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Unguided self-help based on metacognitive training and mindfulness-based interventions targeting auditory verbal hallucinations in persons with psychotic disorders: a randomized controlled trial

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Abstract

Self-help may increase access to psychological care for schizophrenia spectrum disorders (SSDs) and auditory verbal hallucinations (AVHs). We aimed to examine the efficacy, satisfaction, and safety of an unguided, digital self-help intervention based on metacognitive training and mindfulness-based interventions, targeting AVHs in SSDs. Participants were randomized to either the intervention ($SH_{MBI\text{-}MCT}$; n=43) or waiting list control (WL; n=43) group. We found no significant difference between groups in the primary outcome *overall severity of AVHs* in the intention-to-treat (ITT) but per-protocol (PP) analysis (F (3, 69) = 21.02, p = .040, η^2_p = 0.06), favoring $SH_{MBI\text{-}MCT}$ with a medium effect size. Overall, $SH_{MBI\text{-}MCT}$ was observed to be superior in different clinical outcomes, especially in PP analyses. Satisfaction, retention, and adherence of the intervention was high, and reports on (S)AEs and side effects indicated safety of the treatment. Results underpin the importance of individual formulation-based implementation of unguided approaches. Future fully powered trials are needed to verify our results.

Trial registration ClinicalTrials.gov. NCT06186570.

Key words. auditory hallucinations, psychosis, schizophrenia, SSD, self-help, psychological interventions, participant-involvement, randomized controlled trial.

Introduction

Schizophrenia spectrum disorders (SSDs) are associated with functional impairment[1], significant burden of disease[2,3], and considerable challenges for the global healthcare system[4]. Auditory verbal hallucinations (AVHs) are considered one of the hallmark symptoms of SSDs[5,6], with an estimated lifetime prevalence of 64-80% in SSD samples[7]. Although a coherent definition of AVHs remain scares, they are described as auditory perception of speech without external stimulation of the sensory organ[8]. Since they occur in various clinical and non-clinical populations, they can be conceptualized as a fluid experience ranging from ordinary to pathological stages[9]. Phenomenological features of AVHs are markedly heterogenous, comprising acoustic qualities, loudness, location, perceived controllability, and content[10,11]. They are commonly associated with increased distress and functional interferences in clinical populations[12], especially when they are associated with threatening voice content, negative emotional valence, intrusive cognitions, and lacking control[13,14].

National (S3)[15] and international (NICE)[16] guidelines on treatments of SSDs recommend a combination of pharmacological, psychosocial, and psychological interventions with cognitive behavioral therapy (CBT) as first-line psychotherapeutic treatment. However, CBT for psychosis is still associated with structural barriers that are limiting accessibility[17]. Only a minority of affected persons get offered evidence-based psychotherapeutic treatment in accordance with guidelines[17,18] e.g., in Germany only around 1% get psychotherapeutic outpatient treatment[18]. International studies also indicate that merely around 1% of individuals in Canada and the USA[19], and 25% in the UK[20] get access to CBT that further emphasizes the crucial need for low-threshold approaches that can increase accessibility. This is particularly important not only for reaching a broader range of affected individuals but also for providing additional intervention modalities for those having negative attitudes toward conventional psychotherapy or antipsychotic medication[21].

Given this treatment gap in SSDs[22], self-help interventions may contribute to reducing structural barriers in mental health care. They are primarily defined as unguided approaches without professional contact, delivered through online platforms, books, or group settings[23,24]. Self-help can support the affected person by increasing self-efficacy and restoring a sense of control over their distressing experiences[25]. Meta-analytic research has suggested small-to-medium effects of self-help approaches for positive symptoms in SSDs (d=0.42)[24]. Previous studies on symptom-specific approaches for AVHs have further shown effectiveness of self-help groups for voice-hearers[26] as well as an unguided computerized CBT program[27] and a blended-care self-help CBT intervention[28]. However, other studies are contradicting these results, suggesting satisfaction but missing effectiveness of unguided digital self-help[29,30]. Beside the implementation of different approaches and settings, the inconsistent and partially non-significant findings on self-help for AVHs and SSDs are discussed to be potentially linked to insufficient adherence. According to previous research, the involvement of people with lived experiences is a crucial aspect to increase adherence rates of online interventions[31] that needs to be considered in further studies.

Regarding the severe shortcomings in treatment implementation for SSDs, especially unguided treatments could address the gap in mental health care. Overall, the theoretical basis of existing self-help interventions for psychosis are predominantly focusing on conventional cognitive and behavioral approaches[27-29], psychoeducation, peer-support, or a combination of those as augmentative interventions[24]. However, evidence for other approaches using unguided self-help is still lacking. In one of our previous studies, we therefore examined the efficacy of an unguided self-help intervention that was based on metacognitive training (MCT) with non-significant results on AVHs severity but high satisfaction with the intervention in a transdiagnostic sample of voice hearers[30]. Since previous research suggests that interventions integrating multiple techniques yield greater treatment benefits[24], we expanded the unguided intervention

within a participant-involvement approach through mindfulness-based exercises, adapted from mindfulness based group therapy (SENSE manual)[32], to combine the two approaches and their treatment benefits for voice-hearers. The MCT targets metacognitive awareness of emotional and cognitive biases[33,34] and has demonstrated moderate effects on positive symptoms in SSDs[33,35,36]. However, targeted MCT interventions and their specific effects on AVHs remain insufficiently analyzed, especially within low-threshold approaches. In contrast, mindfulness-based interventions (MBIs) can complement this approach by cultivating a non-judgmental and purposeful attention towards inner experiences[37,38] such as AVHs. Meta-analysis on MBIs for psychosis demonstrated small to moderate effects on positive symptoms[39,40], with additional research emphasizing improvements in AVH-related distress and perceived controllability through group-based MBIs[41] and qualitative findings[42]. The combination of the two approaches could be an advantageous strategy for managing AVHs by targeting cognitive biases and re-structuring through metacognition, and a more acceptable and adaptive emotional response to AVHs through mindfulness. However, there is currently no evidence for their combined use within a low-threshold self-help intervention since they are commonly delivered individually and in face-to-face or group settings.

Summarized, the treatment of AVHs is limited by structural shortcomings, severe implementation gaps, and accessibility burdens. To address these flaws in clinical research and practice, we initially developed a self-help intervention based on MCT in a previous trial that showed no sufficient efficacy on voice severity[30]. To further explore the potential of low-threshold self-help for AVHs in SSDs, we expanded the manual through mindfulness and applied it in a more homogenous sample.

The current study aimed, therefore, for the first time to examine the efficacy of this unguided self-help intervention, targeting the treatment of AVHs in SSDs in a randomized-controlled and mixed-methods study design. We hypothesized that (1) the intervention group

will show a significantly greater reduction in the frequency and distress of AVHs (*overall severity*) from baseline to post-intervention after six-weeks, compared to a waiting list control group. Besides, we examined (2) secondary outcomes and hypothesized that the intervention group will also show a significantly greater improvement in various characteristics of AVHs, hallucinatory experiences, negative symptoms, and affect. We additionally examined (3) unwanted and side effects, acceptability, safety, and satisfaction within the intervention group after applying the manual to further analyze the novel self-help approach.

Methods

Design

The present study was conducted as a monocenter, two-armed, randomized controlled trial (RCT) at the Charité – University Medicine Berlin, Germany. The trial was approved by the local ethics committee of the Charité – University Medicine Berlin (EA1/240/22) and pre-registered at ClinicalTrials.gov, first submitted on December 5th in 2023 (NCT06186570).

Participants

Eligible participants were recruited in the whole German speaking area and through the outpatient departments at the Charité – University Medicine Berlin, Campus Mitte and Campus Benjamin Franklin. Besides, we contacted suitable online forums for voice hearers, self-helps groups, and external outpatient departments in Germany. Participant recruitment was conducted from April 9, 2024 (first participant enrolled, baseline), to March 11, 2026 (last participant enrolled, baseline). Inclusion criteria comprised (1) subjectively reported AVHs at least once a week, assessed by an *a-priori* screening procedure and the frequency item of the self-report Psychotic-Symptom Rating Scale, Hallucination Subscale (PSYRATS-AH)[43], (2) a psychiatric diagnosis of a SSD, confirmed by previous medical-reports according to ICD-10[6] or by the Mini-International Neuropsychiatric Interview (M.I.N.I.)[44], (3) age between 18 and 75,

(4) sufficient command of the German language to ensure applicability of the self-help intervention, (5) stable psychiatric medication over at least four weeks before participation, (6) ability to give informed consent for study participation, (7) willingness and ability to engage in the psychotherapeutic self-help intervention, and (8) a mobile device (e.g., tablet, laptop, smartphone) with internet access. Exclusion criteria were (1) hearing voices within another primary psychiatric disorder e.g., borderline personality disorder or posttraumatic stress disorder, (2) acute suicidality, assessed by a structured, literature-based[45,46] screening process and evaluated by experienced psychologists and psychiatrists, (3) acute substance misuse or abuse except for nicotine, (4) any neurological disorders or a severe condition after a traumatic cerebral injury, (5) current treatment with electroconvulsive therapy (ECT), and (6) current inpatient or day-clinic treatment to ensure homogeneity of the sample and treatment as usual (TAU).

Sample size

Sample size was based on an *a-priori* power analysis and calculated using G*Power[47]. Assuming a comparison between two independent groups[48] and targeting medium to large effects (d = .65), a required sample size of N = 78 is estimated to achieve a significance level of α = .05 and a statistical power of .80 (80%) based on previous research[30,35,48]. To ensure robust results and account for potential attrition of around 10%, we aimed to recruit N = 86 participants, although missing data were addressed using imputation methods[49].

Procedure

Prior to baseline-assessments (T_0), a standardized screening procedure was conducted via telephone by trained research assistants to examine inclusion and exclusion criteria. All eligible participants signed a secured online informed consent after verbal and written study clarification by a personalized consent link. After the baseline assessment (T_0), participants were randomly allocated to (1) the intervention group, comprising the self-help manual (PDF-files for

download) in addition to TAU (SH_{AVH}), or (2) the waiting list control group which was equally allowed to continue TAU (*WL*). Participants allocated to the intervention group received a telephone call after three weeks as an interim contact to explore functionality of the manual and to clarify questions. After six weeks, participants from both study groups completed the post-assessment (T_1), subsequently receiving an expanse allowance of 50€, with the WL group additionally receiving the self-help manual after T_1. The randomization was performed by an independent research assistant who was not involved in recruitment, using randomly permuted block sizes by a computer-generated sequence with an allocation ration of 1:1. The randomization sequence was stored on a central computer accessible only to the independent research assistant. After the eligibility criteria for each participant had been assessed and confirmed by a research assistant not involved in randomization, the respective allocation was communicated via email to the enrollment personnel. Participants were informed of their allocation only after T_0. Since the study was performed online to allow for a low threshold participation irrespective of residential and geographic location, we did not include rater-based questionnaires. Due to the psychotherapeutic and methodological nature of the study, participants could not be blinded. See Figure 1 for a visualization of the study procedure.

