Mindfulness-based group therapy in young inpatients with acute early psychosis - *FEEL-GOOD*

Study protocol
Version 2.0 | March 26th, 2026

The following persons agree to the contents of this protocol by signing it and confirm that they are familiar with the DvH and the ICH-GCP guideline and that the clinical trial will be conducted in accordance with these regulations. Any changes affecting the responsibility of any of the signatories must be reported to the ethics committee without delay.

Chief Investigator

Andreas Bechdolf, Prof. Dr. med.	Berlin, 26.03.2026
Name, Title	Place, Date

Study coordination(Charité)/Study lead

Aisha J.L. Munk, PD Dr. rer. nat.	Berlin, 26.03.2026
Name, Title	Place, Date

Co-Chief Investigator

Stephanie Mehl, Prof. Dr. rer. nat.	Marburg/Frankfurt, 26.03.2026
Name, Title	Place, Date

The person listed below is responsible for the biometrics/statistics of the clinical trial (see the relevant sections of the protocol), including the statistical analysis plan.

Biometrician

Daniel Schulze, Dr. rer. nat.	Berlin, 25.03.2026
Name, Title	Place, Date

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- Confidential -

The information contained in this protocol must be treated as strictly confidential. It is intended solely for the information of the investigator, his staff, the ethics committee, the CTO, and for patient education purposes.

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1. General information

1.1. Abbreviations

Abbreviation	Explanation
ACS	Adherence and Competency Scale
AE	Adverse event
CBTp	Cognitive Behavioral Therapy for Psychosis
CERQ	Cognitive Emotion Regulation Questionnaire
CDSS	Calgary Depression Scale for Schizophrenia
CSQ	Client Satisfaction Questoinnaire
CTO	Clinical Trial Office
CTS-R-P	Cognitive Therapy Scale Revised for Psychosis
DALYs	Disability-adjusted life years
DSM-5	Diagnostic and Statistical Manual of Mental Disorders
eCRF	Electronic case report form
EMA	Ecological Momentary Assessment
EP	Early psychosis
ERSQ	Emotion Regulation Skills Questionnaire
FEP	first psychotic episode
GAF	Global Assessment of Functioning
FFMQ-D	Five-Facet Mindfulness Questionnaire German Version
GDPR	General Data Protection Regulation
GCP	Good Clinical Practice
GEP	Good epidemiological practice
IDMC	Independent data monitoring and safety committee
iSAT	Inpatient Social Activity Therapy
MBI	Mindfulness-based Intervention
MVT	Multiple-Choice Vocabulary Intelligence Test
MBCI	Mindulfness-based Crisis Intervention
MBCT-AS	Mindfulness-Based Cognitive Therapy Adherence Scale
OSF	Open Science Framework
PANSS	Positive and Negative Symptom Scale
PANSS-G	Positive and Negative Symptom Scale - General Psychopathology Subscale
PANSS-N	Positive and Negative Symptom Scale – Negative Symptoms Sub-scale
PANSS-P	Positive and Negative Symptom Scale – Positive Symptoms Subscale
PI	Principal Investigator
PPI	Public and Patient Involvement
PROBE	Prospective randomized open blinded end-point
PSW	Peer support workers
PSYRATS-D	Psychotic Symptom Rating Scales for Delusions
PSYRATS-H	Psychotic Symptom Rating Scales for Hallucinations
RCT	Randomized controlled trial
RFS	Role Functioning Scale

RSES	Rosenberg Self-Esteem Scale
SAE	Severe adverse event
SCID-5-RV	Structured Clinical Interview for DSM-5 Disorders - Research Version
SEK	Selbsteinschätzung Emotionaler Kompetenzen
SOP	Standard operating procedure
TAS	Toronto Alexithymia Scale
TAU	Treatment as usual
WHOQOL-BREF	Short version of the World Health Organization Quality of Life
ZUF	Fragebogen zur Messung der Patientenzufriedenheit

1.2. Clinical study sites and responsible staff

FEEL-GOOD is a multi-site clinical study. Andreas Bechdolf in his role as Chief Investigator and Stephanie Mehl as Co-Chief Investigator oversee the conduct of the trial. Andreas Bechdolf is responsible for overall reliability for management, coordination, and study completion. The operational coordination and management of the study across all sites is carried out by Aisha Munk, who acts as study lead and is responsible for the implementation of study procedures and coordination between study sites. FEEL-GOOD will be conducted by the following parts (table 1).

Table 1. Clinical study sites and responsible staff

Sponsor and Chief Investigator	
Name	Charité – Universitätsmedizin Berlin, Department of Psychiatry and Neurosciences, CCM Prof. Dr. Andreas Bechdolf (Sponsor representative/Chief Investigator)
Institution	Charité – Universitätsmedizin Berlin, Charitéplatz 1, Berlin 10117, Germany
Telephone	+49(0) 15114552161
Email	andreas.bechdolf@charite.de
Role and responsibilities	Chief Investigator, who will lead the clinical study and have overall responsibility for management, coordination, and study completion
Qualification	M.D, Specialisation in Psychiatry, Head of the Departments of Psychiatry, Psychotherapy, and Psychosomatics at Vivantes Klinikum Am Urban and Friedrichshain (Charité-affiliated), Professor at Charité –Universitätsmedizin Berlin, Prinicipal Investigator in studies on early psychosis, youth mental health, CBT, home treatment, Safewards, and IPS employment interventions

Study coordination / Study lead	
Name	Charité – Universitätsmedizin Berlin, Department of Psychiatry and Neurosciences, CCM PD. Dr. Aisha J.L. Munk (Study coordination / Study lead)
Institution	Charité – Universitätsmedizin Berlin, Charitéplatz 1, Berlin 10117, Germany
Telephone	+49(0) 30 130
Email	aisha.munk@charite.de
Role and responsibilities	Study coordination / Study lead, responsible for the overall operational management of the trial, coordination across all study sites, implementation of study procedures, and supervision of study conduct.
Qualification	M.D., Licensed physician, Specialist in Psychiatry (in training), PhD in Neuroscience, Habilitation in Psychology, background in translational and clinical research.

Co-Chief Investigator	
Name	Philipps-University Marburg, Department of Psychiatry and Psychotherapy (Clinical Study Site) / **Marburg** Prof. Dr. Stephanie Mehl (Co-Chief investigator)
Address of the institution	Philipps-University Marburg, Department of Psychiatry and Psychotherapy Rudolf-Bultmann-Str. 8 35039 Marburg
Telephone	+49(0) 6421/5865359
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Qualification	Ph.D., Licensed CBT therapist, Licensed CBT supervisor, Managing Psychologist at the Department of Psychiatry and Psychotherapy, University of Marburg, Professor at the University of Applied Sciences Frankfurt am Main, Principal investigator in studies on CBT for psychosis and experimental or EMA studies on CBT for psychosis.

Table 2. Further participating groups/bodies.

Group	Composition	Role(s)
Peer support workers (PSW)	tbd	Involved in improving and shaping the intervention, preparation of patient documents and recruitment strategy; support data analyses and interpretation; collaboration and part of decision-making in publication projects
Clinical Trial Office (CTO), Charité Universitätsmedizin Berlin CCM	Dr. Susen Burock (Head of CTO)	Responsible for regulatory affairs, quality assurance/ on site monitoring and data management
Independent experts	Prof. Dr. Mar Rus-Calafell (Department of Clinical Child and Adolescent Psychology, University of Bochum) Prof. Dr. Stefan Klingberg (University Hospital and Faculty of Medicine, University of Tübingen) Dr. Björn Schlier (Department of Child and Adolescent Psychology, University of Wuppertal)	Support the trial by adding theoretical knowledge and empirical research experience in the field of psychotherapy in patients with psychosis/ schizophrenia-spectrum disorders by giving feedback to the trial protocol, trial manual and supervision procedures as well as data analyses and dissemination and publication of the results.
Independent data monitoring and safety committee (IDMC)	Prof. Dr. Steffen Moritz (University Medical Center Hamburg Eppendorf, Hamburg) Dr. Andreas Gleiss (Center for Medical Data Science (Institute of Clinical Biometrics), Medical University of Vienna)	Management of access to data upon approval; Reviews safety data and interim results during the clinical study to protect participants and recommend whether the study should continue, be modified, or stopped.

	Dr. Christopher Hautmann (Department of Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy, Faculty of Medicine and University Hospital, University of Cologne)	
Trial statistician	Dr. Daniel Schulze (Charité Universitätsmedizin, Institute of Biometry and Clinical Epidemiology)	Statistical analysis plan, statistical analysis

1.3. Title

Mindfulness-based group therapy in young inpatients with acute early psychosis – *FEEL-GOOD*

Acronym of the intervention: *FEEL-GOOD*

The registration is planned in the ISRCTN registry as a primary clinical study registry acknowledged by the World Health Organisation (WHO) and the International Committee of Medical Journal Editors (ICMJE).

1.4. Funding

The study is funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) (Project number: 536597614).

1.5. Agreements

Clinical study site agreement between sponsor and each site will be established prior to the Site Initiation Visits.

