

Aus dem
Max-Planck-Institut für Psychiatrie
Forschungsklinik der Max-Planck-Gesellschaft

***Mechanism-Based Psychotherapy for Acute Psychosis:
Development and Evaluation
of a Modularized Group Intervention***

Dissertation
zum Erwerb des Doktorgrades der Humanbiologie
an der Medizinischen Fakultät
der Ludwig-Maximilians-Universität München

vorgelegt von
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aus
Herrenberg

2025

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Table of contents

Affidavit	3
Table of contents	4
Abbreviations	5
Publication list	6
1. Introductory Summary	7
1.1 Psychological therapies for acute psychosis	8
1.2 Development and evaluation of mechanism-based psychological interventions.....	10
1.3 Publication summaries	11
1.3.1 Publication I: Intervention Development	12
1.3.2 Publication II: Feasibility Study	13
1.4 Discussion	14
1.5 Conclusion	15
2. Contributions to the publications	16
3. Zusammenfassung	17
4. Abstract	19
5. Publication I	21
6. Publication II	57
7. References	110
Acknowledgments	117

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Abbreviations

ACT:	Acceptance and Commitment Therapy
BCIS:	Beck Cognitive Insight Scale
CBTp:	Cognitive Behavioural Therapy for Psychosis
CFQ:	Cognitive Fusion Questionnaire
IM:	Intervention Mapping
MCT:	Metacognitive Training
MEBASp:	Mechanism-Based Psychotherapy for Psychosis
MPI:	Max Planck Institute
MRC:	Medical Research Council
KVTp:	Kognitive Verhaltenstherapie für Psychosen
PANSS:	Positive and Negative Syndrome Scale
PSDs:	Psychotic Spectrum Disorders
PSYRATS:	Psychotic Symptom Rating Scales
RCT:	Randomized Controlled Trial

Publication list

Publication I

Gussmann E, Lucae S, Falkai P, Padberg F, Egli S, Kopf-Beck J. **Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: an Intervention Mapping approach.** *Frontiers in Psychiatry* [Internet]. 2023;14.

Available from: <https://www.frontiersin.org/articles/10.3389/fpsy.2023.1160075>

Clarivate's Web of Science: *Frontiers in Psychiatry*

Impact factor 2022: 4.7

PSYCHIATRY – SSCI: 72.6%

PSYCHIATRY – SCIE: 66.1%

Publication II

Gussmann E, Lindner C, Lucae S, Falkai P, Padberg F, Egli S, Kopf-Beck J. **Targeting metacognitive change mechanisms in acute inpatients with psychotic symptoms: feasibility and acceptability of a modularized group intervention.** *Eur Arch Psychiatry Clin Neurosci* [Internet]. 2023; Sep 23.

Available from: <https://link.springer.com/10.1007/s00406-023-01690-y>

Clarivate's Web of Science: *European Archives of Psychiatry and Clinical Neuroscience*

Impact factor 2022: 4.7

CLINICAL NEUROLOGY – SSCI: 75.7%

PSYCHIATRY – SCIE: 66.1%

1. Introductory Summary

Psychosis spectrum disorders (PSDs), such as schizophrenia and psychotic mood disorders, are among the psychiatric illnesses with the highest global burden worldwide measured in terms of economic impact, adverse health outcomes and mortality rates (1). Disease courses are often characterized by recurrent acute psychotic episodes requiring immediate hospitalization (2). In fact, patients with acute psychosis account for a substantial proportion of the current psychiatric inpatient population worldwide (3) and are also among the patient groups most often subject to involuntary detention (4). Despite being the most expensive form of treatment (5), acute hospitalization can cause significant distress and trauma to patients with PSDs (6,7), often resulting in a disruption of daily functioning (8) and low rates of recovery after discharge (9). Improving inpatient care to make it more effective and conducive to recovery is therefore a key priority for health care services (10). In particular, the inadequate access to psychosocial treatment has led to dissatisfaction among inpatients with PSDs, their families and caregivers (7,11). They criticize the pre-dominance of pharmacological and risk-focused treatments, which do not leave room to address the underlying factors causing and maintaining the illness, nor the coping skills necessary for stabilization and sustainable recovery (12). However, the vast majority of research on psychotherapy for psychosis has been conducted in outpatient settings (13), leaving the following questions unanswered (14,15):

- 1) What constitutes an evidence-based psychological intervention for acute psychosis?**
- 2) Are such interventions feasible in the challenging environment of acute psychiatric settings?**
- 3) Are such interventions acceptable to acute inpatients experiencing psychosis?**

The current doctoral thesis aimed to answer these key questions in a two-stage research project that took place between January 2021 and August 2023. In Stage I, a structured methodological framework was used to develop and describe an evidence-based and needs-oriented intervention specifically adapted for acute psychiatric settings (Publication I). In Stage II, the feasibility, acceptability, and preliminary efficacy of the intervention were assessed in an uncontrolled feasibility study

in order to refine it before proceeding to a full clinical trial (Publication II). The following sections provide further background information on psychological therapies for acute psychosis and methodological approaches to intervention research, before summarizing and discussing the overall results of the research project.

1.1 Psychological therapies for acute psychosis

Psychological therapies, particularly cognitive behavioural therapy for psychosis (CBTp), have been shown to be effective for patients with psychosis (16,17) and are recommended by treatment guidelines even in the acute illness and treatment phase (18,19). According to guideline recommendations, acute inpatients should receive between 16 and 24 sessions of CBTp, supposed to help them link thoughts, feelings and actions, with the ultimate goal of challenging the content of delusional thoughts and hallucinations (18,19). However, despite clear guideline recommendations and available treatment concepts and manuals, implementation rates of CBTp in acute psychiatric settings remain low (10). Several possible reasons for this shortfall in provision have been discussed in the literature (20). First, the acute setting itself poses significant challenges, including short lengths of stay (with an average stay of 34.9 days for inpatients with PSDs in Germany) (21), hectic and restrictive ward environments, staff shortages, and a lack of trained clinicians to provide specialized psychological interventions (12,14). Second, multidisciplinary staff often still view psychology only as an adjunct to, or even in conflict with the medical treatment model, making it difficult to integrate both approaches into holistic care packages (22). Third, acute inpatients with psychosis are often in acute emotional crisis, experience distressing symptoms, are at high risk of harming themselves or others, have severe cognitive deficits and multiple diagnoses, thus making it difficult for them to engage with traditional psychotherapy approaches (14,23–25).

