situation and examine it with the therapist. The process consists of three phases: elicitation, remediation, and generalization. (CBASP) (Klein et al., 2011) • Increase the patient's self-understanding of maladaptive interpersonal patterns and develop alternative ways of responding. (SE) (Jennissen et al., 2021)	

• In the remediation phase, patients work with therapists (CBASP) (Klein et al., 2011) • The treatment is focused on building a strong therapeutic alliance. (SE) (Jennissen et al., 2021)	6.Does the self-management programme promote an open partnership between the care providers? - **Collaborative care partnerships** **Shared decision-making** **Open dialogue**
• An open therapeutic partnership was supported by shared access to progress data and optional discussion of online content in sessions. (Deprexis) (Berger et al., 2017)	
• They shared their experiences and discussed their questions and problems with the stress scientists-psychologists. (PSAI) (Psarraki et al., 2021) • participants were encouraged to raise questions of any kind that they wanted to know or solve (Group psychoeducation) (Morokuma et al., 2013) • The conversation during the phone call would include inquiry of daily routines, vitality status, quality of sleep, mood and social activity participation which aims at conveying the caring component as well as ensuring the sense of connectiveness. (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	
• The model identifies the patient's wishes/needs in the relationship with another person. (SE) (Jennissen et al., 2021) • interpersonal exercises are used to generate an experience of selfcompassion with fellow participants, facilitating feelings of common humanity. (MSC) (Anuwatgasem et al., 2020) • The importance of social support. (CWDP) (Başoğul & Buldukoğlu, 2020). • Modules on interpersonal skills encouraged users to	7.Does the self-management programme address the person's openness to receive social support? - **Openness to social support**

recognize the value of social support and seek connection with others. (Deprexis) (Berger et al., 2017) ● Strategies of social support (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	
● The topics of the didactic parts included 'Patient recognition of depression and its consequences' and 'Course/outcome and review of the sessions'. (Group psychoeducation) (Morokuma et al., 2013)	8.Does the self-management programme inform the person that this is a lifelong task? - **Lifelong task**
● problem-solving therapies (ART) (Ehret et al., 2014) ● Develop alternative ways of responding. (SE) (Jennissen et al., 2021) ● Foster self-awareness and self-control. (DMBI) (Han et al., 2020) ● The primary focus of GMT is to increase the participants' attentional and problem-solving capacity. (GMT) (Hagen et al., 2020) ● Coping with problems. (CWDP) (Başoğul & Buldukoğlu, 2020).	9.Problem solving
● CBASP involves training patients to apply a structured interpersonal problem-solving algorithm, referred to as situational analysis (SA). (CBASP) (Klein et al., 2011) ● The final four sessions focused on improving coping strategies for stress/emotion-induced problems. (QOLEP) (Y. Chen et al., 2015) ● Problem-solving module (Deprexis) (Berger et al., 2017) ● Participants practiced problem-solving through structured coping exercises and discussion of real-life challenges. (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	**Training**

• We focussed on how to cope with family members and the boss at the workplace, prompting use of the problem-solving techniques (Group psychoeducation) (Morokuma et al., 2013)	**Daily problems**
• helping the patient to prioritize a single desired outcome in cases where multiple goals are presented. (CBASP) (Klein et al., 2011) • Goal-conflict in decision-making, and its practical and emotional consequences, are discussed. A To-Do list is incorporated into the STOP!-STATE cycle. (GMT) (Hagen et al., 2020) • Prioritizing choices when planning social skills as well as raising awareness about personal and social values, thinking about what desires, and thinking about what is meaningful to decide on an award. (CWDP) (Başoğul & Buldukoğlu, 2020). • Making decision (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	10.Decisionmaking
• Participants learned to recognize and use personal and environmental resources to support daily functioning and recovery. (QOLEP) (Y. Chen et al., 2015) • Exploration of living environment resources (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	11.Use resources **Internal resources**

• This technique of becoming aware of one's affective states in nonjudgmental ways aims to recruit cognitive resources to facilitate effective affect regulation (ART) (Ehret et al., 2014) • The program provided continuous access to psychoeducation, self-help tools, and therapeutic strategies. (Deprexis) (Berger et al., 2017)	**External resources**
• Participants were encouraged to seek social support and engage in social environments as a way to access external resources. (CWDP) (Başoğul & Buldukoğlu, 2020)	
• There were a variety of questions raised: how they would inform the boss of their absence, how they should respond to family critical attitudes or emotional overinvolvement, how they could discuss trivial-looking family matters with the doctor in charge (Group psychoeducation) (Morokuma et al., 2013) • It begins with supportive techniques to develop a therapeutic relationship, familiarize the patient with the focus on relationship difficulties. (SE) (Jennissen et al., 2021)	12.Ability to work in partnership with health care professional **Translating therapy into real - life contexts**
• In the generalization phase, patients and therapists review what has been learned and explore how the patient's new understanding and skills can be applied to similar situations in the past and future. (CBASP) (Klein et al., 2011)	**Community integration and social participation**
• Engaging in community life (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	

• And to set goals for the following day. (PSAI) (Psarraki et al., 2021) • formulate a more realistic desired outcome or goal, or devise more effective means of achieving the goal (CBASP) (Klein et al., 2011) • The notion of STATING one's goal to reduce slips and facilitate goal maintenance is introduced. STOP!-STATE cycle practiced. (GMT) (Hagen et al., 2020) • Participants set personal goals and reviewed their progress through structured life planning and weekly activity tasks. (CWDP) (Başoğul & Buldukoğlu, 2020) • Setting achievable goals. (Deprexis) (Berger et al., 2017) • Goal setting and review were incorporated through activity planning and reflection on progress toward personal life changes. (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	13.Setting and evaluating goals **Goals for emotional and interpersonal coping**
• Approaching and confronting situations that may cue negative affective states is often necessary to accomplish personally relevant goals (ART) (Ehret et al., 2014) • Set goals to explore a specific, currently problematic interpersonal pattern. (SE) (Jennissen et al., 2021)	
• As educational materials, we developed a textbook describing depression and its treatment and videos illustrating the patients' experiences, depressive symptoms and treatment. (Group psychoeducation) (Morokuma et al., 2013)	14.Medical managament

• Strategies of medication management (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	
• Affect Regulation Training (ART) is a transdiagnostic, group-based intervention developed to enhance adaptive emotion regulation (ER) (ART) (Ehret et al., 2014) • Participants were taught to observe their experiences without judgment, foster kindness toward themselves, recognize shared human experiences (common humanity), and reduce over-identification with distressing emotions or thoughts. (MBCT) (Foroughi et al., 2020) • the individuals had to recall and evaluate all the actions and discussions of the day concerning issues, such as emotions (PSAI) (Psarraki et al., 2021) • Week 6 teaches skills to deal with difficult emotions. (MSC) (Anuwatgasem et al., 2020) • Participants learned to identify and regulate negative emotions through thought diaries, mood tracking, and behavioral strategies. (CWDP) (Başoğul & Buldukoğlu, 2020) • Emotional regulation was fostered through cognitive restructuring, mindfulness, and emotion-focused strategies embedded in the modules. (Deprexis) (Berger et al., 2017) • Emotional regulation was strengthened through reduced rumination, increased self-kindness, and enhanced mindfulness. (MAPs) (Boyle et al., 2017) • Participants explored emotional awareness and expression through targeted sessions on stress, anxiety, and emotional coping. (QOLEP) (Y. Chen et al., 2015) • Emotional awareness and regulation were strengthened through sessions on emotional	15.Emotional management **Cognitive restructuring**

expression and stress management skills. (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	
• Restructure maladaptive thoughts into adaptive thoughts (GMT) (Hagen et al., 2020) • examining the extent to which the individual's thoughts are consistent with, and likely to increase the probability of achieving, the desired outcome, and generating alternative ways of thinking about the problem that might increase the chances of attaining the individual's goal. (CBASP) (Klein et al., 2011)	**Interpersonal insight and awareness**
• facilitate insight into maladaptive interpersonal patterns. (SE) (Jennissen et al., 2021) • increase awareness of how unrealistic desires (i.e., greed), anger and obsession (i.e., craving for something or somebody beyond reality) affect their mental and physical health. (DMBI) (Han et al., 2020)	
• This internal dialogue promotes self-referential awareness and mindfulness, resulting in correct choices and the installation of a healthier lifestyle. (PSAI) (Psarraki et al., 2021) • Self-awareness of lifestyle redesign (LAST) (Y. Chen, Pan, Hsiung, Chung, et al., 2015)	16.Role management **Role planning and routine rebuilding**

• Participants worked on improving social skills and planning meaningful activities to strengthen their roles in personal and social life. (CWDP) (Başoğul & Buldukoğlu, 2020) • Sessions encouraged participants to reflect on their personal roles and rebuild meaningful routines to support role fulfillment. (QOLEP) (Y. Chen et al., 2015)	

11.4. Table 4: Presence of reported self-management attributes across the studies

Self-management attributes	**Reported in No. Studies (%)**
• **Active Participation** ○ Self-reflection/ Self-evaluation ○ Self-analyses	6 (37,5) 1 (6,25) 2 (12,5)
• **Personal responsibility in self-management** ○ Self-observation and early recognition of signals ○ Self-control & behavioral regulation	6 (37,5) 3 (18,75) 2 (12,5)
• **Coping with setbacks in self-management** ○ Acceptance and non-judgmental attitude	8 (50) 1 (6,25) 1 (6,25)

○ Normalization of relapse and setbacks ○ Learning coping strategies and resilience	4 (25)
● **The person is informed about their condition, illness and treatment by the self-management intervention** ○ Psychoeducation	8 (50) 7 (43,75)
● **Expression of the person's needs and priorities** ○ Personal needs and strengths ○ Daily functioning ○ Personal characteristics	10 (62,5) 3 (18,75) 2 (12,5) 3 (18,75)
● **collaborative care partnerships** ○ Shared decision-making	6 (37,5) 1 (6,25) 3 (18,75)

○ Open dialogue	
● **Openness to social support**	5 (31,25)
● **Lifelong Task**	1 (6,25)
● **Problem-solving** ○ Training ○ Daily problems	10 (62,5) 4 (25) 1 (6,25)
● **Decision making**	4 (25)
● **Use resources** ○ Internal resources ○ External resources	5 (31,25) 2 (12,5) 1 (6,25)
● **Ability to work in partnership with healthcare professional** ○ Translating therapy into real-life context ○ Community integration and social participation	4 (25) 1 (6,25) 1 (6,25)

● **Setting and evaluating goals** ○ Goals for emotional and interpersonal coping	8 (50) 2 (12,5)
● **medical management**	2 (12,5)
● **Emotional management** ○ Cognitive restructuring ○ Interpersonal insight and awareness	13 (81,25) 2 (12,5) 2 (12,5)
● **Role management** ○ Role planning and routine building	4 (25) 2 (12,5)

11.5. Table 5: Primary outcomes, Assessment frequency and effect of the intervention

Primary Outcome	Used Assessment/Scale	P-value (Intervention)
(Reduction of) Depressive symptoms	Beck Depression Inventory- II (BDI-II)	p=0.001 (PSAI); p<0.001(DMBI); p<0.001 (CWDP); p<0.05 (Deprexis); p=0.008 (Group psychoeducation); p=0.001 (MBCT)
	Hamilton Psychiatric Rating Scale for Depression (HDRS)	p=0.002 (DMBI); p<0.0005(SOA); p=0.88 (SE); p=0.002 (Group psychoeducation); p=0.001 (MBCT)
	Center for Epidemiologic Studies-Depression scale (CESD)	p=0.002 (MAP with rumination as mediator); p<0.001 (MAP with self-kindness as mediator); p=0.01 (MAP with mindfulness as mediator);
	Montgomery-Åsberg Depression Rating Scale (MADRS)	p=0.003 (MSC)
Daily executive functioning	Behavior Rating Inventory of Executive Function–Adult version (BRIEF-A)	p=0.127 (GMT)
Perceived stress	Perceived Stress Scale (PSS)	p=0.02 (MAP with rumination as mediator); p=0.002 (MAP with self-kindness as mediator); p=0.09 (MAP with mindfulness as

		mediator)
Quality of life (QOL)	The World Health Organization Quality of Life-BREF-Taiwan version (WHOQOLBREF-TW)	p<0.05 (LAST); p<0.05 (QOLEP)
Mood	Mood Rating Scale	p=0.002 (Rumination induction); p=0.001(Distraction induction)
Problem-solving	Means-Ends Problem-Solving (MEPS)	p<0.0005 (Rumination induction); p=0.28 (Distraction induction)
	the Social Problem Solving Inventory-Revised (SPSI-R)	p=0.03 (CBASP)

11.6. Table 6: Frequency SMACC-attributes in Self-management interventions

Artikel	Self management intervention	SMACC
1. The Effects of Mindfulness and Self-Compassion-Based Group Therapy for Major Depressive Disorder: A Randomized Controlled Trial	• **MSC** - Mindfulness and self-compassion-based group therapy	Aanwezig: 3 Gedeeltelijk aanwezig: 2 Niet aanwezig: 11
2. Neuman Systems	• **CWPD** - Coping with	Aanwezig: 7

Model With Depressed Patients: A Randomized Controlled Trial	depression program based on Neuman systems model (NSM)	Gedeeltelijk aanwezig: 4 Niet aanwezig: 5
3. Evaluating an e-mental health program (“deprexis”) as adjunctive treatment tool in psychotherapy for depression: Results of a pragmatic randomized controlled trial	● **Deprexis** = A web-based, computer-assisted self-help program designed to support people with depression, used here as an adjunct to regular face-to-face psychotherapy	Aanwezig: 7 Gedeeltelijk aanwezig:1 Niet aanwezig: 8
4. Improvements in Emotion Regulation Following Mindfulness Meditation: Effects on Depressive Symptoms and Perceived Stress in Younger Breast Cancer Survivors	● **MAPS** - mindful awareness practices	Aanwezig:4 Gedeeltelijk aanwezig:0 Niet aanwezig: 12
5. Quality of Life Enhancement Programme for Individuals with Mood Disorder: A	● **QOLEP** - Quality of life enhancement programme	Aanwezig: 6 Gedeeltelijk aanwezig: 3 Niet aanwezig:7

Randomized Controlled Pilot Study		
6. Life Adaptation Skills Training (LAST) for persons with depression: A randomized controlled study	• **LAST** - Life adaptation skills training	Aanwezig:8 Gedeeltelijk aanwezig:5 Niet aanwezig:3
7. Rumination, mood and social problem-solving in major depression	**Psychological experiment** Participants with major depression were randomly assigned to one of two conditions: 1. Rumination Induction: Participants were guided to think about self-focused, emotion-related topics (e.g., “your level of energy,” “your feelings”). 2. Distraction Induction: Participants engaged in neutral external	Aanwezig:0 Gedeeltelijk aanwezig:0 Niet aanwezig: 16

	tasks (e.g., playing a board game) to shift attention away from internal thoughts.	
8. Goal management training as a cognitive remediation intervention in depression: A randomized controlled trial	• **GMT** - Goal management training	Aanwezig:5 Gedeeltelijk aanwezig:2 Niet aanwezig:9
9.A mind-body lifestyle intervention enhances emotional control in patients with major depressive disorder: a randomized, controlled study	• **DMBI** - Dejian mind-body intervention	Aanwezig: 3 Gedeeltelijk aanwezig:0 Niet aanwezig: 13
10.Adjuvant Guided Exercise Therapy Versus Self-Organized Activity in Patients With Major Depression	• **GET**- Guided exercise therapy = a structured, therapist-led physical activity program designed as an adjunct to antidepressant treatment.	Aanwezig:1 Gedeeltelijk aanwezig:3 Niet aanwezig:12

11. Insight as a Mechanism of Change in Dynamic Therapy for Major Depressive Disorder	• **SE** - supportive - expressive psychodynamic psychotherapy	Aanwezig: 5 Gedeeltelijk aanwezig:3 Niet aanwezig:8
12. Social Problem Solving and Depressive Symptoms Over Time: A Randomized Clinical Trial of Cognitive-Behavioral Analysis System of Psychotherapy, Brief Supportive Psychotherapy, and...	• **CBASP** - Cognitive behavioral analysis system of psychotherapy	Aanwezig:9 Gedeeltelijk aanwezig:1 Niet aanwezig:6
13. Psychoeducation for major depressive disorders: A randomised controlled trial	• **Group psychoeducation** (patient focused)	Aanwezig:8 Gedeeltelijk aanwezig:5 Niet aanwezig:3
14. The effects of Pythagorean Self-Awareness Intervention on patients with major depressive disorder: A pilot	• **PSAI** - Pythagorean self - awareness intervention	Aanwezig:7 Gedeeltelijk aanwezig:3 Niet aanwezig:6

randomized controlled trial		
15. The effectiveness of mindfulness-based cognitive therapy for reducing rumination and improving mindfulness and self-compassion in patients with treatment-resistant depression	• **MBCT** - Mindfulness-based cognitive therapy	Aanwezig:1 Gedeeltelijk aanwezig:3 Niet aanwezig:12
16. Reducing symptoms of major depressive disorder through a systematic training of general emotion regulation skills: protocol of a randomized controlled trial	• **AFT-** Affect regulation training	Aanwezig: 4 Gedeeltelijk aanwezig:4 Niet aanwezig:8

11.7. Table 7: Frequency SMACC-attributes

SMACC	
1: Does your self-management programme allow the person to actively participate in the	Aanwezig: 6 Gedeeltelijk aanwezig: 2

care process?	Niet aanwezig:8
2: Does your self-management programme allow the person to take responsibility in the care process?	Aanwezig:5 Gedeeltelijk aanwezig:3 Niet aanwezig:8
3: Does the self-management programme provide scope to accommodate setbacks the person faces?	Aanwezig: 3 Gedeeltelijk aanwezig:5 Niet aanwezig:8
4: Does the self-management programme inform the person about their condition, illness and treatment?	Aanwezig: 7 Gedeeltelijk aanwezig:3 Niet aanwezig:6
5: Can the person in the self-management programme express their needs, set values and priorities?	Aanwezig: 10 Gedeeltelijk aanwezig:1 Niet aanwezig:5
6: Does the self-management programme promote an open partnership between the care providers?	Aanwezig: 3 Gedeeltelijk aanwezig:5 Niet aanwezig:8
7: Does the self-management programme address the person's openness to receive social support?	Aanwezig:4 Gedeeltelijk aanwezig:3 Niet aanwezig:9
8: Does the self-management programme inform the person that this is a lifelong task?	Aanwezig: 0 Gedeeltelijk aanwezig:1 Niet aanwezig:15
9.1: Problem solving	Aanwezig:10 Gedeeltelijk aanwezig:0 Niet aanwezig:6
9.2: Decisionmaking	Aanwezig:3

