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Schema therapy versus any control condition for adult mental disorders: a systematic review with meta-analysis and trial sequential analysis

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Abstract

Background

Schema therapy is a transdiagnostic psychotherapy targeting complex psychiatric disorders. Previous literature reviews have been on selected mental disorders only and primarily narrative. This systematic review with meta-analysis is the first to synthesize evidence for schema therapy for a wide range of psychiatric disorders.

Methods

Randomized clinical trials comparing schema therapy with active and passive control conditions were included. Primary outcomes were mental disorder symptoms and quality of life. Secondary outcomes were level of functioning, serious adverse events, and treatment dropout. For the meta-analysis, continuous outcomes were summarized as standardized mean differences and dichotomous outcomes as risk ratio, both presented with their 95% confidence intervals.

Results

18 trials (1275 participants) were included. Eight trials were eligible for quantitative synthesis. We found no evidence of a difference between schema therapy and control conditions on the primary outcomes at end of treatment: symptom severity (personality disorders: SMD: -0.55, 95% CI:-1.28-0.18, *p* = 0.14; four trials; N = 517; Bayes factor: 0.34; very low certainty) (depression: SMD: -1.11, 95% CI:-3.25 to 1.04, *p* = 0.31, two trials; N = 166; Bayes factor: 0.64; very low certainty) and quality of life (SMD: 0.02, 95% CI:-0-14 to 0.19, *p* = 0.77; three trials; N = 593; Bayes factor: 367,0; very low certainty), nor on any secondary or exploratory outcomes.

Conclusions

No evidence for differential effects between schema therapy and control conditions was found for any outcomes. More high-quality trials are needed before schema therapy can be recommended for broader clinical implementation.

Study registration

The protocol for this study was preregistered on April 22nd, 2025 (PROSPERO CRD420251015725).

Introduction

Mental disorders remain a worldwide problem, with recent estimated point prevalences of 12.6% according to the World Health Organization [1, 2] and a life time prevalence of 29% across low, middle and high income populations worldwide [3]. Further, mental disorders are a burden for the individual as well as for society [4, 5], with 143.5 million years lost to disability globally every year.

Several psychotherapies have been established as effective for a wide range of mental disorders, both in combination with pharmacological interventions and as stand-alone treatments [6–10]. However, a substantial group of patients does not respond to first-line psychotherapies [11, 12], possibly due to complex and enduring psychological patterns that require more targeted psychotherapies in order to be treated effectively [12].

Schema therapy was developed to address complex mental health issues such as chronic disorders rooted in maladaptive personality functioning [13, 14]. Schema therapy is transdiagnostic by nature in that it targets early developed cognitive, emotional, and behavioral destructive patterns (called early maladaptive schemas and schema modes) proposedly underlying mental health issues. Techniques from cognitive behavior therapy are synthesized with elements from emotion-focused, psychodynamic, and Gestalt therapies for in-depth experiencing and emotional processing. This allows for healing of childhood trauma and unmet needs, allowing for more fundamental psychological changes [13].

Preliminary evidence for schema therapy has been presented in several systematic reviews across a variety of disorders [15–21]. However, syntheses were primarily narrative, based on scarce evidence (e.g., case series, single arm trials, and only few randomized controlled trials), mostly focused on selected disorders only, and with methodological limitations [22]. As research on schema therapy has increased in recent years [23], we found it timely for a methodologically robust review that include the most recent evidence. Further, the current review is, to our knowledge, the first to quantitatively synthesize the evidence for schema therapy for a wide range of the most commonly treated mental disorders.

The present systematic review with meta-analysis therefore aims to investigate the positive and negative effects of schema therapy for a wide range of mental disorders, updating and upgrading past reviews with state-of-the-art methodology, including assessment of the risk for systematic and random errors, and the certainty of findings.

Methods

This review was registered before initiating the literature search and data extraction (PROSPERO ID: CRD420251015725). Deviations from the published protocol [22] are stated in the section ‘Differences between the protocol and the review’-section. Reporting follows the guidelines in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement [24]. A PRISMA 2020 checklist can be found in the Supplementary Material.

Search strategy and selection criteria

Electronic searches

An experienced information specialist searched the Cochrane Central Register of Controlled Trials (CENTRAL), Medical Literature Analysis and Retrieval System Online (MEDLINE), Excerpta Medica database (EMBASE), PsycINFO, Science Citation Index Expanded (SCI-EXPANDED), Social Sciences Citation Index (SSCI), Conference Proceedings Citation Index—Science (CPCI-S), Conference Proceedings Citation Index—Social Science & Humanities (CPCI-SSH), and the Latin American and Caribbean Literature on Health Sciences database (LILACS). The International Society for Schema Therapy database at https://schematherapy.omeka.net/ was hand-searched by the first author (IMA), with the search ending on September 1st, 2025 (the database has not been updated since). All other databases were searched from their inception to June 17th, 2026. For a detailed description of the search strategy, see Supplementary Material.

Searching other resources

The reference list of all included trial publications and all identified reviews on schema therapy were searched for additional trials. Www.clinicaltrials.gov was searched for unpublished trials, and corresponding authors of included trials were contacted to enquire about further unpublished trials.

Data collection

Data extraction and management

Titles and abstracts were screened independently by two authors (IMA and PF) using the screening software Covidence. Relevant full-text papers were screened independently by authors IMA and either PF or BS (interchangeably). Disagreements were resolved by consulting the last author (SBM). Articles that were not in English were translated with Artificial Intelligence translation engines [25-28] with assistance from native speakers (see Acknowledgments).

Data, including relevant background data, were extracted independently by two authors (IMA and PF) and entered in a data extraction sheet [22]. If relevant data were unclear or not reported, corresponding trial authors were contacted.

Inclusion and exclusion criteria

Randomized controlled clinical trials investigating schema therapy against control conditions were included, with no restrictions on setting, year of publication, publication status, or language. The included study population was participants of 18 years of age and older with a primary mental disorder or neurodevelopmental disorder: anxiety disorders, attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder, depressive and bipolar disorders, dissociative identity disorder, eating disorders, obsessive-compulsive disorder, personality disorders, post-traumatic stress disorder, psychotic disorders, or substance use disorders (diagnosed using the *International Statistical Classification of Diseases and Related Health Problems*, 11th ed. (ICD-11)[29], The Diagnostic and Statistical Manual of mental disorders, Fifth version (DSM-5)[30], or earlier versions). Psychiatric or physical comorbidities were not exclusion criteria.

Studies were included if schema therapy was provided by human therapists, defined as 'schema therapy' or 'schema-focused therapy' by the authors *and* incorporated substantial schema therapy interventions (e.g., experiential work). Trials investigating only discrete components of schema therapy (e.g., imagery rescripting) and trials where schema therapy was merged with other treatments (e.g., psychomotor therapy) were excluded.