In addition to the challenging barriers associated with implementing psychotherapy according to guidelines, recent systematic reviews and meta-analyses of the effectiveness of CBTp in inpatient settings have yielded unsatisfactory results, with low-quality evidence and limited effects on few clinical outcomes (13,20,26). Conversely, there is emerging and encouraging evidence for the effectiveness of third-wave therapies (13,20,26), such as Acceptance and Commitment Therapy (ACT) (27), and CBTp approaches that incorporate third-wave components, such

as Metacognitive Training (MCT) (28).

Unlike CBTp, third-wave approaches do not directly confront or challenge patients' thoughts and feelings. Instead, they target transdiagnostic change mechanisms that are believed to alter the way patients respond to their internal experiences (29,30). A change mechanism in this context refers to a psychological process or event that is activated by therapy and that can explain why and how therapeutic change has occurred (31). Mechanism-based approaches, in turn, are thought to improve treatment outcomes in a more targeted manner, leading to meaningful and lasting improvements in patients (30–32). ACT for example focuses on change mechanisms such as acceptance, mindfulness, and cognitive distancing in dealing with distressing internal experiences (33) and has been shown to reduce symptom burden and rehospitalization rates in acute inpatients with PSDs (34–36). MCT, on the other hand, targets cognitive insight for cognitive biases by promoting metacognitive knowledge and awareness (28) and has been shown to reduce acute positive symptoms (37).

Although these less confrontational, transdiagnostic, and mechanism-based therapeutic approaches appear to make treatment more effective for acute inpatients with psychosis, the available evidence must be treated with caution (20). Moreover, both ACT and MCT have been developed in community settings, where patients often have less severe symptoms, thus can deal with more complex therapy contents, and have different needs and treatment goals than acute inpatients (12,25,38). As a result, the mechanisms of change targeted by these therapies may differ from those relevant in acute inpatient care (15). For example, the mechanisms that drive change in acute inpatient settings revolve primarily around minimizing distress and reducing risk (38), whereas outpatient therapy prioritizes processes such as fostering commitment to personal values that help achieve long-term recovery goals (16,33). Researchers have therefore suggested the need to develop novel psychological interventions. This process should include a) identifying specific key change mechanisms relevant to acute inpatients with PSDs, and b) ensuring that novel interventions reflect the complex needs of acute psychiatric settings (7,12,25,39,40).

1.2 Development and evaluation of mechanism-based psychological interventions

The issue of inefficient use of research resources in the context of intervention science has received increasing attention in recent years (41). In particular, authors have criticized weaknesses in the design, reporting and initial testing of novel interventions prior to an expensive randomized controlled clinical trial (RCT). Inadequate attention to the development phase, including a detailed problem definition, consideration of existing evidence and contextual needs, and selection of relevant change mechanisms and associated behavioural change methods to be incorporated into the intervention, may result in ineffective treatments and thus negative or inconclusive trial results (40,42–44).

In studies of psychological interventions for acute psychosis, neglect of the intervention development phase has often resulted in treatments that fail to prioritize the primary goals of inpatient care (15,26). More specifically, most interventions have not been adapted to address change mechanisms associated with reducing admission triggers and inpatient distress, which are arguably the primary needs of this patient population (26). However, these shortcomings could be avoided by initially placing more methodological emphasis on the intervention development process and subsequent evaluation in feasibility or pilot studies (40,42–44).

In this regard, the Medical Research Council (MRC) Framework is a widely accepted guideline for intervention design and evaluation. It outlines the four essential research phases required for scientific intervention design: 1) Development, 2) Feasibility/Pilot testing and intervention refinement, 3) Evaluation, and 3) Final implementation (42). For the methodological implementation of each MRC phase, researchers further recommend the use of existing rigorous approaches to intervention development (40,43,44), such as Intervention Mapping (IM) (45). The rationale for using such an approach is that it provides a clearly structured methodology that has been shown to be effective for other intervention developers (43,44). IM, for example, uses theory and evidence-based development principles and consists of six predefined sequential methodological steps (see Figure 1) that cover the MRC development and feasibility phase (40). In addition to a detailed problem definition, needs assessment and consideration of contextual factors, IM places a particular emphasis on identifying and mapping the hypothesized change mechanisms underlying an intervention to ensure that the intervention is targeted to causal

pathways and the specific patient population (45,46).

While IM has been shown to have potential in mechanism-based intervention science (44), particularly in the area of health behaviour research (47), including alcohol (48), smoking (49), and chronic heart failure (50), it has not yet gained much traction in the fields of clinical psychology or psychiatry (47). Given the urgent need for effective mechanism-based psychological treatments for acute inpatients with PSDs (7,12), the application of such an approach might help to develop an intervention that is mechanism-based and thus targeted, contextually appropriate, widely accepted, and contributes to long-term health improvements for this patient population (40,43,44).

1.3 Publication summaries

IM was chosen as the overall methodological framework because of its systematic and detailed approach, which allowed to cover both the development process of the mechanism-based intervention for acute psychosis (MEBASp) in Stage I and the subsequent feasibility study of MEBASp in Stage II.

Stage I implemented the first four steps of IM, including 1) creating a logical problem model and needs analysis, 2) modeling desired treatment outcomes and hypothesized change mechanisms that should underlie MEBASp, 3) selecting behaviour change methods consistent with the hypothesized change mechanisms and translating them into practical therapeutic applications, and 4) deciding on the format and delivery of MEBASp and producing the actual therapy materials (45).

Stage II used steps 5 and 6 of IM by 1) developing an implementation and evaluation plan, 2) conducting a small-scale feasibility study, and 3) preparing necessary refinements to optimize MEBASp prior to a full RCT (45). Figure 1 visualizes the methodological steps and outcomes for Stage I and II, which are presented in the publications' summaries below.