2. Synopsis

Title	Mindfulness-based group therapy in young inpatients with acute early psychosis – *FEEL-GOOD*
Short title	FEEL-GOOD
Sponsor name and address	Charité – Universitätsmedizin Berlin, Charitéplatz 1, Berlin 10117, Germany

Participating Location(s) and country	Vivantes Klinikum Am Urban, Berlin, Germany, Philipps-Universität-Marburg, Marburg, Germany, Charité – Universitätsmedizin Berlin, Germany, University Medical Center, Munich, Germany University Medical Center Hamburg-Eppendorf, Hamburg, Germany Central Institute of Mental Health, Mannheim, Germany University of Augsburg, Augsburg, Germany University Medical Center Cologne, Cologne, Germany
Rationale	Early psychosis is a critical period for intervention, offering an unique opportunity to prevent symptom deterioration and chronification. Current cognitive behavioral interventions show limited efficacy and low adherence among young patients. Mindfulness-based interventions (MBI) may complement existing CBT approaches by enhancing emotional awareness, acceptance, and regulation. Evidence to date is promising but methodologically limited, particularly for inpatient populations. The FEEL-GOOD trial therefore aims to evaluate the efficacy and mechanisms of a short-term mindfulness-based group intervention (FEEL-GOOD) in combination with treatment as usual (TAU) compared to TAU alone in inpatients with acute early psychosis (EP).
Objectives	To evaluate a mindfulness-based group intervention (FEEL-GOOD, 8 sessions) in addition to treatment as usual (TAU) at post-intervention (t2 after 4 weeks) regarding total psychopathology, positive and negative symptoms, and general psychopathology measured with the Positive and Negative Symptom Scale (PANSS), as well as acceptance of symptoms, mindfulness-related and emotion regulation skills in inpatients with EP in comparison to the control group only receiving TAU.
Design of the study	FEEL-GOOD is an interventional trial conducted as a prospective randomized open blinded evaluation (PROBE). Inpatients with EP will be allocated 1:1 to either the experimental condition receiving FEEL-GOOD + TAU or a control condition solely receiving TAU. Inpatients will be recruited from participating study sites. Outcome data will be collected at 3 time points: baseline (t1), 4-week (t2; post-intervention), and 6-month (t3) follow-up.

Inclusion criteria	Age: 16–35 years Clinical diagnosis of EP, defined as the first psychotic episode within the last 5 years. Diagnoses will be confirmed using the Structured Clinical Interview for DSM-5 Disorders – Research Version (SCID-5-RV), German adaptation (DSM-5: 297.1, 298.8, 295.4, 295.9, 295.7, 298.8, 298.9) Currently receiving inpatient/day clinic treatment with a planned stay of at least 4 weeks Being interested and willing to take part in the FEEL-GOOD and/or TAU intervention
Exclusion criteria	Estimated verbal IQ < 85 assessed with the German Multiple-Choice Vocabulary Intelligence Test Insufficient German language abilities Acute suicidality or acute threat to others
Primary outcome	Observer-rated (blinded) total psychopathology assessed with PANSS at 4 weeks post-intervention
Secondary outcomes	Observer-rated (blinded): Positive and negative symptoms, general psychopathology (PANSS subscales) Delusions and hallucinations (PSYRATS-D/PSYRATS-H) Depressive symptoms (CDSS) Level of functioning (RFS) Serious adverse events (SAEs), i.e., hospitalization, death, symptom worsening, suicidality, or life-threatening events Drop-outs and their causes Global Assessment of Functioning (GAF) Self-reports: Quality of life (WHOQOL BREF) Patient satisfaction (ZUF-8)
Mediators (self-reports)	Emotion regulation skills (SEK-27/ERSQ) Cognitive emotion regulation strategies (CERQ) Emotional awareness (TAS-26) Self-esteem (RSES) Mindfulness skills (FFMQ-D)

Ecological momentary assessments	Total psychopathology, mindfulness skills and emotion regulation in daily life with assessments at baseline (t1) and finishing at 4-weeks post-intervention (t2), with 1 prompt per. The number of items ranges from 39 to 46, depending on conditional branching. Items were developed based on literature review and consensus within the coordinating research team. .
Participant timeline	April 2026: First patient in October 2026: First patient out, last assessment January 2028: Last patient in July 2028: Last patient out, last assessment. All participants willing to participate and having provided informed consent will be screened for eligibility at t0. If enrolled, participants complete baseline assessments at t1. Follow-up assessments will then be conducted at 4-week (t2) and 6-month (t3) from baseline.
Sample size	The target sample size will be N = 252 (*n* =1 26 FEEL-GOOD+TAU vs. *n* = 126 TAU). Expecting a dropout rate of 25% at t2, *n* = 188 are to be included in data analysis.
Statistical Analysis	Changes in total psychopathology, measured with the PANSS total score, will be compared between TAU and FEEL-GOOD+TAU after 4 weeks post-treatment. The primary analysis will follow the intention-to-treat (ITT) principle using a longitudinal mixed model with treatment, time points, and their interaction, gender, and baseline symptom severity as fixed effects, and participant ID, group ID, and recruitment centre as random effects. Secondary outcomes will be analysed descriptively using appropriate models (e.g., linear or logistic mixed-effects regression). Mediation effects will be tested via multilevel structural equation modelling, focusing on mediators at T2 predicting outcomes from T1 to T3. EMA data will be analysed using longitudinal mixed models accounting for nested structures. Sensitivity analyses (e.g., mixed-model vs. complete-case; ITT vs. per-protocol) will be performed. Safety analyses will include frequencies and rates of SAEs. The final statistical analysis plan will be published on the Open Science Framework (OSF).

3. Introduction

3.1 Background and rationale

Psychotic disorders impose a substantial burden on affected individuals, their families, and society. Early psychosis (EP) often develops into chronic schizophrenia, a disorder with a lifetime prevalence of approximately 1%, and up to 10% of affected individuals die by suicide [1,2]. Schizophrenia is among the top ten causes of disability-adjusted life years (DALYs) in individuals aged 15–44 years [3]. Its onset typically occurs during adolescence or early adulthood, resulting in major educational and occupational impairment, with only about 13% of patients completing secondary education or achieving competitive employment [4]. In addition, many individuals experience self-stigma, low empowerment, and reduced social participation. The direct and indirect costs of schizophrenia are the highest among psychiatric disorders in Germany, reaching approximately €9.2 billion annually [5].

Early intervention programs providing phase-specific psychological, psychosocial, and pharmacological treatment can improve outcomes and reduce the long-term consequences of EP [6-10]. However, the effectiveness of existing psychological interventions remains limited. Meta-analyses of cognitive behavioural therapy for psychosis (CBTp) show small-to-moderate effects [11], and adherence among young people is often low [12]. Moreover, CBTp traditionally focuses [13] on modifying delusional beliefs and hallucinations [14], which may not correspond with the treatment priorities of young people, who often seek help for distressing emotions rather than psychotic symptoms [15].

Recent research has highlighted the potential of “targeted” or “causal interventionist” approaches [16,17] that aim to modify underlying mechanisms contributing to psychotic experiences, such as self-esteem, sleep, worry, and reasoning [18-21]. These interventions show larger effect sizes in reducing delusional beliefs than traditional CBTp [22]. In this context, mindfulness-based interventions (MBIs) have emerged as a promising complementary approach. Mindfulness promotes present-moment awareness and nonjudgmental acceptance [23]. MBIs have shown beneficial effects across a range of psychiatric conditions, including psychosis [24], and demonstrate high acceptability among young people with EP [25].

Despite promising results, evidence for the efficacy of MBIs in early psychosis remains limited. While previous studies and meta-analyses have demonstrated that mindfulness-based approaches can improve a range of clinical and psychological outcomes, including positive, negative, and affective symptoms, as well as insight and treatment engagement [26-34], the heterogeneity of study designs and methodological weaknesses significantly limit the strength of the conclusions that can be drawn. Notably, the lack of adequately powered, randomized, and

blinded trials in acute inpatient populations represents a critical gap in current knowledge. This is particularly relevant given that inpatient treatment settings provide a unique therapeutic window during acute episodes, when individuals are typically highly symptomatic but also accessible to structured and closely monitored interventions.

A previous feasibility study provided valuable initial evidence that a brief, structured mindfulness-based group intervention can be successfully implemented in an acute inpatient setting for individuals with EP [35]. Importantly, it demonstrated high levels of acceptance and participation among inpatients, and significant effects on individual emotional goal attainment and on total psychopathology. However, the study used a pre-post design without a control group.

The proposed FEEL-GOOD trial aims to address these gaps by evaluating the efficacy of a short-term mindfulness-based group intervention (FEEL-GOOD) as an adjunct to treatment as usual (TAU) in inpatients with acute EP. The study adopts an innovative design combining blinded clinical assessments with ecological momentary assessment (EMA) to evaluate both clinical outcomes and daily-life changes in mindfulness, emotional awareness, and emotion regulation. This multi-site RCT will be the first to systematically investigate the effects of a mindfulness-based group intervention in acute EP inpatients. Positive findings would provide empirical justification for implementing MBIs as evidence-based, routine components of inpatient care for young people with EP.

3.2 Objectives

The overarching aim of the proposed trial is to examine the effects of a mindfulness-based group intervention (FEEL-GOOD, 8 sessions) in addition to TAU in inpatients with EP in comparison to TAU alone.