Self-help for Auditory Verbal Hallucinations ($SH_{MBI\text{-}MCT}$)

Participants randomized to the $SH_{MBI\text{-}MCT}$ group were offered an unguided self-help intervention over six weeks, based on metacognitive training[30,50] and mindfulness based on a group therapy manual for psychosis[32,51]. The intervention was developed within a multi-disciplinary research team of experiences psychologists, psychotherapists, and psychiatrists. It was based on an initial self-help intervention for voice hearers[30] which was thoroughly revised in design and content through a participant-involvement approach according to research and clinical recommendations[52,53]. As an initial step, five participants from the previous RCT[30] were consulted regarding their experiences with the self-help manual. Based on their feedback, the intervention

was systematically expanded and revised. Subsequently, the revised intervention was pilot tested with a further sample of five persons with lived experiences, who provided feedback after two weeks of usage via a semi-structured interview guide. Following the integration of this feedback, the intervention was finalized and implemented in the current RCT.

After a detailed introduction into the manual, the learning diary, and its recommended use over the six-week intervention phase, the self-help manual consisted of six modules: (1) Psychoeducation for voice hearers, (2) individual analysis of the appearance and causes of the voices, (3) acquisition and training of coping strategies to find adaptive coping with the voices, (4) mindfulness exercises which are guided by audio files that specifically target AVHs, (5) creation and application of an individualized '*suitcase*' with effective coping strategies, and (6) transfer to daily life, including sections for socio-therapeutic strategies and psychosis related information for close relatives according to guidelines[54]. All modules included working sheets based on metacognitive and cognitive-behavioral strategies to allow for an individualized implementation. Participants were instructed to work unguided through the manual, depending on their own needs and pace.

Control condition (WL)

Participants who were randomized to the waiting list control condition (WL) received no additional treatment during the six-weeks study phase. However, they were equally allowed to continue TAU. After T_1, participants from the WL group got access to the intervention.

Treatment As Usual (TAU)

Participants in both study conditions were allowed to continue TAU, comprising any psychological, psychosocial, or psychopharmacological intervention within outpatient treatment irrespective of setting (i.e., group, face-to-face, online) in Germany. We systematically assessed all treatments that were received at baseline (T_0) and changes through post-treatment (T_1) in

both study arms and considered them in the statistical analysis to control for potentially co-founding effects.

Assessment

All assessments were based on self-reports and carried out online via RedCap[55] to allow for a low threshold participation that reaches a wide range of affected persons. See Table S3 in the supplementary material for a schedule of the applied study instruments across each measurement time point and for data safety and monitoring. We additionally conducted qualitative semi-structured interviews in the intervention group to examine potential changes in AVH using thematic analysis[56], which will be reported elsewhere.

Demographics. At baseline, demographic characteristics, including, age, gender, school years, primary diagnosis, comorbidities, psychological and psychopharmacological treatment, and general characteristics of AVHs were assessed. Changes in psychological and psychopharmacological treatment were also collected at post-assessment to consider potentially cofounding effects.

Primary outcome

Change in auditory hallucinations. The primary outcome frequency and distress of AVHs (*Overall AVHs)* was assessed with the self-report version of the Psychotic Symptom Rating Scale, hallucination subscale (PSYRATS-AH)[43]. The PSYRATS-AH evaluates hallucinatory experiences over the past two weeks. It comprises 11 items rated on a five-point ordinal scale (ranging from 0 to 4). According to previous literature[57], we used a four-dimensional model examining *Frequency*, *Distress*, *Attribution*, and *Loudness* associated with AVHs in addition to a total reduction in *Overall AVHs* symptoms (total score). The German version of the PSYRATS-AH has demonstrated good psychometric properties, with an internal consistency of Cronbach's $\alpha = .75$ and good concurrent validity that was indicated by a significant

correlation with the auditory hallucination item of the *Positive and Negative Syndrome Scale* (PANSS; r = .29[58].

Secondary outcomes

Believes about voices. The Revised Believes About Voices Questionnaire (BAVQ-R)[59] is a 35-item measure that assesses beliefs about AVH on different subscales, comprising *Malevolence*, *Benevolence*, and *Omnipotence*. Further, feelings and behavior associated with AVH is measured by two additional subscales (*Resistance* and *Engagement)*. The subscales *Malevolence*, *Omnipotence*, and *Resistance* are associated with maladaptive coping, while *Benevolence* and *Engagement* are associated with adaptive coping[59]. Responses are rated on a 4-point scale (0 = *disagree* to 3 = *agree strongly*), assessing the degree of endorsement. The original version of the BAVQ-R shows good psychometric properties in different studies[59,60]. The German version is reported to have good test-retest reliability and overall satisfying internal consistency[61].

Hallucinatory experiences. The revised Launay-Slade Hallucination Scale (LSHS-R)[62,63] originally contextualizes *Hallucinatory experiences* on a continuum with normal and healthy mental states. We used the initial 12-item version which is rated on a 4-point Likert scale ranging from 0 = *never* to 4 = *nearly all the time*. We used the following three-factor structure according to Waters, et al. [64]: (1) *Vivid mental events*, (2) *Hallucinations with a religious theme*, and (3) *Auditory and visual hallucinatory experiences*. The German version of the LSHS-R shows good psychometric properties[65].

Negative symptoms. The Self-Evaluation of Negative Symptoms (SNS)[66] was implemented to assess negative symptoms with 20 items rated from 0 (*strongly disagree*), 1 (*partially agree*), to 2 (*strongly agree*) in five domains: *Social withdrawal, Reduced emotional range, Alogia, Avolition,* and *Anhedonia*. The SNS is reported to have good convergent and divergent validities examined in a large European multicenter validation study[67].

Positive and negative affect. The Positive and Negative Affect Schedule (PANAS)[68] measures various *Positive* and *Negative affects* using a 20-item self-report that is rated on a 5-point Likert scale from 0 = *not at all* to 4 = *extremely*. Previous research has shown that the PANAS is a reliable and valid measure with good psychometric properties[68]. For the *Positive affect* scale, Cronbach's α was .89 and for the *Negative affect* scale .85[69].

Characteristics of AVH. Associations between voice-hearing, intrusions, and thoughts were assessed with the Thinking Scale (TS)[70] at baseline and post-assessment in both groups. The questionnaire assesses resembles between "imagined" (i.e., AVHs) and "real" voices in three domains: (1) *loudness*, (2) *ego-boundness*, and (3) *reality*. Although there are, to date, no validation studies for the TS, it allows for a descriptive assessment of specific AVH characteristics. Reports on results can be found in the supplement (Table S4).

Patient satisfaction. The Client Satisfaction Questionnaire (CSQ-8)[71] was used to assess the patient's satisfaction at the end of the $SH_{MBI\text{-}MCT}$ intervention on a 5-point Likert scale (ranging from 1 to 5), with higher scores demonstrating higher satisfaction (*maximum total score* = 32). Previous studies in various clinical settings have been reported good psychometric properties of the CSQ-8[72,73], with Cronbach's α ranging from .87 to .93[71]. Furthermore, we determined satisfaction with the manual using several additional and specific questions for the $SH_{MBI\text{-}MCT}$, which were modified according to previous research[30,74].

Further post-assessments. To consider potential cofounding effects, we assessed psychological and pharmacological treatment at T_0 and potential changes at T_1.

Retention and adherence. We examined retention and adherence of $SH_{MBI\text{-}MCT}$ by systematically assessing and examining different data during the recruitment and participation process: (1) We examined the recruitment rate by calculating the proportion of participants who were included and randomized in the study, relative to the number of persons screened who fulfilled the inclusion criteria and were eligible but refused to participate. (2) Additionally, we

examined the retention rate by calculating the proportion of participants who completed the post-assessment (T_1), relative to the number of participants who completed the baseline assessment (T_0). (3) Treatment adherence (engagement in therapy > 50%) was assessed by self-reports at T_1, asking about completed modules and percentual implementation of the $SH_{MBI\text{-}MCT}$ during the six-week intervention phase. (4) Lastly, dropouts were defined as any participant prematurely leaving the study irrespective of cause and not completing the post-assessment.

Adverse events and side effects (safety)

In line with guideline and research recommendations[75-77], we collected and report side effects and (Serious) Adverse Events ((S)AEs) by a range of different measures and outcomes. We administered a specific self-report measure previously used in other trials[78,79] to assessed cognitive, emotional, and somatic unpleasant experiences as unwanted events (UEs) and side effects related to $SH_{MBI\text{-}MCT}$ during the six-week intervention phase at T_1, rated on a 3-point Likert scale (0 = *not applicable* to 3 = *severe*; see Table S2). Besides, we recorded all potential (S)AEs and their severity, relatedness to trial procedures or the intervention, and their expectedness. (S)AEs were classified according to the taxonomy of Linden et al.[80] and judged by experiences clinicians within our study team.

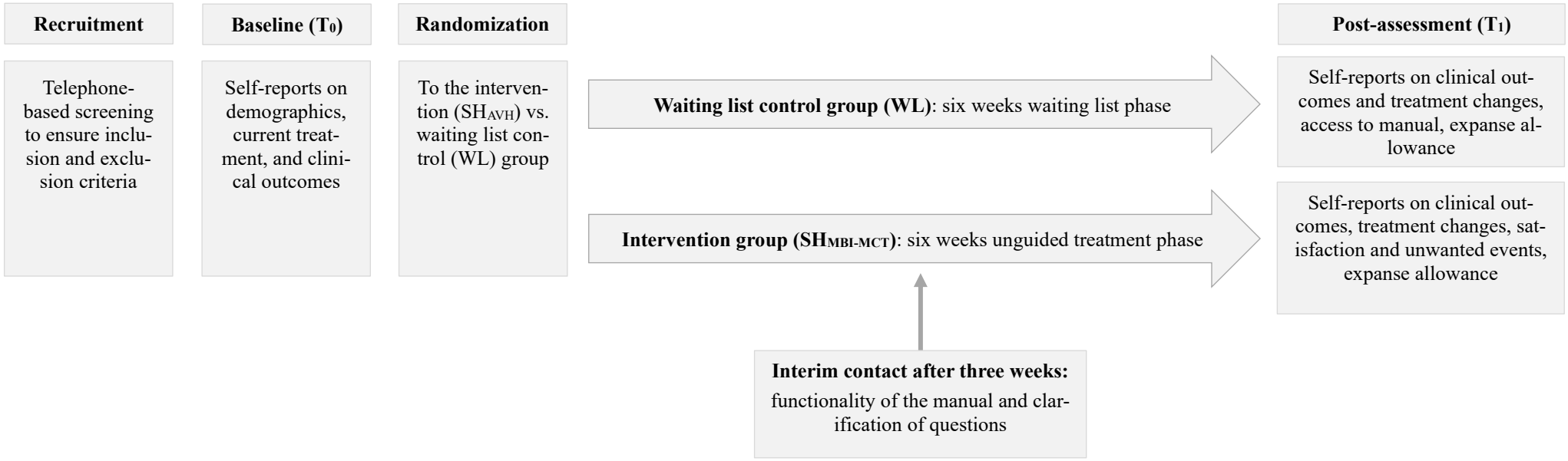
Statistical analysis

All analyses were conducted using R studio for MacOS (version 4.4.1)[81]. Descriptive statistics of recruitment, retention, adherences, and satisfaction were calculated and descriptively summarized to determine safety, retention, and adherence. Between-group differences in participants' baseline characteristics and clinical outcomes were analyzed with *t*-tests for continuous data and Chi-square tests for categorical data. To analyze within-group changes from baseline (T_0) to post-assessment (T_1), paired sample *t*-tests for psychological outcomes were calculated using Cohen's *d* as an effect size (small effect < 0.5, medium effect < 0.8, large effect ≥ 0.8)[82].