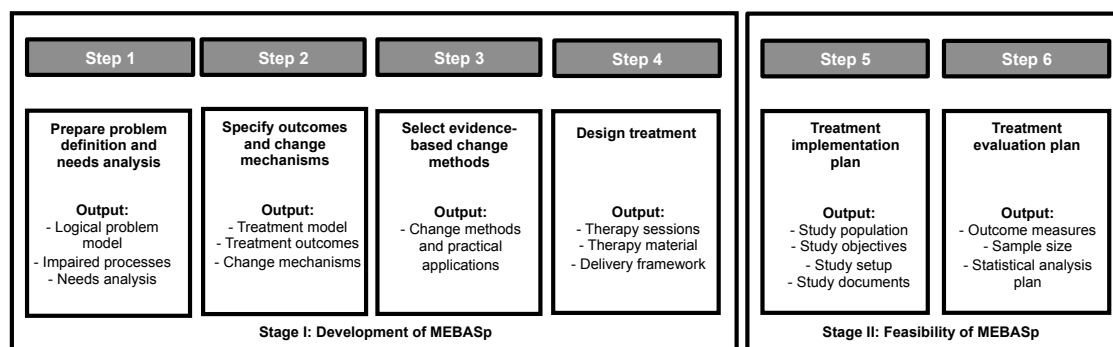


Figure 1. Visualization of the IM methodological steps in Stage I and Stage II of the MEBASp research project. Adapted from “Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: an Intervention Mapping approach” by E. Gussmann, S. Lucae, P. Falkai, F. Padberg, S. Egli and J. Kopf-Beck, 2023, *Frontiers in Psychiatry* (14), p.3 (51). Copyright (2023) by Gussmann, Lucae, Falkai, Padberg, Egli and Kopf-Beck under the Creative Commons Attribution License. Adapted and used with permission.

1.3.1 Publication I: Intervention Development

For Stage I of MEBASp, systematic reviews and meta-analyses (13,20,26,52), relevant psychological theory (53–57), qualitative interview studies (12,22,25,38,58), core competency frameworks, and existing mechanism-based therapies for working with acute inpatients with psychosis (34,36,39,59–63) were excessively studied. The problem model identified two major mental health problems for acute inpatients with psychosis: severe positive symptoms, such as hallucinations and delusions, and resulting dangerous behaviours towards self and others making immediate hospitalization necessary (51). The model furthermore identified metacognitive deficits, including a lack of cognitive insight and maladaptive coping strategies, such as cognitive fusion, as key determinants of the pathogenetic processes associated with acute positive symptoms and crisis development (51). In addition, the needs assessment and change model determined that MEBASp should 1) aim to reduce both symptom severity and symptom distress, 2) be delivered in a group format for economic and social reasons, and 3) incorporate simple, brief, and destigmatizing treatment elements (51). Based on the initial problem definition, metacognitive change mechanisms were selected as the main change determinants for the treatment goals and it was decided to divide MEBASp into three separate treatment modules, each targeting a different change mechanism (51). Modules I and II consist of five sessions and aim to increase patients’ cognitive insight into cognitive distortions and thus reduce acute positive symptoms. Module III consists of four sessions and aims to reduce patients’ distress by promoting cognitive defusion and thus functional coping strategies for dealing with delusions, hallucinations, and

negative symptoms (51). All modules incorporate treatment components from existing metacognitive-oriented therapies such as Metacognitive Training (28), Metacognitive Therapy (64), and Acceptance and Commitment Therapy (27) and were designed to be transdiagnostic and experiential. Finally, it was suggested that therapists adopt an empowering and destigmatizing therapeutic attitude and that MEBASp should take place twice a week, with each session lasting 40 to 50 minutes and a maximum of seven patients per group (51). Overall, the steps taken by IM were found to be invaluable in strengthening the scientific basis and validity of MEBASp, necessary for its successful implementation and evaluation in the patient population and setting.

1.3.2 Publication II: Feasibility Study

In Stage II of the research project, the feasibility, acceptability, and preliminary effectiveness of MEBASp were assessed in a sample of 37 participants recruited from the locked acute ward of the Max Planck Institute of Psychiatry in Munich (65). Primary outcomes were feasibility measures, such as recruitment, retention, and attendance rates, and acceptability criteria, such as subjective treatment satisfaction, obtained from feedback questionnaires and interviews with participants (66). Secondary outcomes were assessed at baseline and post-intervention using measures such as the Positive and Negative Syndrome Scale (PANSS) (67) and the Psychotic Symptom Rating Scale (PSYRATS) (68) to assess general psychopathology, psychotic symptoms, global functioning, and symptom distress. Changes in hypothesized metacognitive change mechanisms were also assessed before and after each treatment module using the Beck Cognitive Insight Scale (BCIS) (69) and the Cognitive Fusion Questionnaire (CFQ) (70). It was hypothesized that 1) measures of feasibility and acceptability would exceed the prespecified benchmark of 80% and that 2) participants would show significant improvement on all clinical and mechanism measures post-intervention (65).

The trial met the feasibility benchmark of 80% for recruitment, retention, and attendance rate (65). Participants provided positive feedback on the different modules, with 80% of participants rating their overall treatment satisfaction as the highest possible, highlighting MEBASp's clear structure, positive atmosphere and helpful content (65). The study also achieved high response rates, with 91.9% of the participants responding to the treatment (65). Statistical analysis also showed

significant medium-to-large pre-to-post effects on all clinical outcomes, including overall psychopathology (Cohen's $d = 0.93$), positive (Cohen's $d = 1.24$) and negative symptoms (Cohen's $d = 0.53$), symptom distress (Cohen's $d = 0.99$), and global functioning (Cohen's $d = 1.58$) (65). With regard to the hypothesized change mechanisms underlying the intervention, an increase in cognitive insight (Cohen's $d = 0.45$) and a decrease in cognitive fusion (Cohen's $d = 0.43$) were observed (65).

1.4 Discussion

The results of the two-stage research project demonstrate that a rigorously designed, mechanism-based psychological intervention for acute inpatients with PSDs is feasible, highly acceptable, and associated with positive preliminary changes in both clinical outcomes and hypothesized mechanisms of change (65). By using IM as a methodological framework in both research phases, it was possible not only to address the initial research questions, but also to develop an intervention that is believed to be appropriately contextualized, targeted at relevant mechanisms of change, and ready for further evaluation in a larger scale RCT (65). The research project thus has the potential to advance intervention research in the field of acute psychosis and to have a positive impact on a patient group that has been historically neglected in the provision of psychotherapy (71).