Control conditions could be either attention control/'psychological placebo' (e.g., supportive therapy), Treatment As Usual (TAU), or no intervention/waitlist. As the aim was to establish the effectiveness of schema therapy, control conditions consisting only of another established psychotherapy (e.g., a trial investigating schema therapy versus psychodynamic therapy where both therapies underwent formal quality and adherence checks) were not eligible for inclusion. This followed the Cochrane Handbook for Systematic Reviews of Interventions guidelines [31]: 'The first two types of comparisons [psychological placebo or a control group such as usual care or no intervention] aim to establish the effectiveness of an intervention, while the last [intervention A vs intervention B] aims to compare the effectiveness of two interventions'.

Outcomes and subgroup analyses

The primary outcomes were symptom severity for the trial's primary diagnosis and quality of life.

Secondary outcomes were serious adverse events (SAE) as defined by the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use - Good Clinical Practice guidelines [32]), level of functioning, and premature treatment dropout as defined by study authors. Trials with wait list or no treatment as control were not included in the dropout analyses since dropout from these conditions was not deemed a meaningful comparison (in effect a trial (not a treatment) dropout). Exploratory outcomes were self-harm, suicide or suicide-attempt, psychiatric hospitalizations, early maladaptive schemas, and schema modes. Our primary time point of interest was at end of treatment (EOT), and secondarily the trial's longest follow-up (FU). If multiple measures for the same outcome were administered, a predefined outcome hierarchy was consulted [22].

Planned subgroup analyses included trials with high vs low risk of bias, different psychotherapy formats (e.g., group, individual), different control conditions (no intervention/waitlist versus specialized TAU (defined as TAU being the best available, but not quality/adherence controlled treatment in the particular context) versus 'psychological placebo'/supportive therapy (understood as consisting of mainly of non-specific therapeutic factors)), and persistent (characterological or developmental, e.g., personality disorder) versus episodic disorders (e.g., major depression).

Assessment of statistical and clinical significance

Meta-analyses followed recommendations by the Cochrane Handbook for Systematic Reviews of Interventions [33], Keus et al. [34], and the procedure for validation of results by Jakobsen et al. [35]. These procedures were similar to those in reviews stemming from the Copenhagen Trial Unit to which the author SJ is affiliated, e.g. [36-38]. STATA version 19.5 Basic Edition and Trial Sequential Analysis [39] were used for analyses.

Continuous outcomes were planned to be summarized as mean differences (MD) with a planned trial sequential analysis-adjusted confidence interval (CI) for identical measurement instruments, or as standardized mean differences (SMD) with 95% CI where the same outcome was measured with different instruments. For dichotomous outcomes, we calculated a risk ratio (RR) and trial sequential analysis-adjusted CI. For trials with multiple schema therapy groups, the number of events and sample size of the control group were divided for dichotomous outcomes to avoid double-counting the control group results, while for continuous outcomes, we divided the sample size and kept the mean and standard deviation (SD) of the control group. Intervention effects were assessed with both random-effects meta-analyses [40] and fixed-effect meta-analyses [41] with the main result being the most conservative of the two (largest *p*-value, secondarily narrowest CI) [35]. To correct for multiple testing, the threshold for statistical significance was set at $p < 0.025$ for the two primary outcomes [35]. Secondary and exploratory outcomes were considered hypothesis-generating and therefore evaluated using a significance threshold of $p < 0.05$. Symptom outcomes were analyzed separately for each mental health disorder. All analyses are displayed in forest plots.

Best-worst/worst-best scenarios were planned as sensitivity analyses for assessing the impact of missing outcome data (see review protocol [22]). For continuous outcomes, a "beneficial" or "harmful" outcome was pragmatically defined as the group mean +/- one or two SD (in two separate sensitivity analyses).

Certainty of evidence was assessed with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) [35, 42-44]. Of these, imprecision was assessed by using Trial Sequential Analysis (TSA) when possible (30, 31), and risk of bias with the Cochrane Risk of Bias - version 2 (RoB2) criteria [33]. Risk of bias and GRADE-assessments were made independently by two authors (PF and IMA) and in case of disagreement, consensus was found through discussion. Reporting bias assessments were planned if ten or more trials were included [22].

For continuous outcomes with identical measurement instruments, TSA was planned to control for random errors [39, 45, 46] using the observed SD, an MD equal to the observed SD/2, an alpha of 2.5% for the primary outcomes and 5% for the remaining outcomes, a beta of 20%, and the observed diversity as suggested by the trials. For dichotomous outcomes, the diversity-adjusted required information size (DARIS; the number of participants needed in a meta-analysis to detect or reject a specific intervention effect) was estimated based on the observed proportion of patients with an outcome in the control group, a relative risk reduction of 20%, an alpha of 2.5% for the primary outcomes and 5% for the remaining outcomes, a beta of 20%, and the observed diversity as suggested by the trials.

Heterogeneity was assessed using visual inspection of forest plots, the chi-squared test (threshold $p < 0.10$), and the I^2 statistic [33, 47, 48]. Preplanned subgroup analyses explored potential sources of heterogeneity. Post hoc analyses were added if deemed necessary to investigate unexplained heterogeneity and were considered exploratory.

Differences between the protocol and the review

The Latin American and Caribbean Literature on Health Sciences database (LILACS) was added to the search.

Symptoms of all personality disorders were analyzed together, decided in the light of recent developments moving toward conceptualizing personality disorders as a unitary, dimensional construct rather than separate syndromal categories (see e.g. [49]), but also pragmatically given the scarcity of trials.

Results

Study characteristics

The database literature search was conducted on June 17th 2026. 5037 records were identified. Additionally, 30 papers were found through other sources. After removal of 1817 duplicates, title and abstract screening of 3250 papers, and full text screening of 64 papers, 19 individual trials were included in the review, of which eight entered quantitative analyses. The 46 excluded and five non-obtainable papers are listed in the Supplementary Material. Figure 1 shows a PRISMA flow chart describing the screening process.

Eight studies investigated effects of schema therapy on personality disorders [50-57], of which five studies focused on borderline personality disorder [50-52, 55, 57]. Three studies assessed schema therapy for depression [58-60], while three studies investigated schema therapy for substance use and comorbid personality disorder [61-63] and one study investigated schema therapy for substance use only [64]. Effects of schema therapy for posttraumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), generalized anxiety disorder (GAD), and social anxiety were assessed by one study each

[65-68]. Countries of origin included Iran (nine studies) [55, 57, 59, 60, 64-68], USA (four studies) [52, 61-63], Netherlands (two studies) [53, 54], Finland, Germany, United Kingdom (one study each) [50, 56, 58], and one international study had sites in Australia, Germany, Greece, and Netherlands [51]. Seven studies applied individual schema therapy [53-56, 61-63], seven studies used a group format only [50, 52, 60, 65-68], while three studies did not report the format [57, 59, 64]. Two studies combined group and individual schema therapy [51, 58]. Control conditions were TAU (of which the TAU for three trials included best practice psychotherapies [51, 53, 54], (e.g., following treatment guidelines and/or providing evidence-based treatments), while the TAU of five studies was less specialized or systematically provided [50, 56, 61-64]). Thow studies had supportive therapy/counselling or similar as an active control [52, 58], while eight studies had control groups with waitlist or no treatment [55, 57, 59, 60, 65-68]. Number of sessions varied widely, ranging from 10 [60, 67, 68], to 212 sessions [53], with a median of 24 sessions. 11 studies only reported results at EOT [50, 53, 55, 59-63, 65-67], while eight studies had a FU of 3-12 months after EOT [51, 52, 54, 56-58, 64, 68]. Characteristics of the included trials are found in Supplementary Table 1.