Between-group effects on clinical outcomes were analyzed using an analysis of covariance (ANCOVA) model, with group differences ($SH_{MBI\text{-}MCT}$ vs. WL) from baseline (T_0) to post-assessment (T_1) as the dependent variable. Baseline data for each clinical outcome and gender were included in the model as covariates to reduce interfering effects[83] and to account for the significant baseline difference in gender between groups. Medication was calculated as dose equivalents based on defined daily doses (DDD-method) according to Leucht et al. (2016)[84]. Analyses followed an intention-to-treat (ITT) and per-protocol (PP) principle to examine the effects of the manual in relation to adherence and routine clinical practice[85]. For the ITT-analyses, we included all participants with available baseline data and handled missing post-data by multiple imputation methods, using chained equations (*mice* package)[86]. Data were assumed to be missing at random. Following previous recommendations, we implemented passive imputation for sum scores[86] that incorporates original and transformed variables into the predictor matrix of the imputation algorithm, and imputed data separately for both groups to control for potential biases[49]. For the PP-analysis, we only included participants with post-data (T_1) who reported to have completed at least 50% of the manual, following previous research on dose-response of psychotherapy and self-help[87]. Besides, we defined significant deviations from the study and treatment protocol when participants stated that they did not truthfully answer the post-assessment or reported severe memory gaps since adherence to the treatment protocol could not be ensured in these cases. We did not apply an alpha correction for multiple testing. Effect sizes of the ANCOVA models are reported as partial eta squared ($\eta^2_{partial}$), with thresholds of ≥ .01 (small), ≥ .06 (medium), and ≥ .14 (large)[88,89]. All tests were conducted two-tailed with a significance level of $\alpha = .05$. For readability, only significant values are reported in body text. All results, including insignificant findings, can be found in Table 2 and Table 3.

Figure 1

Study process



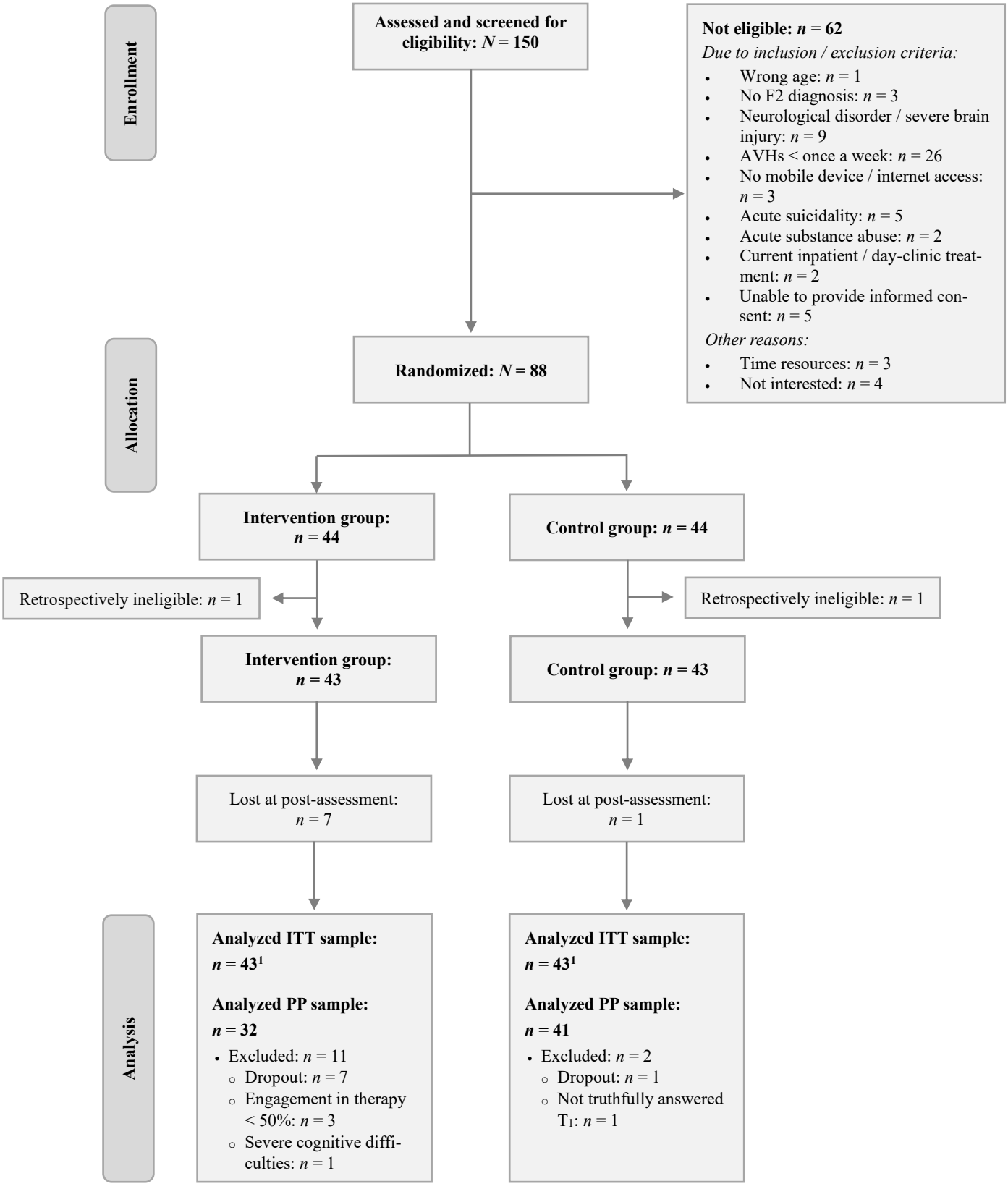
Note. Baseline assessment (T_0) comprised self-reports on demographics, current treatment (psychotherapy, medication), and clinical outcomes including the PSYRATS, BAVQ-R, LSHS-R, SNS, PANAS, and the TS. Post-assessment (T_1) comprised self-reports on potential treatment changes (psychotherapy, medication) and clinical outcomes including the PSYRATS, BAVQ-R, LSHS-R, SNS, PANAS, and the TS. The intervention group further stated satisfaction, using the CSQ-8 and additional questions, as well as unwanted and side effects. Both groups were allowed to continue treatment as usual in outpatient settings.

Results

From April 2024 to March 2026, 150 persons were screened for eligibility after stating interest in study participation. From those, 57 had to be excluded for not meeting the inclusion criteria while seven refused to participate due to time resources or no interest. The recruitment and eligibility process is displayed in the CONSORT diagram (Figure 2). Two participants had to be excluded retrospectively after randomization due to a wrong diagnosis (n = 1 in the intervention group) and AVHs less than once a week (n = 1 in the control group). In total, N = 86 participants fulfilled the inclusion criteria and were randomized to either the intervention (n = 43) or waiting list control group (n = 43), both continuing their regular TAU. Post-assessments were completed until May 2026.

Figure 2

CONSORT Flow Diagram



Note. ITT = Intention-To-Treat, PP = Per-Protocol, T_1 = post-assessment.
[1]Using multiple imputation by chained equations with mice in R[86].

Recruitment, retention, and adherence

We recruited 100% of our targeted sample (N = 86, ITT sample). The intervention group showed a completion rate of 83.72% (n = 7 dropouts, 16.28%), while the waiting list control group showed a completion rate of 97.67% (n = 1 dropout, 2.33%), indicating a retention rate of 90.7% (total n = 8 dropouts after T_0, 9.3%). A group comparison showed a significant difference in the dropout rate between the groups (χ^2 (1) = 4.96, p = .026). Adherence to treatment (engagement in therapy ≥50%, PP data) was 74.4% (n = 32 from n = 43). In total, n = 7 out of N = 93 participants were eligible but not willing to participate, indicating a feasibility of 92.47%. See the supplement for a detailed description about reasons for dropouts and additional information on recruitment.

Demographics and clinical characteristics

Demographic and clinical baseline characteristics are detailed in Table 1. We found no significant differences between the study groups ($SH_{MBI\text{-}MCT}$ vs. WL) in demographic or clinical characteristics, except for gender (χ^2 (2) = 7.45, p = .024) showing significantly more women in the intervention group and significantly more men in the control group. Additionally, to respective baseline values of each outcome, gender was included as a covariate in ANCOVA models. Besides, there were no significant differences between groups in baseline antipsychotic medication, psychotherapy, or other outpatient treatments as well as no significant differences between groups in treatment changes from T_0 to T_1 (Table 1).

Table 1

Demographics and baseline characteristics

Variable	Intervention group (*N* = 43)	Control group (*N* = 43)	Overall (*N* = 86)	Group comparison
	M (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	
Demographics and clinical data				
Age	38.09 (11.04)	42.14 (9.51)	40.09 (10.45)	t (83) = 1.81, p = 0.074
Gender				χ^2 (2) = 7.45, p = **.024 ***
Female	25 (58.1%)	19 (44.2%)	44 (51.2%)	
Male	14 (32.6%)	24 (55.8%)	38 (44.2%)	
Non-binary	4 (9.3%)	0 (0%)	4 (4.7%)	
School Years	12.05 (1.31)	11.50 (1.27)	11.78 (1.31)	t (83) = -1.95, p = .054
Antipsychotic medication[1]	320.90 (333.80)	375.70 (405.40)	348.30 (370.20)	t (84) = 0.68, p = .496
Diagnoses				
Schizophrenia	35 (81.4%)	39 (90.7%)	74 (86.0%)	χ^2 (1) = 1.55, p = .213
Schizoaffective Disorder	13 (30.2%)	8 (18.6%)	21 (24.4%)	χ^2 (1) = 1.58, p = .210
Psychotic Disorder	11 (25.6%)	15 (34.9%)	26 (30.2%)	χ^2 (1) = 0.88, p = .348
Bipolar Disorder	3 (7.0%)	4 (9.3%)	7 (8.1%)	χ^2 (1) = 0.16, p = .693
Post-traumatic stress disorder	10 (23.3%)	9 (20.9%)	19 (22.1%)	χ^2 (1) = 0.07, p = .795
Anxiety Disorder	12 (27.9%)	17 (39.5%)	29 (33.7%)	χ^2 (1) = 1.30, p = .254
Obsessive-compulsive disorder	6 (14.0%)	4 (9.3%)	10 (11.6%)	χ^2 (1) = 0.45, p = .501
Addiction Disorder	12 (27.9%)	9 (20.9%)	21 (24.4%)	χ^2 (1) = 0.57, p = .451
Eating Disorder	6 (14.0%)	6 (14.0%)	12 (14.0%)	χ^2 (1) = 0.00, p = 1.00
Borderline Personality Disorder	4 (9.3%)	3 (7.0%)	7 (8.1%)	χ^2 (1) = 0.16, p = .693

Table (*continued*)