There are several limitations to the overall research project that need to be addressed in future research. First, MEBASp was developed with a specific focus on metacognitive change mechanisms and group delivery format, based on decisions made by the development team during the IM development phase (65). While this focus and approach was beneficial for many patients, it may not be appropriate for all patients, highlighting the need for alternative treatment options (51). Second, the feasibility study is limited by a small sample size and a lack of control conditions, blinded assessments and follow-up time points. Therefore, it is not possible to draw definitive conclusions about the effectiveness of MEBASp and the preliminary clinical results must be interpreted with caution (65).

To investigate the effectiveness of MEBASp and its individual modules, future research should use a more rigorous study design, including larger sample sizes, randomization, blinded ratings, and an active control condition that does not focus on the targeted change mechanisms (65). To further demonstrate the effectiveness of the metacognitive-based treatment model, mediation analyses and follow-up

time points should be included to assess the impact of change mechanisms (72–76). The ultimate goal is to identify outcome moderators that ensure personalized treatment allocation tailored to the patient's needs and personal therapy goals, thereby optimizing individual outcomes (77,78).

1.5 Conclusion

The results of this two-stage doctoral research project highlight the promising potential of targeting metacognitive change mechanisms in psychological interventions for acute inpatients with psychotic symptoms. MEBASp shows a high degree of feasibility and acceptability and suggests improvements in both clinical and mechanism outcomes. The positive study results also highlight the importance of using a structured methodological framework, such as IM, which enhances the scientific basis of interventions and their likelihood of effectiveness during evaluation. Further evaluation of MEBASp and its associated change mechanisms in a larger randomized controlled trial is warranted.

2. Contributions to the publications

I developed the idea for MEBASp within the research group MoMenT ("Modularized and Mechanism-based PsychoTherapy") (Dr. Egli and Dr. Kopf-Beck) and against the background of my work as a clinical psychologist on the locked acute ward at the Max Planck Institute of Psychiatry (MPI) in Munich. In short, my idea was to improve the treatment situation of acute inpatients with psychotic symptoms by developing a targeted, mechanism-based group therapy. Based on my previous experience in the field of psychosis research and with the help of my co-authors, I drafted the study protocol, which was ethically approved by the ethics committee of the Ludwig Maximilian University Munich (PNO-21-0025). I also pre-registered the research project in ClinicalTrials.gov (NCT04874974) (79).

For Stage I (Publication I) of the research project (51) I 1) conducted a comprehensive literature review, 2) engaged with stakeholder groups (researchers, clinicians and patients), 3) developed a detailed problem definition and needs analysis, 4) outlined a prototype intervention, and 5) designed therapy materials (therapy manual, therapy notebook, PowerPoint presentations for sessions) (51). I wrote the entire manuscript on the intervention development process, improved it with the support of the co-authors, and managed the subsequent review process and final submission.

For the Stage II feasibility study (Publication II) (65), I recruited a sample of 37 participants with acute psychotic symptoms from the acute locked ward of the MPI. In addition to recruitment, I was responsible for all study assessments, supervision of co-raters, evaluation and differential diagnosis of participants, communication with stakeholders, and implementation of the group and individual therapies. Once recruitment was complete, I was mainly involved in organizing and analyzing the quantitative (using linear mixed models) and qualitative (using thematic analysis) data under supervision. I was also responsible for critically analyzing the study results, drawing conclusions, and preparing the next steps for a larger randomized controlled trial. Moreover, I was responsible for drafting the entire manuscript, playing a key role in the editing process, and completing the peer review process and the final version that was published.

3. Zusammenfassung

Die Verbesserung der stationären psychotherapeutischen Versorgung von Akutpatienten mit psychotischen Symptomen ist ein zentrales Anliegen der nationalen und internationalen Gesundheitsversorgung (7,10,12,38). Allerdings wurden die meisten Studien zur Wirksamkeit von Psychosenpsychotherapien in ambulanten Behandlungssettings durchgeführt, die sich deutlich von der Akutbehandlung unterscheiden (13,20,26,52). Auch systematische Übersichtsarbeiten und Metaanalysen zur Wirksamkeit der in Leitlinien empfohlenen kognitiven Verhaltenstherapie bei psychotischen Störungen (KVTp) in der Akutversorgung zeigen eher enttäuschende Ergebnisse (13,20,26). Es gibt jedoch zunehmend Evidenz für positive Effekte von mechanismus-basierten Ansätzen der dritten Welle, wie z.B. der Akzeptanz- und Commitmenttherapie, und von Ansätzen, die von der dritten Welle inspiriert sind, wie z.B. dem Metakognitiven Training (20). Obwohl vielversprechend, wurden nur wenige dieser mechanismusbasierten Interventionen speziell für akutpsychiatrische Behandlungssituationen entwickelt oder an die entsprechenden Populationen und deren Bedürfnisse angepasst (20). Die Frage, welche psychotherapeutischen Interventionen für Akutpatienten hilfreich und wirksam sind, bleibt daher unbeantwortet (26). Das Ziel des Forschungsprojektes war es daher, eine neue, bedürfnisorientierte und mechanismus-basierte psychotherapeutische Intervention (MEBASp) für akutpsychiatrische Patienten mit psychotischen Symptomen zu entwickeln und im Rahmen einer Machbarkeitsstudie zu evaluieren.

Der Therapieentwicklungsprozess in Phase I und die anschließende Machbarkeitsstudie in Phase II des Forschungsprojektes orientierten sich methodisch an den Schritten des Intervention Mapping (IM), einem klar strukturierten sechsstufigen Rahmenmodell zur evidenzbasierten Interventionsplanung (45). Die in Phase I entwickelte MEBASp-Intervention umfasst eine Gruppentherapie mit drei Modulen, die jeweils unterschiedliche metakognitive Veränderungsmechanismen ansprechen und niedrigschwellige, erlebnisorientierte und entstigmatisierende Therapieelemente beinhalten. In den Modulen I und II geht es um die Verbesserung der kognitiven Einsicht mit dem Ziel, akute psychotische Symptome zu lindern. Modul III konzentriert sich auf das Training der kognitiven „Defusion“, um Distanz zum inneren Erleben zu schaffen, dessen Einfluss auf das Verhalten zu reduzieren und damit die Symptombelastung der Patienten zu verringern (51). In Phase II des Forschungsprojektes wurde eine Stichprobe von 37 Patienten mit psychotischen