Regarding risk of bias, most trials were assessed as at *some concerns for bias* for the dropout outcome, mostly due to lack of information about deviation from interventions and no predefinition of dropout. All other outcomes in all trials were assessed as at *high risk of bias* with the exception of one trial [58] where depression symptoms, level of function, dropout, and SAE were evaluated as *at low risk of bias*. *High risk of bias* was most often caused by a high amount of missing data with insufficient sensitivity analyses to rule out potential bias, and lack of blinding of outcome assessors (often because the outcome was measured via self-report, meaning that assessors were the unblinded participants themselves). Figure 2 shows a full account of risk of bias per trial and outcome [69].

We could only perform one TSA for the outcome treatment dropout. For other dichotomous outcomes, the information size was too small (>5% of DARIS) to make a TSA graph, and continuous outcomes were measured on heterogeneous outcomes measures and therefore synthesized with SMD, meaning that a TSA was not possible.

The GRADE-assessed certainty of evidence was assessed as very low for all outcomes and time points. Downgrading was due to risk of bias, inconsistency, and imprecision (see Supplementary Material, Table 2).

Outcomes that did not qualify for meta-analysis

Of the 19 included trials, 11 trials could not be included in the meta-analyses: Four trials did not report outcomes relevant for the present study [55, 60, 64, 65]. Four trials did not report outcomes in a usable format for meta-analysis [56, 57, 62, 63], i.e., raw EOT or FU scores with SDs for continuous outcomes, and number of events for dichotomous outcomes. Three trials reported outcomes on symptoms for three different anxiety disorders (GAD, OCD, and social anxiety, respectively)[66-68]. These disorders were estimated as too heterogeneous to be synthesized in a meta-analysis. Further, one trial only reported data in a usable format for part of the outcomes [53]. Only one trial reported on the outcomes

psychiatric hospitalizations, self-harm and *schemas* in a usable way [51]. See Supplementary Material sections *'Trials that did not qualify to enter the meta-analyses'* and *'Outcomes that did not enter the meta-analyses'* for further details.

Meta-analyses results

Due to space constraints, all meta-analytic results not presented in this article are in the Supplementary Material, including the alternative model to the primary result (i.e., if a random effects model found the most conservative result, the corresponding fixed effects model result is presented in the Supplementary Material, and vice versa). Summary of findings for all outcomes is found in the Supplementary Material, Table 2.

Primary outcomes

Symptoms

Due to sparsity of data, it was only possible to perform meta-analyses on two symptom outcomes: Personality disorders and depression.

Personality disorders

Four trials (N=517) had data eligible for quantitative analyses on symptoms. Three trials included patients with borderline personality disorder [50-52] and one trial included patients with cluster C and histrionic, narcissistic, and paranoid personality disorders [54]. Details on outcome measures are shown in Supplementary Material, Table 1.

Random effects meta-analyses showed no evidence of a difference between schema therapy and control conditions for personality disorder symptoms either at EOT (SMD -0.55, 95% CI:-1.28-0.18, p=0.14, four trials, Bayes factor: 0.34; very low certainty of evidence) (Fig. 3) or at FU (SMD -0.60; 95% CI: -1.67 to 0.48; p = 0.28; three trials; very low certainty; see Supplementary Material, Fig. 2). Visual inspection of forest plots and I^2 showed very high heterogeneity (EOT: I^2 =93,75%; FU: I^2 =96.2%) at both time points, indicating substantial inconsistency of results.

Depression

Two trials (N=166) had data eligible for quantitative analyses on symptoms. Risk of bias was assessed as low for one trial [58] and as high for the other trial [59]. It should be noted that the latter trial suffers from poor reporting and is published in a non-indexed, possibly predatory journal, which could mean that the result's validity is compromised.

Random effects meta-analysis showed no evidence of a difference between schema therapy and control conditions on depression symptoms at EOT (SMD -1.11, 95% CI:-3.25 to 1.04, *p*=0.31, two trials, Bayes factor: 0.64; very low certainty) (Fig. 4). Visual inspection of forest plots and I^2 showed very high heterogeneity (I^2 =96.03%).

Quality of life

Three trials (N=593) with patients with personality disorders [51, 54] and depression [58] had data eligible for quantitative analyses on quality of life. All used the self-report WHO-QoL measure, but different versions. Therefore, SMD was used for the analyses.

Random effects meta-analysis showed no evidence of a difference between schema therapy and control conditions on quality of life at EOT (SMD 0.02, 95% CI:-0-14 to 0.19, *p*=0.77, three trials, Bayes factor: 367,0; very low certainty) (Fig. 5) or at FU (SMD 0.06, 95% CI: -0.18 to 0.30 , *p*=0.64, three trials, very low certainty, Supplementary Material, Fig. 6)). Visual inspection of forest plots and I^2 showed low heterogeneity at EOT (I^2 =7.69%, chi^2: *p*=0.78), and substantial, but not statistically significant heterogeneity at FU (I^2 =48.98, chi^2: *p*=0.12).

Secondary outcomes

Level of functioning

Four trials (N=611) with patients with personality disorders [51, 53, 54] and depression [58] had data eligible for quantitative analyses on level of functioning. The outcome was assessed as at low risk of bias for one trial [58], and for three trials as at high risk of bias [51, 52, 54].

Fixed effects meta-analysis showed no evidence of a difference between schema therapy and control conditions on level of functioning at EOT (SMD 0.05, 95% CI:-0.11 to 0.21), *p*=0.55, four trials, very low certainty). Random effects meta-analysis showed no evidence of a difference between schema therapy and control conditions at FU (SMD 0.50; 95% CI: -0.46 to 1.46; *p*=0.30; four trials; very low certainty). Visual inspection of forest plots and I^2 showed substantial heterogeneity at EOT (I^2=60.11%) and very high heterogeneity at FU (I^2=96.18%) (See Supplementary Material, Fig. 8 & 10).

Treatment dropout

Seven trials (N=1235) with patients with personality disorders [50-54], substance abuse [61], and depression [58] had data eligible for quantitative analyses on treatment dropout. The outcome was rated as at low risk of bias for one trial [58], at some concern of bias for five trials [51-54, 61], and at high risk of bias for one trial [50].

Random effects meta-analysis showed no evidence of a difference between schema therapy and control conditions (RR 0.83; 95% CI: 0.56 to 1.23; *p*=0.35; seven trials; very low certainty) (See Supplementary Material Fig. 12). Visual inspection of forest plots and I^2 showed very high heterogeneity (I^2 =80.03%).

The TSA showed that not enough information was collected to confirm or reject realistic intervention effects regarding treatment dropout (required information size: 8550 participants; the TSA graph is displayed in Fig. 6).