	Gedeeltelijk aanwezig:3 Niet aanwezig:10
9.3: Use resources	Aanwezig:2 Gedeeltelijk aanwezig:3 Niet aanwezig:11
9.4: ability to work in partnership with health care professional	Aanwezig:3 Gedeeltelijk aanwezig:2 Niet aanwezig:11
9.5: setting and evaluating goals	Aanwezig:5 Gedeeltelijk aanwezig:2 Niet aanwezig:9
10.1: medical managament	Aanwezig:2 Gedeeltelijk aanwezig:0 Niet aanwezig:14
10.2: Emotional management	Aanwezig:12 Gedeeltelijk aanwezig:3 Niet aanwezig:1
10.3: Role management	Aanwezig:3 Gedeeltelijk aanwezig:3 Niet aanwezig:10

11.8. Table 8: Full text data-analysis

Auteurs	Titel	Research question	Design	Population
(Ben-Zeev et al., 2018)	Mobile Health (mHealth) Versus Clinic-Based Group Intervention for People With Serious Mental Illness: A Randomized Controlled Trial	Can a smartphone-deliverd mHealth intervnetion (FOCUS) produce comparable or better engagement, satisfaction, and clinical outcomes than a clinic-based group intervention (WRAP) for people with serious mental illness?	Randomized controlled trial (RCT) assessor blind, two-arm parallel-group design	Participants were 163 clients, mostly from racial minority groups and with long-term, serious mental illness more specifically: **diagnose included**: schizophrenia or schizoaffective disorder (49%) Bipolar disorder (28%) Major depressive disorder (23%)**Eligibility criteria**: aged 18 or older, diagnosed with one of diagnoses, had sufficient reading ability (minimum 5th-grade English level), No impairments affecting

				smartphone use (hearing, vision or motor skills), Had not participated in focus or wrap in the past three years. **Demographics**: Mean age = 49 years, gender= 59% male, Ethnicity = 65% African American
Chanikan Anuwatgasem, MD	The Effects of Mindfulness and Self-Compassion-Based Group Therapy for Major Depressive Disorder: A Randomized Controlled Trial	Does a mindfulness and self-compassion-based group therapy program improve depressive symptoms, anxiety, stress, self-esteem, and quality of life in patients with major depressive disorder, compared to standard treatment?	Randomized controlled trial (RCT) with two groups.	The study included adults aged 18 to 60 years who were diagnosed with major depressive disorder (MDD) based on DSM-5 criteria. Participants were recruited from Ramathibodi Hospital and through social media advertisements in Thailand. Individuals with other psychiatric disorders, cognitive impairments, substance abuse, recent electroconvulsive therapy (ECT), or changes in treatment during the study were excluded.

(Başoğul & Buldukoğlu, 2020)	Neuman Systems Model With Depressed Patients: A Randomized Controlled Trial	The aim of this study is to determine the effectiveness of the Coping With Depression Program (CWDP) based on the NSM on the coping strategies of depressed patients and their self-esteem and depression levels.	a randomized controlled, quasi-experimental study in the form of pretest-posttest-follow-up test.	The population of this study consisted of ambulatory patients who had been recently diagnosed with depression at the psychiatry clinic of a university hospital in Turkey. The study specifically targeted individuals receiving outpatient treatment for depression and aimed to assess the effectiveness of a psychoeducational intervention based on the Neuman Systems Model. To be eligible for participation, individuals had to meet several inclusion criteria: they needed to have received a clinical diagnosis of depression and started medication on the day of diagnosis. Their depressive symptoms had to fall within

				the mild to moderate range, as indicated by a score between 10 and 30 on the Beck Depression Inventory (BDI). Additionally, participants were required to be at least 18 years old, have completed a minimum of eight years of formal education, and reside within the provincial borders where the study took place.

(Berger et al., 2017)	Evaluating an e-mental health program (“deprexis”) as adjunctive treatment tool in psychotherapy for depression: Results of a pragmatic randomized controlled trial	The main objective of the present study was to investigate a combined treatment approach for depression by evaluating an empirically validated web-based treatment (deprexis) as an adjunctive tool in regular psychotherapeutic treatment in comparison with traditional psychotherapy	Two-armed pragmatic randomized controlled trial (RCT) design. Participants were randomly assigned within therapists to one of two treatment conditions	The population of this study consisted of adult outpatients diagnosed with a unipolar depressive disorder. Participants were recruited from routine outpatient psychotherapy practices in Germany by licensed psychotherapists during their initial therapy sessions. To be included in the study, individuals had to be at least 18 years old, have a score above 13 on the Beck Depression Inventory-II (BDI-II), and meet the diagnostic criteria for a unipolar affective disorder according to the ICD-10 (e.g., depressive episode, recurrent depressive disorder). Additionally, participants were required to have sufficient knowledge of the German language as well as

				access to and the ability to use the Internet. Patients were excluded if they had a psychotic or bipolar disorder, suffered from chronic depression with childhood onset, or were considered at high risk for suicide based on the therapist's clinical assessment. In total, 98 participants met all inclusion criteria and none of the exclusion criteria.

(Boyle et al., 2017)	Improvements in Emotion Regulation Following Mindfulness Meditation: Effects on Depressive Symptoms and Perceived Stress in Younger Breast Cancer Survivors	Do improvements in emotion regulation strategies specifically reductions in rumination and increases in self-kindness mediate the effects of a mindfulness meditation intervention on depressive symptoms and perceived stress in younger breast cancer survivors?	a randomized controlled trial (RCT) design	younger female breast cancer survivors who had completed primary treatment for Stage 0–III breast cancer. A total of 71 women were included, all of whom had been diagnosed at or before the age of 50 and had no evidence of active disease at the time of enrollment. Participants were required to: - Be at least 3 months post-treatment (surgery, chemotherapy, and/or radiation) - Be naïve to mindfulness practice - Provide informed consent - Be able to attend weekly in-person group sessions in Los Angeles Participants were recruited through previous studies, physician referrals, and

				online advertisements. Randomization allocated them to either the 6-week MAPs intervention group or a wait-list control group.
(Y. Chen et al., 2015)	Quality of Life Enhancement Programme for Individuals with Mood Disorder: A Randomized Controlled Pilot Study	Does participation in the Quality of Life Enhancement Programme (QOLEP) improve quality of life, psychosocial, and disease-related factors in individuals with mood disorder compared to a control condition?	a randomized controlled pilot trial design to evaluate the feasibility and preliminary efficacy of the Quality of Life Enhancement Programme (QOLEP) for individuals with mood disorders.	The study population consisted of outpatients diagnosed with mood disorders, specifically major depressive disorder or bipolar disorder. Participants were recruited from a psychiatric outpatient unit at a university hospital in Malaysia. To be eligible, individuals had to: - Be aged 18 years or older - Have a clinical diagnosis of major depressive disorder or bipolar disorder (based on DSM-IV-TR) - Be in a stable phase of their illness (i.e., not in acute crisis or mania)

				- Be able to read and communicate in English or Malay - Be willing and able to attend weekly sessions of the intervention Participants were excluded if they had: - Acute psychotic symptoms - Cognitive impairment - Other comorbid severe mental disorders that could interfere with participation A total of 40 participants were enrolled and randomly assigned to either the intervention or control group.

(Y. Chen, Pan, Hsiung, Chung, et al., 2015)	Life Adaptation Skills Training (LAST) for persons with depression: A randomized controlled study	This study aimed to examine the effects of the LAST program on quality of life, depression, anxiety, suicidal ideation, and psychosocial variables including sense of competence, mastery, environmental resources, and satisfaction with social support	This study used a randomized controlled trial (RCT) design to evaluate the effectiveness of the Life Adaptation Skills Training (LAST) program for individuals diagnosed with depression. Data were collected at three time points: 1)Baseline (pre-intervention) 2)Post-intervention 3)3-month follow-up	The study population consisted of adults diagnosed with depressive disorders receiving care in a community mental health center in Taiwan. Participants were recruited by psychiatric nurses based on referrals from attending psychiatrists. To be eligible for inclusion, individuals had to: -Be 18 years or older -Have a clinical diagnosis of depression -Be mentally stable (not in acute crisis) -Be able to communicate effectively and provide informed consent Exclusion criteria included: - Severe cognitive impairment - Psychotic symptoms - Current suicidal crisis In total, 86 participants met

				the inclusion criteria and were randomly assigned to either the experimental group (LAST + TAU) or the control group (TAU only).
(Cook et al., 2012)	A Randomized Controlled Trial of Effects of Wellness Recovery Action Planning on Depression, Anxiety, and Recovery	Does participation in the Wellness Recovery Action Planning (WRAP) self-management intervention lead to greater reductions in depression and anxiety symptoms, and increased self-perceived recovery, compared to treatment as usual, among individuals with serious mental illness?	This study employed a randomized controlled trial (RCT) design to evaluate the effectiveness of the Wellness Recovery Action Planning (WRAP) intervention among individuals with serious mental illness.	The study population consisted of adults diagnosed with serious mental illnesses, including schizophrenia, schizoaffective disorder, bipolar disorder, and major depressive disorder. Participants were recruited from community mental health programs in the United States. To be eligible, individuals had to: - Be 18 years or older - Have a DSM-IV diagnosis of a serious mental illness - Be currently engaged in mental health treatment - Be able to give informed

				consent and complete assessments in English In total, 519 participants were randomized into either the WRAP intervention group or the treatment-as-usual (control) group.

(Donaldson & Lam, 2004)	Rumination, mood and social problem-solving in major depression	How do trait and experimentally induced rumination and distraction affect mood and social problem-solving in individuals with major depression compared to non-depressed controls?	This study employed a quasi-experimental, mixed design with both between-subjects and within-subjects factors. The researchers compared two groups: The design allowed for: - Between-group comparisons (depressed vs. non-depressed) - Within-group comparisons (effects of rumination vs. distraction inductions) - Examination of interactions between trait rumination, mood changes, and problem-solving performance	The study population consisted of 62 participants, divided into two groups: **1)31 individuals diagnosed with major depressive disorder (MDD**) - Recruited from clinical services - Diagnosis confirmed using the Structured Clinical Interview for DSM-IV (SCID) - All were currently experiencing a depressive episode **2)31 non-depressed control participants** - Recruited through advertisements and matched to the clinical group by age, gender, and education - Had no history of psychiatric illness and scored below the clinical threshold on the Beck

				Depression Inventory (BDI) All participants were between the ages of 18 and 65, fluent in English, and provided informed consent. Individuals with comorbid psychiatric conditions, including psychosis or substance abuse, were excluded.

		What is the effectiveness of GMT (Goal Management Training) on daily life executive function (EF) in patients with Major Depressive Disorder (MDD) when compared to CCT (Cognitive Control Training)?	A randomized controlled trial: Sixty-three participants completed the baseline assessment (T1) and were subsequently randomized using computer-generated simple ran-domization.	The population of the study consisted of individuals who were former patients at Lovisenberg Diaconal Hospital (LDH). A total of 367 former patients were invited to participate in the study. These individuals had previously received a diagnosis of mild or moderate Major Depressive Disorder (MDD), as classified according to the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10). All participants had completed treatment at the LDH Return-to-Work clinic. Out of the 367 individuals contacted, 91 were assessed for eligibility. To be included in the study,

				participants had to meet several inclusion criteria: they had to report executive function (EF) deficits during a customized semi-structured telephone interview, be between 18 and 60 years of age, and have a diagnosis of mild or moderate MDD, either as a primary or secondary diagnosis. Several exclusion criteria were applied to ensure the appropriateness of the sample. Individuals were excluded if they had ongoing alcohol or substance abuse, comorbid neurological conditions, or severe cognitive or mental disorders such as psychotic disorders or personality disorders. Other exclusion criteria included an elevated

				risk of suicide, sensory or physical impairments that would hinder participation in training, and insufficient proficiency in the Norwegian language. The study did not apply specific cut-off scores for depressive symptom severity, in order to ensure the sample was representative of a real-world, treatment-seeking population.

		Does the Dejian Mind-Body Intervention (DMBI) reduce depressive symptoms and modulate neural connectivity and arousal in patients with major depressive disorder, and are these neural effects specific to negative emotional stimuli or also present during neutral and positive affective image viewing?	Randomised controlled trial	The study included 75 adult outpatients from the West Kowloon Psychiatric Centre who were clinically diagnosed with major depressive disorder (MDD) using standardized DSM-IV-TR and SCID-I/P assessments. Participants with a history of neurological disorders, other psychiatric conditions, or suicidal ideation were excluded. All participants were on stable antidepressant treatment, which remained unchanged throughout the study.

		Is standardized guided exercise therapy (GET) more effective than self-organized activity (SOA) as an augmentation to antidepressant treatment in adults with major depressive disorder?	The study was a 6-week randomized controlled trial	A total of 120 patients with a moderate or severe major depres- sive episode according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria were recruited from two participating centers (Bochum and Dortmund), where they underwent standard clinical antidepressant treatment. Exclusion criteria comprised acute suicidality, severe comorbid psychiatric disor- ders, medical contraindications to physical activity, inability to under- stand the informed consent or involuntary legal status, and incapacity

				to complete the self-administered questionnaires. The current presence of major depressive symptoms was confirmed by the Hamilton Depression Scale (HAMD) with a score of 17 or higher (Hamilton, 1960).

	Insight as a Mechanism of Change in Dynamic Therapy	Based on the hypotheses provided, the research questions underlying the study are: Does insight change more significantly over the course of Supportive-Expressive therapy (SE) compared to Cognitive Therapy (CT)? Do changes in insight and depressive symptoms occur concurrently (i.e., simultaneously) in SE, and is this different from CT? Does an increase in insight lead to improved subsequent treatment outcomes in SE, but not in CT?	A randomized controlled trial: A total of 237 patients met the inclusion criteria and were randomized to treatment (118 SE, 119 CT). This study included patients who attended at least two sessions of psychotherapy and completed assessments at baseline, month 2, and month 5.	Those aged between 18 and 65 years with a QIDS score of 11 or higher were referred to the research staff for a brief phone screening. To be included in the study, participants had to meet the diagnostic criteria for Major Depressive Disorder (MDD). Individuals were excluded if they had a diagnosis of bipolar disorder; a current or past diagnosis of schizophrenia, psychosis, MDD with psychotic features, or seizure disorder; depression linked to organic causes; substance or alcohol abuse requiring immediate specialized treatment; a referral to partial hospitalization; or suicidal ideation requiring more intensive care.

				Out of the 3,951 patients initially screened, 1,110 met the QIDS criteria and were referred for a phone screen. Of those, 581 completed the baseline assessment. Ultimately, 344 patients were excluded at this stage for various reasons, such as being used as training cases (116), having disqualifying diagnoses (100), lacking a current MDD diagnosis (78), or due to other exclusion factors (50). The final study sample consisted of patients aged 18 to 64 years, with a mean age of 39.6 years (SD = 12.5). The majority were female (80%) and not in a long-term relationship (60%), while 19% were married or living with a partner. Approximately half

				of the participants (51%) identified as members of a minority group, including 42% Black or African American. Most patients had a high school diploma or less as their highest educational qualification (57%) and were unemployed at the time of enrollment (56%).

		(a) do CBASP plus pharmacotherapy produce greater change in social problem solving than BSP plus pharmacotherapy and pharmacotherapy alone; (b) is social problem solving associated with subsequent depression over time; and (c) is this association stronger for CBASP than for each of the two comparison treatments conditions?	A randomised controlled trial: REVAMP consisted of two 12-week phases. During phase 1, patients were assigned to receive an antidepressant medication according to a pharmacotherapy algorithm, and their response was evaluated. Patients achieving less than full remission were randomized into phase 2. Phase 2 participants all received the next-step treatment in the pharmacotherapy algorithm and were randomly assigned to one of three treatment cells in a 2:2:1 ratio	Participants were recruited from eight clinical sites through clinician outreach and advertising. All participants met DSM-IV criteria for a current Major Depressive Disorder (MDD) episode, assessed using the Structured Clinical Interview for DSM-IV Axis I Disorders – Patient Edition (SCID-P). To be included, the current MDD episode had to: Last at least four weeks, Be part of a chronic depressive condition (e.g., double depression, chronic MDD, or recurrent MDD with incomplete recovery between episodes), Have been present for over two years without full

				remission. Participants were: Aged 18–75 years, Fluent in English, Scored ≥20 on the 24-item Hamilton Rating Scale for Depression (HAM-D) at baseline, Provided informed consent. Exclusion criteria included: Pregnancy, psychotic disorders, bipolar disorder, or dementia, Principal diagnosis of PTSD, anorexia, bulimia nervosa, or OCD, Severe antisocial,

				schizotypal, or borderline personality disorder, Substance dependence (other than nicotine) requiring detoxification. Conditional inclusion: Patients with substance abuse issues could participate if they: Agreed to sobriety plans (e.g., Alcoholics Anonymous or counseling), Coordinated their sobriety with study treatment. Additional exclusions: Prior treatment with CBASP, Failure of ≥4 pharmacotherapy steps,

				Refusal to discontinue other psychiatric treatments, Presence of serious or terminal medical illnesses affecting study participation. Note: Interviews were conducted by trained raters certified in SCID administration by an external exper

	Psychoeducation for major	Is simple psychoeducation, focused on coping with family members, colleagues, and superiors in the workplace, more effective than treatment as usual in improving outcomes for patients with Major Depressive Disorders (MDDs)?	A randomised controlled trial: After the agreement, the participants were randomly allocated to intervention and control groups. We used a straightforward random sequence without stratification or block as generated by use of a random number table. The random allocation list was centrally kept by a research assistant and the allocation was conveyed to the investigators and clinicians only after the partici-pant was registered.	a) age between 20 and 70; b) diagnosis of MDD in (partial) remission according to the Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV) (APA, 2000); c) not having undergone electroconvulsive therapy (ECT) or not having ECT already planned for the index episode; and d) a Mini-Mental State Examination (Folstein et al., 1975) score of 24 or higher when patients are over 60.