Symptomen (ICD-10 F20-39: Schizophrenie, schizotype, wahnhaft und affektive Störungen mit psychotischen Symptomen) aus der geschlossenen Akutstation des Max-Planck-Instituts für Psychiatrie (MPI) in München, Deutschland, für die Machbarkeitsstudie rekrutiert, die an bis zu neun Sitzungen der Intervention teilnahmen (65). Die primären Outcome-Messungen umfassten die Durchführbarkeit (Rekrutierungs-, Bindungs- und Anwesenheitsquote) und die Akzeptanz (Zufriedenheit der Teilnehmenden mit der Therapie) der Intervention. Zu den sekundären Outcome-Maßen gehörten der Schweregrad der allgemeinen Psychopathologie und der psychotischen Symptome, das globale Funktionsniveau und die Symptombelastung, die jeweils zu Beginn und am Ende der Intervention erhoben wurden. Hypothetische Veränderungsmechanismen wurden vor und nach jedem Modul erhoben (65).

Die hohe Durchführbarkeit der Intervention wurde durch eine Rekrutierungsquote von 78,8%, eine Bindungsrate von 89,2% und eine Anwesenheitsquote von 86,5% belegt. 80% der Teilnehmer bewerteten ihre Gesamtzufriedenheit mit MEBASp als sehr hoch, was auf eine sehr gute Patientenakzeptanz hinweist. Obwohl die Machbarkeitsstudie aufgrund ihres Designs nicht darauf ausgelegt war, die klinische Wirksamkeit der Intervention zu evaluieren, ergaben sich Hinweise auf signifikante Prä-Post-Effekte für alle klinischen Maße und Veränderungsmechanismen (65).

Die Ergebnisse des zweistufigen Forschungsprojektes MEBASp liefern überzeugende Evidenz für die Machbarkeit und Akzeptanz einer auf einem metakognitiven Modell basierenden Gruppenintervention bei Patienten mit psychotischen Symptomen in stationärer Akutbehandlung. Die beobachteten positiven Ergebnisse hinsichtlich klinischer Verbesserungen und Veränderungsmechanismen rechtfertigen eine weitere Untersuchung der Intervention in einer randomisierten kontrollierten Studie (65).

4. Abstract

Improving psychotherapeutic inpatient care for acute patients with psychotic symptoms is a key issue for national and international health care services (7,10,12,38). However, most studies of psychotherapy for psychosis have primarily focused on outpatient settings, leaving a knowledge gap regarding effective interventions for acute inpatients (13,20,26,52). Furthermore, recent systematic reviews and meta-analyses of the effectiveness of guideline-recommended cognitive behavioural therapy for psychosis (CBTp) in acute settings have reported rather disappointing results (13,20,26). Nevertheless, there is increasing evidence for mechanism-based third-wave therapies, such as the Acceptance and Commitment Therapy, and third-wave-inspired approaches, such as the Metacognitive (20). However, although promising, few of these mechanism-based interventions have been specifically developed or adapted for acute psychiatric settings (20). Therefore, the current research aimed to develop and test a novel mechanism-based and needs-oriented psychological intervention (MEBASp) for acute inpatients with psychotic symptoms.

Intervention Mapping (IM) (45), a six-step structured methodological framework for scientific intervention design, was used to guide both the rigorous development process of MEBASp in Stage I (Publication I) and the subsequent feasibility study in Stage II (Publication II). The MEBASp intervention designed in Stage I consists of a three-module, low-threshold, experiential, and destigmatizing group intervention focusing on different aspects of metacognitive change mechanisms. Modules I and II focus on enhancing cognitive insight to alleviate acute symptoms, while Module III emphasizes cognitive defusion to reduce participants' distress (51). In Stage II, a sample of 37 participants with psychotic symptoms (ICD-10 codes F20-39: schizophrenia, schizotypal, delusional and psychotic mood disorders) was recruited from the locked acute ward of the Max Planck Institute of Psychiatry (MPI) in Munich, Germany, and received up to nine sessions of MEBASp (65). Primary outcome measures were feasibility (recruitment, retention and session attendance rates) and acceptability (participant satisfaction with treatment). Secondary outcome measures included general psychopathology, psychotic symptoms, global functioning, symptom distress, and symptom severity assessed at baseline and post-intervention. Measures of the hypothesized mechanisms of change were administered before and after each module (65).

High feasibility was demonstrated by a recruitment rate of 78.8%, retention rate of 89.2% and attendance rate of 86.5%. 80% of participants rated their overall satisfaction with the treatment as the highest possible, further indicating a high level of acceptability. In addition to the primary outcome measures, the feasibility and acceptability of MEBASp were supported by secondary outcome measures and qualitative data. Although the feasibility study was not designed or powered to assess clinical effectiveness, there was evidence of significant pre-post effects on all secondary clinical outcomes and hypothesized mechanisms of change (65).

The results of the two-stage MEBASp research project provide compelling evidence for the feasibility and acceptability of a group intervention based on a metacognitive model for patients with psychosis in acute inpatient settings. The positive outcomes observed in terms of clinical improvements and mechanisms of change warrant further investigation in a randomized controlled trial (65).

5. Publication I



TYPE Original Research
 PUBLISHED 01 June 2023
 DOI 10.3389/fpsy.2023.1160075



OPEN ACCESS

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RECEIVED 06 February 2023

ACCEPTED 05 May 2023

PUBLISHED 01 June 2023

CITATION

Gussmann E, Lucae S, Falkai P, Padberg F, Egli S and Kopf-Beck J (2023) Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: an Intervention Mapping approach.
Front. Psychiatry 14:1160075.
 doi: 10.3389/fpsy.2023.1160075

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Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: an Intervention Mapping approach

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Background: Treatment guidelines for psychosis recommend offering psychotherapy already in the acute illness phase. However, there is a lack of available interventions adapted to the specific needs and key change mechanisms of inpatients experiencing severe symptoms and crisis. In this article we outline the scientific development process of a needs-oriented and mechanism-based group intervention for acute psychiatric inpatients with psychosis (MEBASp).

Methods: To guide our intervention design, we used Intervention Mapping (IM), a six-step framework for developing evidence-based health interventions that consisted of an extensive literature review, an in-depth problem definition and needs analysis, the modeling of change mechanisms and outcomes and the production of an intervention prototype.