The primary objective is to assess the effect of FEEL-GOOD+TAU on total psychopathology as measured by the total score of the Positive and Negative Syndrome Scale (PANSS) [58] compared to only TAU in inpatients with EP. PANSS integrates positive, negative, and general psychopathological symptoms in people with psychotic disorders, which have all been shown to respond to MBIs in meta-analyses [26-31] as well as in our pilot trial [35], and it was suggested as the primary outcome by involved peer support workers (see Section 3.5.).

3.3 Hypotheses

To meet the objectives of the interventional trial, we will test the following hypothesis:

Inpatients with EP receiving mindfulness-based group intervention (FEEL-GOOD, 8 sessions) in addition to treatment-as-usual (TAU) will show lower levels of total psychopathology (pri-

mary outcome), positive and negative symptoms, general psychopathology, and improved acceptance of symptoms, mindfulness-related and emotion regulation skills in comparison to the control condition (TAU) at post-intervention (t2 after 4 weeks).

3.4 Study design

FEEL-GOOD is an interventional trial conducted as a prospective multi-site randomized controlled open trial with blinded ratings (PROBE). Inpatients with EP will be randomly assigned in a 1:1 ratio to one of two conditions: (a) the experimental condition, in which participants receive FEEL-GOOD and TAU, or (b) the control condition (TAU). Observer-rated (blinded) data and self-reports will be collected at 3 time points: at baseline (t1), at 4-week (t2), and 6-month (t3) follow-up (also see figure 1).

3.5 Public and Patient Involvement

The study also integrates public and patient involvement (PPI). Peer support workers (PSW) with lived experience were included in conceptualizing and planning the trial, including determining relevant outcomes and reviewing and approving the final concept. They will further contribute to improving and shaping the intervention, particularly in describing treatment modules and specific mindfulness tasks. During the preparation phase, PSW will be involved in writing all study-related documents for participants in plain language (e.g., informed consent forms and patient relatives and patients' information sheets) and in developing the recruitment strategy. After data collection is completed, PSW will support data analysis and interpretation. In the translational phase, collaborative publications with PSW are planned. The target audiences will include patients, family members, and the general public. The aim is to use stigma-free and accessible language to communicate the purpose and results of the research. PSW will also take part in decision-making related to publication projects. Additional forms of involvement include invitations for PSW to participate in (peer) conferences, with the opportunity to present study-related content. Feedback sheets on the trial’s structure and implementation of the intervention will be distributed to study participants, and articles for patient newsletters will be provided. PSW will be fully compensated for their efforts.

3.6 Study timeline

The whole study duration is 3 years starting in January 2026 till December 2028. Study preparation takes place in the end of 2025/beginning of 2026 with obtaining ethical approval in all sites by March 2026. A recruitment period of 22 months for reaching the target sample size (N=252) is planned, starting in April 2026. The duration of the follow-up is 6 months per participant and includes 3 assessments which take place at baseline (t1), 4-weeks (t2), and 6-

month follow-up (t3). In July 2028, data collection will be finalized by data checking and database preparation completion as well as close-out visits at each site which also marks the end of the study. Criteria for premature end of the study can be 1) a shortage of staff or 2) inability to meet recruitment target. Statistical analysis will be done until December 2028 to write and complete planned reports until April 2029. For further details, please also see figure 2.

Figure 1. Flow chart of study design.

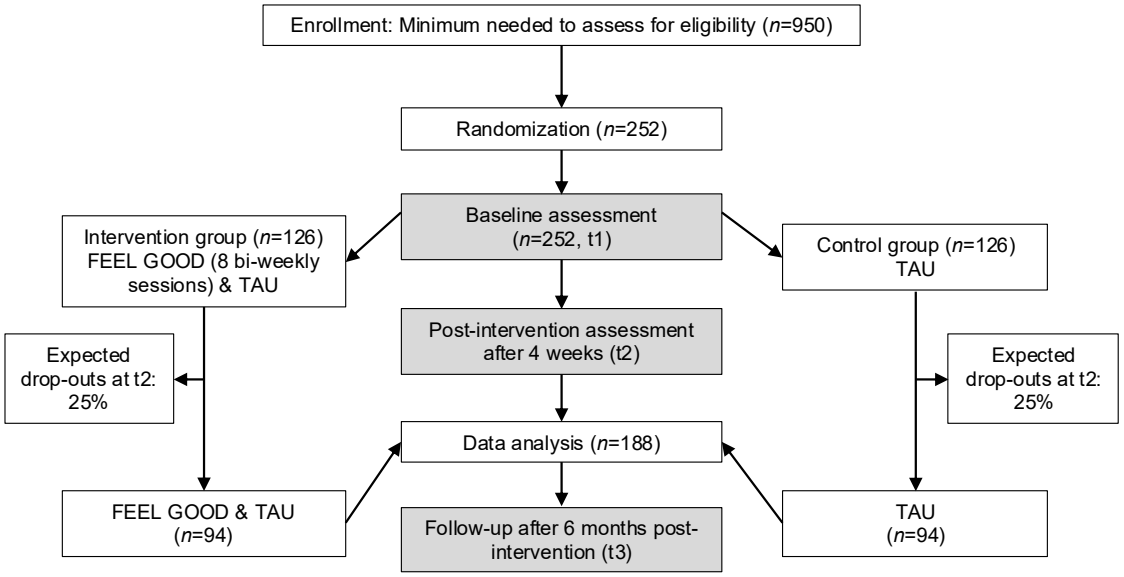
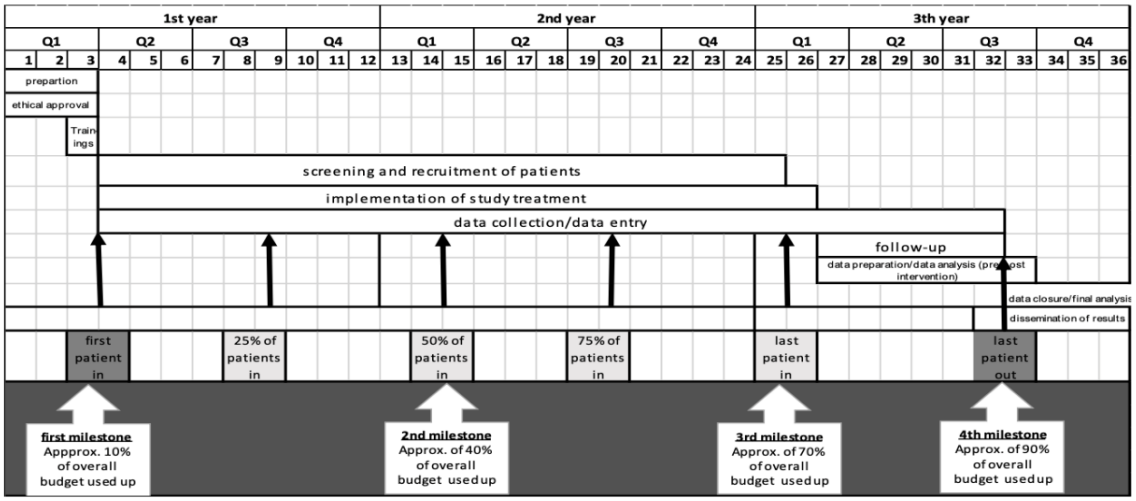


Figure 2. Trial Time Flow.



4. Methods: Participants, interventions, and outcomes

4.1 Study setting

The prospective multi-site randomized controlled open trial will be conducted in eight large psychiatric hospitals or university departments of psychiatry and psychotherapy with extensive expertise in the relevant research fields. Compared to routine clinical samples, it is expected that the study population will be highly representative because the study settings vary across Germany in terms of geography (Northwest, East, South), academic versus non-academic settings, and metropolitan versus non-metropolitan areas.

4.2 Eligibility criteria

The study population consists of young people aged 16 to 35 years with a clinical diagnosis of EP, defined in accordance with the largest trial of early intervention in psychosis worldwide so far [36]. Participating individuals must have had their first psychotic episode (FEP) within the past 5 years [8] and fulfil any of the DSM-5 schizophrenia spectrum and other psychotic disorder criteria (297.1, 295.4, 295.9, 295.7, 298.8, 298.9) confirmed with SCID-5-RV interviews [37]. Moreover, participants need to receive inpatient or day clinic treatment with a planned stay of at least 4 weeks and willing to take part in FEEL-GOOD and/or TAU.

Participants will be excluded if at least one of the following criteria is applicable.

Estimated verbal IQ < 85 assessed with the German Multiple-Choice Vocabulary Intelligence Test (MVT-B) [38]

Insufficient German language abilities

Acute suicidality or threat to others

The inclusion of minors aged 16–17.9 years is justified by the fact that psychoses most commonly occur during adolescence and early adulthood [6]. In addition, the early stage of psychosis can be identified in the majority of patients already before the age of 18 [39]. Most young people with FEP get hospitalized during the acute phase; thus, inpatients with FEP represent a highly relevant clinical population [40]. In Germany, the average inpatient length of stay per case in psychiatry is 25 days (all diagnoses, age 15-45 years [41]), for FEP presenting with 30 to 40 days per stay (based on internal controlling data at study centre I on Vivantes Hospital Am Urban and Vivantes Hospital im Friedrichshain, at Department of Psychiatry, Psychotherapy and Psychosomatic Medicine with FRITZ) and 103.8 days over 7 years on average [40]. Thus, most FEP spend more than 28 days in hospital as requested for the study and the results of the trial are highly generalizable to the studied population.