Variable	Intervention group (*N* = 43)	Control group (*N* = 43)	Overall (*N* = 86)	Group comparison
	M (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	
Depression	16 (37.2%)	14 (32.6%)	30 (34.9%)	χ^2 (1) = 0.20, *p* = .651
Other Diagnosis	3 (7.0%)	3 (7.0%)	6 (7.0%)	χ^2 (1) = 0.00, *p* = 1.00
Characteristics of Voices				
Onset AVH, age	24.57 (9.54)	24.40 (9.36)	24.49 (9.39)	*t* (92) = -0.08, *p* = .936
Number of Voices Heard				χ^2 (3) = 0.26, *p* = .968
Voices >5	15 (34.9%)	16 (37.2%)	31 (36.0%)	
4 or 5 Voices	5 (11.6%)	6 (14.0%)	11 (12.8%)	
2 or 3 Voices	16 (37.2%)	14 (32.6%)	30 (34.9%)	
One Voice	7 (16.3%)	7 (16.3%)	14 (16.3%)	
Other Hallucinations				
Visual	28 (65.1%)	23 (53.5%)	51 (59.3%)	χ^2 (1) = 1.20, *p* = .277
Olfactory	19 (44.2%)	12 (27.9%)	31 (36.0%)	χ^2 (1) = 2.47, *p* = .116
Gustatory	8 (18.6%)	6 (14.0%)	14 (16.3%)	χ^2 (1) = 0.34, *p* = .559
Tactile	23 (53.5%)	16 (37.2%)	39 (45.3%)	χ^2 (1) = 2.30, *p* = .130
Highest Distress Associated with AVH	30 (69.8%)	23 (53.5%)	53 (61.6%)	χ^2 (1) = 2.41, *p* = .121
Treatment and treatment experiences				
Current Outpatient Treatment				
Psychotherapy	20 (46.5%)	12 (27.9%)	32 (37.2%)	χ^2 (1) = 3.19, *p* = .074
Psychopharmacological Treatment	38 (88.4%)	37 (86.0%)	75 (87.2%)	χ^2 (1) = 0.10, *p* = .747
Other Treatment	5 (11.6%)	10 (23.3%)	15 (17.4%)	χ^2 (1) = 2.02, *p* = .155
No Treatment	2 (4.7%)	2 (4.7%)	4 (4.7%)	χ^2 (1) = 0.00, *p* = 1.00

Table (*continued*)

Variable	Intervention group (*N* = 43)	Control group (*N* = 43)	Overall (*N* = 86)	Group comparison
	M (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	*M* (*SD*) / *n* (%)	
Previous treatment Experiences				
Outpatient Psychotherapy	40 (93.0%)	34 (79.1%)	74 (86.0%)	χ^2 (1) = 3.49, *p* = .062
Inpatient Treatment (open or protected)	39 (90.7%)	43 (100%)	79 (91.9%)	χ^2 (1) = 0.16, *p* = .693
Psychopharmacological Treatment	40 (93.0%)	39 (90.7%)	79 (91.9%)	χ^2 (1) = 0.16, *p* = .693
Mindfulness Treatment	10 (23.3%)	16 (37.2%)	26 (30.2%)	χ^2 (1) = 1.98, *p* = .159
Self-help (group, book, online)	26 (60.5%)	21 (48.8%)	47 (54.7%)	χ^2 (1) = 1.17, *p* = .279
Experience MCT	18 (41.9%)	20 (46.5%)	38 (44.2%)	χ^2 (1) = 0.19, *p* = .664
Frequency Inpatient Treatment				χ^2 (5) = 5.54, *p* = .353
≥ 5 x	23 (53.5%)	22 (51.2%)	45 (52.3%)	
4 x	2 (4.7%)	7 (16.3%)	9 (10.5%)	
3 x	9 (20.9%)	6 (14.0%)	15 (17.4%)	
2 x	4 (9.3%)	4 (9.3%)	8 (9.3%)	
1 x	3 (7.0%)	4 (9.3%)	7 (8.1%)	
Never	2 (4.7%)	0 (0%)	2 (2.3%)	
Expectations Treatment ($SH_{MBI\text{-}MCT}$)	3.07 (0.77)	3.00 (0.85)	3.04 (0.80)	*t* (84) = -0.40, *p* = .690
Changes in treatment				
Change in Medication (from $T_0 - T_1$)	9 (20.9%%)	5 (11.6%)	14 (16.3%)	χ^2 (1) = 2.26, *p* = .133
Change in Treatment, overall ($T_0 - T_1$)	3 (7.0%)	3 (7.0%)	6 (7.0%)	χ^2 (1) = 0.04, *p* = .844
Additional Self-Help ($T_0 - T_1$)	8 (18.6%)	10 (23.8%)	18 (20.9%)	χ^2 (1) = 0.03, *p* = .868

Note. *t* = t-Test, χ^2 = Chi-squared test, % = percentage, *p* = significance, MCT = Metacognitive Training, T_0 = baseline assessment, T_1 = post-assessment, SH_{AVH} = Self-Help manual. Multiple answers were possible for diagnoses, current treatments, and treatment experiences. Treatment expectations ranged from 1 = *treatment will be not successful at all* to 5 = *treatment will be very successful*. Missing values were excluded for post assessment outcomes (*changes in treatment*).

[1]Medication equivalents calculated according to Leucht et al., 2016 (defined-daily-dose method).

* $p < .05$, ** $p < .01$, *** $p < .001$

Intention-To-Treat and Per-Protocol samples

In the ITT-sample, we included all $N = 86$ participants randomized ($n_{SH\text{-}MF\text{-}MCT} = 43$, $n_{WL} = 43$) and imputed data according to multiple imputation methods. For the PP-sample, we excluded all participants without post-assessment data ($n = 8$) and $n = 3$ from the intervention group who reported to have completed < 50% of the manual. Additionally, we excluded one person from the intervention group who stated severe memory gaps after T_1 regarding the manual (*UE unrelated to treatment*, see Table S1) that resulted in a restricted verification of treatment application. Furthermore, one participant from the control group was also excluded from PP-data after reporting to have not completed the post-assessment truthfully. This resulted in a final PP-sample of $N = 73$ ($n_{SH\text{-}MF\text{-}MCT} = 32$, $n_{WL} = 41$).

Changes in clinical characteristics: Primary outcome

Frequency and distress of AVH. Between-group analyses in the ITT sample revealed no significant differences between groups, neither in *Overall AVHs* ($F = 1.58$, $p = .209$, $\eta^2_p = 0.02$) nor in any of the subscales. In contrast, the PP analysis showed a significant between-group difference in *Overall AVHs* (F (3, 69) = 21.02, $p = .040$, $\eta^2_p = 0.06$), favoring $SH_{MBI\text{-}MCT}$ with a medium effect size. Subscales of AVH again did not differ significantly between groups (Table 2).

Within-group analyses in the ITT sample demonstrated significant reductions in *Overall AVHs* by $\Delta = 3.55$ points with a medium effects size ($t = 3.01$, $p = .005$, $d = 0.48$) and *Distress of AVH* by $\Delta = 2.06$ points again with a medium effect size ($t = 2.73$, $p = .010$, $d = 0.46$). PP-analyses also showed a significant reduction in *Overall AVHs* by $\Delta = 3.89$ points ($t = 3.09$, $p = .004$, $d = 0.55$), *Distress of AVH* by $\Delta = 2.00$ points ($t = 2.64$, $p = .013$, $d = 0.47$), and additionally in the *Frequency of AVH* by $\Delta = 1.16$ points ($t = 2.76$, $p = .005$, $d = 0.54$), all referring to medium-sized effects. No significant within-group changes were found in the WL group (Table 3). See Figure 3 and Figure 4 for a visualization of changes in AVHs in both ITT and PP samples.

Changes in clinical characteristics: Secondary outcomes

Beliefs about voices. Between-group analyses showed no significant differences in *Beliefs about voices* in the ITT and PP sample (Table 2).

Within-group comparisons did not indicate significant reductions in *Beliefs about voices* in the ITT sample (Table 3). However, PP analyses in the $SH_{MBI\text{-}MCT}$ revealed a

significant reduction in the subscale *Omnipotence* (Δ = 1.38, t = 2.80, p = .009, d = 0.49), referring to a medium-sized effect. No other significant within-group changes for $SH_{MBI\text{-}MCT}$ were observed for the remaining subscales or for any outcomes in the WL group (Table 3).

Hallucinatory experiences. Between-group analyses demonstrated significant differences in overall *Hallucinatory experiences* in both the ITT (F = 6.14, p = .013, η^2_p = 0.07) and PP analysis (F (3, 69) = 35.78, p = .001, η^2_p = 0.14), favoring the $SH_{MBI\text{-}MCT}$ group with medium to large-sized effects. Significant between-group differences in both the ITT and PP samples were also observed for *Hallucinations with a religious theme* (ITT: F = 10.52, p = .001, η^2_p = 0.12; PP: F (3, 69) = 20.91, p = .002, η^2_p = 0.13) and *Auditory and visual hallucinations* (ITT: F = 6.51, p = .011, η^2_p = 0.09; PP: F (3, 69) = 28.27, p = .003, η^2_p = 0.12), again favoring $SH_{MBI\text{-}MCT}$ with medium- to large-sized effects. *Vivid mental events* only significantly differed in the PP-analysis (F (3, 69) = 20.03, p = .022, η^2_p = 0.07), with a significant symptom reduction in $SH_{MBI\text{-}MCT}$ compared to WL and a medium effect size (Table 2).

Within-group changes in both the ITT and PP analyses revealed significant reductions in the $SH_{MBI\text{-}MCT}$ group for overall *Hallucinatory experiences* (ITT: Δ = 3.88, t = 3.17, p = .003, d = 0.50; PP: Δ = 5.25, t = 4.31, p < .001, d = 0.76) with medium- (ITT) to large- (PP) sized effects, *Hallucinations with a religious theme* (ITT: Δ = 1.53, t = 3.86, p = .001, d = 0.62; PP: Δ = 1.72, t = 3.99, p < .001, d = 0.70) with medium-sized effects, and *Auditory and visual hallucinations* (ITT: Δ = 1.81, t = 3.93, p < .001, d = 0.68; PP: Δ = 1.97, t = 4.31, p < .001, d = 0.76) again with medium- (ITT) to large- (PP) sized effects (Table 3). Additionally, the PP analysis revealed a significant within-group reduction in *Vivid mental events* in the $SH_{MBI\text{-}MCT}$ group by Δ = 2.50 points and a medium effect size (t = 2.65, p = .013, d = 0.47). No significant within-group changes were observed in the WL group, both in the ITT and PP sample (Table 3).

Negative symptoms. We found no significant between-group differences in any outcome of *Negative symptoms* in either the ITT or PP sample (Table 2).

Within-group analyses in the ITT sample indicated a significant reduction of *Avolition* by Δ = 0.82 points in the $SH_{MBI\text{-}MCT}$ group (t = 2.18, p = .036, d = 0.36), corresponding to a small- to medium effect size. We found no other within-group changes in either study group or analysis sample (Table 3).

Positive and negative affect. Between-group analyses in the ITT sample revealed no significant differences in *Positive* or *Negative affect* (Table 2). In contrast, the PP analysis showed a

significant between-group difference in *Negative affect* (F (3, 69) = 32.79, p = .039, η^2_p = 0.06), favoring the $SH_{MBI\text{-}MCT}$ group with a medium effect size, whereas *Positive affect* did not differ significantly between groups (Table 2).