Serious adverse events

Four trials (N=915) with patients with personality disorders [51, 53, 54] and depression [58] had data eligible for quantitative analyses on SAE. Outcomes from three trials were assessed as at high risk of bias [51, 53, 54] and from one trial as at low risk of bias [58].

Random effects meta-analyses found no evidence of a difference between schema therapy and control conditions in SAE during treatment (RR 0.94; 95% CI: 0.22 to 4.00; *p*=0.94; four trials; very low certainty) or the FU period (RR 1.63; 95% CI: 0.24 to 10.96; *p*=0.61; two trials; very low certainty) (See Supplementary Material Fig. 14 & 16). Visual inspection of forest plots and I^2 showed low heterogeneity for SAE as outcomes both during treatment (I^2 =6.13%) and after treatment (I^2= 20.47%).

Exploratory outcomes

Meta-analyses on suicides or suicide attempts during treatment showed no evidence of a difference between schema therapy and control conditions (three trials, high risk of bias, very low certainty of evidence (for details and forest plot, see Supplementary Material: '*Exploratory outcomes - Meta-analysis of suicide and suicide attempts* ', and Supplementary Fig. 18).

Meta-analyses on changes in healthy or dysfunctional schema modes at EOT and FU showed no evidence of a difference between schema therapy and control conditions (three trials, high risk of bias, very low certainty of evidence (as shown in the Supplementary Material, '*Exploratory outcomes - Meta-analysis of healthy and dysfunctional schema modes at end of treatment and follow-up'* and Fig. 20, 22, 24 & 26).

Subgroup analyses

High vs low risk of bias

We were only able to perform one of the preplanned subgroup analysis on two trials with symptoms of depression (low risk of bias [58]) and (high risk of bias [59]), as the trial outcomes of personality disorder symptoms [50-52] and quality of life [51, 54, 58] were all evaluated as at high risk of bias.

A subgroup analysis with a fixed-effects model showed a statistically significant difference ($Q_b(1)=26.06$, p >0.001) where the depression symptoms outcome in trials at high risk of bias had higher effect estimates than trials at low risk of bias at EOT (see forest plot in Supplementary Material Fig. 28).

Treatment As Usual, 'psychological placebo', or no treatment as comparator

For this subgroup analysis, four trials had outcomes eligible for comparison of treatment effects on personality disorder symptoms [50-52, 54] and three trials for quality of life [51, 54, 58]. Also, two trials were eligible for the comparison on depression symptoms; however, these were the same trials as in the above analysis of risk of bias [58, 59] and are therefore not reported again in this section.

A subgroup analysis fixed-effects model showed that using a non-specific supportive therapy as control condition gave higher effects for schema therapy than in trials were treatment as usual was control for reducing personality disorder symptoms at EOT ($Q_b(1)=17.82$, p>0.001, four trials), and at FU ($Q_b(1)=21.41$, p >0.001, three trials (see forest plots in Supplementary Material Fig. 30 & 32).

A subgroup analysis random-effects model found no evidence of a difference in quality of life between trials using treatment as usual and a non-specific supportive therapy control condition, at EOT ($Q_b(1)=0.24$, p=0.78), nor at FU using a fixed-effects model ($Q_b(1)=0.28$, p=0.60) (see forest plots in Supplementary Material Fig. 34 & 36).

Group versus individual schema therapy

Three trials were entered in group versus individual schema therapy subgroup analysis on personality disorders symptoms [50, 52, 54]. A subgroup analysis random-effects model showed no evidence of a difference between individual and group schema therapy at EOT ($Q_b(1)=3.42$, p=0.06, three trials). At FU, the group format was significantly more effective (fixed-effects model): $Q_b(1)=26.53$, p >0.001 (two trials) (see forest plots in Supplementary Material Fig. 38 & 40).

Treatment effects on persistent versus episodic disorders

Three trials were eligible for comparison of effects on quality of life in patients with personality disorder [51, 54] (persistent disorder) and depression [58] (episodic disorder), respectively. A subgroup analysis random-effects model showed no evidence of a difference at EOT ($Q_b(1)=0.24$, p=0.63) nor at FU (fixed-effects model, $Q_b(1)= 0.28$, p=0.60) (see forest plots in Supplementary Material Fig. 42 & 44).

Sensitivity analyses

For depression and personality disorder symptoms, random-effects meta-analyses of the best-worst case scenarios shifted the statistically non-significant main results to significant results in favor of schema therapy (except for best-worst (1SD) for depression, p=0.06). In the worst-best case scenarios, the results remained statistically non-significant (see Supplementary Material, Fig. 46-53).

For quality of life, random-effects meta-analyses of the best-worst case scenarios shifted the statistically non-significant main results to significant results in favor of schema therapy, while worst-best case scenario meta-analyses shifted the results in the opposite direction, to significant results in favor of TAU (see Supplementary Material, Fig. 54-57).

Post hoc exploratory analyses

The meta-analyses on personality disorder symptoms showed very high heterogeneity (EOT: I^2 = 93.75%); FU: I^2=96.92). Visual inspection of the forest plots revealed one small trial (N=32) with unusually large effect sizes [52]. When excluding this trial, meta-analyses for both EOT and FU reduced heterogeneity while maintaining the statistically non-significant result (see Supplementary Material, Fig. 58-59).

Discussion

This systematic review and meta-analysis investigated the effects of schema therapy compared to active control interventions or no treatment on a wide range of mental disorders. A total of 19 trials were eligible for inclusion in the review, whereof eight trials had data suitable for meta-analysis, randomizing a total of 1275 participants.

The meta-analyses found no evidence of a difference between schema therapy and control conditions on this study's primary outcomes (symptoms of personality disorders (four trials) or depression (two trials); quality of life (three trials)), secondary outcomes (level of functioning (four trials), treatment dropout (seven trials), and serious adverse events (four trials), or exploratory outcomes (suicide or a suicide-attempt (three trials), healthy or dysfunctional schema modes (three trials). The GRADE-rated certainty of evidence was very low for all outcomes due to risk of bias, inconsistency, and imprecision.

This study's results do not support suggestions of promising effects of schema therapy by previous (primarily narrative) reviews [15–21]. But neither can they be interpreted as evidence for lack of effect: Effect size estimates were in some cases (e.g., symptoms) moderate to large, and the Bayes factors (0.34 for personality disorder and 0.64 for depression symptoms) do not rule out a possible beneficial effect of schema therapy over control conditions on disorder symptoms. However, our analyses in the current study were likely underpowered: confidence intervals were generally wide, and TSA results for dichotomous outcomes showed insufficient information sizes to draw conclusions.

Several subgroup analyses were conducted to investigate possible effect moderators and sources of heterogeneity. No evidence for differential effects was found on quality of life between persistent disorders (i.e., personality disorders) and episodic disorders (i.e., episodic depression). This is in line with previous meta-analyses showing almost identical effect sizes for psychotherapy on quality of life in depression [70] and personality disorders [71]. Note that the trial representing 'episodic disorders' in our analysis included quite complex cases of severe depression requiring inpatient treatment after having received more than two previous treatments on average.