4.3 Intervention

Control condition (TAU):

Patients receive inpatient TAU for young adults with EP for at least 4 weeks. This includes medical review, pharmacological treatment, individual supportive counselling sessions, psychotherapeutic group interventions (psychoeducation), and access to physiotherapy, occupational therapy, and social work. TAU is expected to provide at least one individual counselling session (25 minutes) and one psychotherapeutic group session (50 minutes) per week. Pharmacological treatment will be assessed during the study period, and the respective chlorpromazine equivalents will be calculated. All centres will document treatment procedures in detail for the TAU condition. Although there is no specific control treatment to match the attention

received during the time that patients in the experimental condition receive FEEL-GOOD sessions, the overall potential difference in treatment exposure between the intervention and control group of 100 minutes attention per week seems rather small compared to the total attention that patients receive during inpatient standard treatment (840 min/week [42]).

Experimental condition (FEEL-GOOD+TAU):

TAU will be delivered as described above. The mindfulness-based group intervention, FEEL-GOOD, consists of one individual session and eight modularized group sessions (50 minutes each) over four weeks, involving four to eight participants per session and including practice and homework tasks. Clinical psychologists or psychiatrists will conduct the intervention based on a detailed manual. It will follow the principals of MBI adapted for patients with psychosis [23]. The patients will join the group therapy sessions (open-enrolling group) at any time and then participate at 8 consecutive sessions. Prior to the first group session, there will be an individual session with the study therapist, in which the participants will discuss and write down individual treatment goals related to mindfulness, emotional awareness and emotion regulation. The core of the intervention will be to provide insights into and to practice the essential elements of mindfulness and emotion regulation: attention to the present moment, as well as non-judgmental awareness and acceptance, and application of emotional awareness and emotion regulation skills. The following modules will be provided: 1. Information on emotions and how to reduce one's vulnerability for distressing emotions (2 sessions); 2. How to use mindfulness to better cope with distressing emotions and symptoms. (3 sessions); 3. How to regulate specific emotions (fear, anger, shame, guilt, envy and sadness; 3 sessions). FEEL-GOOD has been successfully implemented and evaluated in two pilot trials [35, 43]. An earlier version of the FEEL-GOOD group intervention was piloted in a feasibility study at study centre I in inpatients with EP fulfilling the same inclusion criteria as in the present protocol [35]. In this pilot study, the intervention was completed by all patients, and 37% of the patients would have been interested in continuing the intervention. Aside from the dropouts associated with the COVID-19 pandemic and government restrictions, there were no (treatment-related) dropouts in the study between pre- and post-group assessment, suggesting a high acceptability and feasibility in inpatient settings in EP patients. Furthermore, participants reported significant changes in relevant outcome measures, e.g., PANSS, delusions, and hallucinations. However, to further improve the compliance and given the length of inpatient stays of 30-40 days on average (unpublished Vivantes hospital group controlling data), the MBI group intervention will be offered in a shorter and more intensive format than in the feasibility trial (twice a week for 4 weeks, instead of once a week for 8 weeks). In addition, patients who will be discharged from inpatient setting will be offered to continue the MBI on an outpatient basis.

To minimize bias due to trial-site effects and differences in persons executing treatment, different strategies will be implemented. Therapists will be clinical psychologists (M.Sc.) or psychiatrists with at least three years of clinical experience. They will receive 20 training hours prior to the start of the therapy and will be regularly supervised and evaluated throughout the trial to ensure adequate quality of FEEL-GOOD. To ensure and maintain the same standards of FEEL-GOOD across centres, we will provide a detailed manual and standardized training based on intervention videos.

Prior to study initiation, each therapist is required to submit an audio recording of an individual session for fidelity assessment. Recordings are evaluated using adapted versions of the Cognitive Therapy Scale Revised for Psychosis (CTS-R-P) [44] and the Mindfulness-Based Cognitive Therapy Adherence Scale (MBCT-AS) [45]. A minimum rating of “good competence” must be achieved for all relevant components to allow the start or continuation of therapy within the study If a therapist’s rating falls below the predefined adherence threshold, additional training and supervision will be provided, and a further recording must be submitted and approved before the therapist is authorized to deliver the intervention within the study.

Throughout the trial, therapists will receive biweekly central supervision to ensure ongoing adherence to the intervention protocol. Audio recordings from intervention sessions will be used for supervision and feedback purposes, as well as rated using adapted versions of the Cognitive Therapy Scale Revised for Psychosis (CTS-R-P) [44] and the Mindfulness-Based Cognitive Therapy Adherence Scale (MBCT-AS) [45]. If predefined treatment quality criteria are not met, additional supervision and training will be provided.

All participants will be informed about the audio recording of sessions and will provide written consent for audio recording for the purposes of clinical supervision and fidelity assessment. At each study site, 25% of the therapy sessions will be randomly selected for audio recording.

Audio recordings will be pseudonymized and uploaded to a secure Nextcloud server hosted by Charité – Universitätsmedizin Berlin. Access to the audio files will be restricted to authorized external project staff responsible for fidelity assessment. Audio files may be downloaded solely by the designated evaluator for the purpose of rating and will be deleted after completion, of the respective evaluation, but latest after six months.

4.4 Outcomes

4.4.1 Primary outcome

The primary outcome is the observer-rated (blinded) total psychopathology as measured by the total score of PANSS [45] after 4 weeks (t2). PANSS is widely used and the gold standard for psychopathological outcomes in people with psychotic disorders [47]. It integrates positive, negative, and general psychopathological symptoms, which have all been shown to respond to MBIs in meta-analyses [26-31] as well as in the pilot trial [35], and it was suggested as the primary outcome by involved peer support workers.

4.4.2 Secondary outcomes

The following observer-rated (blinded) outcomes will be considered:
Positive and negative symptoms, general psychopathology as measured by PANSS sub-scales [45]
The Psychotic Symptom Rating Scales to assess delusions (PSYRATS-D) and hallucinations (PSYRATS-H) [48]
Depressive symptoms using the Calgary Depression Scale for Schizophrenia (CDSS) [49]
Level of functioning assessed by the Role Functioning Scale (RFS) [50], as well as the Global Assessment of Functioning (GAF) [73].
Occurrence and frequency of (severe) adverse events ((S)AEs), i.e., hospitalization, death, symptom worsening, suicidality, or life-threatening events
Drop-outs and their causes

Using self-report measures the following outcomes will be considered:
Quality of life measured with the short version of WHO Quality of Life (WHOQOL BREF) [51]
Patient satisfaction using the ZUF-8 [52].

4.4.3 Other parameters

4.4.3.1 Potential mediators

As potential mediators of the treatment effect, the following outcomes will be measured using self-report instruments, which have been successfully applied in the pilot studies [35,42] or in other ‘causal interventionist’ [16] or ‘targeted’ approaches [17, 53]. They will be measured on t1, t2, and t3 in order to allow mediation analysis.
Emotion regulation skills assessed using Emotion-Specific Regulation Skills (ERSQ; dt. Selbsteinschätzung Emotionale Kompetenzen, SEK-27) [54]
Cognitive emotion regulation strategies measured with the Cognitive Emotion Regulation Questionnaire (CERQ) [55]
Emotional awareness with the Toronto Alexithymia Scale (TAS-26) [56]

Self- esteem with the Rosenberg Self-Esteem Scale (RSES) [57, 58]
Mindfulness skills with the German version of the Five Facet Mindfulness Questionnaire (FFMQD) [59]

4.4.3.2 Ecological Momentary Assessments

To capture the efficacy of the intervention on patients' total psychopathology, on mindfulness skills and emotion regulation in daily life, Ecological Momentary Assessments (EMA) will start on the day of the patient's inclusion of the study, and continue throughout the four-week intervention period. It will end seven days after completion of the intervention. During this period, participants will receive one EMA prompt per day between 10:00 am and 10:00 pm CET. Each assessment will consist of approximately 39 to 46 items, depending on participants' responses and condition-specific branching logic, and will take about five minutes to complete. In the event of non-response, one reminder will be sent after a predefined interval. If no response is received thereafter, the assessment for that day will be closed. EMA items will assess current emotional states, psychopathological symptoms, mindfulness, emotional instability, and emotion regulation. EMA data will be analysed to examine within-person changes over time and between-group differences in daily symptom dynamics. This includes investigating trajectories of change across the assessment period, associations between momentary processes and clinical outcomes, and individual differences in response to the intervention. The longitudinal structure of the EMA data will further allow for the identification of early indicators of improvement or deterioration and for exploratory analyses of mechanisms underlying treatment effects. Overall, EMA findings will contribute to refining the FEEL-GOOD intervention and informing future adaptations toward more personalized and context-sensitive treatment approaches.