Results: Our low-threshold modularized group intervention consists of nine stand-alone sessions (two per week) within three modules and targets different aspects of metacognitive and social change mechanisms. Module I and II aim to reduce acute symptoms by fostering cognitive insight, Module III focuses on reducing distress via cognitive defusion. Therapy contents are adapted from existing metacognitive treatments such as the Metacognitive Training and presented in a destigmatizing, simply understandable and experience-oriented way.

Conclusion: MEBASp is currently evaluated in a single-arm feasibility trial. Using a systematic and rigorous development methodology and providing a detailed description of the development steps demonstrated to be invaluable in improving the intervention's scientific foundation, validity, and replicability for similar research.

KEYWORDS

intervention mapping, intervention development, mechanism-based, acute inpatients, psychosis, metacognition, group therapy

1. Introduction

Psychological therapies have demonstrated to be effective for patients experiencing psychotic symptoms (1, 2) and are recommended by treatment guidelines already in the acute illness and treatment phase (3, 4). However, recent systematic reviews and meta-analyses investigating treatment effects for acute psychiatric inpatients with psychosis revealed an outcome superiority of third-wave therapies (5–7) over guideline-recommended second-wave cognitive behavioral therapy for psychosis (CBTp) (3, 4). In contrast to disorder-specific CBTp protocols that aim to alter the occurrence and form of psychotic symptoms such as delusional thoughts and hallucinations (8), third-wave therapies often focus on the behavioral function of internal experiences rather than their content per se (9). Instead of examining and disputing the content of voices and thus giving them increased attention and importance for example, third-wave therapies train patients to mindfully experience auditory hallucinations in order to reduce their negative impact on behavior (10). They also emphasize the therapeutic importance of targeting evidence-based change mechanisms, which are the underlying (psychological) processes responsible for positive treatment outcomes, instead of solely focusing on changing symptoms (11). Third-wave interventions e.g., aim at changing impaired reasoning processes behind delusional thoughts and not necessarily the content of the specific delusion (9). Change mechanisms thereby draw on impaired processes believed to contribute to the maintenance and onset of various mental health problems and thus often operate as transdiagnostic change factors (11). Cognitive distortions associated with depressive disorders for instance can also be improved through interventions targeting general reasoning abilities (12). Understanding what leads to change and tailoring therapy to directly address those change mechanisms hence seems to be important to generally optimize therapeutic strategies and thus to improve overall treatment outcomes for patients (9, 13).

Given the urgent need for effective inpatient care (14, 15), prioritizing change mechanisms in therapy therefore might hold a great potential to positively impact disease progression and prognosis of patients with acute psychosis (16). Major third-wave therapies that explicitly focus on potential change mechanisms in psychosis are the Acceptance and Commitment (ACT) and the Metacognitive Training (MCT) (9). ACT for instance fosters acceptance and cognitive distancing from delusions and hallucinations (17) and has shown to reduce general psychopathology and rehospitalization rates in acute inpatients with psychosis (18–20). MCT on the other hand aims to promote patients' cognitive flexibility by raising metacognitive awareness and knowledge for cognitive biases (21) and showed significant effects on reducing positive symptoms (8, 22, 23). Although the mechanism-based principles of these approaches seem promising in the treatment of acute inpatients with psychosis, existing evidence has to be treated with caution (5). Until now, evidence is based on a small number of randomized controlled trials (RCTs) with relatively heterogeneous study conditions and methodological shortcomings (5–7). On top of that, ACT and MCT were developed for outpatient settings where patients' symptom

severity and hence key change mechanisms and needs can be assumed to differ from those of patients experiencing acute crises (24). Change mechanisms in acute inpatient environments for example mainly comprise of mechanisms associated with distress and risk reduction (16), while outpatient therapy focuses on processes like value commitment that support long term recovery goals (1). In addition, acute psychiatric settings by themselves represent challenging environments to deliver psychotherapy, counting involuntary admissions, brief inpatient stays and staff shortage as major obstacles (25). Researchers therefore argue that further intervention development is needed that (a) identifies and adapts to specific inpatient change mechanisms and (b) reflects the complex requirements of acute psychiatric ward (25–28).

However, the actual development process of interventions in psychotherapy is often kept short and under-reported (29). Neglecting the actual development phase can be problematic, as a poor problem definition, insufficient attention to existing evidence and context needs, a missing model underlying the intervention, and an unsound selection of hypothesized change mechanisms can lead to inefficient treatments (30–32). An “intervention black box” then makes it difficult to understand why specific therapy components didn't work in a clinical trial (31). Furthermore, a published, in-depth description of the development process is necessary for other researchers to replicate findings and for clinicians to understand how to implement the intervention (33).

In order to overcome these shortcomings, Bleijenberg et al. (31) suggest using structured methodological frameworks such as the Intervention Mapping (IM) that fulfills the Medical Research Council's (MRC) quality criteria on intervention development (31, 32). Although the use and reporting of IM approaches is prevalent in health and prevention research (34–39), there are only a limited number of comparable academic articles published in the field of (clinical) psychology (40, 41). The current article's objectives are therefore twofold: We aim to describe the development and theoretical underpinnings of a mechanism-based and needs-oriented intervention for inpatients with psychosis (MEBASp) treated in an acute psychiatric setting. By using Intervention Mapping in doing so, we also hope to provide an example and highlight the benefits of how existing rigorous development frameworks can be used to enhance the design and reporting standards for psychological therapies in psychiatric research.

2. Materials and methods

We chose IM as our conceptual development framework due to its systematic and detailed protocol allowing an effective selection of treatment mechanisms and procedures in six consecutive steps (42). In the practical application of those steps, we were guided by the approach of van Agteren et al. (40), who adapted the IM method for mental health research. Next to following IM principles, we made sure to adhere to relevant reporting guidelines (e.g., Template for Intervention Description and Replication) when describing and explaining our development milestones (33). **Figure 1** provides an overview of the development steps undertaken to design our intervention that are described in detail in the sections below.