Within-group analyses showed no significant changes in *Positive* or *Negative affect* in the ITT sample for either study group (Table 3). In the PP sample, within-group analyses in the $SH_{MBI\text{-}MCT}$ group indicated a significant reduction in *Negative affect* by Δ = 2.88 points (t = 2.36, p = .025, d = 0.42), corresponding to a medium effect size, whereas *Positive affect* did not change significantly. In the control group, neither *Positive* nor *Negative affect* significantly changed (Table 3).

Table 2

Between-group differences for intention-to-treat (ITT) and per-protocol (PP) samples in clinical outcomes

	ITT-data				**PP-data**				**ITT-data**			**PP-data**		
	$SH_{MBI-MCT}$		WL		$SH_{MBI-MCT}$		WL		ANCOVA ($SH_{MBI-MCT}$ vs. WL)			ANCOVA ($SH_{MBI-MCT}$ vs. WL)		
Domain	*M (SD)*: Pre	*M (SD)*: Post	*M (SD)*: Pre	*M (SD)*: Post	*M (SD)*: Pre	*M (SD)*: Post	*M (SD)*: Pre	*M (SD)*: Post	*F (df [1])*	*p*	η^2_p	*F (df)*	*p*	η^2_p
Auditory verbal hallucinations, PSYRATS														
Total score	25.56 (7.35)	22.01 (9.74)	25.12 (5.39)	23.80 (8.59)	25.84 (7.80)	21.97 (9.96)	25.07 (5.52)	24.37 (7.92)	1.58 (1, 41263)	.209	0.02	21.02 (3, 69)	**.040***	0.06
Frequency	6.56 (2.56)	5.71 (3.09)	6.49 (2.20)	6.05 (2.57)	6.72 (2.67)	5.56 (3.06)	6.56 (2.21)	6.20 (2.43)	0.29 (1, 3657)	.593	0.01	17.29 (3, 69)	.129	0.03
Distress	12.35 (4.03)	10.29 (4.95)	12.56 (3.19)	11.82 (4.88)	12.38 (4.31)	10.38 (5.10)	12.56 (3.25)	12.12 (4.61)	1.72 (1, 6549)	.190	0.02	17.3 (3, 69)	.096	0.04
Attribution	4.70 (1.71)	4.28 (2.09)	4.16 (1.57)	4.01 (1.63)	4.72 (1.73)	4.31 (2.13)	4.07 (1.54)	4.10 (1.53)	0.29 (1, 3091)	.591	0.01	25.54 (3, 69)	.121	0.03
Loudness	1.95 (1.00)	1.77 (1.07)	1.91 (0.78)	1.91 (0.91)	2.03 (1.03)	1.72 (0.92)	1.88 (0.78)	1.95 (0.86)	0.68 (1, 381)	.411	0.02	12.58 (3, 69)	.052	0.05
Beliefs about voices, BAVQ-R														
Omnipotence	8.60 (4.64)	7.50 (4.44)	8.98 (3.07)	8.42 (3.88)	9.09 (4.18)	7.72 (4.02)	9.24 (2.86)	8.63 (3.65)	0.82 (1, 1377)	.365	0.01	27.43 (3, 69)	.168	0.03
Malevolence	7.56 (4.69)	6.36 (4.32)	7.67 (4.76)	7.51 (4.67)	7.75 (4.49)	6.63 (4.13)	7.76 (4.82)	7.46 (4.70)	2.61 (1, 3668)	.106	0.04	32.85 (3, 69)	.158	0.03
Benevolence[2]	3.63 (4.69)	3.57 (4.48)	4.21 (4.83)	4.05 (4.51)	3.19 (4.15)	3.00 (3.88)	4.37 (4.89)	4.07 (4.47)	0.14 (1, 7157)	.712	0.00	41.66 (3, 69)	.894	0.00
Resistance	14.95 (6.52)	14.64 (6.57)	14.93 (6.71)	15.26 (6.47)	14.97 (6.26)	15.34 (5.41)	14.90 (6.38)	15.46 (6.38)	0.35 (1, 2407)	.555	0.01	31.65 (3, 69)	.692	0.00

Table 2 (*continued*)

	ITT-data				**PP-data**				**ITT-data**			**PP-data**		
	$SH_{MBI-MCT}$		WL		$SH_{MBI-MCT}$		WL		ANCOVA ($SH_{MBI-MCT}$ vs. WL)			ANCOVA ($SH_{MBI-MCT}$ vs. WL)		
Domain	*M (SD):* Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*F (df 1)*	*p*	η^2_P	*F (df)*	*p*	η^2_P
Engagement[2]	4.12 (5.18)	3.83 (4.91)	4.44 (5.22)	4.33 (4.72)	3.94 (4.35)	3.16 (3.90)	4.56 (5.31)	4.39 (4.68)	0.17 (1, 6735)	.682	0.00	57.88 (3, 69)	.248	0.02
Hallucinatory experiences, LSHS-R														
Total score	37.37 (9.02)	33.49 (9.73)	36.21 (9.35)	35.30 (9.28)	38.69 (9.33)	33.44 (10.34)	36.41 (9.50)	35.44 (9.41)	6.14 (1, 34504)	**.013***	0.07	35.78 (3, 69)	**.001****	0.14
Vivid mental events	22.47 (6.02)	20.81 (7.23)	22.02 (6.54)	21.74 (7.01)	23.03 (6.49)	20.53 (7.72)	22.17 (6.57)	22.00 (6.96)	2.07 (1, 16910)	.150	0.03	20.03 (3, 69)	**.022***	0.07
Hallucinations with a religious theme	8.63 (2.60)	7.10 (2.19)	8.74 (2.84)	8.28 (2.43)	8.81 (2.82)	7.09 (2.29)	8.73 (2.83)	8.10 (2.21)	10.52 (1, 10052)	**.001****	0.12	20.91 (3, 69)	**.002****	0.13
Auditory and visual hallucinatory experiences	14.40 (2.75)	12.58 (3.40)	12.98 (3.50)	12.67 (3.52)	14.81 (2.78)	12.84 (3.44)	13.07 (3.50)	12.78 (3.50)	6.51 (1, 3134)	**.011***	0.09	28.27 (3, 69)	**.003****	0.12
Negative symptoms, SNS														
Total score	18.88 (8.27)	18.30 (9.07)	16.35 (7.01)	16.73 (6.65)	19.34 (8.84)	18.75 (8.95)	16.46 (7.14)	16.80 (6.68)	0.16 (1, 12208)	.691	0.00	30.63 (3, 69)	.987	0.00
Social withdrawal	3.51 (2.58)	3.26 (2.56)	3.05 (2.06)	2.91 (1.81)	3.78 (2.67)	3.13 (2.69)	2.98 (2.08)	2.88 (1.83)	0.12 (1, 12680)	.726	0.00	17.82 (3, 69)	.431	0.00
Diminished emotional range	3.14 (2.22)	3.77 (2.31)	2.47 (1.83)	2.92 (1.82)	3.00 (2.34)	3.78 (2.37)	2.49 (1.86)	2.90 (1.84)	1.73 (1, 4835)	.188	0.02	10.64 (3, 69)	.129	0.03
Alogia	3.47 (2.32)	3.61 (2.50)	2.72 (2.44)	2.74 (2.01)	3.72 (2.51)	3.72 (2.57)	2.76 (2.50)	2.68 (2.01)	1.14 (1, 3782)	.286	0.02	26.31 (3, 69)	.190	0.02

Table 2 (*continued*)

Domain	ITT-data				PP-data				ITT-data			PP-data		
	$SH_{MBI-MCT}$		WL		$SH_{MBI-MCT}$		WL		ANCOVA ($SH_{MBI-MCT}$ vs. WL)			ANCOVA ($SH_{MBI-MCT}$ vs. WL)		
	M (SD): Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*M (SD):* Pre	*M (SD):* Post	*F (df 1)*	*p*	η^2_p	*F (df)*	*p*	η^2_p
Avolition	5.12 (2.03)	4.29 (2.22)	4.86 (2.46)	4.98 (2.23)	4.88 (2.00)	4.38 (2.08)	4.95 (2.48)	5.12 (2.11)	2.72 (1, 2007)	.099	0.04	21.49 (3, 69)	.123	0.03
Anhedonia	3.65 (2.49)	3.60 (2.50)	3.26 (2.24)	3.17 (2.19)	3.97 (2.58)	3.75 (2.33)	3.29 (2.26)	3.22 (2.19)	0.23 (1, 4641)	.635	0.00	27.69 (3, 69)	.924	0.00
Positive and negative affect, PANAS														
Positive affect	24.58 (7.06)	25.98 (8.56)	26.98 (5.93)	27.94 (6.90)	23.44 (6.84)	25.28 (8.61)	27.07 (6.03)	27.78 (6.98)	0.27 (1, 3020)	.602	0.01	10.77 (3, 69)	.920	0.00
Negative affect	27.42 (8.39)	25.34 (8.87)	28.42 (8.48)	28.11 (7.89)	27.91 (8.13)	25.03 (8.81)	28.61 (8.52)	28.27 (7.90)	1.70 (1, 1458)	.192	0.03	32.79 (3, 69)	**.039***	0.06

Note. *M* = mean, *SD* = standard deviation, *n* = sample, % = percentage, η^2_p = partial eta squared, *p* = significance, PSYRATS = Psychotic Symptom Rating Scale, BAVQ-R = Beliefs About Voices Questionnaire Revised, LSHS-R = Launay-Slade Hallucination Scale Revised, SNS = Self-Evaluation of Negative Symptoms, PANAS = Positive and Negative Affect Schedule. Between-group tests were ANCOVAs with respective baseline data and gender as covariates.

[1]Degrees of freedom (df_2) are derived under the assumptions that the complete-data (multiple imputed) degrees of freedom are infinite according to Meng and Rubin [90].

[2]According to Chadwick et al., 2000, higher scores indicate more adaptive coping to voices and therefore a positive outcome.