4.5 Participant timeline

Based on relevant diagnoses documented with their recent admission, a planned inpatient stay of at least 4 weeks ahead, and sufficient German language abilities and absence of acute suicidality or threat to others as assessed by staff, patients will be considered for study participation. After providing written informed consent, participants will perform the MVT-B [38] and diagnoses will be confirmed with SCID-5-RV interviews [37]. The investigator will complete a standardized screening checklist to verify that all inclusion and exclusion criteria are (not) met prior to enrolment in the study. For further details, please refer to section 4.2 or see table 3. If they meet the required inclusion criteria and the exclusion criteria do not apply, participants will complete baseline data before randomization which will be performed adaptively from within the data management system SecuTrial. Subjects will be randomized in a 1:1 allocation for each study site and will be balanced adaptively for gender and symptom severity as measured by the PANSS total score (3 strata: mild with <54 points, moderate with 54-74 points,

and high with >74 points). Participants will further complete two assessments at 4-week and 6-month post-intervention. The first patient will be enrolled in April 2026 with their last assessment in October 2026. The last patient will be enrolled in January 2028 with the final assessment in July 2028. The final assessment for each participant (t3) constitutes the individual end of study participation. As participation is voluntary, participants may withdraw from the study prematurely at any time. Any withdrawal, and the reason for withdrawal will be documented. Reasons for withdrawal may include: 1) withdrawal of consent by participant defined as drop-out (without the need to provide justification), or 2) incorrect inclusion (e.g., subsequent determination of ineligibility).

Table 3. Schedule of enrolment, intervention, and assessments in FEEL-GOOD.

	Enrolment	**Baseline**	**Post-intervention**	
TIMEPOINT	***t_0***	***t_1***	***t_2 4-week follow up***	***t_3 6-month follow up***
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
INTERVENTIONS:				
FEEL-GOOD+TAU		X		
TAU		X		
CONTENT OF ASSESSMENT:				
SCREENING				
Estimation of verbal intelligence (MVT-B) [a]	X			
Sociodemographic data (age, gender, education, migration background, residential status, employment status) [a]	X			
Clinical characteristics (primary, secondary, comorbid diagnosis) (SCID-5-RV) [a]	X			
Treatment and mental health service use prior to/during trial [a]	X			
Psychopharmacological treatment [a]	X	X	X	X
PRIMARY OUTCOME				
Symptoms of psychosis (PANSS total score) [a]		X	X	X
SECONDARY OUTCOMES				
Positive, negative symptoms, general psychopathology scale (PANSS-P, PANSS-N, PANSS-G) [a]		X	X	X
Delusions and hallucinations (Psychotic symptom rating scales delusions scale		X	X	X

(PSYRATS-D), PSYRATS hallucinations scale (PSYRATS-H) [a]				
Role Functioning Scale (RFS) [a]		X	X	X
Global Assessment of Functioning (GAF) [a]		X	X	X
Depression (CDSS) [a]		X	X	X
Quality of Life (WHOQOL-BREF) [b]		X	X	X
Patient satisfaction (ZUF-8) [b]			X	X
PUTATIVE MEDIATORS				
Emotion regulation skills (SEK-27/ERSQ) [b]		X	X	X
Cognitive emotion regulation strategies (CERQ) [b]		X	X	X
Mindfulness skills (FFMQ-D) [b]		X	X	X
Emotional knowledge/alexithymia (TAS-26) [b]		X	X	X
Self-esteem (RSES) [b]		X	X	X
Ecological momentary assessments (EMA) (psychotic symptoms, mindfulness, emotional regulation skills) [b]		X	X	
ADHERENCE TO TREATMENT				
Cognitive Therapy Scale Revised for Psychosis (CTS-R-P) and the Mindfulness-Based Cognitive Therapy Adherence Scale (MBCT-AS)[a]		X		
SAE monitoring: continuously during study period				

Note. [a] Assessment by raters/interview by clinicians; [b] Self-assessments.

CDSS Calgary Depression Scale for Schizophrenia, **CTS-R-P** Cognitive Therapy Scale Revised for Psychosis, **CERQ** Cognitive Emotion Regulation Questionnaire, **FFMQ-D** Five-Facet Mindfulness Questionnaire German Version, **GAF** Global Assessment of Functioning, **MBCT-AS** Mindfulness-Based Cognitive Therapy Adherence Scale, **MVT-B** Multiple-Choice Vocabulary Intelligence Test, **PANSS** Positive and Negative Syndrome Scale, **PSYRATS** Psychotic symptom rating scale; **RFS** Role Functioning Scale, **SCID-5-RV** Structured Clinical Interview for DSM-5 Disorders - Research Version, **SEK-27/ERSQ** Selbsteinschätzung Emotionaler Kompetenzen (German Version of Emotion Regulation Skills Questionnaire, **RSES** Rosenberg Self-Esteem Scale, SAE serious adverse events, **TAS-26** Toronto Alexithymia Scale (German Version of Toronto Alexithymia Scale), **WHOOL-BREF** World Health Organization Quality of Life-BREF, **ZUF-8** Fragebogen zur Messung der Patientenzufriedenheit (German Version of Client Satisfaction Questionnaire).

4.6 Sample size calculation

To determine the number of patients required for the RCT, insights on patient availability and dropouts from the related feasibility study [35], as well as the effect sizes reported in recent meta-analyses [26-31] were considered. They ranged between d = .46 and d = .62 for total psychopathological symptoms according to Khoury et al. [31] and Cramer et al. [26], respectively, and have been judged as clinically meaningful. According to a power calculation, a total sample of n = 188 patients who have completed the intervention is required for the RCT (comparing FEEL-GOOD+TAU with TAU post-intervention in a mixed effects model with an expected effect size of d = .4, ICC = .05 for the center random effect, and a power of .80 at a two-sided .05 significance level). Considering the pre-post dropout rate of the FEEL-GOOD feasibility study (25%) [35], the required sample ITT size is N = 252 patients. As reported above, the effect sizes of mindfulness interventions in previous meta- analyses on psychosis and schizophrenia partly exceed d = .4; however, the included studies varied greatly in treatment intensity and duration and often had more intensive treatments or did not include inpatients with acute psychosis [26, 29] Therefore, a smaller effect in FEEL-GOOD is expected. In addition, mixed-model adjusted for the baseline scores, gender, and study site will be used. The model is used for the primary efficacy analysis. This will yield a power increase compared to the power analysis, which ignored the adjustment due to covariates beyond study site.

4.7 Recruitment

The feasibility study recruited 36 inpatients with EP in 13 months [35]. Patients received the FEEL-GOOD group intervention over 8 weeks; outcomes were measured before (n = 36) and after the intervention (n = 27), as well as 16 weeks after the latter (n = 21). The recruitment numbers of the FEEL-GOOD feasibility study (2.77 included patients per month) were extrapolated to 22 months to determine the number of patients to be included per month in the RCT. This means that about 61 patients can be included during this time. However, given that the feasibility study was conducted at a treatment unit specialized for EP, which attracted up to 40% of the patients from outside the catchment area, it is conservatively expected that on average (i.e., across different centres involved), 31-32 inpatients can be included across a 22 months period (1.5 per month) over all study sites.

In order to avoid waiting times until the start of the intervention groups and to ensure continuous implementation, interested non-study participants will also be considered for participation in the group intervention. Site-specific recruitment strategies will be established at each site, which will account for differences in service organisation and facilitate recruitment of a representative sample. In case a site is recruiting less than expected, Chief investigators can decide

to initiate contingency strategies. These contingency strategies may include comparative recruitment (i.e., that sites can recruit more than their target number to balance out the slow recruitment rate at another site). The number of cases per site is shown in table 4.

Table 4. Numbers of cases to be recruited per study site.

STUDY SITE	Berlin I	Marburg	Berlin II	Munich	Hamburg	Mannheim	Augsburg	Cologne	Total
n	32	31	32	32	32	31	31	31	252

5. Methods: Assignment of interventions (for controlled trials)

5.1 Allocation

Randomization will be performed via a block-randomized ID list created by the programming language R and its package “blockrand”. Subjects will be randomized in a 1:1 allocation using block randomization with variable block lengths. Study site, gender and symptom severity as measured by the PANSS total score will be used for stratification [43].

5.2 Blinding (masking)

Trial outcomes will be assessed by trained staff masked to individual treatment assignments; blindness will be documented, and unblinding will be reported. Given the obvious differences between treatment arms, it is not possible that the involved patients or study therapists will be blinded. Blinded raters will be trained to improve the reliability and validity of the assessments (especially PANSS) using training videos and receiving feedback and supervision. At the end of the study, assessors will be asked to guess participants' treatment allocation. The success of the blinding procedure will be reported by the ratio of agreements between guesses of the treatment allocation by assessors and the real treatment allocation, and correlations with treatment allocation will be computed and reported. This procedure has been successfully employed in a recent RCT [6,60].

6. Measurements, data collection, management, and analysis

6.1 Measurements

Cognitive Therapy Scale for Psychosis Revised (CTS--P-R)

The CTS-P-R is an observer-rated instrument specifically developed to evaluate competence in cognitive behavioural therapy for psychosis (CBTp). It extends the original CTS framework by incorporating competencies specific to working with psychotic symptoms [44].

The 14-items scale assesses both general therapeutic skills (e.g., collaboration, agenda setting, interpersonal effectiveness) and psychosis-specific CBT competencies, including normalization of psychotic experiences, development of coping strategies for delusional beliefs and hallucinations and relapse prevention strategies.

Items are rated on a 6-point Likert scale (0–5), where higher scores indicate greater competence and flexibility in applying CBTp techniques. A score in the mid-range reflects competent delivery consistent with CBTp principles. In previous research, inter-rater reliability based on independently rated audio recordings was acceptable (ICC = .77), and internal consistency was also acceptable (Cronbach's α = .76) [61].