Next, subgroup analyses contrasting trials with different control conditions showed that effect sizes on schema therapy for personality disorder symptoms were *higher* in trials with supportive therapy or no treatment as control conditions, rather than trials with (mostly specialized) TAU as control. This partly contrasts a recent Cochrane review on psychotherapy trials control conditions [72] which found that effect sizes of 'psychological placebo' *itself* (administering common factors of psychotherapy without active components) were higher than for both usual care and no treatment/waitlist, meaning that psychological placebo as a comparison in our case would give *lower* effect estimates of schema therapy. One possible explanation is that TAU in the included trials was more specialized and intensive, and therefore more effective than 'usual care' in the Cochrane review, making it harder to detect an additional benefit of schema therapy. However, the discrepancy may also reflect the influence of a single, small trial that represents 'supportive therapy' control [52] in our meta-analyses, which showed unusually high effect sizes for schema therapy. This interpretation is supported by two findings: the reduction in heterogeneity when that trial was removed in post hoc sensitivity analyses, and that no differences were found in effects in the quality-of-life analysis where the supportive treatment control condition was represented by a large, high-quality trial with more plausible effects [60]. Accordingly, both the subgroup effect by control condition and the apparent superiority of group schema therapy over individual therapy for personality disorder symptoms at FU should be considered provisional.

Finally, we conducted best-worst/worst-best sensitivity analyses to assess the potential impact of data missing not at random (e.g., participants that get better in schema therapy do not attend follow-ups, and participants that get worse in TAU do not attend follow-ups). The analyses show that the impact of missing data could be substantial: schema therapy's effects on symptoms may have been underestimated in our analyses, and effects on quality of life may be vastly different in the favor of either schema therapy or the control condition. Missing data is a notorious issue in most psychotherapy research, but the inclusion of 'hard' binary outcomes such as serious adverse events extracted from registries or medical journals could supplement data subject to loss to follow-up [73].

This study's strengths include preregistration of the trial protocol (PROSPERO CRD420251015725) and a rigorous methodology which considered the risk for both random and systematic errors. Article screening, data extraction and inclusion of trials were done independently by two authors, ensuring adherence to the protocol's inclusion and exclusion criteria and minimizing risks of faulty exclusion of eligible trials or inaccurate data entering the meta-analyses. Our pre-defined outcome hierarchy ensured that our selection of outcome variables was not data driven. Using the Risk of Bias-2 tool enabled

separate risk of bias-assessment of different outcomes that may vary substantially within a trial, e.g., evaluations by blinded assessors vs self-report by unblinded patients. The eight-step procedure by Jakobsen et al. [35] and the GRADE-framework ensured both the methodological and clinical robustness of our results.

The body of evidence has several limitations: Most outcomes were estimated as at high risk of bias, meaning possible underestimation of the harmful effects of schema therapy (i.e., for SAE) and overestimation of beneficial effects (i.e., bettering of symptoms, quality of life, and other related parameters). Further, the lack of trials and insufficient reporting of eligible data meant that we were not able to perform all planned analyses. Finally, the heterogeneity of continuous outcome measures and limited reporting of dichotomous outcomes meant that only one Trial Sequential Analysis could be performed. Therefore, the hypothesis that lack of data was the primary reason for not finding treatment effects could not be tested for most outcomes.

This study also has limitations. First, we did not distinguish between reasons for treatment dropout in the meta-analyses. This means that the many reasons why a patient may terminate treatment prematurely - deterioration of the condition, dissatisfaction with treatment, external factors (e.g., the patient moving away), or conversely, substantial bettering of condition before EOT – were not considered, possibly distorting the findings. Second, we were not able to assess publication bias towards non-publications of null or negative findings as this requires a minimum of ten trials in a meta-analysis [35]. Third, the use of the medically oriented Cochrane Risk of Bias-tool may be considered less suited for evaluation of psychotherapeutic trials. A tool tailored specifically to psychotherapy quality assessment (e.g., [74]) may have given more appropriate estimates of risk of bias. Fourth, the methods in this aggregate meta-analysis did not correct for skewness of data distribution, differences in baseline measurements, site effects and other factors that the individual trials' analyses could correct for. A future direction could be to perform individual patient data meta-analyses to take these factors into account.

The present study had end of treatment as its primary endpoint, and many treatment periods were relatively short. However, schema therapy is usually considered a long-term treatment, and effects may occur only after years of treatment for the complex cases that it aims to treat. Although the current study also investigated effects after follow-up, this was a secondary outcome, and follow-ups may not have been long enough to capture differences in later-occurring and longer-lasting effects between schema therapy and control groups.

This review only included trials with conditions that were not bona fide therapies, e.g., Cognitive Behavioral Therapy as this provides the baseline for evaluating whether schema therapy offers benefit beyond usual care and non-specific influences (see 'Inclusion and exclusion criteria'). Searching the literature, we came across several trials that compared schema therapy to other therapies with no formal control groups as defined by the Cochrane Handbook (e.g.,[75–79]). Further, several trials attempted to investigate the effects of schema therapy combined with other treatments, making it impossible to

discern the effects of schema therapy itself (e.g., [80–85]). While it is understandable that schema therapy researchers and clinicians have been curious to investigate how schema therapy might relate to or be combined with other approaches, such comparisons may be premature before the effectiveness of schema therapy on its own has been clearly established. In line with recommendations from a recent Delphi study on schema therapy research [86], we therefore recommend conducting further randomized trials that investigate schema therapy compared to Treatment as Usual or other active control conditions. Trials should report raw (i.e., unchanged) scores at EOT and FU time points along with their SDs so the results can be used in future meta-analyses. Efforts should be made to minimize potential risk of bias (e.g., ensuring blinding of outcome assessors, predefinition and preregistration of analyses and outcomes, and minimization of missing data).

This study has implications for clinical practice: The evidence base from trials comparing schema therapy with active and passive control conditions is not yet strong enough to justify recommending broader implementation in routine clinical practice. Schema therapy remains a promising treatment and cannot yet be reliably framed as 'evidence-based' for patients seeking psychotherapy. However, current limited evidence for superiority over control conditions should not be interpreted as evidence that schema therapy is proven ineffective. The evidence also does not suggest that schema therapy is less effective or more harmful than other psychotherapies. Schema therapy may therefore still be offered where clinically appropriate, guided by patient preferences and needs, therapist competence and availability, and clinical indication, e.g., a theoretical match to the model (strong schemas, modes, problematic personality traits, childhood adversity), particularly when used as a second line-treatment.

Conclusions

The current body of evidence is insufficient to draw conclusions regarding the beneficial and harmful effects of schema therapy. More randomized controlled trials of high quality, comparing schema therapy to control conditions with sufficiently long treatments and follow up periods, are still needed to establish the effects of schema therapy and recommendations for wider clinical implementation.