* $p < .05$, ** $p < .01$, *** $p < .001$

Table 3

Within-group changes for intention-to-treat (ITT) and per-protocol (PP) samples in clinical outcomes

	ITT-Data								**PP-Data**							
	$SH_{MBI\text{-}MCT}$ (*n* = 43)				WL (*n* = 43)				$SH_{MBI\text{-}MCT}$ (*n* = 32)				WL (*n* = 41)			
Domain	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*
Auditory verbal hallucinations, PSYRATS																
Total score	3.01	**.005****	3.55	0.48 (0.16; 0.79)	1.24	.223	1.32	0.19 (-0.11; 0.49)	3.09	**.004****	3.89	0.55 (0.17; 0.91)	0.75	.456	0.71	0.12 (-0.19; 0.42)
Frequency	1.92	.066	0.85	0.35 (0.04; 0.65)	1.26	.215	0.43	0.20 (-0.11; 0.49)	3.05	**.005****	1.16	0.54 (0.16; 0.91)	1.06	.296	0.37	0.17 (-0.14; 0.47)
Distress	2.73	**.010****	2.06	0.46 (0.14; 0.77)	1.33	.193	0.74	0.20 (-0.10; 0.50)	2.64	**.013****	2.00	0.47 (0.10; 0.83)	0.85	.401	0.44	0.13 (-0.18; 0.44)
Attribution	1.43	.165	0.41	0.28 (-0.02; 0.59)	0.56	.576	0.15	0.09 (-0.21; 0.39)	1.82	.079	0.41	0.32 (-0.04; 0.67)	-0.11	.911	-0.02	-0.02 (-0.32; 0.29)
Loudness	0.77	.449	0.19	0.19 (-0.11; 0.50)	-0.04	.967	-0.01	-0.01 (-0.31; 0.29)	1.90	.067	0.31	0.34 (-0.02; 0.69)	-0.65	.519	-0.07	-0.10 (-0.41; 0.21)
Beliefs about voices, BAVQ-R																
Omnipotence	1.50	.147	1.11	0.30 (-0.01; 0.60)	1.18	.246	0.55	0.19 (-0.11; 0.49)	2.80	**.009****	1.38	0.49 (0.12; 0.86)	1.49	.145	0.61	0.23 (-0.08; 0.54)
Malevolence	1.68	.102	1.19	0.29 (-0.02; 0.59)	0.35	.729	0.17	0.04 (-0.25; 0.34)	1.78	.085	1.13	0.31 (-0.04; 0.67)	0.67	.506	0.29	0.10 (-0.20; 0.41)
Benevolence	0.09	.928	0.06	0.02 (-0.28; 0.32)	0.33	.745	0.16	0.05 (-0.25; 0.35)	0.42	.680	0.19	0.07 (-0.27; 0.42)	0.62	.537	0.29	0.10 (-0.21; 0.40)
Resistance	0.31	.757	0.31	0.05 (-0.25; 0.35)	-0.39	.698	-0.33	-0.06 (-0.36; 0.24)	-0.50	.624	-0.38	-0.09 (-0.43; 0.26)	-0.84	.407	-0.56	-0.13 (-0.44; 0.18)
Engagement	0.43	.668	0.28	0.08 (-0.22; 0.38)	0.23	.820	0.11	0.04 (-0.26; 0.34)	1.99	.056	0.78	0.35 (-0.01; 0.71)	0.37	.713	0.17	0.06 (-0.25;0.36)

Table 3 (*continued*)

	ITT-Data								**PP-Data**							
	$SH_{MBI\text{-}MCT}$ (*n* = 43)				WL (*n* = 43)				$SH_{MBI\text{-}MCT}$ (*n* = 32)				WL (*n* = 41)			
Domain	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*
Hallucinatory experiences, LSHS-R																
Total score	3.17	**.003****	3.88	0.50 (0.18; 0.81)	0.85	.398	0.91	0.13 (-0.17; 0.43)	4.31	**<.001*****	5.25	0.76 (0.36; 1.15)	0.89	.381	0.98	0.14 (-0.17; 0.45)
Vivid mental events	1.78	.083	1.66	0.29 (-0.02; 0.59)	0.38	.706	0.29	0.06 (-0.24; 0.36)	2.65	**.013****	2.50	0.47 (0.10; 0.83)	0.22	.826	0.17	0.03 (-0.27; 0.34)
Halluci-nations with religious theme	3.86	**.001****	1.53	0.62 (0.29; 0.95)	1.37	.179	0.46	0.21 (-0.09; 0.51)	3.99	**<.001*****	1.72	0.70 (0.31; 1.09)	1.98	.054	0.63	0.31 (-0.01; 0.62)
Auditory and visual hallucinatory experiences	3.93	**<.001*****	1.81	0.68 (0.35; 1.01)	0.72	.477	0.31	0.11 (-0.19; 0.41)	4.31	**<.001*****	1.97	0.76 (0.36; 1.15)	0.67	.508	0.29	0.10 (-0.20; 0.41)
Negative symptoms, SNS																
Total score	0.46	.650	0.59	0.09 (-0.22; 0.38)	-0.47	.644	-0.38	-0.07 (-0.37; 0.23)	0.57	.575	0.59	0.10 (-0.25; 0.45)	-0.42	.678	-0.34	-0.07 (-0.37; 0.24)
Social withdrawal	0.72	.479	0.26	0.13 (-0.17; 0.43)	0.42	.677	0.13	0.06 (-0.24; 0.36)	2.24	**.032***	0.66	0.40 (0.03; 0.75)	0.30	.766	0.10	0.05 (-0.26; 0.35)
Diminished emotional range	-1.60	.119	-0.63	-0.26 (-0.57; 0.04)	-1.62	.114	-0.45	-0.25 (-0.55, 0.06)	-1.97	.057	-0.78	-0.35 (-0.70; 0.01)	-1.45	.155	-0.41	-0.23 (-0.54; 0.08)
Alogia	-0.43	.670	-0.15	-0.07 (-0.37; 0.23)	-0.08	.935	-0.02	-0.01 (-0.31; 0.29)	0.00	1.00	0.00	0.00 (-0.35; 0.35)	0.26	.800	0.07	0.04 (-0.27; 0.35)

Table 3 (*continued*)

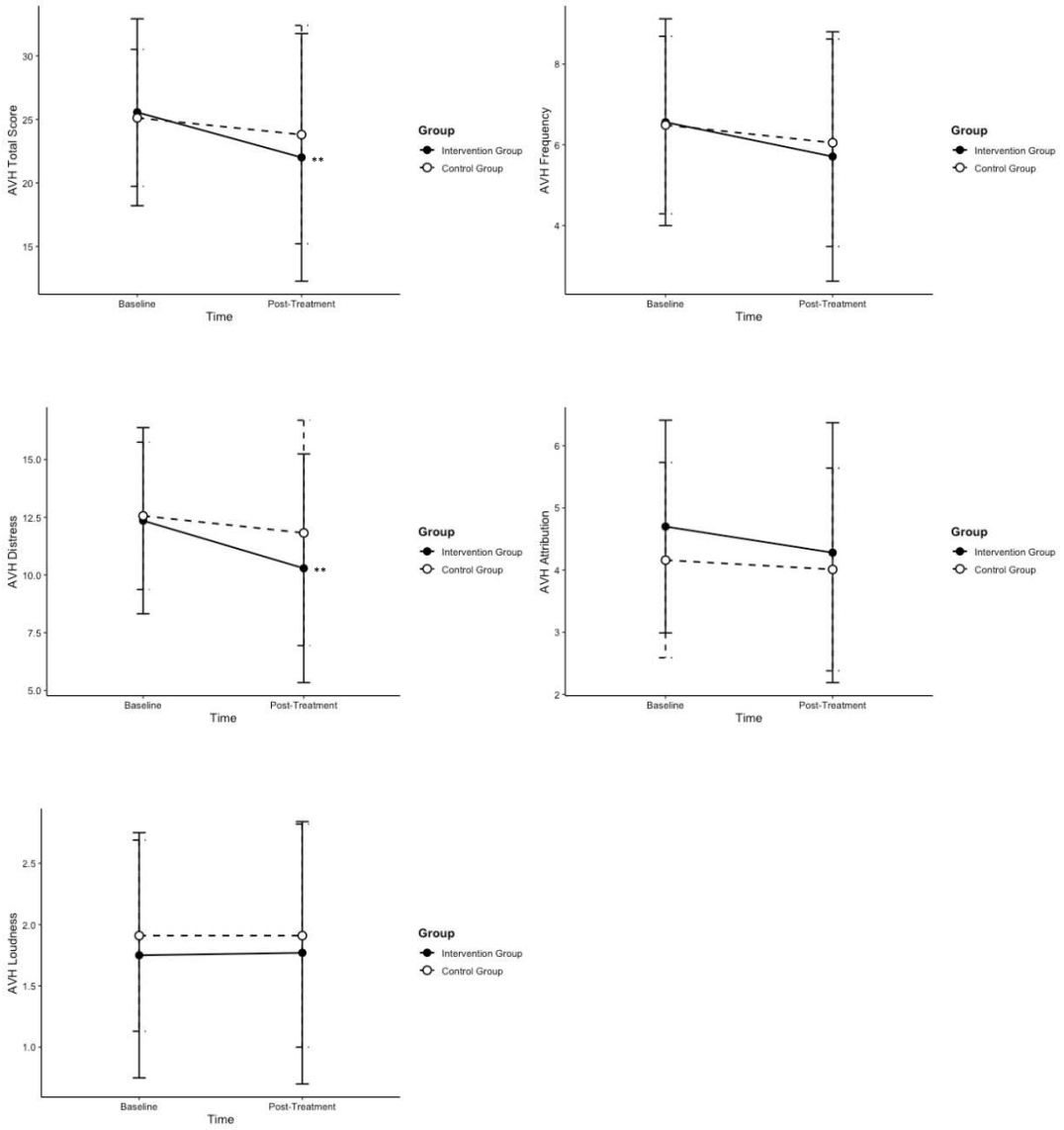
	ITT-Data								**PP-Data**							
	$SH_{MBI\text{-}MCT}$ (*n* = 43)				WL (*n* = 43)				$SH_{MBI\text{-}MCT}$ (*n* = 32)				WL (*n* = 41)			
Domain	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*	*t*	*p*	Δ	*d (95% CI)*
Avolition	2.18	**.036***	0.82	0.36 (0.05; 0.67)	-0.41	.683	-0.12	-0.06 (-0.36; 0.24)	1.62	.114	0.50	0.29 (-0.07; 0.64)	-0.62	.541	-0.17	-0.10 (-0.04; 021)
Anhedonia	0.13	.895	0.05	0.02 (-0.28; 0.32)	0.31	.761	0.08	0.05 (-0.25; 0.35)	0.71	.481	0.22	0.13 (-0.22; 0.47)	0.28	.784	0.07	0.04 (-0.26; 0.35)
Positive and negative affect, PANAS																
Positive affect	-1.05	.303	-1.40	-0.18 (-0.48; 0.12)	-0.92	.366	-0.96	-0.14 (-0.44; 0.16)	-1.53	.135	-1.84	-0.27 (-0.62; 0.08)	-0.66	.512	-0.71	-0.10 (-0.41; 0.20)
Negative affect	1.52	.139	2.08	0.25 (-0.05; 0.56)	0.37	.712	0.31	0.06 (-0.24; 0.36)	2.36	**.025***	2.88	0.42 (0.05; 0.78)	0.45	.655	0.34	0.07 (-0.24; 0.38)

Note. SH_{AVH} = self-help intervention group, $WL_{control}$ = waiting list control group, T_0 = baseline assessment, T_1 = post-assessment, Δ = mean difference from T_0 to T_1; PSYRATS = Psychotic Symptom Rating Scale, BAVQ-R = Beliefs About Voices Questionnaire Revised, LSHS-R = Launay-Slade Hallucination Scale Revised, SNS = Self-Evaluation of Negative Symptoms, PANAS = Positive and Negative Affect Schedule. Within-group tests were paired sample *t*-tests, with two-sided *p*. According to Chadwick et al. (2000), higher scores in the subscales *Omnipotence*, *Malevolence*, and *Resistance* indicate maladaptive coping (negative outcome), while *Benevolence* and *Engagement* indicate adaptive coping with voices (positive outcome). Positive mean differences indicate a reduction in symptoms (pre-value minus post-value) while negative mean differences indicate an increase in symptoms, except for the BAVQ-R subscales *Benevolence*, *Engagement*, and *Positive Affect*.