(Psarraki et al., 2021)	The effects of Pythagorean Self-Awareness Intervention on patients with major depressive disorder: A pilot randomized controlled trial	The primary aim was to evaluate the effect of PSAI compared to the standard care provided for adults with MDD with respect to the reduction of depressive symptoms.	This two-arm pilot randomized controlled trial was conducted at the Mental Health Center of Peristeri, department of the Psychiatric Hospital of Attica, Greece, from December 2018 to January 2020.	A sample size of 30 participants per group. All participants were outpatients of the Center. Inclusion criteria were: MDD diagnosis made by a psychiatrist of the Center according to the DSM-V criteria, age 18–65 years, residency in Attica, ability to speak and write fluently in the Greek language. Exclusion criteria were: antecedent psychotic or manic episode, current feeding or eating disorder, obsessive-compulsive disorder, self-harming behaviors or recent suicide attempt and current drug abuse or addiction. Additional exclusion criteria were current treatment with Cognitive-Behavioral

				Therapy and denial to participate in the research.

		Is Mindfulness-Based Cognitive Therapy (MBCT) effective in reducing depression symptoms and improving mindfulness, self-compassion, and rumination in patients with treatment-resistant depression (TRD)?	The study design is experimental research (pre-test, post-test, and follow-up) with experimental and control groups.	The study populations were all patients with TRD from Farabi Psychiatric Hospital. Participants were selected with a purposive sampling method and randomly assigned to experimental or control groups. The inclusion criterion was major depressive disorder diagnosed by psychiatrists and a clinical psychologist on the basis of structured clinical interviews. Additional criteria were lack of therapeutic response to adequate doses of two antidepressants for sufficient time (18 weeks); a moderate level of depression (score 17 or higher) according to the

				Beck Depression Inventory – Second Edition; minimum and maximum ages of 18 and 50 years old, respectively; the minimum educational level necessary to complete the questionnaire and; finally, patient's consent to participate in the study and signature of written consent. The exclusion criteria were severe suicidal thoughts, psychiatric disorder, and acute phases of mental disorders (e.g. signs and symptoms of psychosis, bipolar disorder, comorbid anxiety disorders, panic disorder, posttraumatic stress disorder, seasonal depression, or depressive disorder

				due to substance abuse or medical condition) lack of treatment assignments, absence from more than two sessions, or patient's unwillingness to continue taking part in the research

		Does enhancing general emotion regulation (ER) skills through Affect Regulation Training (ART) reduce depressive symptom severity, and does it improve the effectiveness of subsequent individual CBT for depression (iCBT-D)?	Prospective randomised controlled trial	Inclusion criteria will include MDD as the primary diagnosis, age 18 or above, and sufficient German language skills. Exclusion criteria will include high risk of suicide, indication of substantial secondary gain (e.g., compensation issues), additional psychotherapeutic treatments, comorbid psychotic, substance-related, bipolar disorders, organic brain or other severe medical disorders, and severe cognitive impairments. Other comorbid disorders, including

				personality dis- orders, will be accepted to increase validity of the study.

Comparison	Intervention	Outcome measures
The study compared a mobile health intervention (FOCUS) and a clinic-based group intervention (WRAP) for individuals with serious mental illness. FOCUS was delivered through a smartphone app supported by remote coaching, while WRAP consisted of weekly in-person group sessions led by peer facilitators. Both interventions led to comparable improvements in clinical outcomes and participant satisfaction. FOCUS was associated with higher rates of treatment initiation and engagement, and greater improvements in quality of life at the six-month follow-up.	The intervention used in the experimental ggroud was FOCUS, a mobile health (mhealth) program designed to support people with serious metal illness in their daily lives. It was delivered through a smartphone app, which offered users daily check-ins, self-assessments prompts, and access to tools targeting common challenges such as depression, anxiety, hallucinations, sleep problems, and medication management. The content was provided through short videos, audio clips, and interactive written material. In addition to using the app, participants received weekly phone calls from a mental health support specialist, who helped with both technical and clinical aspects of the program. The intervention aimed to make mental health support more accessible by allowing users to receive help wherever and whenever they needed it, essentially acting	To assess the effectiveness of the interventions, the study examined a range of outcome measures that captured both clinical progress and the personal experiences of the participants. Engagement was one of the key indicators, measured by how consistently participants used the FOCUS app or attended WRAP sessions over the 12-week period. Treatment satisfaction was also evaluated through a self-report questionnaire, where participants rated how helpful, enjoyable, and interactive they found the intervention. Clinical outcomes were assessed through several validated instruments. General psychopathology was measured using the Symptom Checklist–9 (SCL-9), which reflects the overall severity of mental health symptoms such as anxiety, paranoia, and emotional distress. Depressive symptoms were evaluated with the Beck

	acting as a portable, personalized support system	Depression Inventory–II (BDI-II), a widely used scale for assessing the intensity of depression. For participants experiencing psychosis, the study used the Psychotic Symptom Rating Scales (PSYRATS), focusing on hallucinations and delusional thinking. In addition to symptom-focused outcomes, the study also measured personal recovery and well-being. The Recovery Assessment Scale (RAS) was used to assess aspects such as personal confidence, hope, and goal orientation. Finally, participants' overall quality of life was measured through self-ratings of their satisfaction with daily life, social relationships, and participation in meaningful activities

The control group received standard treatment, which included medication (antidepressants or other psychotropics) and 30-minute monthly counseling sessions with a psychiatrist, as typically provided at the hospital’s psychiatric department.	The intervention consisted of a mindfulness and self-compassion-based group therapy (MSC) program, delivered in weekly 90-minute sessions over the course of seven weeks. The sessions were conducted in small groups and focused on teaching participants how to become more aware of their thoughts and feelings in the present moment, without judgment, and to treat themselves with kindness and understanding during difficult experiences. The program integrated principles from Buddhist psychology, combining mindfulness practices, such as breathing and body awareness, with self-compassion techniques that help individuals respond to their suffering with warmth rather than self-criticism. The aim was to reduce depressive symptoms and emotional distress by fostering emotional balance, resilience, and a more positive self-view.	To evaluate the effectiveness of the intervention, the study used a range of psychological and quality of life measures assessed both before and after the seven-week program. The primary outcome was the severity of depressive symptoms, measured using the Montgomery-Åsberg Depression Rating Scale (MADRS), a clinician-rated tool designed to capture treatment-responsive changes in mood and functioning. In addition to depression, several secondary outcomes were assessed. These included self-compassion, using the Self-Compassion Scale (Thai version); sleep quality, assessed with the Pittsburgh Sleep Quality Index (Thai-PSQI); and anxiety and depressive symptoms, measured by the Hospital Anxiety and Depression Scale (Thai-HADS). The study also evaluated perceived stress using the Thai Perceived Stress Scale-10 (T-PSS-10), self-esteem through the Rosenberg Self-Esteem Scale (Thai version), and overall quality of life using the WHOQOL-BREF Thai version, which covers physical, psychological, social, and environmental domains. These outcome measures provided a comprehensive view of participants' mental

		health and well-being, allowing the researchers to assess both symptom reduction and positive psychological change.

the control group received standard psychiatric treatment only, without any additional psychoeducation or therapeutic intervention related to the NSM or CBT.	The intervention applied in this study was the Coping With Depression Program (CWDP), developed based on the Neuman Systems Model (NSM) and incorporating techniques from Cognitive Behavioral Therapy (CBT). The program aimed to strengthen patients' lines of defense and resistance against psychological stressors, thereby reducing depressive symptoms and improving coping strategies and self-esteem. Participants in the intervention group received individual psychoeducation over the course of six structured sessions, conducted within a four-week period. Each session lasted approximately 50 to 60 minutes and was held in a private training room within the psychiatric clinic. The content of the sessions focused on several core areas: Understanding depression and its effects Behavioral and cognitive strategies to manage symptoms	The effectiveness of the intervention was evaluated using three standardized outcome measures, alongside a demographic questionnaire: **Beck Depression Inventory (BDI)** Used to measure the severity of depressive symptoms. This self-report scale consists of 21 items assessing emotional, cognitive, and physical symptoms of depression. Scores range from 0 to 63, with higher scores indicating more severe depression. **Rosenberg Self-Esteem Scale (RSES)** This scale assesses global self-esteem through 10 items rated on a 4-point Likert scale. Higher scores indicate lower self-esteem, and scores were interpreted to reflect high, moderate, or low levels of self-regard. **Coping Strategies Indicator (CSI)** Developed by Amirkhan, the CSI evaluates coping behavior through 33 items across three subscales: - Problem-solving - Seeking social support - Avoidance:Participants rated how often they used each strategy on a 3-point scale. Higher scores indicate more frequent use of the specific

	Improving social skills and seeking social support Goal setting and problem-solving Strengthening personal values, beliefs, and spiritual awareness Participants also received a CWDP workbook, which included session content, worksheets, and homework assignments to reinforce learning and encourage active participation. The program was delivered by a researcher trained in CBT, and interaction during sessions involved discussions, exercises, and regular follow-up on homework tasks.	coping strategy. Data were collected at three time points: 1)Pretest (before the intervention) 2)Posttest (immediately after the intervention) 3)Follow-up test (two months after the intervention) These measures allowed for a comprehensive evaluation of changes in depression severity, self-esteem, and coping strategies over time.

The control group received regular face-to-face psychotherapy only, without access to the deprexis platform during the study period. Importantly, the number and structure of psychotherapy sessions were not standardized or restricted for either group, allowing therapists to provide treatment according to their usual clinical judgment. The only difference between groups was the availability of the deprexis program as an adjunctive treatment tool for those in the intervention group.	The intervention in this study consisted of giving participants access to deprexis, a web-based self-help program designed to support the treatment of depression. This program was used in addition to regular face-to-face psychotherapy and served as an adjunctive treatment tool. Deprexis is based on principles of cognitive-behavioral therapy (CBT) and includes interactive modules covering topics such as psychoeducation, behavioral activation, cognitive restructuring, mindfulness, relaxation, and interpersonal skills. Participants in the intervention group were introduced to the program by their therapists, who had attended a training workshop prior to the study. The program was used independently by the patients between therapy sessions, and therapists were free to decide how or whether to integrate it into face-to-face treatment. Therapists also had access to a “therapist cockpit” that allowed them to monitor patients’ program use and progress, though they were not required to intervene or guide usage in a structured way.	The effectiveness of the intervention was assessed using several standardized outcome measures. The primary outcome was the severity of depressive symptoms, measured with the Beck Depression Inventory-II (BDI-II) at baseline and after 12 weeks. The BDI-II is a widely used self-report questionnaire with strong psychometric properties for evaluating depression severity. Secondary outcomes included: 1)Anxiety symptoms, measured with the Generalized Anxiety Disorder Scale (GAD-7) 2)Somatic symptoms, assessed using the Patient Health Questionnaire (PHQ-15) 3)Health-related quality of life, measured by the Short-Form Health Survey (SF-12), which includes both a mental health and a physical health subscale In addition, the study measured treatment satisfaction using the Client Satisfaction Questionnaire (CSQ-8) at 12 weeks, and the working alliance between therapist and patient using the Working Alliance Inventory – Short Revised (WAI-SR), completed by both patients and therapists at 6 and 12 weeks.

	The deprexis program included 10 content modules and 1 summary module, and was designed to be flexible and user-driven. It provided psychoeducation and therapeutic exercises aimed at enhancing treatment outcomes and patient autonomy.	

A wait-list control group, which received no intervention during the study period but were offered the program after the follow-up assessment This comparison allowed researchers to examine whether the MAPs intervention led to greater improvements in depressive symptoms and perceived stress compared to no immediate treatment. Both groups completed assessments at baseline, post-intervention, and at a 3-month follow-up, allowing for between-group comparisons over time	The intervention consisted of a 6-week mindfulness meditation program called Mindful Awareness Practices (MAPs), developed at the University of California, Los Angeles. Participants in the intervention group attended weekly 2-hour group sessions led by an experienced instructor. Each session included: - Presentation of theoretical material on mindfulness -Guided experiential practices, such as breath awareness, mindful walking, and relational mindfulness - Strategies to integrate mindfulness into daily life - Discussion of barriers to practice - A psychoeducational component tailored to breast cancer survivors Participants were also instructed to engage in daily home practice, beginning with 5 minutes per day and gradually increasing to 20 minutes. They logged their practice each week. the program explicitly addressed emotion regulation, including: - Self-kindness, practiced through loving-kindness meditation (weeks 3 and 4) -Reducing rumination, through exercises in	The study assessed outcomes using validated self-report questionnaires, administered at baseline, post-intervention, and 3-month follow-up. The primary psychological outcomes were: 1)Depressive symptoms, measured with the **Center for Epidemiologic Studies Depression Scale (CES-D)** – A 20-item scale assessing depressive mood, somatic symptoms, and interpersonal difficulties over the past week. 2)Perceived stress, measured with the **Perceived Stress Scale (PSS)** – A 10-item scale evaluating the extent to which individuals view their lives as stressful and uncontrollable. To examine potential mediators of intervention effects, the following emotion regulation strategies were also measured: 3)Rumination, assessed using a 6-item subscale of the **Rumination and Reflection Scale (RRS)** 4)Self-kindness, measured with a 5-item subscale of the **Self-Compassion Scale (SCS)** 5)Mindfulness, evaluated using the total score

	disidentifying from negative thoughts (weeks 4 and 5)	of the **Five Facet Mindfulness Questionnaire (FFMQ)**
The control group, which received treatment as usual only, without any additional structured intervention Treatment as usual consisted of standard psychiatric care provided at the outpatient clinic, including medication management and routine follow-up sessions with mental health professionals. The comparison allowed the researchers to evaluate whether adding the QOLEP to standard care would result in greater improvements in quality of life, psychosocial functioning, and clinical outcomes compared to standard care alone.	The intervention tested in this study was the Quality of Life Enhancement Programme (QOLEP), a structured, group-based psychoeducational programme designed to improve the quality of life and psychosocial functioning of individuals with mood disorders. The program was developed based on the Quality of Life Model by Schalock and Verdugo, focusing on eight core domains: emotional well-being, interpersonal relations, material well-being, personal development, physical well-being, self-determination, social inclusion, and rights. The QOLEP was delivered over eight weekly sessions, each lasting approximately two hours, in a group format. Sessions included: - Psychoeducation on quality of life and mental health - Cognitive-behavioral strategies for mood and stress management - Skills training in areas such as communication,	The study used several validated self-report instruments to assess both primary and secondary outcomes, administered at pre- and post-intervention. **Primary Outcome:** -Quality of Life: Measured using the WHOQOL-BREF (World Health Organization Quality of Life – Brief version). This tool assesses four domains: 1)Physical health 2)Psychological health 3)Social relationships 4)Environment Higher scores indicate better perceived quality of life. **Secondary Outcomes:** - Mood Symptoms: Assessed using the Hospital Anxiety and Depression Scale (HADS), which includes separate subscales for anxiety and depression. - Self-efficacy:

	self-care, and goal-setting - Group discussions and interactive activities to encourage reflection and application Participants were also given homework assignments and were encouraged to apply what they learned in daily life. The program was led by trained facilitators with a background in mental health care.	Measured with the General Self-Efficacy Scale (GSE), a 10-item questionnaire evaluating an individual's belief in their ability to handle difficult situations. - Subjective Well-Being: Evaluated using the Personal Well-being Index – Adult (PWI-A), which assesses satisfaction across life domains such as standard of living, health, achievement, relationships, and safety.

Treatment as usual (TAU) consisted of routine psychiatric care provided by the mental health center, including regular outpatient visits, pharmacological treatment, and psychiatric nursing services. This comparison allowed the researchers to examine whether the addition of the structured LAST program produced significantly greater improvements in quality of life and psychological well-being compared to standard care alone	The intervention tested in this study was the Life Adaptation Skills Training (LAST) program, a structured group-based intervention designed to enhance quality of life and psychosocial functioning in individuals with depression. The program was delivered over 8 weekly sessions, each lasting 90 to 120 minutes, and focused on helping participants develop practical life skills to cope with the challenges of living with depression. The content of the sessions was based on the World Health Organization's Quality of Life (WHOQOL) framework and included the following components: - Physical health management (e.g., sleep hygiene, exercise) - Psychological adjustment (e.g., cognitive reframing, managing emotions) - Social skills (e.g., communication, interpersonal relationships) - Environmental adaptation (e.g., accessing resources, safety awareness) The sessions included psychoeducation, group discussion, experience sharing, role-playing, and homework assignments. The program was led by trained psychiatric nurses and was designed	The study evaluated the effectiveness of the LAST intervention using a range of validated self-report instruments, targeting both primary and secondary outcomes. These measures were administered at baseline, post-intervention, and 3-month follow-up. **Primary Outcome:** **Quality of Life (QoL):** Measured using the WHOQOL-BREF, which assesses four domains: 1)Physical health 2)Psychological health 3)Social relationships 4)Environment Higher scores indicate better quality of life. **Secondary Outcomes:** **-Depression and Anxiety**: Assessed using the Depression and Anxiety subscales of the BSRS-5 (Brief Symptom Rating Scale). **-Suicidal Ideation:** Measured using the Suicidal Ideation Scale (SIS), a tool evaluating the severity and frequency of suicidal thoughts. **-Sense of Competence:**

	to be both therapeutic and skills-oriented.	Evaluated with the Sense of Competence Questionnaire, measuring participants' perceived ability to manage their condition and life responsibilities. **Mastery:** - Measured using the Pearlin Mastery Scale, which assesses personal control and the extent to which individuals feel they can influence important life events. **- Social Support Satisfaction:** Assessed via the Satisfaction with Social Support Scale, capturing participants' satisfaction with the support they receive from their social network. **- Environmental Resources:** Measured using the Environmental Resources Questionnaire, which includes items on access to housing, finances, and safety.

The control group, which received treatment as usual (TAU) through community mental health services Treatment as usual included access to standard mental health care services such as medication management, counseling, and case management, but did not include any structured self-management training like WRAP. This design allowed researchers to assess the added value of WRAP beyond standard care.	The intervention tested in this study was Wellness Recovery Action Planning (WRAP), a structured, peer-led self-management program designed to help individuals with serious mental illness manage their symptoms and promote recovery. WRAP was delivered in group settings by trained peers who had lived experience with mental illness. The intervention was conducted over 8 weekly sessions, each lasting approximately 2.5 hours. The program included the following core components: - Wellness tools identification (strategies for staying well) - Daily maintenance plan (routines for emotional stability) - Triggers and early warning signs (recognizing and responding to early symptoms) - Crisis planning (identifying supports and strategies during acute episodes) - Post crisis planning (recovering and regaining control after a crisis) The WRAP model emphasizes hope, personal responsibility, education, self-advocacy, and support. It is designed to empower participants to take charge of their recovery using	The study used self-report questionnaires administered at baseline and 8 weeks post-intervention to evaluate the impact of the WRAP program on psychological well-being and recovery. Primary Outcomes: **Depression:** Measured using the Center for Epidemiologic Studies Depression Scale (CES-D), a 20-item scale that assesses the frequency of depressive symptoms in the past week. **Anxiety:** Assessed using the Brief Symptom Inventory (BSI) anxiety subscale, which captures the severity of anxiety symptoms over the past week. **Self-perceived recovery:** Measured with the Recovery Assessment Scale (RAS), a widely used 41-item instrument that evaluates various dimensions of recovery, including: 1)Personal confidence and hope 2)Goal orientation 3)Reliance on others 4)Not being dominated by symptoms 5)Sense of self

	personalized strategies.	All instruments had previously demonstrated good validity and reliability, and were chosen to capture changes in emotional distress and the subjective recovery experience.