Abbreviations

ADHD = Attention-Deficit/Hyperactivity Disorder

BPD = Borderline Personality Disorder

CENTRAL = Cochrane Central Register of Controlled Trials

CI = Confidence Interval

CPCI-S = Conference Proceedings Citation Index—Science

CPCI-SSH = Conference Proceedings Citation Index—Social Science & Humanities

DARIS = Diversity-Adjusted Required Information Size

DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

EOT = End of Treatment

EMBASE = Excerpta Medica Database

FU = Follow-Up

GAD = Generalized Anxiety Disorder

GRADE = Grading of Recommendations Assessment, Development and Evaluation

ICD-11 = International Statistical Classification of Diseases and Related Health Problems, 11th Revision

ICH-GCP = International Council for Harmonisation – Good Clinical Practice

ISST = International Society for Schema Therapy

LILACS = Latin American and Caribbean Literature on Health Sciences

MD = Mean Difference

MEDLINE = Medical Literature Analysis and Retrieval System Online

OCD = Obsessive-Compulsive Disorder

PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PTSD = Post-Traumatic Stress Disorder

QoL = Quality of Life

RoB2 = Cochrane Risk of Bias - version 2 tool

RR = Risk Ratio

SAE = Serious Adverse Event

SCI-EXPANDED = Science Citation Index Expanded

SD = Standard Deviation

SMD = Standardized Mean Difference

SSCI = Social Sciences Citation Index

TAU = Treatment As Usual

TSA = Trial Sequential Analysis

WHO-QoL = World Health Organization Quality of Life Instrument

YSQ = Young Schema Questionnaire

Declarations

Ethics approval and consent to participate

This study did not require approval from an ethics committee or written informed patient consent.

Availability of data and materials

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Competing interests

IMA has received funding for and published research on schema therapy.

PF, SJ, BS and CH have no conflicts of interest to declare.

MV provides workshops and lectures on Schema Therapy (schema therapy). He is also on the executive board of the ISST 2024-2026, where he gets a fee for the voluntary work and is a part of the Dutch Society of Schema Therapy (VST). Furthermore, MV has received funding for and published research on schema therapy and receives publishing fees for books about schema therapy. MV is a schema therapy practitioner and works at a clinic that provides schema therapy.

JK has provided workshops and lectures on schema therapy and has received funding for and published research on schema therapy.

BB is a practitioner of schema therapy and works in a clinic that provides schema therapy. BB has received publishing fees for books about schema therapy. Furthermore, BB has received funding for and published research on schema therapy.

AA has provided workshops and lectures on schema therapy and received fees from societies that are promoting schema therapy. AA has received publishing fees for books about schema therapy and has received funding for and published research on schema therapy. The renumeration goes to the university to support research. Furthermore, he is a practitioner of schema therapy.

SBM has received funding for and published research on schema therapy, is a member of the International Society for Schema Therapy (ISST) and a practitioner of schema therapy.

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Authors' Contributions

IMA is the guarantor of the project and conceptualized this study, developed the methodology, collected the data, made Risk of Bias and GRADE assessments, performed the statistical analyses, administered the project, and drafted and revised the manuscript. PF developed the methodology, collected the data, made Risk of Bias and GRADE assessments, supervised the statistical analyses, and revised the manuscript. SJ developed the methodology, supervised the statistical analyses, and revised the manuscript. CH developed the methodology and revised the manuscript. BS collected the data and revised the manuscript. MV, BB, AA, and JK revised the manuscript. SBM conceptualized the study, developed the methodology, and revised the manuscript.

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Figures

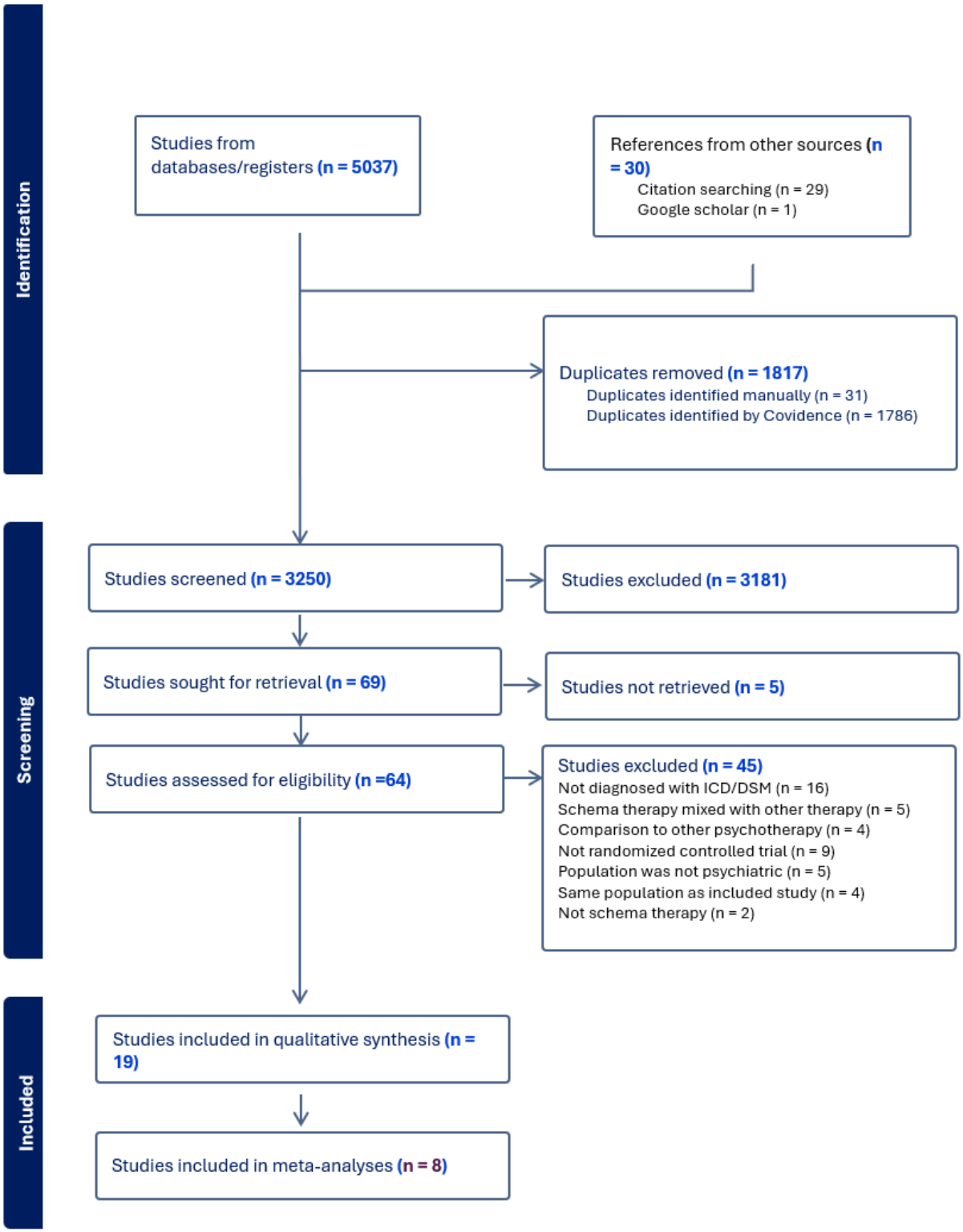


Figure 1

PRISMA flow chart.