* $p < .05$, ** $p < .01$, *** $p < .001$

Figure 3

Changes in auditory hallucinations in the intention-to-treat (ITT) sample

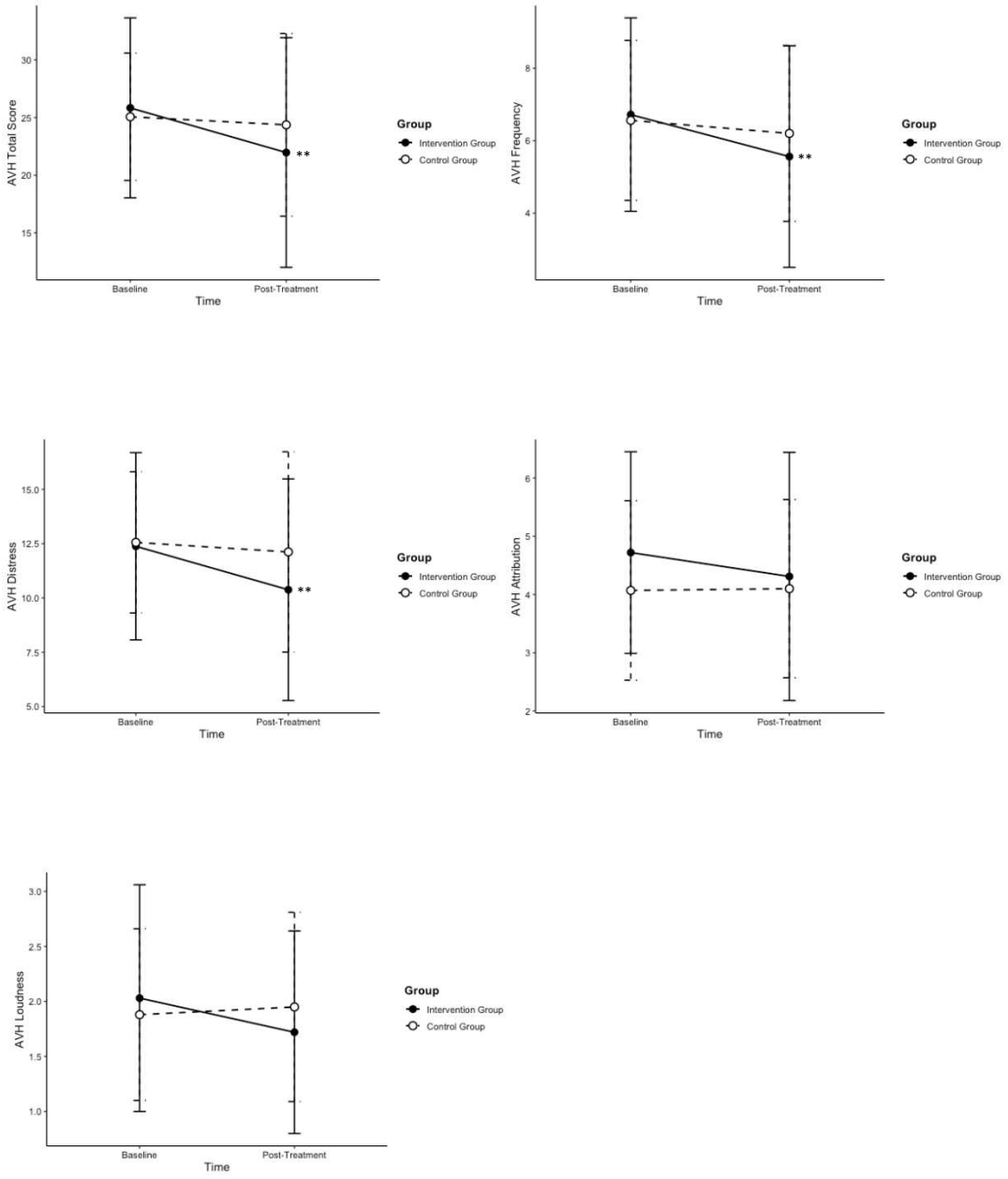


Note. AVH = Auditory Verbal Hallucinations. Points indicate group means over time, with time shown on the x-axis and auditory hallucinations scores on the y-axis. Error bars represent ±1 standard deviation. The solid line represents the intervention group, and the dashed line represents the control group. Significance indicates within-group changes over time for each outcome.

* $p < .05$, ** $p < .01$, *** $p < .001$

Figure 4

Changes in auditory hallucinations in the per-protocol (PP) sample



Note. AVH = Auditory Verbal Hallucinations. Points indicate group means over time, with time shown on the x-axis and auditory hallucinations scores on the y-axis. Error bars represent ±1 standard deviation. The solid line represents the intervention group, and the dashed line represents the control group. Significance indicates within-group changes over time for each outcome.

* $p < .05$, ** $p < .01$, *** $p < .001$

Satisfaction with the intervention

The CSQ-8 total score (ITT: $M = 26.50$, $SD = 4.45$; PP: $M = 26.78$, $SD = 4.35$) indicated very high satisfaction with the intervention and predominantly excellent to good ratings (ITT: range 86.11%-97.22%, PP: range 87.50%-96.88%; see Table 4). Furthermore, additional questions indicated overall high satisfaction with the manual (ITT: $M = 2.99$, $SD = 0.69$; PP: $M = 3.07$, $SD = 0.65$). The *improvement of symptoms* with excellent to good ratings by 50.0% of participants and *implementation in daily life* with excellent to good ratings by 71.9% of participants was appraised less satisfying compared to the other items, while still suggesting high satisfaction in those domains (Table 4).

(Serious) adverse events in both study groups

We recoded a total of five AEs (5.8%). Two were rated as SAEs (*hospitalization during participation*) and one as an AE (*death of a relative*) unrelated to treatment and trial procedures[80], all occurring in the WL control group. One person from the $SH_{MBI\text{-}MCT}$ group experienced a serious Pre-Treatment Emergent Event (PTEE) unrelated to treatment or trial procedures[80], referring to a hospitalization one day after T_0 to avoid homelessness. Only one registered AE in the $SH_{MBI\text{-}MCT}$ group was temporarily related to trial procedures, causing an inner conflict and distress of the participant that omitted after stopping the participation (transient, non-harmful, mild without consequences). A statistical comparison showed no significant differences in AEs between study groups (χ^2 (1) = 0.21, p = .645). See the supplement for details on recorded (S)AEs.

Unwanted Events (UEs) and side effects reported in the $SH_{MBI\text{-}MCT}$ group

A total of n = 12 (37.5%) participants from the intervention group reported at least one UE during the participation period, with cognitive (n = 10) and emotional (n = 10) UEs as the most reported, followed by somatic (n = 7) and other (n = 2) UEs. However, only in n = 6 participants the UEs were related to treatment and rated as a side effect of $SH_{MBI\text{-}MCT}$, indicating high safety of the intervention. Emotional UEs were on average moderate (M = 1.70, SD = 0.67) and mostly comprised transient distress associated with the exposure and analysis of voices in the beginning of the intervention. Cognitive (M = 1.70, SD = 0.67) and somatic (M = 1.71, SD = 0.76) UEs were on average mild to moderate. According to Linden [80], reported UEs were overall mild, expectable, transient, and non-harmful. Only one UE was rated as *moderate to severe* since the person reported substantial distress in the beginning of treatment that caused support from their psychotherapist and social worker. However, the UE was transient and non-harmful

since distress decreased over time and the treatment was experienced as helpful. See the supplementary material for a detailed extraction, classification, and possible relatedness to $SH_{MBI\text{-}MCT}$ of each reported UE (Table S1 and S2).

Table 4

Subjective satisfaction with the intervention at post-treatment

	ITT-data (*n* = 36)		**PP-data (*n* = 32)**	
Item, post-treatment (T_1)	$SH_{MBI\text{-}MCT}$ *M* (*SD*)	Positive Rating *n* (%)	$SH_{MBI\text{-}MCT}$ *M* (*SD*)	Positive Rating *n* (%)
CSQ-8				
How do you rate the quality of $SH_{MBI\text{-}MCT}$?	3.28 (0.66)	32 (88.89%)	3.31 (0.64)	29 (90.62%)
Did you receive the kind of treatment you expected with $SH_{MBI\text{-}MCT}$?	3.17 (0.66)	31 (86.11%)	3.22 (0.61)	29 (90.62%)
To what extent did $SH_{MBI\text{-}MCT}$ met your needs?	3.19 (0.67)	31 (86.11%)	3.25 (0.62)	29 (90.62%)
Would you recommend $SH_{MBI\text{-}MCT}$ to a friend with similar symptoms?	3.58 (0.55)	35 (97.22%)	3.59 (0.56)	31 (96.88%)
How satisfied are you with the extent of help you received from $SH_{MBI\text{-}MCT}$?	3.36 (0.64)	33 (91.67%)	3.38 (0.66)	29 (90.62%)
Did $SH_{MBI\text{-}MCT}$ help you to better cope with your problems?	3.25 (0.65)	32 (88.89%)	3.31 (0.59)	30 (93.75%)
How satisfied are you with $SH_{MBI\text{-}MCT}$ overall?	3.33 (0.76)	32 (88.89%)	3.34 (0.79)	28 (87.50%)
Would you use $SH_{MBI\text{-}MCT}$ again?	3.33 (0.76)	32 (88.89%)	3.38 (0.75)	29 (90.62%)
Mean total score	26.50 (4.45)		26.78 (4.35)	
Additional Questions				
I consider the manual suitable for a self-guided use.	3.31 (0.75)	30 (83.33%)	3.38 (0.71)	28 (87.50%)
My symptoms improved because of using the manual.	2.36 (0.96)	17 (47.22%)	2.44 (0.88)	16 (50.00%)
I consider the manual suitable as an adjunct to psychotherapy.	3.36 (0.93)	29 (80.56%)	3.38 (0.94)	26 (81.25%)
I was able to integrate working through the manual into my daily life.	2.78 (0.93)	24 (66.67%)	2.88 (0.83)	23 (71.88%)
I consider the manual suitable for my symptoms.	3.17 (0.97)	28 (77.78%)	3.28 (0.92)	26 (81.25%)
Mean total score	13.97 (3.43)		14.34 (3.27)	

Note. $SH_{MBI\text{-}MCT}$ = self-help intervention, ITT = Intention-To-Treat, PP = Per-Protocol, *M* = mean, *SD* = standard deviation, *n* = sample, % = percentage. Both scales are ranging from 1 to 4, with higher scores indicating higher satisfaction. If one item was rated on 3 (reflecting *good* satisfaction) or 4 (reflecting *excellent* satisfaction), it was coded as a positive rating. The CTQ-8 has a maximum total score of 32. The additional questions had a maximum total score of 20.

Discussion

To the best of our knowledge, this is the first RCT that examined the efficacy, satisfaction, and retention of an unguided self-help intervention for AVHs and SSDs, based on MCT and mindfulness, compared to a waiting list control group in Germany. We found no significant difference between groups in the *overall severity of AVHs* in the ITT-, however, PP-sample. Overall, our results indicate the intervention to be efficacious in different outcome domains, especially those measuring severity of AVHs and when participants adhered to the treatment protocol. Findings also demonstrated high acceptability and satisfaction with the intervention, suggesting the self-help manual to be a promising and accessible tool that addresses the severe treatment and implementation gap for this marginalized population.