The study compared outcomes across both diagnostic status and experimental condition, resulting in a 2 × 2 design: **1)Diagnostic comparison:** Depressed group (MDD) vs. Non-depressed control group **2)Experimental comparison** (randomized): Rumination induction vs. Distraction induction This design allowed researchers to examine: - Whether individuals with depression responded differently to rumination or distraction than non-depressed individuals - How trait rumination and mood interacted with these conditions to influence social problem-solving ability In total, participants were divided into four comparison groups (e.g., depressed + rumination, depressed + distraction, etc.), enabling both between-group and within-group comparisons.	The intervention in this study consisted of an experimental mood induction, where participants were randomly assigned to one of two conditions: **1)Rumination Induction:** Participants were instructed to focus inwardly on the meanings, causes, and consequences of their feelings (e.g., "Think about why you feel the way you do", "Think about the kind of person you are"). This was designed to simulate ruminative thinking typical in depression. **2)Distraction Induction:** Participants were instructed to focus their attention externally on neutral, engaging topics unrelated to themselves (e.g., "Think about the layout of a typical supermarket", "Think about a boat slowly crossing a lake"). This aimed to interrupt negative self-focused thinking. Each induction lasted approximately 8 minutes and was followed by post-induction assessments of mood and performance on a social problem-solving task.	The study used a combination of self-report questionnaires and performance-based tasks to assess the effects of rumination and distraction on mood and social problem-solving. **1. Trait Rumination:** - Measured using the Ruminative Responses Scale (RRS) - Assesses the tendency to respond to negative mood with repetitive, self-focused thinking **2. Depressive Symptoms:** - Measured using the Beck Depression Inventory (BDI) - Used to confirm group status (depressed vs. control) and assess severity of depressive symptoms **3. Mood (state level):** - Assessed at three time points (baseline, post-induction, post-task) using a self-report visual analogue scale (VAS) - Participants rated how sad and happy they felt at each time point **4. Social Problem-Solving Ability:** - Measured using the Means-End Problem-Solving Task (MEPS) - Participants were presented with hypothetical

		social scenarios and asked to generate step-by-step solutions to achieve a positive outcome -Responses were rated based on: 1)Relevance and effectiveness of means 2)Number of relevant steps 3)Overall problem-solving quality

The Computerized Cognitive Training (CCT) program utilized exercises from BrainHQ, a web-based cognitive training platform based on neuroplasticity. The program aimed to achieve cognitive improvements and reduce depressive symptoms. CCT included seven exercises targeting attention, memory, processing speed, and executive function (EF) with adaptive difficulty levels, maintaining a success rate of approximately 80%. Participants received immediate feedback on their performance through the BrainHQ platform. The CCT consisted of nine biweekly one-hour sessions over approximately 4.5 weeks. A clinical psychologist led groups of three participants, with some receiving individual sessions due to practical reasons. The first session included psychoeducational content on neuroplasticity and cognitive deficits in depression. Participants had online access to the training platform and were encouraged to practice for at least 30 minutes between sessions. To be	Goal Management Training (GMT) is a manual-based cognitive remediation intervention designed to improve executive functions (EF) and can be delivered in both individual and group settings. The study utilized the Norwegian translation of the standard GMT protocol, which consists of nine weekly two-hour sessions that include PowerPoint slides and participant workbooks. Adjustments were made to the original material to better suit a depression sample, focusing on the emotional consequences of executive deficits. The primary aim of GMT is to enhance participants' attentional and problem-solving abilities through the internalization of metacognitive strategies applicable to real-life situations. A central concept of GMT is that automatic actions can lead to errors and the displacement of goals in working memory. Strategies taught include self-instruction to stop ongoing behavior ("STOP!"), defining and splitting goals into sub-goals, and performance monitoring. Incorporating principles from	The study on Goal Management Training (GMT) as a cognitive remediation intervention in depression utilized several outcome measures to assess its effectiveness. Here's a summary of the key outcome measures used in the randomized controlled trial: Primary Outcome Measure: The primary outcome measure was the Behavior Rating Inventory of Executive Function – Adult version (BRIEF-A), which assesses self-reported everyday executive functioning. It consists of 75 items across nine non-overlapping subscales, including Inhibit, Self-Monitor, Plan/Organize, Shift, Initiate, Task Monitor, Emotional Control, Working Memory, and Organization of Materials. Secondary Outcome Measures: Cognitive Failures Questionnaire (CFQ): This 25-item questionnaire measures self-reported errors in everyday tasks, with participants rating how often they make mistakes. Beck Depression Inventory (BDI): This 21-item inventory assesses the severity of depressive symptoms, with a total score range from 0 to 63. Performance-Based Measures: The study also included performance-based

classified as a completer, participants had to attend a minimum of six sessions. The treatment period ran from April 2018 to April 2019.	cognitive-behavioral therapy (CBT), GMT also emphasizes identifying negative automatic thoughts. The current version includes mindfulness exercises to promote present-mindedness, which is believed to positively impact cognitive functions, including executive functions. In-class activities involve practicing compensatory strategies, mindfulness exercises, and discussing personal experiences. Between sessions, participants monitor incidents of inattention and cognitive errors, practice mindfulness, and apply learned strategies in daily life. Additionally, automated text messages reading "STOP!" were sent to participants after the fourth session to reinforce goal management in their daily activities. Overall, GMT aims to provide participants with tools to manage their executive functions more effectively, particularly in the context of depression.	measures of executive functioning, such as the Conners' Continuous Performance Test – Third edition (CPT-3), which assesses sustained attention and response inhibition. The Color-Word Interference Test (CWIT) from the Delis-Kaplan Executive Function System (D-KEFS) was used to assess inhibition and mental flexibility.

The cognitive behavioural therapy (CBT) protocol in the study incorporated standard CBT components. It began with psychoeducation on the biopsychosocial model of depression and the triadic connection between mood, cognition, and behaviour. This framework helped participants understand how altering their thoughts and actions could positively influence their mood. They were taught to identify and challenge maladaptive thought patterns, such as overgeneralization, catastrophizing, and minimizing positives, and to adopt more realistic and effective thinking strategies. Additionally, participants learned progressive muscle relaxation techniques to help promote a calm and relaxed mental state.	The Dejian Mind-Body Intervention (DMBI) is a holistic lifestyle intervention rooted in Buddhist philosophy, designed to alleviate both psychological distress and physical health issues. It integrates three key components: understanding the root of problems through Buddhist principles, practicing Nei Gong (a mind-body exercise), and making dietary modifications. A central tenet of DMBI is encouraging individuals to adopt these changes naturally within their own lifestyle, fostering awareness of the resulting mental and physical changes.	The primary outcome measures in the study focused on changes in participants' mood between pre- and post-intervention assessments. Depressive symptoms were assessed using two validated instruments: Hamilton Psychiatric Rating Scale for Depression (HAM-D) a 17-item clinician-rated scale with a maximum score of 52. Higher scores indicated more severe depression. Additionally, the global depression subscale (eight mood-related items based on the five-factor model) was used to specifically assess mood-related symptoms. Beck Depression Inventory-II (BDI-II) a 21-item self-report scale in its Chinese version, with scores ranging up to 63. Higher scores indicated greater severity of depression. The cognitive-affective subscale (based on a two-factor model) was used to assess mood-related aspects. While the HAM-D was rated by blinded psychiatrists, the BDI-II was completed by the participants. Neither was used as part of the screening criteria but rather as outcome measures.

		The secondary outcome measures evaluated the neurophysiological responses related to emotional processing, specifically through electroencephalogram (EEG) coherence. EEG coherence assessed the degree of synchronized neural activity (or functional connectivity) between different brain regions. The focus was on theta band activity (4–7.5 Hz), which is known to be associated with emotional arousal. The key area of interest was the frontoposterior coherence in the right hemisphere, as lower coherence in this region has been linked to impaired emotional regulation in depression. EEG was recorded under both resting-state (eyes closed) and during an affective image viewing task. This task involved showing participants 60 images (20 each in neutral, positive, and negative categories) selected from the International Affective Picture System (IAPS). EEG data were captured during each image block, cleaned of artifacts (e.g., eye blinks), and processed via Fast Fourier Transform (FFT) to extract theta-band power and compute coherence values.

		In addition, standardized low-resolution brain electromagnetic tomography (sLORETA) was used to localize the brain sources of theta activity. sLORETA generates 3D images of standardized current density in the brain, using EEG signals projected into a realistic head model (MNI152 template). The solution space was restricted to gray matter and consisted of 6239 voxels. The regions of interest (ROIs) for this analysis included the prefrontal cortex, parietal cortex, limbic system, and insular cortex brain areas previously implicated in emotional processing. Anatomical labels were mapped using MNI space with corrections to Talairach space.

standardized guided exercise therapy (GET). Exercise therapists at both centers jointly arranged the GET sessions so that both locations had a consistent and standardized program. GET was performed in a group setting mode of 12 patients maximum over a 6-week period (three sessions per week), each session lasting 50 minutes. The groups were supervised by certified therapists and comprised mixed exercise modalities, such as endurance training with workout music, body awareness and relaxation, as well as group matches and activities.	self-organized activity (SOA). Patients of the SOA group were also encouraged by the same therapists to perform physical activity three times a week. Their physical condition, depressive symptoms, and motivational troubles were discussed in regular meetings.	The severity of depression was assessed using the 21-item version of the Hamilton Depression Rating Scale (HAMD-21). To evaluate social and functional performance, the Personal and Social Performance (PSP) scale was used. This scale rates four domains (socially useful activities, personal and social relationships, self-care, and aggressive behavior) on a 6-point scale, which is then converted into a global score ranging from 0 to 100 using a specific algorithm. Well-being was measured using several validated instruments: The WHO-5 Well-Being Index, a brief self-report scale with five positively worded items, assessed general well-being and aspects of physical and mental health. Psychosocial aspects of exercise were evaluated using the German WSBB (Weinsberger Skalen zur Bewegungsbeobachtung), which includes 11 behavioral categories such as self-confidence, tension, movement expression, and verbal communication.

		Body image was assessed via the German FKB-20 questionnaire, which provides two subscales: body dissatisfaction (negative self-appraisal) and body vitality (experiences of energy and vitality associated with the body). Mood changes were captured using the German Befindlichkeitsskala (BFS), which includes 40 items covering eight mood dimensions (e.g., anger, tension, calmness, and depressiveness), measuring along both activation and valence axes. The German FAHW (Questionnaire on General Habitual Subjective Well-Being) was used to assess subjective well-being at baseline and after 6 weeks. It includes six subscales: physical well-being, physical ill-being, psychological well-being, psychological ill-being, social well-being, and social ill-being. To assess physical performance, three standard tests were used: The Timed Up-and-Go Test (for evaluating mobility and balance),

		The Sit-and-Reach Test (for assessing flexibility), And the Unipedal Stance Test (for postural balance and stability). Together, these measures provided a comprehensive evaluation of participants' mental health, psychosocial function, physical condition, and subjective well-being.

The CT treatment followed the manuals for cognitive therapy for depressive disorders (Beck, 1970; Beck et al., 1979). Treatment consists of a series of structured sessions focused on behavioral activation and a cognitive approach to modify negative automatic thoughts that are assumed to cause and maintain depressive symptoms. Standard interventions are activity scheduling, using thought records to identify and evaluate automatic thoughts, and behavioral experiments. Further in the treatment process, the focus shifts towards examining underlying dysfunctional attitudes and beliefs.	The SE treatment was delivered following the manual for supportive-expressive psychodynamic psychotherapy (Luborsky, 1984) and the supplemental clinical case manual (Book, 1998). The treatment is focused on building a strong therapeutic alliance to facilitate insight into maladaptive interpersonal patterns. It begins with supportive techniques to develop a therapeutic relationship, familiarize the patient with the focus on relationship difficulties, and set goals to explore a specific, currently problematic interpersonal pattern. The therapist then uses expressive techniques such as clarifications, confrontations, and interpretations to increase the patient's self-understanding of maladaptive interpersonal patterns and develop alternative ways of responding. Interpersonal patterns are formulated using the Core Conflictual Relationship Theme (CCRT; Luborsky et al., 1994) model. The model identifies the patient's wishes/needs in the relationship with another person, the other person's typical response, and the patient's subsequent stereotypic response.	In this study, several validated instruments were used to assess depressive symptom severity, psychiatric diagnoses, and insight into interpersonal relationship patterns. The Quick Inventory of Depressive Symptomatology – Self-Report (QIDS-SR) was utilized as a self-report measure of depression. This 16-item scale captures symptom severity across nine core domains of depression, such as mood, sleep, and appetite, using a 4-point response format. The QIDS-SR has previously demonstrated good reliability and high convergent validity with the Hamilton Depression Rating Scale (HAM-D) in samples of patients with chronic major depressive disorder (MDD). However, in the present study, the internal consistency of the QIDS-SR was relatively modest, with a Cronbach's alpha of .58. To determine diagnostic eligibility and confirm the presence of MDD, the researchers used the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I). This is a semi-structured diagnostic interview that allows trained clinicians to reliably assess and diagnose mental

		disorders according to DSM-IV criteria. The SCID-I is well-established in clinical research and has shown high interrater reliability in previous studies. To assess psychological insight, the study employed the Insight into Conflictual Relationship Patterns (ICR) scale. This is an observer-rated measure based on audio or video recordings of psychotherapy sessions. The ICR scale evaluates patients' awareness of problematic interpersonal dynamics, their connection to past experiences and current symptoms, the defensive function of these patterns, and the capacity to alter them. The scale consists of 12 items rated on a 5-point scale, where higher scores indicate greater insight. In previous studies, the ICR has demonstrated high interrater reliability, retest reliability, and adequate convergent and discriminant validity. In the present study, the internal consistency of the ICR was high, with a Cronbach's alpha of .81. Lastly, the Hamilton Depression Rating Scale (HAM-D) was used to measure the severity of

		depressive symptoms. This clinician-administered instrument includes 17 items with various scaling formats and assesses symptom severity over the past two weeks. Total scores are calculated by summing item responses, with higher scores indicating more severe depression. The HAM-D has been widely used in clinical research and supported by meta-analytic findings that confirm its good internal consistency and interrater reliability. In this study, the internal consistency of the HAM-D at the five-month follow-up was acceptable, with a Cronbach's alpha of .78.

The pharmacotherapy approach followed an evidence-based algorithm, drawing on models like the Texas Medication Algorithm Project and the STAR*D study. Medication Sequence: First-line treatment: Two SSRIs: Sertraline hydrochloride Escitalopram oxalate Second-line/augmentation: Bupropion hydrochloride (used if patients didn't respond to SSRIs or showed partial response) Further options (if earlier treatments failed): Venlafaxine hydrochloride Mirtazapine Lithium carbonate (augmentation) Treatment Guidelines:	CBASP is a structured, manualized psychotherapy specifically developed to treat chronic depression. Its core goals are to help patients: Improve interpersonal functioning, Understand the impact of their thoughts and behaviors, Develop more effective coping strategies. Core Technique: Situational Analysis (SA) SA is a structured interpersonal problem-solving algorithm introduced in session 3. It involves: Elicitation phase – Patients describe: A specific recent interpersonal situation, Their thoughts, behaviors, and outcomes, Their desired outcome and whether it was achieved. Remediation phase – Therapists and patients:	In this study, social problem-solving ability was assessed using the Social Problem Solving Inventory – Revised (SPSI-R), a 52-item self-report measure grounded in the theoretical framework developed by D'Zurilla and colleagues. The SPSI-R was administered on a biweekly basis starting in the second week after randomization, prior to the initiation of Situational Analysis (SA) in the CBASP condition. According to D'Zurilla's model, social problem solving consists of two main components: problem orientation—a motivational process reflecting a person's general awareness of problems and confidence in their problem-solving ability—and problem-solving proper, which involves the rational application of four key skills: (1) problem definition and formulation, (2) generation of alternative solutions, (3) decision making, and (4) solution implementation and verification. The SPSI-R evaluates five empirically derived dimensions: positive problem orientation, negative problem orientation, rational problem solving, and two dysfunctional styles—impulsivity/carelessness and avoidance.