Figure 2

Risk of Bias-table.

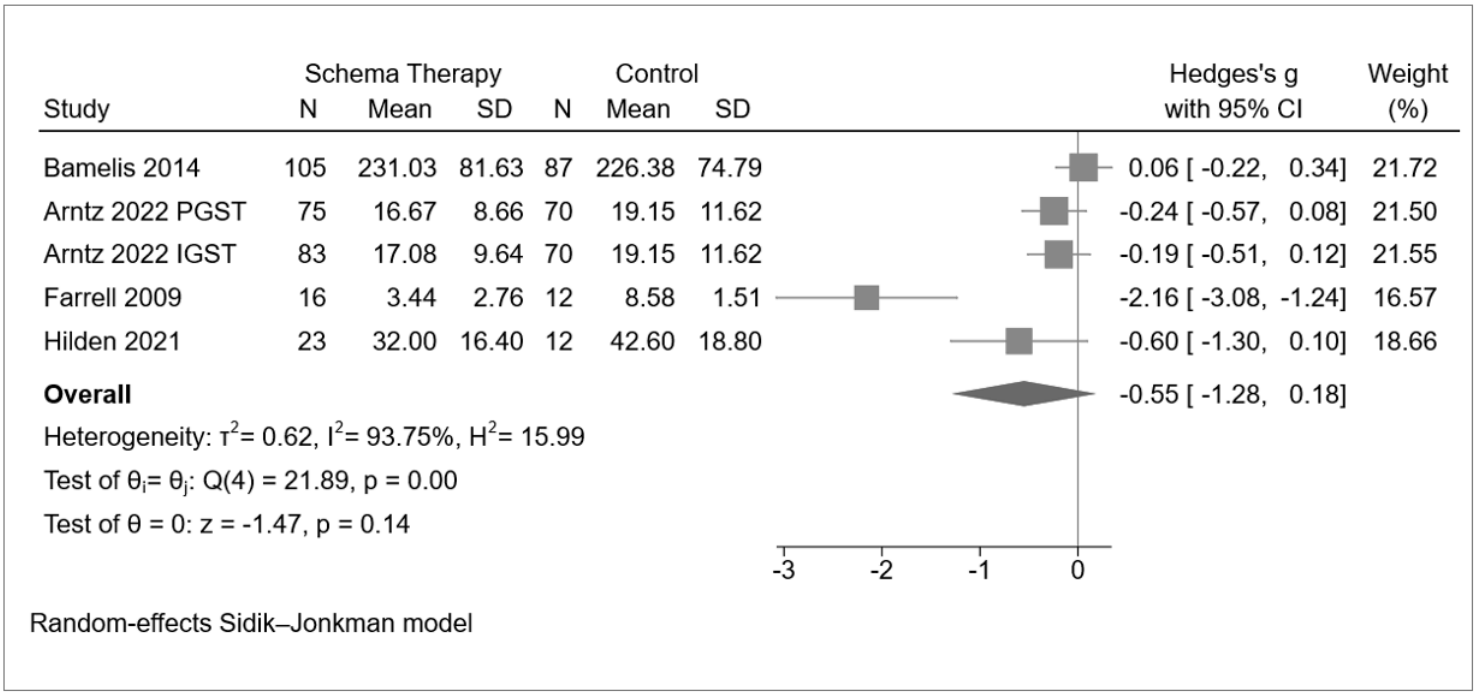


Figure 3

Forest plot, personality disorder symptoms at end of treatment. CI: Confidence Interval; SD: Standard Deviation; IGST: Combined individual and group schema therapy; PGST: Predominantly group schema therapy

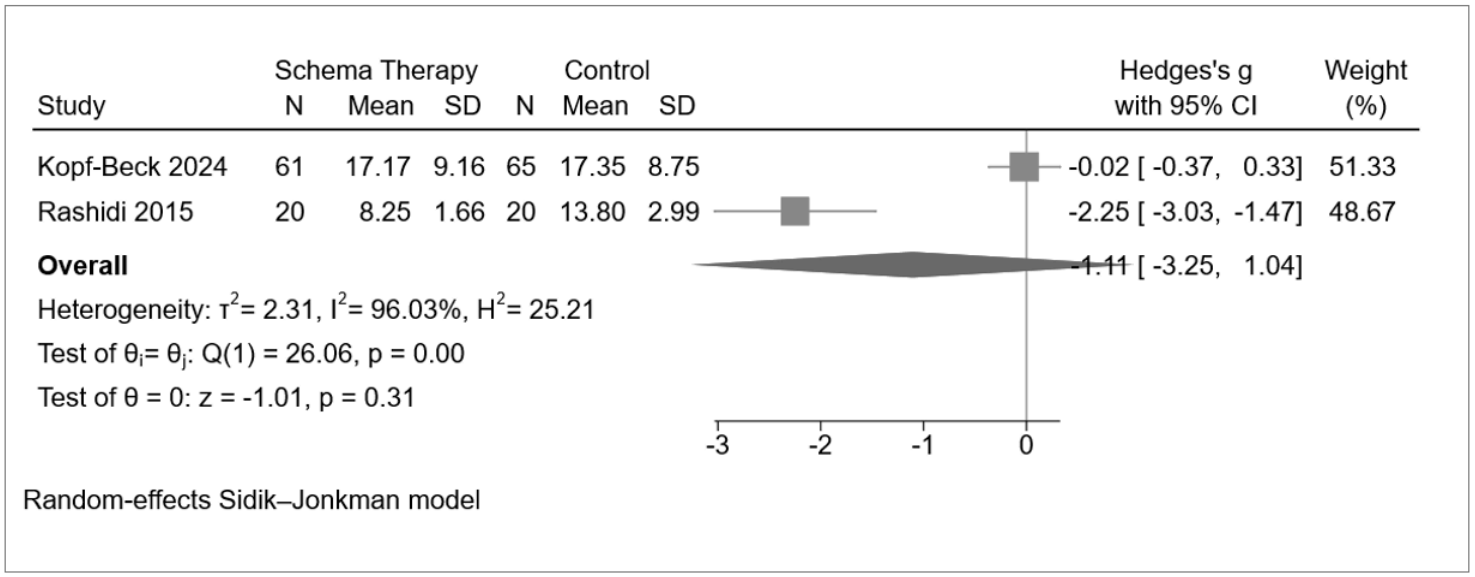


Figure 4

Forest plot, depression symptoms at end of treatment. CI: Confidence Interval; SD: Standard Deviation