We found no significant difference in the ITT sample between the $SH_{MBI\text{-}MCT}$ and WL group in our primary outcome *frequency and distress of AVHs* (*overall severity of AVHs*). This is not in line with our hypothesis but could have different explanations. One could be that the effects of our self-help approach are not superior to standard care. However, another could be adherence to treatment that is of particular importance when applying an unguided intervention. We conclude that this is reflected in our results since, despite the non-significant findings in the ITT sample, the $SH_{MBI\text{-}MCT}$ group showed a significantly greater reduction in the *overall severity of AVHs* in the PP sample compared to the WL group with a medium effect size (p = .040, η^2_p = 0.06). Besides, only the intervention group showed a significant reduction in the *severity of AVHs* with medium-sized effects in both the ITT (d = 0.49) and PP sample (d = 0.55), whereas the *severity of AVHs* did not significantly decrease in the control group. The differing between-group significance and effect sizes in the ITT and PP sample is in line with previous research, suggesting that PP samples with high adherence to treatment and trial protocols indicate higher effect sizes than ITT analyses[91,92]. Our results also imply that the self-help intervention is predominantly effective in reducing the *severity of AVHs* when patients

adhere to the assigned treatment (≥50% of manual used). The change in *severity of AVHs* aligns with findings from a previous meta-analysis examining general self-help interventions for psychosis, indicating small-to-medium sized effects for positive symptoms ($d_{weighted}$ = 0.42)[24]. Although previous studies emphasize the superiority of guided over unguided interventions[28,93,94], self-guided approaches incorporate important advantages such as the reduction of social, structural and stigma related barriers, a low-threshold and independent access, as well as minimal treatment costs. This further accentuate our unguided self-help manual to be a promising tool in addressing the implementation and treatment gap in psychotherapy for psychosis[95].

The subscales *Frequency*, *Distress*, *Controllability*, and *Loudness* of the PSYRATS-AH did not differ significantly between the groups in both samples. However, *Distress* significantly decreased in the $SH_{MBI\text{-}MCT}$ group, both in ITT and PP analyses with medium-sized effects (d = 0.47), while a reduction in *Frequency* was only observed in the PP sample (d = 0.54). None of the AVH subscales significantly decreased in the control group. The reduction in AVH distress aligns with the rational of MCT[96] and mindfulness[97,98] interventions that aim to ameliorate distress associated with psychotic symptoms through metacognitive insights and acceptance for the self and psychotic experiences, rather than focusing solely on reducing the frequency of AVHs. While within-group reductions are promising, our manual could not reach between-group effectiveness, potentially explained by a small sample size that increases the possibility of type II errors[99]. Future research should examine the self-help manual in a larger sample to verify our results and to further analyze the effects on AVHs characteristics that could influence the development of novel and low-threshold interventions for SSDs.

Beliefs about voices did not significantly differ between groups, neither in the ITT nor in the PP sample. Nevertheless, *Omnipotence* of voices significantly decreased in the $SH_{MBI\text{-}MCT}$ group in PP analysis with a medium effect (d = 0.49), indicating a reduction in maladaptive coping with voices that is associated with decreased distress[59,60]. Reduction in *Omnipotence* of

voices was possibly addressed by the intervention in adherend participants through the development of adaptive coping strategies.

Regarding *Hallucinatory experiences*, the intervention group showed a significantly greater reduction with medium- to large-sized effects (η^2_p = 0.07 to η^2_p = 0.14) in all LSHS-R outcomes and both samples (ITT and PP) compared to the control group, except for *Vivid mental events* in the ITT sample. The same results were found for within-group changes in the $SH_{MBI\text{-}MCT}$ group, where significant symptom reductions could be observed for all outcomes, except for *Vivid mental events* in the ITT sample. Again, none of the outcomes were decreased in the control group. Those results further emphasize the efficacy of the $SH_{MBI\text{-}MCT}$ in addressing experiences closely linked to AVHs such as general hallucinatory experiences[13,100]. The LSHS-R may also be more sensitive for change as it does not merely assess pathological stages of hallucinations but rather considers a continuum model of AVHs, capturing various hallucinatory facets[64,101].

Negative symptoms were not significantly different between groups, neither in ITT nor in PP analyses. However, *Avolition* in the ITT sample (d = 0.35) and *Social withdrawal* in the PP sample (d = 0.40) both significantly decreased with a medium effect size. No significant reductions were observed for the control group. Those results refer to promising improvements in some negative symptom domains, although we found no between-group differences. The inconsistencies in our results are also reflected in previous meta-analytic research, where medium effects were found for self-help for psychosis on negative symptoms ($d_{weighted}$ = 0.37)[24] while psychological interventions targeting AVHs are less effective in treating negative symptoms[102]. The reduction in AVHs characteristics through our manual may also contribute to improvements in secondary negative symptoms which were found to be associated with positive symptoms[103,104]. However, future studies on the relationship between (secondary) negative symptoms and AVHs are crucial to draw valid conclusions.

Furthermore, a significant difference in *Negative affect* between groups in the PP sample with a medium effect size ($p = .039$, $\eta^2_p = 0.06$) indicated the intervention to be effective in reducing negative feelings when adhering to the treatment that is possibly liked to changes in AVHs severity[105]. All other outcomes on *Positive and Negative affect* were not significant.

Overall, results on secondary outcomes partly indicate superiority of the intervention compared to the WL across domains, with significant symptom reductions in the $SH_{MBI\text{-}MCT}$ group that were not observed in the WL group, especially in symptoms closely linked to AVH severity. Again, significant results could be predominantly observed when participants adhered to the study and treatment protocol, emphasizing predictors for adherence as a crucial aspect in the efficacy of psychological self-help that should be considered in future trials and the development of treatments. However, we did not control for multiple testing, examined a small sample size, and only included self-ratings that should be considered when interpreting our results.

The retention rate of 90.7% was high and comparable to other guided and unguided digital interventions for schizophrenia (mean pooled retention: 87.6%)[106]. Overall, the drop-out rate of 9.3% was low. Meta-analytic results of psychological interventions targeting AVHs in SSDs indicated pooled study drop-out rates of 15.01% in intervention and 16.21% in control groups[102]. The drop-out rate for intervention groups aligns with our results that indicated 16.28% of drop-out in $SH_{MBI\text{-}MCT}$, while the control group had a minimal drop-out rate of 2.33%. This substantial difference between groups in study dropout could possibly be explained by the delayed access to the manual of the WL group. Participants in the control group received access to the intervention after T_1 with a potentially higher incentive to stay in the study, while the $SH_{MBI\text{-}MCT}$ group immediately accessed the treatment after T_0. Future studies should examine the intervention in comparison to other conditions e.g., (in-) active controls.

Although guided interventions have been proposed superior to unguided approaches in several studies[28,93,94], our trial could reach a comparable[107,108] treatment adherence of 74.4% without ongoing guidance or support. One potential explanation could be the present participant involvement approach that has been shown to increase adherence[31], further emphasizing the acceptability and satisfaction of the applied self-help manual. Subjective reports on satisfaction with the intervention additionally indicated that participants were overall very satisfied with different domains of the manual. The feasibility rate of 92.47% further supports the high applicability of the self-help manual in routine care.

The collection of subjective UEs and reported (S)AEs indicated only few side effects that were related to treatment and expectable, as reported in previous trials on psychotherapy[109,110] and self-help[108] for psychosis. Overall, UEs and side effects of the intervention were mild, transient, and non-harmful[80], further emphasizing the safety of the manual for an unguided use. However, one *moderate to severe* but transient UE was related to treatment, occurring in the beginning of the intervention. As reflected in our findings, reported UEs and side effects predominantly occurred in early stages of the treatment when exposure to voices can be distressful. Side effects and UEs should be considered in following trials and application of unguided interventions that might need individual formulation-based implementation[111] according to different symptom domains and characteristics of voices hearers such as associations to trauma[112]. Future studies should also examine if low-threshold guidance or regular contact with health care providers, especially in the beginning of working with the manual, could further increase efficacy and safety of the treatment.

Strengths and limitations

The findings of this RCT provide evidence for the efficacy of an unguided self-help manual for AVHs in SSDs based on MCT and MBIs in a homogenous sample. The study was preregistered and incorporated several predefined outcomes, assessed by validated rating

scales. Participation was self-guided and online, ensuring a low threshold access. Analyses were statistically controlled for potential confounding effects, including significant demographics and baseline outcomes. Besides, recruitment took place nationwide around Germany. The assessment of antipsychotics, psychological treatments, and changes throughout participation allowed for analyses on differences between groups. Results for ITT and PP samples provided interpretation of results both under clinically *'real world'* (ITT) and *'perfect conditions'* when persons adhere to the treatment protocol (PP). Compared to the initial self-help manual[30], our results suggest that adherence and efficacy of the $SH_{MBI\text{-}MCT}$ intervention could be substantially improved.

However, our findings must be considered alongside some limitations. To sustain low barriers, we only applied self-reports whereas rater-based outcomes might have achieved different results[113]. Although the waiting list control group correspond to real-world outpatient settings, is was found to be at risk for nocebo effects[114] that should be considered when interpreting our results. Even though the sample size was adequate to achieve initial findings, future fully powered trials are crucial to further examine the efficacy of $SH_{MBI\text{-}MCT}$. Results on secondary outcomes should be interpreted in consideration of potential biases of multiple testing[115]. Lastly, our study only included one post-treatment assessment, lacking evidence for longer follow-up periods. Since coping strategies for AVHs have been found to be effective after some time[116], future studies should incorporate follow-up measurement points.

Conclusion and implications

The present trial provides preliminary evidence for the efficacy of a low-threshold intervention that seems to be a promising approach to address the implementation and treatment gap in AVHs and SSDs. Although the overall severity of AVHs could not be substantially reduced by the intervention compared to the control group in the ITT sample, we found a significant difference in the PP analysis. The combination of MCT and mindfulness appeared to have reduced

characteristics of AVHs and closely associated symptoms, especially when participants adhered to the treatment protocol. Results on retention and adherence further indicate high feasibility of the manual in routine care. Comprehensive research endeavors should further focus on the efficacy of the present self-help manual in a larger sample with longer follow-up periods and blended care approaches incorporating human contact[117]. A comprehensive understanding of the effects and mechanisms of action of self-help for AVHs will not only inform clinicians and voices hearers about effective strategies to cope with AVHs but also enhance the access to evidence-based treatment.

Data availability. Additional material is available in an online supplement. Data and codes can be supplied upon reasonable request.

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Declaration of interests

All authors declare no financial or non-financial competing interests.

Authors contributions

L.F., K.B., and S.M. led the conceptualization and design of the study with significant contributions regarding methodology from all authors. L.F. and K.B. acquired funding. L.F. led the data curation with supervision from K.B. and randomization from I.H. L.F. coordinated and administered the project, with supervision from K.B., S.M., M.B., and C.K. Data analysis, figure and table preparation, and writing the original draft was carried out by L.F. All other authors provided revisions and approved the final manuscript.

AI use

The authors used ChatGPT (OpenAI) and Mistral.AI for language editing, assistance with improving the clarity and structure of the manuscript, and support in developing and refining R

codes for data processing and statistical analyses. The authors independently verified all codes, analyses, and results. The authors take full responsibility for the content of the manuscript. No content was generated with AI.

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