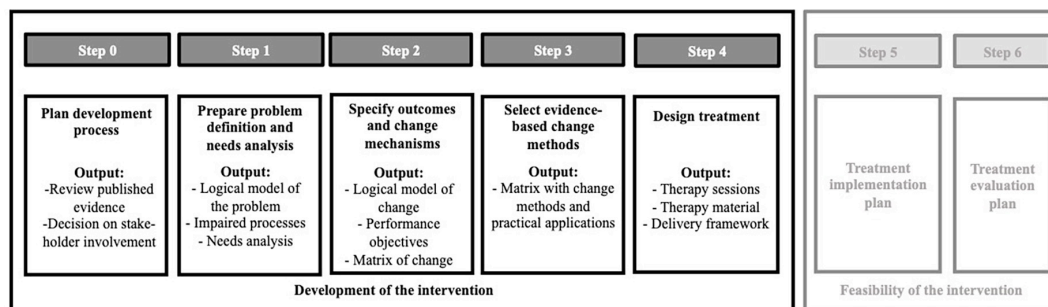


FIGURE 1

Illustration of the IM intervention development process and selected steps undertaken in the MEBASp project.

2.1. Step 0: planning process and decision on stakeholder involvement

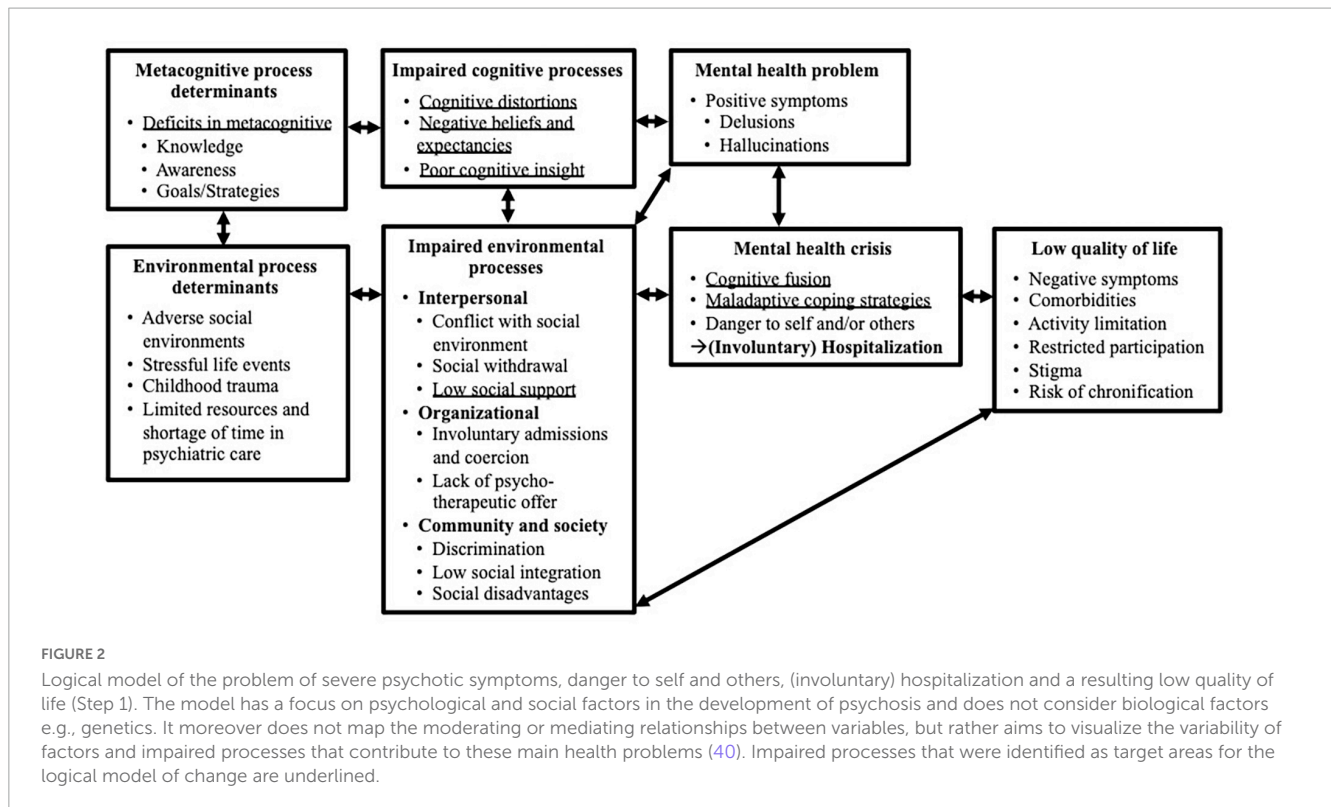
Next to theory and evidence-based development principles, the IM approach emphasizes participatory research activities e.g., involving the target population in all planning phases through qualitative research (43). Collaborative care planning approaches, such as codesign and coproduction, have thereby become increasingly important in mental health intervention design and delivery, and have been shown to improve service quality (44–47). Nevertheless, the implementation of codesign in psychiatric research settings can be challenging due to the significant time and cost involved (48), as well as the ethical challenges that arise when conducting qualitative research with severely burdened and highly vulnerable patient groups (49, 50). To address this challenge, Locock et al. developed an accelerated codesign approach that drew on pre-existing qualitative patient data and that proved to be acceptable to patients and staff (48). Building on this approach, we first of all reviewed pre-existing qualitative research involving acute inpatients with psychosis (for an overview see [Supplementary Table 1](#)). Published studies were primarily conducted in a psychiatric context in the UK, which was found to be very similar to the German system (51), thus making available data transferable to our current research context. By deciding to draw on secondary data for our project instead of conducting primary research, we aimed to take advantage of synergistic effects by implementing patients perspective from prior research, while also considering the constraints of time and resources discussed above. However, we included various codesign activities in our subsequent feasibility study such as feedback rounds and questionnaires, and interviews with both participants and staff (see future directions) to ensure that the intervention prototype will be refined according to the needs and preferences of our target population (52).