Mindfulness-Based Cognitive Therapy Adherence Scale (MBCT-AS)

The MBCT-AS consists of 17 items rated on a 3-point scale (0 = no evidence, 1 = slight evidence, 2 = definite evidence of the item). The scale comprises two subscales. The Mindfulness (M) subscale includes nine items assessing therapist behaviours specific to MBCT (e.g., movement-based awareness exercises). The Cognitive Therapy (CT) subscale consists of eight items reflecting therapeutic practices shared with cognitive behavioural therapy (e.g., linking thoughts with feelings). The MBCT-AS has demonstrated very high overall inter-rater reliability (ICC = .82). Subscale analyses showed extremely high reliability for the Mindfulness subscale (ICC = .97) and moderate reliability for the Cognitive Therapy subscale (ICC = .59). [45].

Calgary Depression Scale for Schizophrenia

The CDSS is considered as the gold standard to assess depression specifically in people with schizophrenia spectrum disorders. The 9 items are observer-rated on a scale ranging from 0 (=absent) to 3 (=severe). It distinguishes between depressive symptoms, positive, negative, and extrapyramidal symptoms in adolescents and adults [62,63]. The German version has been shown to be reliable and valid with high internal consistency [49]. It is sensitive to change over time, making it suitable for monitoring treatment outcomes.

Client Satisfaction Questionnaire

The ZUF-8 is the German version adapted for inpatients based on the CSQ-8 [52,64]. It consists of 8 items self-rated on a 4-point Likert-scale and assesses patients' overall satisfaction with the clinical treatment received. It has shown to be a valid, reliable instrument with excellent internal consistency ranging from .87 to .93 [65,66].

Cognitive Emotion Regulation Questionnaire

The CERQ measures cognitive coping strategies, i.e., thoughts after negative events or situations on 9 subscales (self-blame, blaming others, acceptance, refocusing on planning, positive refocusing, rumination, positive reappraisal, putting into perspective, and catastrophizing) each consisting of 4 items [67]. Items are self-rated on a 5-point Likert-scale (1=almost never, 5=almost always). The CERQ has a good reliability, convergent and discriminant validity was proved and shows good internal consistency ranging from .68 to .86 [67].

Ecological Momentary Assessment

Participants will complete EMA via the m-Path mobile application [68] starting 7 days before the start of the intervention and ending 7 days post-intervention. There will be 1 prompt per day for 42 consecutive days . Each prompt will include approximately 39-46 items, depending on conditional branching. The questions will cover several domains, such as current emotional state, psychopathological symptoms, mindfulness, emotional (in-)stability, and emotional regulation skills. The choice and development of specific items will be informed by a literature review and feedback rounds within the coordinating research team.

Emotion Regulation Skills Questionnaire

The ERSQ consists of 27 items with 9 subscales assessing competencies that are considered essential for successful emotion regulation (i.e., attention, clarity, bodily awareness, understanding, acceptance, resilience, self-support, willingness to confront, and regulation). Self-reports are rated on a 5-point Likert-scale from 0 (= not at all) to 4 (= almost always) [54]. It has shown to be valid and reliable with good internal consistency ranging from .68 to .90 for the subscales and total score.

Five-Facet Mindfulness Questionnaire

The FFMQ consists of 39 items forming the 5 subscales non-reactivity to inner experience, observing, acting with awareness, describing/labelling with words, and nonjudging of inner experience [59,69]. Items are self-rated on a 5-point Likert-scale ranging from 1 (= never or very rarely true) to 5 (= very often or always true). Internal consistencies range from .67 to .92 in different populations (e.g., students, community sample, (non-)meditators).

Multiple-Choice Vocabulary Intelligence Test

The MVT-B is used to assess premorbid intelligence and comprises 37 items [38]. The task is to discriminate a “correct” word among pseudo-words (e.g., Sukiff –Fasek – Siuke – Fiskus – Fuske) with every identified word worth one point and increasing difficulty.

Positive and Negative Syndrom Scale

The PANSS is an observer-rated scale widely used and known as the “gold standard” for psychopathological outcome assessment in people with psychotic disorders [46,47]. It distinguishes between negative and positive symptoms with 7 items each, as well as general psychopathology with 16 items rated from 1 (= absent) to 7 (= extreme).

Psychotic Symptom Rating Scale

The PSYRATS consist of 17 items assessing specific dimensions of hallucinations and delusions [48]. Each item is observer-rated on a 5-point scale ranging from 0 (= absent) to 4 (= severe). The PSYRATS include two subscales: hallucinations with 11 items (PSYRATS-H) and delusions with 6 items (PSYRATS-D) with excellent inter-rater reliability.

Role Functioning Scale

The RFS measures performance on 4 single rating scales: working productivity, independent living, immediate social network relationships (friends and family), and extended social network relationships (other social contacts) [50] with observer ratings from 0 (= minimal functioning) to 12 (= optimal functioning). Mean scores can be conducted for general functioning and social functioning ranging from 0-12.

Global Assessment of Functioning Scale

In the GAF scale, clinicians rate a patient’s overall level of psychological, social, and occupational functioning using a single score ranging from 1 to 100. A score of 100 represents superior functioning, whereas a score of 1 indicates a persistent risk of serious harm to oneself or others, severe impairment in basic self-care, or a suicidal act with clear expectation of death. Changes of approximately 4, 10, or 12 points have been suggested to represent clinically meaningful differences [73].

Rosenberg Self-Esteem Scale

Global self-esteem will be assessed with the RSES [57], which is a widely used measure to assess global self-esteem with good reliability and validity. The RSES consists of 10 items self-rated on a 4-point Likert-scale ranging from 1 (= strongly disagree) to 4 (= strongly agree). Scores range from 10 to 40. Higher scores indicate higher global self-esteem.

Socio-demographic characteristics

Socio-demographic data will be collected by raters at baseline to describe the study population. Core variables include age, gender, education, migration background, residential status, and employment status.

Structured Clinical Interview for DSM-5 Diagnosis-Research-Version

The Structured Clinical Interview for DSM-5 Disorders – Research Version (SCID-5-RV) is a semi-structured diagnostic interview used to assess DSM-5 psychiatric disorders in research settings [37]. It is designed to be administered by clinicians or trained mental health professionals to ensure standardized and reliable diagnostic assessment.
In contrast to the clinician version, the SCID-5-RV is specifically structured for research purposes and allows a systematic and comprehensive assessment of DSM-5 diagnostic criteria across multiple diagnostic modules. Each section begins with a screening question that allows the interviewer to skip subsequent items if diagnostic criteria are not met. For each diagnosis, symptoms are coded as present, subthreshold, or absent.

Toronto Alexithymia Scale
The TAS-26 is the German version of the TAS [70] and consists of 26 items with the 3 subscales Difficulties Identifying Feelings, Difficulties Describing Feelings, and Externally Oriented Thinking self-rated on a 5-point Likert-scale [56]. It is a valid instrument with good internal consistency ranging from .67 to .84.

WHO Quality of Life
The WHOQOL-BREF assesses quality of life as a subjective evaluation, embedded within the individual's cultural, social, and environmental context using 26 items divided into 4 domains: physical health, psychological well-being, social relationships, and environment [51]. Self-ratings range from 1 to 5. It is a valid instrument with good internal consistency ranging from .66 to .88.

6.2 Data collection methods

All protocol-required information collected during the trial will be documented in electronic case report forms (eCRFs) using the study software secuTrial® (interActive Systems, Berlin) provided by the Clinical Trial Office (CTO) of Charité. secuTrial® features remote web based data capture and real-time monitoring. The software has been designed to meet the requirements of the FDA (21 CFR Part 11) and the guidelines for Good Clinical Practice (GCP).
An individual pseudonym will be generated by the study software during patient registration. The data will be entered by RDE (Remote Data entry). The CTO will assign all accounts for investigators, monitor etc. in coordination with the study management. The study software performs authentication procedures, role management, and encrypted and secured connections. The environment will be hosted on the GB IT servers.
All parties will file all data electronically. Range, validity, and consistency checks are integrated into the eCRF to increase accuracy of the data. These checks create soft or hard alerts and prompt the user to re-inspect and possibly change the data before storing the information.

At specific time points (milestones, timeframe, set dates) a full data validation is performed following a data validation plan. Found inconsistencies, implausible or missing data will be tagged by a data management query. The possibly false information can be corrected through directly changing values within the eCRF or must be flagged as accepted failures or false positives. Changes within the documented information will be tracked via the audit trail, which is a basic function of the eCRF.

Most of the false data will be corrected within the eCRF. A data correction performed by the data management (SEC - self evidence correction, documented deletion of wrong data) can be added as a second control layer. After termination of the study and after all entries have been completed, the database will be closed for further entries. This process will be documented.

The analysis will be performed using the following commercial software:

- SAS
- SPSS
- R

To ensure high-quality data collection, blinded raters will be trained to improve reliability and validity of the assessments (especially PANSS) using training videos and receiving feedback and supervision. The trial's outcome measures have demonstrated good psychometric properties and are widely used (see section 6.1).