Protocols defined dosage ranges, speed of dosage increase, and trial durations. Patient evaluations occurred every two weeks. If patients could not tolerate a drug during the first 4 weeks, they were moved to the next treatment step to reduce dropout. Additional Notes: No other psychotropic drugs were allowed, except: Zolpidem tartrate and zaleplon (for insomnia) Pharmacotherapists followed the NIMH TDCRP manual by Fawcett et al. (1987), providing minimal psychotherapy. Sessions were audiotaped during the randomized phase for fidelity checks. Supervision occurred bimonthly by senior pharmacotherapists to ensure protocol adherence.	Identify unrealistic goals and reformulate them, Align thoughts and behaviors with the desired outcome, Use role-plays to rehearse alternative behavioral strategies. Generalization phase – Patients learn to apply new skills and understanding to past and future situations. Patients monitored interpersonal situations between sessions using the Coping Style Questionnaire. Therapy Schedule: Sessions 1–4: Twice weekly Sessions 5–12: Weekly Optional: Up to 4 extra sessions in weeks 5–8 if needed Total sessions: 16–20	This instrument has demonstrated excellent psychometric properties, including high internal consistency, strong test-retest reliability, and good convergent and discriminant validity. It correlates well with independent assessments of real-world problem-solving competence and is distinguishable from related psychological constructs such as intelligence, experiential coping, optimism, and trait affectivity. Although the SPSI-R and the CBASP model were developed independently, they show a high degree of conceptual overlap. The CBASP's core intervention, Situational Analysis, directly engages the rational problem-solving components outlined in the SPSI-R. Specifically, the elicitation phase of SA corresponds with problem identification and formulation; the remediation phase focuses on generating alternative solutions and making decisions aimed at achieving realistic and attainable outcomes; and homework assignments promote the application and verification of new problem-solving strategies in real-life settings. Furthermore, CBASP addresses impulsive and avoidant problem-solving styles by encouraging

Patients received daily pill packets and had to return unused pills at each session. At every visit, treatment adherence was discussed. Brief Supportive Psychotherapy As defined in an unpublished treatment manual (Markowitz & Sacks, 2002), BSP emphasizes the nonspecific or “common” factors assumed to be important ingredients across psychotherapies (Frank, 1971; Rogers, 1951), including reflective listening, empathy, evoking affect, therapeutic optimism, and acknowledgment of patients’ assets. Specific interpersonal, cognitive, behavioral, and psychodynamic interventions, and especially situational analyses, were strictly proscribed. Paralleling the CBASP condition, 16–20 BSP sessions were scheduled during the 12 weeks of treatment. The BSP therapists’ professional degrees, amount of clinical experience, training, and supervision were comparable to those of the CBASP therapists. The certification and training procedures were led by JCM (see Markowitz, Manber & Rosen, 2008).	.	patients to analyze interpersonal situations in a detailed and structured manner. While CBASP does not explicitly target problem orientation, it is assumed that successful problem-solving performance, which is a primary goal of the therapy, may lead to improvements in this area. In addition to social problem-solving assessment, depressive symptoms were evaluated every two weeks using the 24-item Hamilton Rating Scale for Depression (HAM-D). This extended version of the HAM-D includes items that capture the cognitive aspects of chronic depression and has been widely used in previous clinical studies on this population. Evaluations were conducted by trained, independent raters who were blinded to treatment conditions. These raters underwent annual certification and were kept separate from clinical staff to ensure the integrity of the assessment process. Patients were also instructed not to disclose any information about their psychotherapy during these evaluations to maintain blinding.

All the patients received outpatient treatment given by psychiatrists who were different from those administering psychoeducation, performing the psychometric assessments or judging relapse. This TAU consisted of clinical management including assessment of the psychiatric symptoms and subsequent prescription of antidepressant(s) once every 2 weeks. The duration of a clinical visit was about 15 min. All the patients were asked not to undertake any formal psychotherapy during the trial.	Group psychoeducation was administered to the patients for six sessions that were held on a weekly basis. Each group consisted of between two and six patients, depending on the patient accrual and to minimise the waiting time. Each session lasted for about 1.5 h: the first 20–30 min were used for a didactic lecture and were followed by group discussions using problem-solving techniques. The topics of the didactic parts included 'Patient recognition of depression and its consequences', 'Causes and risk factors', 'Signs and symptoms', 'Drug treatment', 'Side effects of antidepressants' and 'Course/outcome and review of the sessions'. As educational materials, we developed a textbook describing depression and its treatment and videos illustrating the patients' experiences, depressive symptoms and treatment. In the group meeting, participants were encouraged to raise questions of any kind that they wanted to know or solve. There were a variety of questions raised: how they would inform the boss of their	To assess the severity of depressive symptoms, we administered the 17-item Hamilton Rating Scale for Depression (HRSD-17), which is observer-rated instrument designed to assess depressive symptoms over the previous week (Hamilton, 1967), and the Beck Depression Inventory-Second Edition (BDI-II), which is a 21-item, self-report measure of depressive symptoms using a 0–3 scale (range, 0–63) (Beck et al., 1961), at baseline, after the last session of psychoeducation in the case of the intervention group, at any point when a relapse was suspected and after 9 months. We also administered the Clinical Global Impression (CGI, Guy, 2000) severity score at baseline and after 9 months, and the CGI improvement score after 9 months. In addition, the Global Assessment of Functioning (GAF, APA, 2000) was rated at baseline and after 9 months. All the observer-rated instruments including HRSD-17, CGI and GAF were administered by an independent psychiatrist (IM), who was different from those administering the treatment or judging relapse and who was also

	absence, how they should respond to family critical attitudes or emotional overinvolvement, how they could discuss trivial-looking family matters with the doctor in charge, how they could distinguish between mental disorder and character and so on. We focussed on how to cope with family members and the boss at the workplace, prompting use of the problem-solving techniques among the participants. We did not use psychother-apeutic techniques and homework tasks in our sessions. The staff consisted of one psychiatrist, one clinical psychologist and a clerk. The psychiatrist provided all the lectures and led the group meetings supported by the clinical psychologist.	kept blind to the group assignment of the patients. Relapse was declared when the diagnostic threshold for a major depressive episode as specified in DSM–IV was met according to the interview by this independent psychiatrist. Remission was defined as an HRSD score of 6 or lower (Shimazu et al., 2011). We defined the state of partial remission according to DSM- IV.

the control group, receiving the standard care provided by the Center for patients with MDD, namely medical treatment (antidepressants and other psycho-tropics) or 30-min counseling sessions conducted by the Center's psy-chiatrists once a month,	The PSAI technique was instructed to be practiced on a daily basis, in the morning and at night, just before going to sleep, for 30 min approximately. The patients were advised to perform the technique in a quiet place, after 5 min of diaphragmatic breathing. Specifically, in every practice of this technique at night, the individuals had to recall and evaluate all the actions and discussions of the day concerning issues, such as diet, physical exercise, human relationships and emotions. During the evaluation, the individuals needed to observe themselves from a "third person" perspective and to stay emotionally detached. They had to pose to themselves three questions: "What have I done wrong? What have I done right? What have I omitted that I ought to have done?". The evaluation was based on the lifestyle and moral framework which is dictated by the Golden Verses of Pythagoras. Sub-	various outcome measures were employed to evaluate the effectiveness of the intervention on participants diagnosed with Major Depressive Disorder (MDD). The following measures were utilized: **Sociodemographic Characteristics:** Participants were asked about their gender, age, marital status, parity, education level, satisfaction with income, smoking habits, BMI, and whether they received medical treatment for MDD. This information is crucial for understanding the demographic context of the study population and potential confounding factors in the analysis. **Beck Depression Inventory-II (BDI-II):** The BDI-II is a self-report questionnaire consisting of 21 items that assess the severity of depression in individuals aged 13 and older. In this study, the BDI-II demonstrated high reliability, with Cronbach's alpha values of 0.92 at baseline and 0.93 at the final assessment, indicating its effectiveness in measuring depressive symptoms. **Healthy Lifestyle and Personal Control Questionnaire (HLPCQ):** This self-report instrument assesses various aspects of lifestyle,

	sequently, the patients had to reward or reprimand themselves based on the distinction of the actions in these three categories. With regard to the actions in which they found themselves wrong, they were asked to consider what could be corrected and to set goals for the following day. in the following four group sessions, patients were trained on PSAI and the second relaxation technique, progressive muscular relaxation. They shared their experiences and discussed their questions and prob- lems with the stress scientists-psychologists. In the last week, the final measurements were made. Every week, personal diaries were distributed, so as patients to report their compliance to the program. All ses- sions lasted for 120 min, except for the final one, which lasted for 60min.	including dietary choices, harm avoidance, daily routines, organized physical exercise, and social and mental balance. The HLPCQ also showed satisfactory reliability, with Cronbach's alpha values of 0.91 at baseline and 0.93 at the final assessment, supporting its validity in evaluating lifestyle factors related to mental health. **Depression, Anxiety, and Stress Scale-21 (DASS-21):** This scale comprises three subscales—depression, anxiety, and stress—designed to assess individual disturbances rather than making clinical diagnoses. The DASS-21 exhibited strong internal consistency, with Cronbach's alpha values of 0.95 for the depression subscale, 0.91 for anxiety, and 0.89 for stress at baseline, indicating its robustness as a measure of psychological distress. various outcome measures were employed to evaluate the effectiveness of the intervention on participants diagnosed with Major Depressive Disorder (MDD). The following measures were utilized: **Positive and Negative Affect Schedule (PANAS):** This self-reported instrument assesses two main dimensions of mood: positive and negative

		affect. The PANAS demonstrated satisfactory reliability, with Cronbach's alpha values of 0.83 for positive affect and 0.84 for negative affect at baseline, and 0.82 and 0.86 at the final assessment, respectively, confirming its utility in capturing emotional states. **Pittsburgh Sleep Quality Index (PSQI):** The PSQI is a self-report questionnaire that evaluates sleep quality and disturbances over the past 30 days. It showed good reliability, with Cronbach's alpha values of 0.74 for both baseline and final measurements, indicating its effectiveness in assessing sleep-related issues in the study population. Brief International Assessment of Cognition for Multiple Sclerosis (BICAMS): This standardized battery was utilized to assess the cognitive functions of the patients, providing insights into the cognitive impacts associated with MDD. The use of BICAMS is significant for understanding cognitive deficits in this population, although specific reliability metrics were not provided in the study. **Hair Cortisol Concentration:** Hair samples were collected to measure cortisol levels, which serve as a biomarker for chronic stress. This method

		provides valuable information regarding long-term stress exposure in participants, although specific reliability data was not mentioned in the study. **Salivary Cortisol Concentration:** Salivary cortisol levels were measured to reflect diurnal stress levels, offering insights into the participants' immediate stress responses. This measure is crucial for understanding the physiological aspects of stress in relation to MDD, although specific reliability metrics were not detailed in the study.

the control group only received antidepressants.	In this study, participants with treatment-resistant depression (TRD) received a combination of Mindfulness-Based Cognitive Therapy (MBCT) and antidepressant medication as their intervention. Mindfulness-Based Cognitive Therapy (MBCT): MBCT is a structured psychological intervention that integrates elements of mindfulness meditation with cognitive behavioral therapy (CBT). It is designed to prevent relapse in individuals with a history of recurrent major depressive disorder and is particularly relevant for those with chronic or treatment-resistant forms of depression. The MBCT intervention focused on the following key components: Mindfulness training: cultivating non-judgmental awareness of the present moment, based on the definition by Kabat-Zinn. This involves purposefully paying attention with openness and acceptance. Cognitive elements: helping participants	To assess the effectiveness of MBCT combined with antidepressants in individuals with treatment-resistant depression (TRD), a variety of validated clinical tools were used. These measures targeted diagnostic assessment, depression severity, mindfulness, self-compassion, and rumination: 1. Structured Clinical Interview for DSM-IV Disorders (SCID) The SCID is a semi-structured diagnostic interview administered by trained mental health professionals. It helps establish psychiatric diagnoses based on DSM-IV criteria. The Persian version of the SCID has demonstrated moderate reliability, with a general kappa coefficient of 0.6, and weighted kappa scores of 0.52 for current and 0.55 for lifetime diagnoses. 2. Beck Depression Inventory – Second Edition (BDI-II) The BDI-II is a 21-item self-report inventory measuring various dimensions of depression, including cognitive, emotional, physical, and vegetative symptoms. It has shown strong psychometric properties, including a high

	become aware of and respond differently to negative thought patterns. Four key mechanisms targeted by MBCT: Increased mindfulness Reduced depressive rumination Increased acceptance and self-compassion Reduced avoidance of unpleasant thoughts and feelings Participants were taught to observe their experiences without judgment, foster kindness toward themselves, recognize shared human experiences (common humanity), and reduce over-identification with distressing emotions or thoughts.	one-week test-retest reliability (α = 0.91), and a significant positive correlation (r = 0.71) with the Hamilton Depression Rating Scale (HDRS). 3. Hamilton Depression Rating Scale (HDRS) This is a clinician-administered scale widely used to assess depression severity. The HDRS comes in 17- and 24-item versions, both showing good internal reliability (ranging from 0.65 to 0.91). The 17-item version has an internal consistency coefficient of 0.83, while the 24-item version scores 0.88. 4. Self-Compassion Scale – Short Form (SCS-SF) The SCS-SF is a 12-item self-report measure that evaluates how individuals respond to personal suffering or perceived inadequacy. It assesses dimensions such as self-kindness vs. self-judgment, mindfulness vs. over-identification, and common humanity vs. isolation. The short form shows a very high correlation (r = 0.97) with the full version and has strong test-retest reliability (0.92). In Iranian samples, the total scale had a Cronbach's alpha of 0.86, with subscale alphas ranging from 0.68 to 0.86.

		5. Ruminative Response Scale (RRS) The RRS includes 22 items that assess how individuals respond to depressed mood through rumination. It has shown acceptable reliability and validity across its two subscales. It is positively correlated with measures such as the BDI, State-Trait Anxiety Inventory, and SF-36, demonstrating both convergent and discriminant validity. The Persian version has been confirmed to have solid psychometric support. 6. Southampton Mindfulness Questionnaire (SMQ) The SMQ contains 16 items and measures mindful awareness and acceptance of distressing thoughts and images. Internal consistency is high (α = 0.89 for normal samples and 0.82 for clinical samples). The Persian version demonstrated good fit in confirmatory factor analysis (CFI = 0.9; NFI = 0.83; RMSEA = 0.08) and showed positive correlations with self-compassion (0.59) and positive affect (0.40), along with negative correlations with negative affect (−0.35), depression (−0.36), anxiety

		(−0.30), and stress (−0.50), indicating good convergent and divergent validity.

In this study, CFT-C (Clarification-Focused Therapy – Control condition) was designed as an active control group to account for non-specific change mechanisms of psychotherapy, such as therapeutic alliance, resource activation, motivational clarification, problem activation, and problem solving. The approach begins with identifying personally relevant goals and their associated motives. If goals are no longer achievable, participants are guided through acceptance strategies. If goals are still achievable, structured problem-solving processes are initiated. These include identifying and describing the problem and relevant situational features, defining goals, developing and evaluating potential solutions, selecting and implementing solutions, and monitoring progress. If necessary, the process is revisited to either reinitiate problem-solving or support further acceptance. In addition, participants receiving Individual Cognitive Behavioral Therapy for Depression (iCBT-D) undergo a manualized, 4-month treatment consisting of 16 weekly 50-minute sessions. The protocol, based on the work of	Affect Regulation Training (ART) is a transdiagnostic, group-based intervention developed to enhance adaptive emotion regulation (ER) in individuals either diagnosed with mental disorders or at risk of developing them. ART is designed to function both as a stand-alone treatment or as an adjunctive therapy, and draws on techniques and principles from multiple psychotherapeutic traditions. These include cognitive behavioral therapy, dialectical behavioral therapy, emotion-focused therapy, mindfulness-based interventions, neuropsychotherapeutic and translational approaches, compassion-based therapies, problem-solving therapies, and strength-focused interventions. At the start of the training, participants receive psychoeducation about emotions, covering their biological and psychological bases, functions, benefits, and potential risks. The program then introduces seven “vicious cycles” of emotion, identified through affective neuroscience research, which are believed to contribute to the chronic maintenance of negative affect.	Primary Outcome The Hamilton Rating Scale for Depression (HRSD) is used as the primary outcome measure. This clinician-administered interview assesses the severity of depressive symptoms based on 24 items such as depressed mood, guilt, sleep problems, and anxiety. Each item is rated on a 3- or 5-point Likert scale, with higher total scores indicating more severe depression. Established cut-off points categorize depression as mild, moderate, severe, or very severe. The HRSD is sensitive to clinical changes and correlates well with overall assessments of depression severity. Secondary Outcomes and Other Measures 1. Depressive Symptoms Beck Depression Inventory-II (BDI-II): A 21-item self-report questionnaire covering cognitive, emotional, behavioral, and physical symptoms of depression. It is widely used and has strong psychometric properties. 2. Emotion Regulation Emotion Regulation Skills Questionnaire (ERSQ): A 27-item self-report scale assessing nine key

Hautzinger, includes psychoeducation about major depressive disorder (MDD), behavioral activation, cognitive restructuring, social skills training, stress reduction, and relapse prevention. This structured approach aims to provide comprehensive therapeutic support for individuals with depression.	To counter these cycles and promote adaptive ER, participants learn a variety of skills, such as: Muscle and breathing relaxation techniques Nonjudgmental emotional awareness Acceptance and tolerance of emotions Compassionate self-support Identifying causes of emotional responses Modifying negative affective states A key component of ART is the emphasis on regular practice and training of these skills to support their long-term effectiveness. Further details and structured guidance for implementing the training are outlined in the ART manual.	competencies from the ART model (e.g., awareness, clarity, acceptance, self-support). It includes both self- and observer-rated versions. ERSQ – Emotion Specific (ERSQ-ES): Evaluates emotion regulation in specific affective states; also available in self- and observer-rated formats. Difficulties in Emotion Regulation Scale (DERS): Assesses problems with emotional awareness, acceptance, goal-directed behavior, and access to regulation strategies. Negative Mood Regulation Scale (NMR): Measures individuals' belief in their ability to manage emotions through behaviors or cognitive strategies. Trait Meta-Mood Scale (TMMS): Focuses on emotional intelligence, including emotional attention, clarity, and mood repair. 3. Psychological Well-Being Scales of Psychological Well-Being (SPWB): Assesses six domains—autonomy,

		environmental mastery, personal growth, positive relations, purpose in life, and self-acceptance. This study uses the total score, given variability in factor structure. 4. Affective States Positive and Negative Affect Schedule (PANAS): A 20-item scale measuring the frequency of positive and negative emotional experiences over the past week. Short Scales for the Assessment of Affective States (SHARP): A 50-item self-report scale for assessing specific emotional reactions during the previous week. 5. Stressors List of Situational Stressors (LSS): Evaluates exposure to daily stressors (e.g., interpersonal conflicts, financial problems, transportation issues) in the past week, across different domains of life. 6. Diagnostic Assessment Structured Clinical Interview for DSM-IV Axis I & II (SCID I & II): Used to diagnose major

		depressive disorder (MDD) and other psychiatric comorbidities. DSM-5 diagnoses will be integrated when possible. 7. Comorbid Symptoms Brief Symptom Inventory (BSI): Used to calculate a Global Severity Index (excluding depression items), covering a broad range of psychological symptoms like anxiety, hostility, and somatization. Depression Anxiety Stress Scale (DASS-21): A shortened version of the original DASS, it measures the three related states of depression, anxiety, and stress. While no German validation exists yet, the English version has good reliability. Confounding Variables To account for possible confounds in the analyses, the following are also assessed: General self-efficacy: Measured with the 10-item ASE scale (Skala zur Allgemeinen Selbstwirksamkeitserwartung).

		Perfectionism: Measured with the Multidimensional Perfectionism Scale (MPS), covering concerns about mistakes, personal standards, parental expectations and criticism, doubts, and organization. Self-esteem: Assessed with the Rosenberg Self-Esteem Scale (RSE). Socio-Demographic Variables The study will collect a range of demographic data, including: age, gender, marital and partnership status, children, living situation, education, occupation (learned and current), and immigration background.