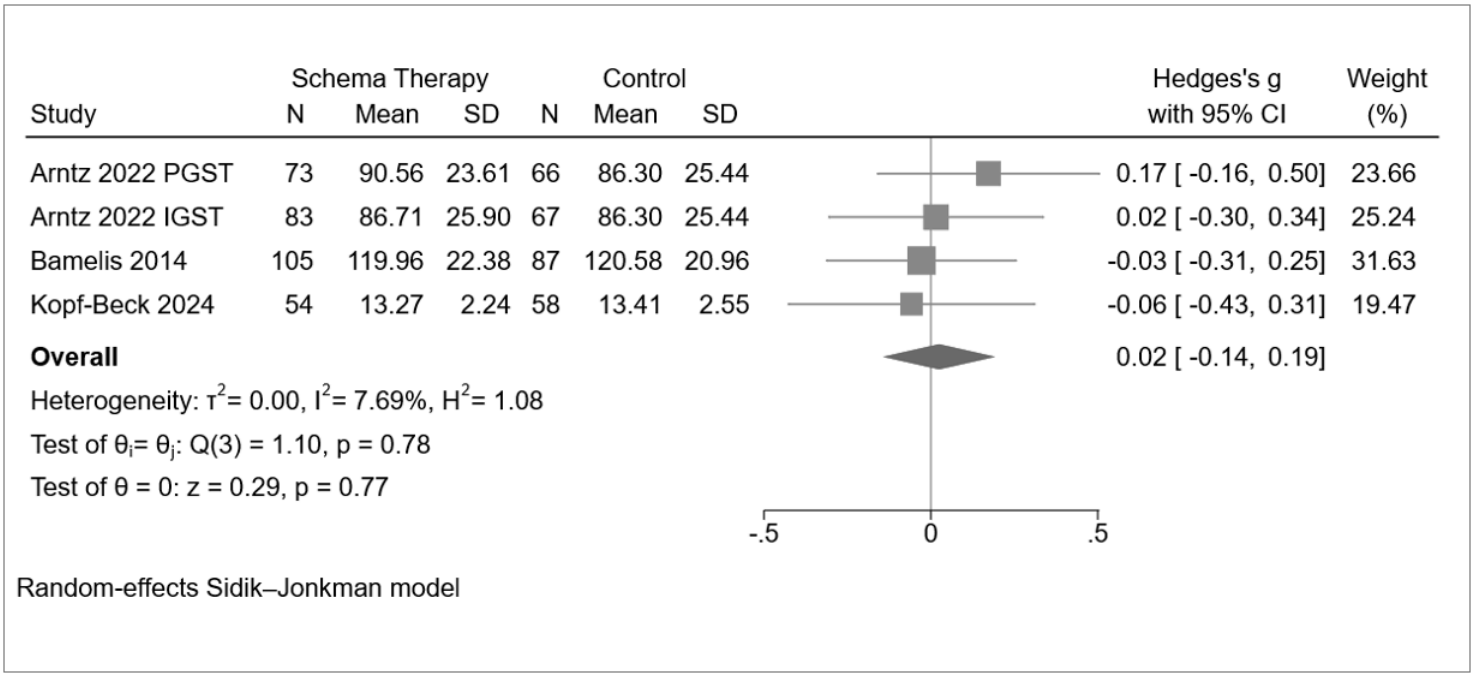


Figure 5

Forest plot, quality of life at end of treatment. CI: Confidence Interval; SD: Standard Deviation; IGST: Combined individual and group schema therapy; PGST: Predominantly group schema therapy

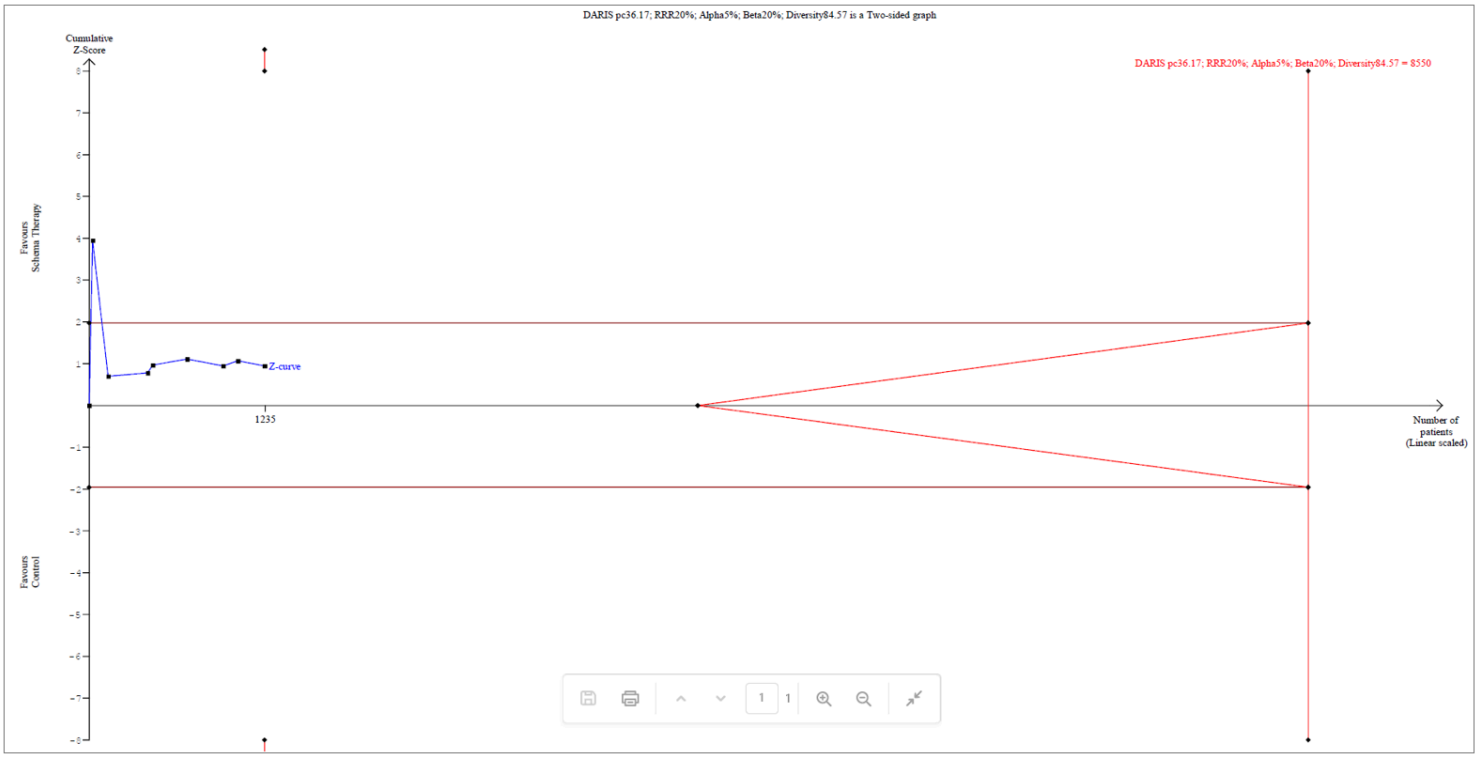


Figure 6

Trial Sequential Analysis, dropout of treatment. DARIS pc: Diversity-Adjusted Required Information Size; RRR: Relative Risk Reduction

Supplementary Files

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- ArendtBMCPsychiatrySUPPLEMENTARYMATERIAL.docx
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