EMA will be administered via the m-Path mobile application [68], operated and developed by m-Path Software, a company that originated as a spin-off of KU Leuven (Belgium). Participants can use their own smartphones or smartphones provided by the study team. At each prompt, the app will present the relevant items and record the responses directly in the m-Path system. Participants will be instructed to complete the questionnaire as soon as reasonably possible after the prompt. To support compliance, the app will provide a short reminder if the prompt is not responded to within a predetermined window (e.g., 15 minutes). All assessments will be time-stamped and logged in the m-Path backend. Data collected through m-Path are automatically encrypted in transit and stored securely on the provider's servers (Microsoft Azure servers in Germany). The study uses active self-report only, i.e., no passive sensor or continuous monitoring data will be collected. The m-Path app can access certain smartphone functions or data only if the corresponding permissions are explicitly granted and the specific feature is implemented as part of the research purpose (not applicable). Without this permission (default setting), it has no access to the calendar, contacts, or similar data. The study team will export data from m-Path after completion of each assessment period for subsequent aggregation and analysis.

Plans to promote participant retention and ensure complete follow-up include:

Reimbursement of participants (€10/hour; total up to €130 plus €40 completion bonus for full assessment participation, t1–t3).

Continuous motivational support from blinded raters, particularly for completing EMA and regular consultation hours for participant inquiries regarding EMA use.

Offering flexible assessment formats (e.g., videoconference using Zoom/Microsoft Teams or telephone) if face-to-face visits cannot be arranged by the participant. Participants will be informed of these different assessment formats. However, if they wish to use another format than the standard face-to-face visit, they need to inform the responsible study staff and express their preferred format.

Participants who discontinue or deviate from the intervention protocol will still be invited to complete all follow-up assessments. Reasons for withdrawal will be recorded to explore missing data mechanisms (e.g., missing at random).

All data collection forms and instruments will be available upon request from the study team or CTO Charité.

6.3 Data management

Data entry, coding, storage, and management will be handled electronically through secuTrial®. The CTO Charité will oversee user account assignment (investigators, supervisors, monitors, etc.) in coordination with study management. The system performs authentication, role-based access control, and uses encrypted and secure connections for all data transmissions. All trial data will be stored on secure servers of the Charité. Electronic documentation will include all exported datasets, SAS scripts, data protocols, and the final locked database. All personal data collected as part of the study, following the consent of the study participant, are subject to confidentiality and the provisions of the GDPR. All questionnaire, interview, and rating data are collected pseudonymously within the eCRF. This means that the participant's name and all direct identifiers are replaced with a pseudonym. Re-identification of participant data is only possible at the local study site through the pseudonymization key.

All EMA data will be managed through the m-Path dashboard and data export functions. According to the m-Path "Data Processing" documentation, the platform processes personal data on behalf of the client (the researcher) and acts as data processor under GDPR and other relevant frameworks. The researcher remains the data controller responsible for specifying the purpose, lawful basis and retention period of the data. Data are transmitted via secure channels from the participants' mobile devices to the m-Path servers and stored in encrypted

form using HTTPS/TLS encryption. Access to the dashboard is restricted by individual login credentials; role-based permissions will limit dataset export to the core study team. Only pseudonymised identifiers (participant codes) will be used in exported files; no direct identifiers will be included. The m-Path “Subcontractors” documentation clarifies that third-party providers may support hosting, backups, and infrastructure operations, under contract and subject to confidentiality and data-protection obligations. All subcontractors engaged for the platform will adhere to EU data-protection standards (e.g., GDPR) and will not have access to direct personal identifiers. The research team will ensure that the contract between the sponsor institution and m-Path includes appropriate data-processing agreements, specifying the roles of data controller (sponsor) and data processor (m-Path) including subcontracting oversight. After each assessment, the exported dataset (i.e., Participant ID, responses, time stamps) will be downloaded as csv-files to and saved on the Sponsor’s secure server by authorised staff. According to m-Path’s data-processing agreement, the processor may retain data only as required by law or contract; otherwise, data are deleted or anonymised at the researcher’s instruction.

Data management will include:

Range/plausibility checks for key variables.

Continuous on-site and central monitoring according to a predefined monitoring plan based on risk assessment (ICH GCP).

Verification of key study data (e.g., signed informed consent, inclusion/exclusion criteria, participant safety, and primary outcomes).

Central monitoring for consistency and completeness of data across sites.

An Independent Data Monitoring and Safety Committee (IDMC) will regularly review AEs and SAEs in accordance with ICH GCP and report any relevant group imbalances to trial management. After database lock, trial data will be exported and tested for plausibility and consistency using SAS software. Data will be archived for 10 years. Upon qualified request, de-identified trial data will be made available for meta-analyses, disease registries, or other scientific reuse, as appropriate.

6.4 Statistical methods

The final statistical analyses plans will be published on the Open Science Framework (OSF).

6.4.1 Primary efficacy outcome

To determine group-specific change in the primary outcome, we will compare change in overall psychopathological symptoms as measured by the PANSS total score in the TAU vs. FEEL-GOOD + TAU group at post-treatment (4 weeks). Primary analysis will be conducted under the ITT principle. Thus, patients will be analysed according to group assignment after randomization, regardless of actual participation at the treatment sessions, according to their group. Dropout in this respect will be defined as no PANSS assessment at post-treatment. Secondly, a sensitivity analysis will be carried out under the per-protocol principle. Here, patients will be assigned to the treatment group (FEEL-GOOD+TAU) if they have attended at least 75% of the FEEL-GOOD sessions (6 of 8 sessions); otherwise, they will be handled as control group members (TAU) in this analysis. Primary analyses will comprise a longitudinal mixed model, including treatment and time and their interaction as fixed effects. Additionally, fixed effects of gender and baseline symptom severity will be included, and the random effects of participant ID, group ID, and recruitment centre will be included. The mixed model will serve as a method to handle drop-out (or temporary missingness) under the assumption of MAR. As a sensitivity analyses towards this missingness assumption, 1) an ANCOVA including data of t1 and t2 of complete cases only will be conducted. 2) the same ANCOVA will be estimated with values imputed using 20x multiple imputation (R package: mice).

6.4.2 Secondary outcomes

Descriptive methods will be used for the analysis of the secondary outcomes, including the calculation of appropriate summary measures of the empirical distribution as well as 95% confidence intervals. All secondary outcomes will be analysed according to variable type: Continuous variables will be subject to linear mixed model to the primary outcome; categorical outcomes will be subject to mixed logistic regression. P values of secondary outcomes will be treated in an exploratory manner, i.e., no adjustments for multiple testing will be made. Additionally, sensitivity and sub-group analyses will be conducted for different populations (e.g., per-protocol population, patients with complete cases).

6.4.3 Mediation

Potential mediating variables will be treated as outcome variables in a first analytical step, because we expect the intervention to have direct effects on them. To obtain results on their potential indirect effects on the primary and secondary outcome measures, we will use multilevel structural equation models in the form of path analysis. As mediators and outcomes will be assessed at only two occasions (t1, t2) and not during therapy, the complete causal chain cannot be assessed [71]. Mediation will furthermore be explored including an additional follow-

up time point (t3) and path analyses. Here, we will analyse whether the effects of the intervention on the mediators at t2 mediate the effects of the intervention from t1 to t3. Statistical inference will be drawn from the indirect effect in the path model.

6.4.4 EMA

Data from EMA will be analysed using a longitudinal mixed model to account for the nested data structure [72]. Data will be nested into five levels: momentary assessments, nested in bursts, nested in participants, nested in group ID, and nested in study site. This allows for the assessment of changes over time as well as differences in these changes between treatment groups.

6.4.5 Safety

The safety analysis includes calculation of frequencies and rates of SAEs like unexpected hospital stays, death, severe worsening of symptoms, suicidality, or life-threatening events. Data will be analysed using validated statistical software.

7. Monitoring

In the preparation phase of the proposal, a feasibility analysis at each trial site was performed. In addition, during the preparation phase prior to enrolment in the trial, a risk analysis will be conducted on the patient population and the data's validity. During the trial, quality control and quality assurance will be ensured through a combination of on-site and central monitoring based on the risk assessment of the study according to ICH GCP. The CTO Charité will perform the coordination, implementation, and conduction of monitoring at the study site following its applicable standard operating procedures (SOPs). Monitoring will be performed according to SOPs and study-specific requirements, including a site initiation and closeout visit, as well as regular on-site visits per site in accordance with the patient recruitment. The monitoring strategy and responsibilities will be defined in a monitoring plan with special attention to critical data and processes (see table 5). The on-site verification will focus on the key study data, e.g., signed informed consent, adherence to inclusion and exclusion criteria and participant safety. All the other data will be checked based on a representative sample, e.g., documentation on primary objectives (or other key study data). Unclear and incomplete data will result in in-depth monitoring of the respective data. An IDMC will regularly control for AEs and SAEs according to ICH GCP guideline and will inform the trial management about relevant imbalances between the groups. Safety assessments will include monitoring and recording all AEs and SAEs.

Table 5. Intensity and amount of monitoring required.