Data analysis	**Outcome (Ook de P-waarde toevoegen)**

the researchers used an intent-to-treat approach, meaning that all participants who were randomly assigned to one of the two treatment groups (FOCUS or WRAP) were included in the final analysis, regardless of how much of the intervention they actually completed. This approach ensures that the results reflect real-world conditions and reduces bias. To examine changes in clinical outcomes over time, the researchers applied mixed-effects models. These models included variables for the treatment condition (FOCUS or WRAP), time of assessment (baseline, 3 months, and 6 months), and the interaction between treatment and time. This allowed them to assess whether either intervention led to greater improvements over time. For most outcomes, such as depression and general psychopathology, linear mixed models were used. For psychotic symptoms, which had many zero scores (participants without symptoms), the researchers used a nonlinear Poisson hurdle model, which is better suited for skewed data with a large number of zeros. Differences in treatment engagement between groups were tested using chi-square tests, while treatment satisfaction was analyzed using t-tests. All analyses were conducted with appropriate statistical controls, and significance was determined using standard p-values (with $p < .05$ considered statistically significant).	The study found that both interventions—FOCUS and WRAP—led to significant improvements in clinical outcomes among participants with serious mental illness. General psychopathology, the primary outcome, decreased significantly in both groups from baseline to the end of treatment. In the FOCUS group, symptoms reduced with a mean difference of –2.73 ($p < .001$), while the WRAP group showed a similar improvement with a mean difference of –2.14 ($p = .005$). Depressive symptoms, measured using the Beck Depression Inventory-II, also improved significantly in both groups. Participants in the FOCUS group showed a reduction of –2.76 points ($p = .01$), and those in the WRAP group improved by –2.33 points ($p = .03$). These improvements were sustained at six-month follow-up, with both groups showing further reductions in depressive symptoms ($p < .001$). In terms of recovery, measured by the Recovery Assessment Scale, participants in the WRAP group experienced a significant increase immediately after treatment ($p = .03$), while those in the FOCUS group showed a stronger increase at the six-month follow-up ($p < .001$). Additionally, quality of life improved significantly in the FOCUS group over time ($p = .01$), whereas no significant changes were observed in the WRAP group for this measure. Although both interventions led to similar clinical outcomes overall, the FOCUS group demonstrated higher treatment engagement and more consistent gains in recovery and quality of life across the study period.

Data analysis in the study was conducted using the intention-to-treat principle, meaning that all participants who were randomized were included in the analysis, regardless of whether they completed the intervention. The normality of data distribution was tested using the Shapiro-Wilk test. Depending on whether variables were normally distributed, results were reported as either means with standard deviations or medians with interquartile ranges. To compare differences within groups (before and after treatment), the researchers used paired t-tests for normally distributed variables and appropriate non-parametric tests for non-normal data. To examine differences between groups, independent t-tests were applied. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using Stata Statistical Software, version 15.	The results of the study showed that participants who received mindfulness and self-compassion-based group therapy (MSC) experienced significant improvements in several psychological outcomes. Most notably, depressive symptoms, measured by the Montgomery-Åsberg Depression Rating Scale (MADRS), decreased by an average of 8.49 points, which was statistically significant ($p < .001$). Anxiety levels, assessed using the Hospital Anxiety and Depression Scale (HAD-A), also declined significantly by 6.23 points ($p < .001$), while depressive symptoms on the HAD-D scale improved by 3.22 points ($p < .001$). Additionally, participants reported significantly lower perceived stress, with a 7.05-point reduction on the Thai Perceived Stress Scale ($p = .001$), and showed improvements in overall quality of life, as measured by the WHOQOL, which increased by 13.48 points ($p < .001$). Self-esteem also improved, with a 4.05-point increase on the Rosenberg Self-Esteem Scale ($p = .005$). Finally, mindfulness and self-compassion levels rose by 0.48 points ($p = .002$). Although the control group, which received standard treatment, also showed statistically significant improvements in several areas, the comparison between groups did not reveal any significant differences in outcome scores ($p > .05$). This suggests that both interventions were effective, but that MSC therapy did not produce significantly greater improvements than standard care over the seven-week period.

Data were analyzed using IBM SPSS Statistics 21.0. Descriptive statistics such as percentages, means, and standard deviations were used to summarize demographic characteristics. To compare the baseline characteristics between the intervention and control groups, the Mann–Whitney U test and chi-square test were applied. To evaluate the effectiveness of the intervention, a two-way mixed ANOVA (split-plot design) was used. This allowed the researchers to assess: 1)The within-subjects factor: time (pretest, posttest, and follow-up) 2)The between-subjects factor: group (intervention vs. control) The key focus was on the Time × Group interaction effect, which indicated whether changes over time differed significantly between the two groups. When significant differences were found, Bonferroni post hoc tests and Bonferroni-corrected Mann–Whitney U tests were used to identify the specific time points at which the differences occurred. Additionally, Spearman correlation analysis was conducted to examine the relationships between changes in depression, self-esteem, and coping strategies from pretest to follow-up within the intervention group. A significance level of $p < 0.05$ was used throughout, and effect sizes (Cohen's d) were also calculated to determine the strength of the intervention effects.	The study found that the Coping With Depression Program (CWDP) had a statistically significant effect on reducing depression, increasing self-esteem, and improving coping strategies among participants in the intervention group. **1. Depression (BDI scores)** There was a significant decrease in depression scores in the intervention group compared to the control group across time points. - Time effect: $F(1, 43.011) = p = 0.000$ - Group effect: $F(1, 6.565) = p = 0.000$ - Time × Group interaction: $F(1, 9.142) = p = 0.000$ Bonferroni-corrected post hoc comparisons showed significant differences: - Pretest vs Posttest: $p = 0.001$ - Pretest vs Follow-up: $p < 0.016$ **2. Self-Esteem (RSES scores)** Self-esteem scores significantly improved (i.e., lower scores indicating higher self-esteem) in the intervention group: - Time effect: $F(1, 35.932) = p = 0.000$ - Group effect: $F(1, 28.312) = p = 0.000$ - Time × Group interaction: $F(1, 22.569) = p = 0.000$ Post hoc tests showed significant improvement: - Pretest vs Posttest and Follow-up: $p < 0.016$ **3. Coping Strategies (CSI subscales)** <u>Problem-Solving</u> - Time × Group interaction: $F = 26.243$, $p = 0.000$

	- Posttest and follow-up scores were significantly higher in the intervention group (z = -6.356, p < 0.001; z = -4.491, p < 0.001) <u>Seeking Social Support</u> - Time × Group interaction: F = 6.091, p = 0.007 - Intervention group showed greater improvement (z = -5.532, p < 0.001; z = -3.438, p < 0.001) <u>Avoidance</u> - Time × Group interaction: F = 15.104, p = 0.000 - Avoidance scores decreased more significantly in the intervention group (z = -4.296, p < 0.001; z = -2.555, p = 0.011)

Data analysis was conducted according to the intention-to-treat (ITT) principle, meaning that all participants were analyzed in the groups to which they were originally assigned, regardless of whether they completed the intervention. To evaluate treatment effects over time, the researchers used mixed-model repeated measures ANOVAs with time (baseline to 12 weeks) as the within-subject factor and treatment condition (intervention vs. control) as the between-subject factor. This approach allowed for the inclusion of participants with incomplete data, as the mixed-effects model uses all available data without imputing missing values. Effect sizes (Cohen's d) were calculated for both within- and between-group comparisons to assess the magnitude of change. In addition, chi-square tests were used to evaluate rates of reliable and clinically significant improvement or deterioration on the BDI-II, based on the Reliable Change Index (RCI) and clinical cut-offs as defined by Jacobson and Truax. Non-parametric tests (e.g., Mann–Whitney U and Spearman's correlations) were used for variables that were not normally distributed, such as program usage and working alliance scores.	The study found that the combination of face-to-face psychotherapy and the web-based program deprexis was significantly more effective than psychotherapy alone in reducing depressive symptoms at the 12-week primary endpoint. **Primary Outcome – Depression (BDI-II)** There was a statistically significant group × time interaction on the Beck Depression Inventory-II (BDI-II): - $F(1,70.6) = 4.50$, $p < .05$ - The between-group effect size was Cohen's $d = 0.51$, indicating a medium effect in favor of the intervention group. **Secondary Outcomes** - Mental Health (SF-12 Mental Subscale): $F(1,71.5) = 5.7$, $p < .05$, Cohen's $d = 0.55$ (medium effect, favoring the intervention group) - Somatic Symptoms (PHQ-15): $F(1,67.9) = 8.80$, $p < .01$, Cohen's $d = 0.27$ (small effect, favoring the intervention group) - Anxiety (GAD-7): No significant difference: $F(1,77.4) = 1.05$, $p = .31$, Cohen's $d = 0.31$ - Physical Health (SF-12 Physical Subscale): No significant difference: $F(1,70.5) = 0.4$, $p = .84$, Cohen's $d = 0.07$ **Clinical Significance** - Reliable improvement on the BDI-II was achieved by 31.4% in the

	intervention group vs. 19.1% in the control group (p = .17, not statistically significant). - Clinically significant improvement: 15.7% (intervention) vs. 4.3% (control), p = .062 (trend, but not significant)

The study used a mediation analysis framework to examine whether improvements in emotion regulation (rumination, self-kindness, and mindfulness) mediated the effects of the mindfulness intervention on depressive symptoms and perceived stress. The primary statistical approach was analysis of covariance (ANCOVA), controlling for baseline levels of each mediator and outcome. Mediation was assessed using: - Single mediator models to test each emotion regulation variable separately - Multiple mediator models when more than one variable showed significant indirect effects Indirect (mediated) effects were tested using a non-parametric bootstrap approach with 5,000 resamples, producing bias-corrected 95% confidence intervals (CIs). An indirect effect was considered statistically significant if the confidence interval did not include zero. Missing data were handled through listwise deletion, with intent-to-treat analyses (last observation carried forward) conducted to confirm robustness of results. All analyses were performed using Stata 13.1.	The mindfulness intervention (MAPs) led to significant improvements in emotion regulation, and these improvements mediated changes in depressive symptoms and perceived stress, particularly in the short term. **1. Depressive Symptoms (CES-D)** At post-intervention, significant indirect effects (mediated effects) were found: - Rumination: b = −2.03, SE = 1.14, 95% CI [−5.05, −0.31] - Self-kindness: b = −4.45, SE = 1.51, 95% CI [−7.83, −1.93] - Mindfulness: b = −3.17, SE = 1.43, 95% CI [−6.58, −0.82] In the multiple mediator model, only self-kindness remained a significant mediator: - b = −3.51, SE = 1.48, 95% CI [−6.41, −0.61] **2. Perceived Stress (PSS)** At post-intervention, only self-kindness significantly mediated the reduction in perceived stress: - b = −2.53, SE = 1.20, 95% CI [−5.37, −0.62] At the 3-month follow-up, the total indirect effect of self-kindness and mindfulness together was significant: - b = −3.56, SE = 1.64, 95% CI [−6.77, −0.35] Individually: - Self-kindness: b = −2.05, SE = 1.27, 95% CI [−5.67, −0.22] - Mindfulness: b = −2.64, SE = 1.39, 95% CI [−5.51, −0.16]

	No significant mediation was found for depressive symptoms at follow-up, suggesting the short-term effects were stronger than longer-term effects.
All statistical analyses were performed using IBM SPSS Statistics software. The data analysis followed these main steps: - Descriptive statistics (mean, standard deviation, frequency, percentage) were used to summarize participants' demographic and baseline characteristics. -To examine within-group differences (pre- vs. post-intervention), paired sample t-tests were used. -To assess between-group differences (intervention vs. control), the researchers used independent sample t-tests and ANCOVA (analysis of covariance), with pre-intervention scores as covariates to control for baseline differences. -The level of statistical significance was set at $p < 0.05$ for all tests. The study also examined effect sizes using Cohen's d to estimate the practical significance of the findings. All analyses were conducted according to the intention-to-treat principle, meaning that all randomized participants were included in the analysis, regardless of dropout.	The primary outcome, quality of life measured by the WHOQOL-BREF-Taiwan version, showed no statistically significant improvements across the four domains (physical, psychological, social, environmental) between the intervention and control groups ($p > .05$). However, a significant reduction in depressive symptoms was observed in the intervention group, measured by the BDI-II ($p < .05$).

The statistical analysis was performed using SPSS version 18.0. The study applied both descriptive and inferential statistics to evaluate the effects of the LAST intervention. Key analytical steps included: - Descriptive statistics (means, standard deviations, frequencies) to summarize demographic data and baseline characteristics. - Chi-square tests and independent t-tests to assess group differences at baseline. - To analyze the effects of the intervention over time, the researchers used Generalized Estimating Equations (GEE). This method was chosen because it accounts for repeated measures across three time points (baseline, posttest, and 3-month follow-up) and handles correlated data. - The main effects of group, time, and group × time interaction were tested to determine the intervention's effectiveness across outcomes. -A significance level of $p < .05$ was set for all statistical tests.	The study found that participants in the LAST intervention group showed significantly greater improvements across multiple domains compared to the control group, both immediately after the intervention and at the 3-month follow-up. **1. Quality of Life (WHOQOL-BREF)** Significant group × time interaction effects were found in all four domains: 1)Physical health: $p = .021$ 2)Psychological health: $p = .001$ 3)Social relationships: $p = .037$ 4)Environment: $p = .011$ **2. Depression and Anxiety (BSRS-5)** - Depression: Significant reduction in the intervention group compared to control $p = .001$ - Anxiety: Also significantly reduced in the intervention group $p = .001$ **3. Suicidal Ideation (SIS)** - Significant decrease in suicidal ideation scores for the intervention group $p = .001$ **4. Sense of Competence** - The intervention group showed significantly greater improvement $p = .002$ **5. Mastery (Pearlin Mastery Scale)** - Increased sense of mastery observed in the intervention group

	p = .007 **6. Social Support Satisfaction** - Participants reported higher satisfaction with social support p = .014 **7. Environmental Resources** - Improved perceptions of environmental resources p = .025 These results indicate that the LAST program was effective in enhancing both quality of life and a range of psychosocial outcomes, with sustained effects observed at follow-up.

Data were analyzed using SPSS software. The research team conducted both descriptive and inferential statistical analyses to assess the effects of the WRAP intervention. Key steps in the analysis included: - Descriptive statistics to summarize demographic characteristics and baseline measures. - Independent samples t-tests and chi-square tests to examine baseline equivalence between the intervention and control groups. - To assess intervention effects, the researchers used ordinary least squares (OLS) regression models to compare post-intervention scores on depression, anxiety, and recovery between the two groups, while controlling for baseline scores. - A significance level of $p < .05$ was used for all inferential tests. - Effect sizes (Cohen's d) were also calculated to estimate the practical magnitude of observed differences between groups. This statistical approach allowed the researchers to determine whether WRAP participants experienced greater improvements than the control group across key psychological and recovery-related outcomes	The results showed that participation in the WRAP program led to significant improvements in psychological well-being and self-perceived recovery compared to treatment as usual. **1. Depression (CES-D)** Participants in the WRAP group reported significantly lower depression scores at post-intervention compared to the control group: -$p = .013$ **2. Anxiety (BSI – Anxiety Subscale)** Anxiety levels were also significantly reduced in the WRAP group relative to the control group: - $p = .005$ **3. Recovery (RAS – Recovery Assessment Scale)** The WRAP group showed significantly greater self-perceived recovery, particularly in the following RAS subscales: - Personal confidence and hope: $p = .019$ - Goal and success orientation: $p = .034$ - Not dominated by symptoms: $p = .017$ There were no significant between-group differences in the RAS subscales related to reliance on others and sense of self, though both groups showed some within-group improvements.

The data were analyzed using SPSS, and the researchers applied several statistical techniques to test their hypotheses. Key steps in the analysis included: - Descriptive statistics to summarize participant characteristics and baseline measures (e.g., age, BDI scores, RRS scores). - Independent samples t-tests were used to confirm baseline differences between the depressed and non-depressed groups on key variables such as mood and rumination. - To assess the effects of the experimental manipulation, the researchers used mixed-design ANOVAs with: - Group (depressed vs. control) as a between-subjects factor - Condition (rumination vs. distraction) as a between-subjects factor - Time (pre- and post-induction) as a within-subjects factor - Post hoc tests and simple effects analyses were conducted where significant interactions were found. - For the problem-solving task (MEPS), ANOVAs were used to compare the number and quality of generated solutions across groups and conditions. A significance level of $p < .05$ was used throughout the analyses.	The primary outcomes of the study were mood and social problem-solving ability, assessed using a Visual Analogue Scale (VAS) for depressed mood and the Means-End Problem Solving (MEPS) task. Analyses revealed that participants with major depression who underwent a rumination induction experienced a significant increase in self-reported sadness ($t = 3.6$, $p = .002$), whereas those in the distraction condition showed a significant decrease in sadness ($t = 4.1$, $p = .001$). For social problem-solving, depressed participants in the rumination condition performed significantly worse post-induction ($t = 4.5$, $p < .0005$), while no significant change was observed in the distraction group ($t = 1.1$, $p = .28$). In addition, trait rumination was examined as a moderator. Regression analyses indicated that higher trait rumination significantly predicted greater sadness post-induction among both depressed ($p = .002$) and non-depressed controls ($p = .018$). It also predicted poorer problem-solving performance in the depressed group ($p = .002$), independent of condition. Trait distraction, however, was not a significant predictor in any of the models.