No. of patients assigned to the trial	252

No. of recruiting centres	8
Average no. of patients per trial site	31-32
Average no. of monitoring visits per trial site (site selection and close-out visits are excluded)	3
No. of doctor's visits per patient during the course of the whole trial	During the intervention phase doctors are available every day and at least two visits per week will take place as part of routine care, at follow up most participants will be treated by the respective outpatient departments and will be seen by doctors at least every 8 weeks.
Expected number of AEs and SAEs	SAEs are not expected to be a direct effect of the intervention. In the previous feasibility study [35], there were no AEs throughout this study. In the study conducted by Mehl et al. [42] were 2 adverse events during the trial: 2 patients were hospitalized, one of them committed suicide in hospital. With regard to the general clinical diagnoses of the study cohort: studies have consistently shown that individuals with psychosis have mortality rates that are 2-3 times higher than that of general population (15 to 20 years); 5 to 10% of people with psychosis commit suicide (6 to 12 higher risk compared to the general population); 10% have chronic disabilities and 45 to 80% have somatic comorbidities. In the FEEL-GOOD pilot study at the Berlin I study centre, the rehospitalisation rate at 6 months was 23.2%. In a cohort study of inpatients in the early intervention and therapy centre (FRITZ) at the Berlin I study centre, the rehospitalisation rate was 30.5% at 6 months and 43.2% at 12 months.
Complexity of inclusion and exclusion criteria	Inclusion and exclusion criteria are explicit and assessable by questioning the patient and testing verbal intelligence (MVT-B). Assessment will be conducted by corresponding project staff of each study centre.

8. Ethics and dissemination

8.1 Research ethics approval

The study will be conducted in line with the Declaration of Helsinki, the Guidelines and Recommendations for Ensuring Good Epidemiological Practice (GEP) and GCP. The ethical application, study protocol, patient information and informed consent will be submitted to the ethics committee for review. The study will not commence until the ethics committee has given

its approval in the respective study sites. The application is submitted to the responsible ethics committee in accordance with the relevant professional code of conduct and the recommendations of the Working Group of Medical Ethics Committees (AKEK) 2024 (one study - one vote). In addition to the primary vote of the ethics committee of the Chief Investigator/Sponsor, a registration with other ethics committees involved is carried out (in accordance with the recommendations of the AKEK).

The PI or Sponsor will immediately inform the ethics committee of any changes to the study protocol and any events that may affect participant safety. The Ethics Committee will also be informed if the study is stopped early or completed as planned.

The trial will be prospectively registered at ClinicalTrials.gov in accordance with the International Committee of Medical Journal Editors (ICMJE) requirements.

8.2 Protocol amendments

Only the Chief investigator can initiate and approve changes or amendments to the protocol. The Ethics Committees of the participating sites will be informed of any changes to the protocol. If necessary, a new ethical review will be obtained. Changes requiring an ethical review should not be implemented before the Ethics Committee has reached a decision.

This includes

Changes to the study that have been approved by the Ethics Committee and that may affect the safety of the study participants.

Additional measurements or analysis that requires a change in the patient information and/or consent.

Changes in the interpretation of the scientific documents on which the trial is based.

Changes that affect the scientific significance of the study results.

Significant changes in the manner the trial is managed or conducted.

8.3 Consent or assent

Prior to enrolment, each potential participant will be informed orally and in writing about the nature, objectives, expected benefits and possible risks of their study participation by a member of the project staff at the study site. Each participant must give written informed consent to participate in the study. The participant will be given sufficient time and opportunity to decide whether to participate and to clarify any outstanding questions before the study procedures begin. The informed consent form will be signed and personally dated by the participant and the project member at the study site. For adolescents under 18 years of age, informed consent will be provided by young participants and their legal guardian.

The study information and consent form are signed in duplicate. One copy is kept at the study site, and the other is given to the participant. Participation in the study can be cancelled at any

time. A cancellation of the study must be documented accordingly. If possible, the reasons for the cancellation should be documented. Reasons for cancellation of the study are:
Withdrawal of consent by the study participant, whereby it is not necessary to state the reasons.
Incorrect study inclusion (e.g., study participant does not meet the inclusion criteria)
In the case of early withdrawal, the data previously collected will be included in the analysis, unless the participant objects to this procedure.

8.4 Confidentiality

As part of the study, it is necessary to collect and process personal data (e.g., full name, date of birth) and data on treatment and disease progression (e.g., medical findings, treatment types, prescribed medications) from study participants. These data are collected at the study sites and stored electronically. However, the outcome data will be stored centrally in a database at the sponsor's site in pseudonymised form (i.e., without direct reference to the patient's name) using a patient identification number. Identifying data will be stored locally at the study sites. All data will be handled as confidential and will not be transferred or shared with other third parties. Only authorized project staff can access data after the CTO Charité has granted access. Participants must provide informed consent for their data to be stored in pseudonymised form and used for scientific evaluation (publications). Participants have the right to be informed about the stored data.

8.5 Declaration of interests

There are no competing interests for the principal investigators in recruiting participants for the trial.

8.6 Ancillary and post-trial care

Continued access to appropriate care will be ensured for all participants beyond the study period, regardless of self-withdrawal or refusal to participate. Should additional or alternative healthcare services be required or requested, clinicians will provide appropriate recommendations and support the person in initiating further care.

8.7 Insurance

The investigator is insured by the public liability insurance of the respective hospital against liability claims that could result from his or her culpable conduct. The study must be reported to the public liability insurance of the respective hospital.
Since these are regular inpatients at the clinic, no invasive or risky procedures are performed, and all study examinations take place within the scope of normal patient contact, meaning that

no additional travel is required for study participants, there is no need for study-specific insurance.

8.8 Data protection

The data protection provisions of the GDPR and the Federal Data Protection Act (BDSchG) as well as the State Data Protection Act (LDSchG) apply.

As part of the study, it is necessary to collect and process personal data (e.g., full name, initials of first and last name, date of birth, address) and data on treatment and disease progression (e.g., diagnoses, types of treatment, prescribed medications) from study participants. This data is collected at the clinical study sites and stored electronically in pseudonymized form (i.e., without direct reference to the patient's name) using a patient identification number, transmitted to the responsible data processing department, and evaluated.

If a participant withdraws their consent to participate in the study, including further data collection, no further data will be collected from the time of withdrawal. The data collected to date will continue to be used and evaluated within the study, unless the study participant explicitly objects to this procedure.

Participants are informed that their disease-related data will be stored in pseudonymized form and used for scientific evaluations (publications). Participants have the right to be informed about the stored data.

EMA data are transmitted via secure channels from the participants' mobile devices to the m-Path servers and stored in encrypted form using HTTPS/TLS encryption. Access to the dashboard is restricted by individual login credentials; role-based permissions will limit dataset export to the core study team, i.e., authorized study staff of the Sponsor. Only pseudonymised identifiers (participant codes) will be used in exported files; no direct identifiers will be included. After each assessment, the exported dataset (i.e., Participant ID, responses, time stamps) will be downloaded as csv-files to and saved on the sponsor's secure server by authorised staff.

As part of the study, audio recordings of group therapy sessions will be collected for the purpose of intervention fidelity assessment and supervision. Audio recordings are conducted within the scope of the informed consent provided by the study participants. The audio recordings will be stored in pseudonymized form and will not contain direct personal identifiers. Each audio file will be labelled using a study-specific code. Audio files will be uploaded to and stored on a Nextcloud server operated by the Charité Universitätsmedizin Berlin. The server infrastructure complies with the requirements of the General Data Protection Regulation (GDPR/EU-DSGVO) and applicable national data protection regulations. Access to the audio recordings will be restricted to authorized study personnel only. Access rights are granted on an individual and role-based basis.

Audio recordings will be retained only for as long as necessary to complete the planned fidelity assessments. After completion of the respective evaluations, the audio files will be deleted. The maximum retention period is eight weeks after upload to the server.

8.9 Archiving

After the end of the trial, the originals of all trial-specific documents must be stored by the Chief Investigator according to national regulations for at least 10 years. At the individual participating study sites, the investigator site files will be retained for the same time period. Original data on study patients (medical records) shall be retained in accordance with the archiving period applicable to the study sites (investigators), but for no less than 10 years. Data on the m-Path servers will be deleted with the end of study. The exported data on the sponsor's server will be stored by the Chief investigator for at least 10 years.
No trial data or documents must be destroyed without prior written agreement between the Chief Investigator and the investigator(s) or their designee.

9. Benefit-Risk-Assessment

9.1 Individual and Potential Group/External Benefits of Study Participation

Participation may provide individual benefits, including reduced overall psychopathology, improved symptom control, higher functioning, and enhanced quality of life compared to TAU alone. Additionally, positive study outcomes could support group MBI as evidence-based approaches for inpatient care of patients with EP, potentially benefiting future patient groups.

9.2 Burdens and Risks Associated with Study Participation

Participation may involve certain burdens and risks, including suicidal thoughts, symptom worsening, or hospitalization. Serious adverse events directly caused by the FEEL-GOOD intervention are not expected; previous inpatient studies reported no adverse events, and outpatient studies reported only two hospitalizations, including one suicide occurring during a separate clinical stay. All participants will be thoroughly informed about potential risks.

9.3 Statement on Medical Justifiability (Benefit-Risk Assessment)

Given the expected clinical benefits of the FEEL-GOOD intervention and the structured, closely supervised inpatient setting with daily access to physicians and psychologists and regular medical visits the potential benefits clearly outweigh the minimal risks. The intervention is medically justifiable and can be safely implemented alongside TAU.

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11. Appendices

Appendix A: Model consent form (German)

Appendix B: Model study information letter (German)