Descriptive statistics were used to summarize the study data. For continuous variables, the mean and standard deviation (SD) were reported. Categorical variables were presented using counts and percentages to describe their distribution. To assess baseline differences between groups (GMT vs. CCT), as well as differences between completers and non-completers and between assessors at follow-up (T3), several statistical tests were employed. The Mann-Whitney U test was used for continuous variables, while Chi-square tests were applied to compare dichotomous variables. The primary analysis followed the intention-to-treat (ITT) principle and was conducted using a linear mixed model for repeated measures. All randomized participants were included in this analysis. The model used an unstructured covariance matrix and included fixed effects for Group, Time, and the Group-by-Time interaction. Estimation was based on restricted maximum likelihood (REML). To assess the magnitude of between-group differences at follow-up (T3), Cohen's d effect sizes were calculated. A sensitivity analysis was carried out to compare results obtained from the ITT analysis with those from the treatment completers only. In addition, a Mann-Whitney U test was used to assess crude group differences on new measures that were introduced at the follow-up stage. Post hoc analyses included the calculation of the Reliable Change Index	Descriptive Analysis and Baseline Results At baseline, there were no statistically significant differences between the groups on any variable in the randomized sample (n = 63). Both the GMT and CCT groups reported elevated global executive dysfunction scores on the BRIEF-A GEC (GMT: M = 64.9, SD = 8.8; CCT: M = 63.2, SD = 8.1), indicating deficits relative to normative data. However, both groups performed at average or above-average levels on performance-based measures, and reported mild depressive symptoms (GMT: M = 16.7, SD = 7.4; CCT: M = 15.8, SD = 7.3).. Treatment Effects Primary Outcome – BRIEF-A GEC (Global Executive Composite) No significant Group × Time interaction was found ($p > .05$), meaning there was no difference in treatment effects between GMT and CCT. A significant main effect of Time was observed ($p < .05$), with both groups showing a reduction in self-reported executive dysfunction post-intervention. Within-group analyses: GMT group showed a significant reduction in BRIEF-A GEC at post-intervention (T2) and 6-month follow-up (T3) compared to baseline (T1) ($p < .05$). On subscales:

(RCI) for the BRIEF-A Global Executive Composite (GEC) score to evaluate whether observed changes were statistically reliable. This calculation used follow-up (T3) scores as endpoints, along with standard deviations and test-retest reliability data from the BRIEF-A manual. Further exploratory analysis examined the covariation between changes in BRIEF-A GEC and BDI scores. This was done by calculating standardized residuals, using baseline (T1) scores to predict follow-up (T3) scores, and applying the Pearson correlation coefficient to assess the relationship between these residuals. All statistical tests were conducted as two-tailed tests. A p-value of less than 0.01 ($p < 0.01$) was considered statistically significant, in part to account for multiple comparisons. All statistical analyses were performed using SPSS version 24.0 for Windows.	GMT group showed significant improvements on the Metacognition Index (MI), Behavioral Regulation Index (BRI), and the Working Memory, Initiate, Plan/Organize, and Inhibit subscales at T3 compared to T1 ($p < .05$). CCT group showed a significant reduction only on the Emotional Control subscale at T3 ($p < .05$). Self-Reported Executive Functioning – Cognitive Failures Questionnaire (CFQ) No significant Group × Time interaction ($p > .05$). A significant main effect of Time was found ($p < .05$), with both groups reporting fewer cognitive failures at follow-up. Within-group analyses showed significant improvements in both groups from baseline (T1) to follow-up (T3) ($p < .05$). Performance-Based Executive Functioning No significant Group × Time interactions for any performance-based measures ($p > .05$). A significant main effect of Time was detected for the EF composite ($p < .05$), with both groups showing improvement at follow-up (T3).

	For the Tower Test (D-KEFS) at follow-up: No significant difference between GMT (M = 17.8, SD = 2.6) and CCT (M = 17.5, SD = 3.1) ($p > .05$). Depressive Symptoms – Beck Depression Inventory (BDI) No significant Group × Time interaction ($p > .05$). A significant main effect of Time was found ($p < .05$), with both groups reporting decreased depressive symptoms over time. Within-group analysis revealed a statistically significant reduction in depressive symptoms for the GMT group only between T1 and T3 ($p < .05$). Post Hoc Exploratory Analysis A moderate and statistically significant correlation was found between improvement in executive dysfunction (BRIEF-A GEC) and reduction in depressive symptoms (BDI) across the whole sample ($r = 0.52$, $p < .05$). Sensitivity Analysis and Assessor Comparisons Analyses restricted to completers only confirmed the main findings, with no changes in significance. No significant differences were found between assessors on any outcome measure ($p > .05$), and estimates appeared consistent across assessors upon visual inspection

To assess baseline differences between the CBT, DMBI, and control groups, the researchers used ANOVAs for continuous variables and chi-squared tests for categorical variables. Yates's correction was applied when necessary. The Shapiro–Wilks test showed normal distribution for most mood and EEG variables (Ps < .05), allowing the use of parametric tests such as ANOVAs and t-tests. Mood outcomes were analyzed using a mixed-design ANOVA with time (pre vs. post) as the within-subjects factor and group (CBT, DMBI, control) as the between-subjects factor. This analysis covered total and subscale scores of the Hamilton Depression Rating Scale (HAM-D) and the Beck Depression Inventory-II (BDI-II). Post hoc paired t-tests were used within each group to assess changes over time. EEG coherence was analyzed through a four-way mixed-design ANOVA (time × coherence pair × group × condition) and repeated-measures ANOVAs within each group. Because of the small sample size and focused hypotheses, t-tests were used without alpha correction to maintain statistical power. Cohen's d was calculated to measure effect sizes. To explore links between mood and brain function, Pearson's correlations were computed between right frontoposterior theta coherence and post-intervention depression scores. Finally, sLORETA was used to localize changes in theta current density using voxel-by-voxel paired-sample t-tests based on nonparametric permutation, focusing on key emotion-related brain regions (e.g., prefrontal cortex, limbic lobe, insular	Before the intervention, demographic and clinical characteristics showed no significant differences between the CBT, DMBI, and control groups in terms of age, education level, gender, onset age, illness duration, or baseline depression scores (Ps > .19 for demographics; Ps > .42 for clinical features). Although three participants scored within the normal range on either the Hamilton Psychiatric Rating Scale for Depression (HAM-D) or the Beck Depression Inventory-II (BDI-II), they were still included in the analysis. Treatment Effects on Depression Symptoms A mixed-design ANOVA revealed a significant group × time interaction for the cognitive-affective subscale of the BDI-II ($F(2, 43) = 3.32$, $P = .046$), indicating differential improvement between groups. There were also trends toward significance in the total BDI-II score ($F(2, 43) = 2.69$, $P = .079$) and the HAM-D score ($F(2, 45) = 2.44$, $P = .099$). No significant group × time effect was observed for the HAM-D subscales. However, there was a significant main effect of time across all mood measures (Ps < .001), reflecting overall improvement post-intervention. Post hoc paired t-tests showed that both CBT and DMBI participants experienced significant reductions in all HAM-D and BDI-II scores (Ps ≤ .008). In the control group, there was a smaller but statistically significant reduction in total BDI-II score (P = .045), though no significant change was

cortex).	found in the HAM-D total score (P = .20). While the HAM-D global depression subscale score decreased significantly (P = .002), the cognitive-affective subscale of the BDI-II did not (P = .094). Independent-sample t-tests revealed larger pre-post improvements in the DMBI group than the control group in total and global depression BDI-II scores (Ps ≤ .066). The CBT group also outperformed the control group in HAM-D and BDI-II total scores, as well as BDI-II global depression subscale scores (Ps < .046). No significant differences were found between CBT and DMBI (Ps > .45), suggesting that both interventions were similarly effective. EEG Coherence During Affective Picture Viewing At baseline, intra-hemispheric theta coherence was comparable across all groups (Ps > .05). Repeated-measures ANOVAs (Time × Hemisphere × Condition) showed no significant three-way interaction in any group (Ps > .094). However, there was a significant main effect of Hemisphere across all groups (Fs = 56.99–80.46, Ps < .001), a main effect of Time in the DMBI group (F = 5.46, P = .035), and a significant Time × Condition interaction in the CBT group (F = 5.84, P = .007). Post hoc analyses indicated that the DMBI group exhibited a significant increase in right frontoposterior coherence across all picture types (Ps ≤ .031), while the CBT group showed increased coherence only when viewing negative images (P = .009). No significant EEG changes were

	observed in the control group (Ps ≥ .43), and no group showed changes in left hemisphere coherence (Ps ≥ .095). These results point to a treatment-specific enhancement of right hemisphere connectivity during emotional processing, particularly for the DMBI group. Importantly, coherence values measured during the resting-state (eyes-closed) did not significantly change in any group (Ps > .070), supporting the idea that EEG changes were state-specific responses to affective stimuli rather than generalized neurophysiological shifts. Correlations Between EEG and Mood Outcomes In the combined sample, stronger increases in right hemisphere frontoposterior theta coherence during emotional picture viewing correlated with lower post-treatment BDI-II scores (Ps ≤ .019) and lower HAM-D scores during neutral picture viewing (P ≤ .020). However, these correlations did not remain significant when the CBT and DMBI groups were analyzed separately, likely due to smaller sample sizes. No significant correlations were found between changes in EEG coherence and changes in total mood scores (Ps > .20). Still, Pearson correlations revealed that baseline symptom severity predicted treatment responsiveness: participants with higher initial depression scores showed greater reductions in HAM-D ($r = 0.52$, $P = .002$) and BDI-II scores ($r = 0.60$, $P < .001$). Thus, participants with more severe baseline symptoms experienced larger improvements.

The study employed an intention-to-treat (ITT) approach, meaning all participants were analyzed in the group to which they were originally randomized, regardless of their adherence to the intervention. Statistical analyses were conducted using SPSS Version 22 for Mac.

To verify assumptions, a one-sample Kolmogorov-Smirnov test was used to check the normal distribution of interval-scaled variables. Descriptive statistics were applied to all parameters. For continuous variables, measures such as sample size (n), mean, and standard deviation were reported. For categorical data, results were presented as frequency counts and percentages.

Group comparisons at baseline (for demographic, clinical, and anthropometric data) were carried out using independent samples t-tests and Pearson chi-square tests.

Two key clinical outcomes were defined:

A 50% reduction in the HAMD total score from baseline was considered an “antidepressive response.”

A HAMD total score of 7 or lower indicated “remission.”
Group differences in response and remission rates were analyzed using Pearson chi-square tests.

To evaluate the effects of the two interventions (GET and SOA) over time

The primary and secondary outcomes included measures of depression, well-being, physical activity, and exercise-related parameters.

Depression-Related Data:

Antidepressive Response and Remission: At 3 weeks, 38.9% of the GET group showed a significant reduction in depression (≥50% reduction in HAMD total score), while 25% of the SOA group showed similar results. However, the difference between the two groups was not statistically significant. At 6 weeks, the percentage of patients showing an antidepressive response was 54.5% in the GET group and 55.6% in the SOA group, with no significant difference observed between the groups.

Regarding remission, defined as a HAMD total score of ≤7, there was a significant difference at 3 weeks. The GET group had a 27.8% remission rate, compared to 10% in the SOA group ($p = 0.046$). However, after 6 weeks, remission rates were 40.9% in the GET group and 25.9% in the SOA group, with no significant difference.

Primary Outcome Parameter (HAMD total score): The analysis of the HAMD total score revealed no significant interaction between the intervention type and time ($p = 0.091$), suggesting no clear difference between the GET and SOA groups over time. However, a substantial main effect for time was found ($p < 0.0005$, partial $\eta^2 = 0.66$), indicating that both groups showed a significant reduction in depression symptoms across the three periods. Furthermore, a significant main effect

on multiple outcomes—such as depression (HAMD, PSP, WHO-5) and exercise-related parameters (functional performance tests, BFS, WSBB, FKB-20, FAHW)—a mixed-design ANOVA (between-subjects and within-subjects) was conducted across three time points: baseline, 3 weeks, and 6 weeks. Prior to these analyses, Levene's test was performed to assess equality of variances. Cohen's effect size guidelines were applied to interpret the magnitude of treatment effects. A significance level of 5% ($p < .05$) was used for all statistical tests.	comparing the interventions was found ($p = 0.017$, partial $\eta^2 = 0.12$), suggesting that the GET group experienced a greater reduction in depression symptoms than the SOA group. Secondary Outcome Parameters: A significant interaction between time and group was found for the PSP total score ($p = 0.002$), indicating that the GET group showed greater improvement in social functioning than the SOA group. For the WHO-5 total score, no significant interaction was found ($p = 0.175$), although both groups showed significant improvements over time ($p < 0.0005$, partial $\eta^2 = 0.59$). At the item level, significant improvements were noted for three PSP items: "socially useful activities" ($p < 0.0005$, partial $\eta^2 = 0.41$), "personal and social relationships" ($p < 0.0005$, partial $\eta^2 = 0.36$), and "disturbing and aggressive behavior" ($p = 0.012$, partial $\eta^2 = 0.18$). In the HAMD scale, significant interactions favored the GET group in reducing early insomnia (HAMD 4, $p = 0.048$), middle insomnia (HAMD 5, $p = 0.022$), psychomotor retardation (HAMD 8, $p = 0.029$), and psychological anxiety (HAMD 10, $p = 0.019$). Furthermore, the GET group demonstrated superiority in reducing suicide risk (HAMD 3, $p = 0.028$), time of diurnal variation (HAMD 18a, $p = 0.003$), and severity of diurnal variation (HAMD 18b, $p = 0.027$). Exercise-Related Data: Weekly Physical Activity: During the first 3 weeks, participants in the GET

	group engaged in 615.18 ± 520.38 minutes of SOA, whereas the SOA group engaged in 878.55 ± 688.1 minutes. There was no significant difference between the groups during this period. However, in weeks 4 to 6, the SOA group increased their physical activity to 897.22 ± 562.96 minutes, while the GET group reduced their activity to 568.57 ± 325.6 minutes. This difference was significant ($p = 0.022$), indicating that the SOA group continued to engage in more physical activity after the structured intervention period. Secondary Outcome Parameters: A significant interaction effect was observed for the Unipedal Stance Test, showing superiority of the SOA group ($p = 0.017$). There were no significant interaction effects for the Timed Up-and-Go Test or the Sit-and-Reach Test, although substantial main effects for time were noted for both tests: $p = 0.025$ for the Timed Up-and-Go Test (partial $\eta^2 = 0.16$) and $p = 0.002$ for the Sit-and-Reach Test (partial $\eta^2 = 0.25$). On a subdimensional level, significant interaction effects in favor of the GET group were found for BFS anger ($p = 0.003$), BFS tension ($p = 0.009$), FKB-20 body vitality ($p = 0.04$), and FAHW physical ill-being ($p = 0.027$), indicating that the GET group showed greater improvements in emotional well-being and physical health. Additionally, there was a substantial main effect for time for most exercise-related parameters, although no significant differences were observed between the two groups.

Before conducting the main analyses, the researchers calculated propensity scores to adjust for potential selection bias. These scores were based on baseline covariates previously shown to influence dropout and treatment outcomes, including age, education, race, physical health, psychotic symptoms, drug use, trauma history, emotional instability, interpersonal issues, and overall quality of life. The scores were later used as covariates in the regression models to control for these pre-existing differences between treatment groups. Insight Change Over Time To assess whether insight changed during therapy, a multilevel modeling (MLM) strategy was used to account for the nested data structure (multiple measurements per participant). Although the model initially included therapist as a random effect, it failed to converge and showed no variability at the therapist level. As a result, the final model used a 2-level structure: repeated measurements nested within patients. This model predicted insight based on the session number, and found meaningful between-patient variability (ICC = .17), justifying the MLM approach. Concurrent Changes in Insight and Depression The next step examined whether changes in insight occurred alongside changes in depression symptoms. Change scores (difference from baseline to month 2, and from baseline to month 5) were calculated for both insight and depressive severity. Despite concerns in the literature about the reliability of difference scores, the researchers noted that these	At baseline, there were no significant differences between treatment groups in depression severity (HAM-D: $t(98) = 1.3$, $p = .18$) or insight (ICR: $t(98) = 0.9$, $p = .39$). Over the course of treatment, insight significantly increased in the SE (Supportive-Expressive) group ($p < .05$), but not in the CT (Cognitive Therapy) group ($p = .60$). A marginally significant interaction was found between session number and treatment type, suggesting that insight gains were more prominent in SE than CT. The effect size for session number on insight in SE was modest (partial $r = .20$). Concurrent changes in insight and depressive symptoms were examined, but baseline depression severity emerged as the only consistent predictor of improvement ($p < .05$), indicating that more severely depressed patients improved more. Critically, gains in insight from baseline to month 2 predicted subsequent reductions in depression severity from month 2 to month 5 in SE ($p < .05$, partial $r = -.211$), but not in CT ($p = .88$, $r = -.02$). This supports the hypothesis that insight plays a significant role in therapeutic change in SE, but not in CT.

concerns are less relevant when standard deviations vary across timepoints, as is common in treatment studies. Again, meaningful variability was only observed at the patient level (ICC = .51), leading to the use of a 2-level hierarchical model that predicted depression severity from concurrent changes in insight. Temporal Sequence of Change Finally, the researchers explored the temporal order of change by testing whether early changes in insight (baseline to month 2) predicted later changes in depressive symptoms (month 2 to month 5). A linear regression model was used for this analysis, introduced in three steps: Step 1: Included the main effects. Step 2: Adjusted for propensity scores and treatment length (when relevant). Step 3: Tested for treatment-specific effects using interaction terms between treatment type (coded as 0 = SE, 1 = CT) and insight change. Statistical Estimation All models were estimated using the Maximum Likelihood (ML) method. Partial correlation coefficients were calculated to quantify the unique contribution of each predictor variable, controlling for other variables in the model. Analyses were conducted using R software with the lme4 and lmerTest packages.	

To evaluate the comparability of randomized treatment groups at baseline, researchers conducted statistical comparisons across demographic and clinical variables. For continuous or ordinal variables, analyses of variance (ANOVA) or Kruskal-Wallis tests were employed, depending on distributional characteristics. For categorical variables, chi-square (χ^2) tests were used. These same statistical approaches were applied to compare individuals who completed the study with those who dropped out, based on their baseline characteristics. All statistical tests were conducted using a two-tailed alpha level of .05. The primary strategy for assessing treatment efficacy utilized mixed effects linear regression models. These models were selected for their flexibility in handling unequal numbers of observations per participant and for their ability to accommodate changes in symptom severity over the course of the trial. The models incorporated two random effects (intercept and slope) to account for individual variability in symptom trajectories, along with fixed effects for treatment condition, study site, time, and response status at the end of phase 1 (categorized as either partial remission or non-remission). To explore potential differences in treatment effects over time, interaction terms (treatment × time) were added to the models, and log-likelihood ratio tests were used to assess whether these interaction terms significantly improved model fit. The first set of regression models was designed to examine the effects of	In total, 808 patients enrolled in phase 1 of the study, of whom 632 (78.2%) completed this phase. Among them, 491 participants (77.7%) did not achieve remission and were subsequently enrolled into phase 2. The demographic and clinical characteristics of these 491 participants were generally well-balanced across the three randomized treatment groups. The only significant baseline difference observed was a slightly higher proportion of white participants in the group receiving combined psychotherapy and medication (CBASP or BSP) compared to the medication-only group. Patients assigned to the Brief Supportive Psychotherapy (BSP) condition attended an average of 13.1 (SD = 7.0) therapy sessions, while those in the Cognitive Behavioral Analysis System of Psychotherapy (CBASP) group attended an average of 12.5 (SD = 6.6) sessions. Across all treatment arms, the mean number of pharmacotherapy visits was consistent, ranging from 5.2 to 5.4 sessions. Adherence to treatment protocols was high, with only one CBASP session (and none in the BSP or pharmacotherapy arms) rated as insufficient. When examining the effects of treatment on social problem-solving abilities, as measured by the Social Problem Solving Inventory–Revised (SPSI-R), significant differences emerged among the three treatment conditions. Improvements over time in overall SPSI-R scores and all subscales—except for Negative Problem Orientation—were observed. Patients receiving CBASP plus medication demonstrated significantly

treatment condition on social problem-solving outcomes over time, as measured by the SPSI-R. The second set of models investigated whether the relationship between social problem-solving abilities and subsequent depressive symptoms (measured via the HAM-D) varied by treatment condition. In these latter models, SPSI-R scores were lagged by two weeks to predict later depressive symptom levels. For instance, SPSI-R scores from week 2 were used to predict HAM-D scores at week 4, week 4 SPSI-R scores predicted week 6 HAM-D scores, and so on, with week 10 SPSI-R scores predicting HAM-D outcomes at week 12.	greater improvements in total SPSI-R scores over time compared to those receiving BSP plus medication (coefficient = 0.0999; $p < .001$). A trend toward greater improvement was also noted compared to the medication-only group (coefficient = 0.0614; $p = .09$). In contrast, there was no significant difference in improvement between the BSP plus medication and medication-only groups. Calculated Cohen's d values indicated medium-sized effects for CBASP compared to the other conditions (.34 vs. BSP and .29 vs. medication alone), while the effect between BSP and medication alone was negligible (d = .03). Analysis of SPSI-R subscales revealed that CBASP plus medication led to significantly greater increases in rational problem solving and positive problem orientation compared to both BSP plus medication and medication alone. For rational problem solving, CBASP outperformed BSP (coefficient = .4993; $p < .001$) and medication alone (coefficient = .1052; $p = .02$). For positive problem orientation, CBASP again showed superiority over BSP (coefficient = .1201; $p = .001$) and medication alone (coefficient = .1052; $p = .02$). However, BSP plus medication did not differ from medication alone on either of these subscales. Interestingly, patients receiving BSP plus medication demonstrated significantly less change over time in avoidant problem solving and impulsivity/carelessness than those receiving CBASP plus medication and medication alone. For avoidant problem solving, BSP showed less improvement than CBASP ($p = .01$) and medication alone ($p = .04$). Similarly, BSP participants showed less improvement in

	impulsivity/carelessness than those receiving CBASP ($p < .01$), with a trend-level difference compared to medication alone ($p = .09$). In contrast, CBASP and medication-only groups did not significantly differ from one another in terms of avoidant or impulsive/careless problem-solving trajectories. To investigate whether social problem solving predicted subsequent depressive symptoms over time, the researchers conducted longitudinal analyses using lagged models. Given that treatment condition did not significantly influence changes in the Negative Problem Orientation subscale, this component was excluded from further analysis. In the model analyzing total SPSI-R scores, three significant predictors of depressive symptoms—as measured by the Hamilton Depression Rating Scale (HAM-D)—emerged: Time was a significant predictor, with depressive symptoms decreasing across assessments (coefficient = −.4804, $p < .001$). Phase 1 response status significantly predicted outcomes, showing that patients who had entered phase 2 as non-responders experienced greater reductions in HAM-D scores compared to partial responders (coefficient = −6.7573, $p < .001$). Total SPSI-R score significantly predicted future depressive symptoms, indicating that improvements in social problem solving were associated with lower depressive symptoms at subsequent time points (coefficient =

	−.3136, p < .001). In contrast, treatment condition and study site were not significant predictors of depressive symptom trajectories in these models. Further analyses of SPSI-R subscales supported the overall findings. Across subscales, time and phase 1 response status remained significant predictors of HAM-D scores, while site and treatment condition did not contribute meaningfully. Specifically: Positive problem orientation was associated with a reduction in depressive symptoms (coefficient = −.1320, p = .007). Avoidant and impulsive/careless problem-solving styles were associated with higher subsequent depressive symptoms (coefficient = .1466, p < .001 and coefficient = .0800, p = .008, respectively). In contrast, rational problem solving was not a significant predictor of future depressive symptoms.

Statistical Package for the Social Sciences (SPSS) for Windows version 18.0 was used for statistical analysis. Where data were continuous, parametric analysis such as the unpaired t-test was employed and where data were categorical, non- parametric analysis such as the chi-squared test/Fisher exact test was used. In order to compare the time to relapse, we used Kaplan–Meier survival analysis and Cox proportional hazard analysis to control for possible confounders. We showed the results of the intention-to-treat sample for these survival analyses. The 'end' point HRSD-17, BDI-II, CGI severity and GAF scores were compared between the intervention and control groups among the completers.	the majority of subjects were in their middle age and in a mildly depressive state. Comparison of the variables between the two groups showed no significant differences regarding demographic variables such as sex, age, education, living conditions (i.e., living with family/others or living alone), time from home to the hospital and clinical variables such as duration of illness, baseline HRSD-17, BDI-II, CGI severity or GAF scores. Kaplan–Meier survival analysis showed that time to relapse was significantly longer in the intervention group than in the control group (Log-rank chi-squared=.48, df=1, P=.011). The median time to relapse was 274 days for the intervention group and 221 days for the control group. The crude risk ratio of relapse by 9 months was 0.12 (95% confidence interval (CI); 0.02–0.87, P=.015), corresponding with a number needed to treat (NNT) of 3.2 (95%CI: 2.8–21.4). In order to control for possible confounders, they conducted Cox proportional hazard analysis by entering sex, age, illness duration, baseline HRSD-17 score, baseline antidepressant dosage and intervention; only intervention emerged as a significant predictor of the time to relapse (hazard ratio, HR=.091, 95%CI: 0.01–0.87, P=.038). There were no significant differences between relapsers and non-relapsers in terms of other variables such as sex, age, education, living conditions, baseline HRSD-17, BDI-II scores and baseline dose of antidepressant(s). All the HRSD-17, the BDI-II, the CGI severity and the GAF scores were statistically significantly better in the intervention group than in the control group while controlling for their respective baseline scores. The CGI-improvement score was also significantly better in the psychoeducation group.

	Sensitivity analyses were conducted by substituting the missing 9-month follow-up data for HRSD-17, BDI-II, CGI severity and GAF by their baseline values. Again, all the scores were significantly better in the intervention group than the control group. The rate of remitted patients in the intervention group was 10 out of 17 (58.8%) and that in the control group was two out of 10 (20.0%), indicating no significant difference between the two groups (Fisher's exact test; P=.110). Among the completers, the baseline dose of antidepressant tended to be higher in the control group but was not significantly different between the intervention and the control groups (mean (S.D.) amitriptyline equivalent dose of 107.5 (52.8) vs. 134.0 (71.5) mg; t=1.89, P=.072). At 9 months, the mean (S.D.) dose of antidepressant in the intervention group was 102.7 (59.2) mg and that in the control group 124.0 (57.1) mg, showing again no difference between the groups (F=.079, P=.78).

The SPSS program v.25 for Windows was used to perform statistical analyses. Data is presented as N (%) for categorical variables, such as gender, marital status, education level etc., and as mean and standard deviation (SD) for quantitative variables, such as age, BMI etc. The Pearson's chi-square test was used for the assessment of differences between categorical variables. Normality of data distribution was tested and, as it was violated, the non-parametric Mann-WhitneyU test was used for assessing the differences of baseline quantitative variables and measurements based on the group that participants were assigned to. In addition, measurements' change (final measurement-baseline measurement) was calculated and differences between the intervention and control group were estimated with the non-parametric Mann-Whitney U test. For assessing the differences within each group (intervention and control) the non-parametric Wilcoxon test was used. The effect size of the intervention was calculated for each measurement with the formula effectsize r = $Z/\sqrt{N}$. Values of effectsize < 0.3 were considered to be low, from 0.3 to 0.5 moderate and over 0.5 high. The level of significance was set at 0.05 for all the analyses.	Thirty patients of the intervention group and 32 patients of the control group participated in the final measurements and were analyzed. The intervention group's patients showed medium (practicing 2–4 times a week) or high (practicing 5–7 times a week) adherence to PSAI, as reported in the personal weekly diaries. The post-hoc power analysis which was performed based on this study's results revealed 85.3% power to detect between groups difference in BDI scores. Regarding participants' sociodemographic characteristics, there were no significant differences between intervention and control group at the beginning of the study. At baseline no significant group differences were found, except for a higher score in Visual memory (BVMTR) for control group ($p = 0.049$) and a marginally higher score in the Social and mental balance subscale of HLPCQ for intervention group ($p = 0.050$). (Δ = final measurement–baseline measurement). Significantly lower scores were noted for the intervention group in ΔDepression (BDI) ($p = 0.001$) with moderate effectsize ($r = 0.41$), in ΔNegative affect (PANAS) ($p = 0.001$) with moderate effectsize ($r = 0.41$), in ΔStress (DASS) ($p = 0.040$) with low effectsize ($r = 0.29$) and in ΔSleep Quality (PSQI) ($p = 0.002$) with moderate effectsize ($r = 0.46$). Moreover, the intervention group demonstrated significantly higher scores in ΔVisual memory (BVMTR) ($p < 0.0001$) with moderate effectsize ($r = 0.48$), in ΔDietary healthy choices (HLPCQ) ($p = 0.002$) with moderate effectsize ($r = 0.42$), in ΔDietary harm avoidance (HLPCQ) ($p = 0.015$) with moderate effectsize ($r = 0.32$), in ΔDaily routine (HLPCQ) ($p = 0.001$) with moderate effectsize ($r = 0.48$), in ΔOrganized physical exercise (HLPCQ) ($p < 0.0001$) with high effectsize ($r = 0.53$), in ΔSocial and

	mental balance (HLPCQ) ($p = 0.005$) with moderate effectsize ($r = 0.37$), and in ΔHealthy lifestyle (HLPCQTotal) ($p < 0.0001$) with high effectsize ($r = 0.60$). In addition, the intervention group demonstrated higher score in ΔHair cortisol ($p = 0.359$) and lower scores in ΔFirst morning salivary cortisol ($p = 0.081$), ΔSecond morning salivary cortisol ($p = 0.493$) and ΔNight salivary cortisol ($p = 0.624$). However, between groups differences in hair and salivary cortisol concentrations were non-significant. Both the intervention and control group demonstrated significant augmentations between the first and the second measure- ment in Information processing speed (SDMT) ($p < 0.0001$) and in Verbal memory (CVLT-II) (intervention group-$p = 0.002$, control group-$p = 0.024$). Additionally, Depression (BDI) ($p < 0.0001$), first morning salivary cortisol ($p = 0.029$), Negative affect (PANAS) ($p < 0.0001$), Stress (DASS) ($p = 0.012$), Depression (DASS) ($p = 0.007$), and Sleep Quality (PSQI) ($p < 0.0001$) were significantly reduced in the inter-vention group. Furthermore, Visual memory (BVMTR) ($p < 0.0001$), Dietary healthy choices (HLPCQ) ($p = 0.001$), Dietary harm avoidance (HLPCQ) ($p = 0.022$), Daily routine (HLPCQ) ($p = 0.001$), Organized physical exercise (HLPCQ) ($p < 0.0001$), Social and mental balance (HLPCQ) ($p = 0.001$), and Healthy lifestyle (HLPCQTotal) ($p < 0.0001$) were found significantly increased in the intervention group. No sig- nificant change was found in hair cortisol concentration (intervention group-$p = 0.150$, control group-$p = 0.472$).

Data were coded, input to the Statistical Package for the Social Sciences (SPSS), version 18, and analyzed using descriptive statistics (mean and standard deviation) and inferential statistics (mixed analysis of variance for repeated measures). It should be noted that the data analysis process was blinded.	Results demonstrated significant improvements in key psychological variables in the experimental group, with most improvements persisting over time. Group Comparisons and Preliminary Analyses There were no significant differences between the experimental and control groups in terms of sex, age, education, or marital status. Tests for normality (Kolmogorov-Smirnov) and homogeneity of variances (Levene's test) confirmed that assumptions for parametric analysis were met ($p > 0.05$). Main Outcome Measures and Statistical Findings 1. Depression (Beck Depression Inventory - BDI) Pre- to post-test (experimental group): Significant reduction of 27.66 points ($p = 0.001$) Pre-test to follow-up: Significant reduction of 26.66 points ($p = 0.001$) Post-test to follow-up: No significant change ($p = 0.79$), indicating stability over time Control group: Minor improvements from pre- to follow-up (5.88 points, $p = 0.04$), but significantly less than the experimental group 2. Depression (Hamilton Depression Rating Scale - HDRS)

	Pre- to post-test (experimental group): Significant reduction of 15.66 points (p = 0.001) Pre-test to follow-up: Significant reduction of 16.33 points (p = 0.001) Post-test to follow-up: No significant change (p = 0.72) Control group: No significant changes across any time points (p-values = 1) 3. Ruminative Response (RRS) Experimental group: Pre- to post-test: Significant reduction of 24.22 points (p = 0.001) Pre-test to follow-up: Significant reduction of 27.88 points (p = 0.001) Post-test to follow-up: Not significant (p = 0.62) Control group: Pre- to post-test: Small but significant reduction (8.66 points, p = 0.001) Pre-test to follow-up: Slightly larger reduction (11.33 points, p = 0.001) Post-test to follow-up: Not significant (p = 0.172)

	4. Self-Compassion (SCS-SF) Experimental group: Pre- to post-test: Significant improvement of 17 points (p = 0.001) Pre-test to follow-up: Significant improvement of 21.55 points (p = 0.001) Post-test to follow-up: No significant change (p = 0.60) Control group: Pre- to post-test: Small but significant improvement (2.88 points, p = 0.041) Pre-test to follow-up: Slightly larger improvement (4.22 points, p = 0.006) Post-test to follow-up: Not significant (p = 0.28) 5. Mindfulness (Southampton Mindfulness Questionnaire - SMQ) Experimental group: Pre- to post-test: Significant increase of 27 points (p = 0.002) Pre-test to follow-up: Significant increase of 40.88 points (p = 0.001)

	Post-test to follow-up: Continued improvement (13.88 points, p = 0.001) Control group: No significant changes observed at any time point (p-values ranging from 0.31 to 0.88) Mixed-Design Repeated Measures ANOVA Results All interaction effects between time and group were statistically significant (p = 0.001) for all variables (BDI, HDRS, RRS, SCS, SMQ), indicating that the experimental group improved more over time than the control group. The effect sizes (Eta squared) were notably large for all outcomes: Depression (BDI): 0.79 Depression (HDRS): 0.84 Self-compassion: 0.93 Ruminative response: 0.50 Mindfulness: 0.80

The study's data will be analyzed using both the intent-to-treat and treatment completers approaches, with intent-to-treat serving as the primary analytic strategy. This ensures that all participants are included in the analyses according to their assigned conditions, regardless of whether they completed the full intervention. To address missing data and handle the complexity of the data structure, mixed-effects modeling will be the central analytic method. This approach allows for the inclusion of all available data points over time and provides a robust way to examine changes in outcome measures. The main outcomes—emotion regulation (ER) and depressive symptom severity—will be assessed over time using growth curve modeling, based on multiple measurement points: before (T1–T5) and during individual cognitive behavioral therapy (CBT) (T6–T10). This will enable the evaluation of both stand-alone and augmentation effects of ART. It is hypothesized that participants in the ART condition will show steeper positive slopes in ER and greater reductions in depressive symptoms compared to both active control and waitlist control groups. These findings would support ART's effectiveness in enhancing adaptive ER skills and reducing depressive symptom severity. In secondary analyses, the effects of ART on broader indicators of mental health—such as psychological well-being, positive affect, and negative affect—will be evaluated.	

To explore the mechanisms of change, bootstrapped multilevel mediation analyses will be conducted to test whether improvements in emotion regulation mediate the health benefits observed in the ART group. These analyses will consider both a total score of ER skills and individual ER skills separately, providing insights into which specific skills contribute most to the observed outcomes. Further, moderated mediation analyses will examine whether the effectiveness of individual ER skills depends on personal characteristics or other variables, helping to identify potential moderators of ART's impact. Advanced statistical techniques like latent growth curve modeling and latent change score modeling will also be used to investigate reciprocal relationships between ER changes and health outcomes over time. To account for potential confounding variables, measures of general self-efficacy, perfectionism, self-esteem, and comorbid symptom severity will be included in the analyses as moderators. Additionally, analyses of ecological momentary assessment (EMA) data and experimental and biological measures will help strengthen the overall validity of the ART evaluation. Finally, a Structural Equation Modeling (SEM)-based Multi-Trait, Multi-Method (MTMM) approach will be used to examine the	

psychometric properties of the assessment tools and compare outcomes obtained through different measurement methods.	

11.9. Table 9: Full text data-analysis SMACC-attributes

1: Does your self-management programme allow the person to actively participate in the care process?	2: Does your self-management programme allow the person to take responsibility in the care process?	3: Does the self-management programme provide scope to accommodate setbacks the person faces?	4: Does the self-management programme inform the person about their condition, illness and treatment?	5: Can the person in the self-management programme express their needs, set values and priorities?	6: Does the self-management programme promote an open partnership between the care providers?	7: Does the self-management programme address the person's openness to receive social support?	8: Does the self-management programme inform the person that this is a lifelong task?	9.1: Problem solving	9.2: Decisionmaking	9.3: Use resources	9.4: ability to work in partnership with health care professional	9.5: setting and evaluating goals	10.1: medical management	10.2: Emotional management	10.3: Role management
aanwezig	aanwezig	Gedeeltelijk	aanwezig	aanwezig	Gedeeltelijk	aanwezig	Gedeeltelijk	aanwezig	aanwezig	aanwezig	Gedeeltelijk	aanwezig	aanwezig	aanwezig	Gedeeltelijk

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Gedeeltelijk aanwezig	niet aanwezig	Gedeeltelijk aanwezig	aanwezig	niet aanwezig	niet aanwezig	niet aanwezig	niet aanwezig	aanwezig	niet aanwezig	Gedeeltelijk aanwezig	niet aanwezig	aanwezig	niet aanwezig	aanwezig	Gedeeltelijk aanwezig