2.2. Step 1: logical model of the problem and needs analysis

The first step of IM involved an exact description of our development context including our target population and setting. We moreover conducted an extensive literature study to create a logical model (theory) of our problem (see [Figure 2](#)) from

which we derived the theoretical underpinnings, the requirements for and the scope of the intervention (43). To structure the literature research behind the problem determination and resulting needs analysis, IM suggests using the PRECEDE-framework (an acronym for Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation), which is an established research method to assess health issues on the basis of four predefined assessment phases (53). Going through the different phases, research teams ask themselves the following questions: What is the problem and who has it (epidemiological assessment)? How does it affect patients (social assessment)? What may be its causes (ecological assessment)? How do policies contribute to the problem (policy assessment)? (54). Following the framework's phases, we covered information on (1) mental health problems of acute inpatients with psychotic symptoms, (2) their effects on quality of life (QoL), (3) potentially associated pathogenetic psychological and environmental processes causing the problem and 4) characteristics (policies) of acute psychiatric wards. Our sources of information included systematic reviews and meta-analyses (5–7, 55), qualitative interview studies (16, 25, 28, 56, 57), core competency frameworks and existing mechanism-based therapies for working with acute inpatients with psychosis (8, 18, 20, 22, 23, 26, 58, 59).

Impaired psychological processes e.g., cognitive distortions found to be relevant in psychosis (60) were grouped into different overarching process domains such as cognition (see [Supplementary Table 2](#)). A psychological process thereby refers to an aspect of human cognition, affect, behavior or physical sensation that may be involved in the predisposing, etiology or maintenance of a disorder (61). As impaired processes are believed to causally interrelate with several mental disorders (62), we made sure to include transdiagnostic findings in our overview. To organize the overview, we utilized the available subdivisions found in the transdiagnostic process collection by Harvey et al. (61) which summarizes research results on cross-diagnostic altered processes in five different domains. Using existing process-oriented etiological models for psychosis (63–67), we then identified the most important environmental and psychological processes for our problem model. Existing intervention concepts focusing on identified processes as mechanisms of change were then extensively studied to estimate common practices, their effectiveness and potential barriers (31) (see [Supplementary Table 3](#)).



2.3. Step 2: intervention outcomes, change mechanisms and logical model of change

In a second step, we used our logical problem model and needs analysis (Step 1) to define desired cognitive, behavioral and environmental intervention outcomes necessary to prevent or reduce our health problems (e.g., patient critically reflects on internal experiences) and thus positively influence quality of life effects. Following the IM framework, we then addressed the question of *why* patients would make these changes by selecting impaired processes from our problem theory (e.g., poor cognitive insight) and rewriting them into hypothesized change mechanisms (e.g., higher cognitive insight) (43). Overarching change domains were chosen from the Theoretical Domains Framework (TDF) (68), an integrative framework that provides intervention developers with a possible selection of 14 change domains e.g., behavioral regulation and 84 change mechanisms e.g., self-monitoring from evidence-based behavior change theories. We summarized our overall findings in a graphical logical model (theory) of change (43) (see Figure 3).

Our intervention outcomes were further divided into so-called performance objectives (e.g., Patient understands the cognitive model of CBT) (see Table 1). These objectives describe specific behaviors that need to be pursued in order to reach the desired treatment outcome (43). By linking performance objectives with selected change mechanisms from above, we were able to phrase specific change objectives. Simply put, change objectives concretely verbalize what occurs through a change mechanism (e.g., The patient demonstrates increased knowledge about the impact of

internal experiences on behavior) (40). As a result, all change objectives were organized in a matrix of change (43) (see Table 2).

2.4. Step 3: evidence-based change methods

In Step 3 of IM, we used our matrix of change to link our change objectives to so called change methods. Change methods describe theory-based behavior change techniques (BCTs) (69) that are believed to influence change objectives (e.g., knowledge increase may be achieved through the change method psychoeducation) (69). Instead of asking *Why does change occur?* we were now concerned with the question *How does change occur?* (43). We selected our evidence-based change methods from various literature resources (70, 71) including IM's comprehensive taxonomy of BCTs (43, 69) and translated them into practical applications. A practical application refers to a therapeutic strategy derived from the change technique that can be implemented in a real-world setting (40). For example, to achieve our change objective of increasing knowledge about the impact of internal experiences on behavior, the intervention utilizes psychoeducation as a change technique. This is practically done by providing an everyday example (such as "Imagine your best friend doesn't call on your birthday") (72) (p. 104) to the patients and asking them how they might feel, think, and react (73). Practical applications were informed by existing mechanism-based intervention practices for (acute) settings as identified in Step 1 (8, 18, 20, 22, 23, 59). The final output for Step 3 comprised of a matrix of change methods containing all procedures planned to be incorporated into our intervention (43) (see Table 3).

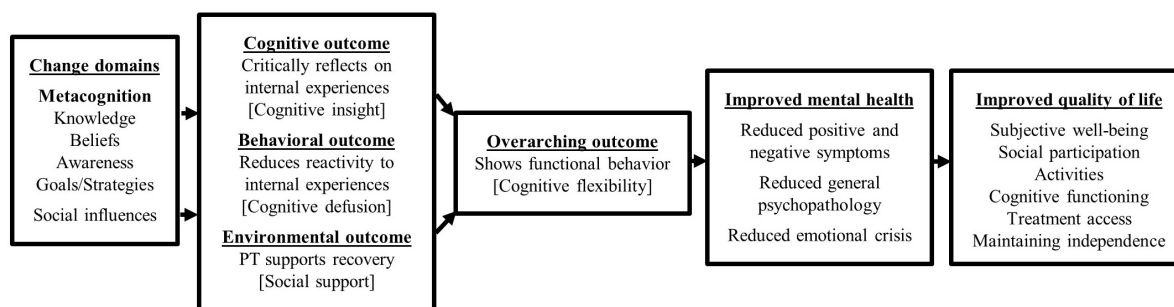


FIGURE 3

Logical model of change showing what change is needed to manage the main health problems of severe psychotic symptoms and danger to self and others (Step 2). It points out the change domains and belonging change mechanisms expected to influence the cognitive, behavioral and environmental outcomes that are in turn believed to improve mental health and quality of life. Hypothesized underlying target change mechanisms are put into square brackets.

2.5. Step 4: intervention outline

In line with our intervention draft of Step 3, we designed treatment modules, the associated sessions (see [Table 4](#)), produced therapy materials and decided on our delivery format outlining therapy frequency and duration of sessions. Next to creating completely new materials, we made sure to thoroughly examine existing therapy manuals for usable parts. If some materials of an intervention were suitable, we made adjustments before integrating them into our intervention. During the development process, project team members and independent clinical fellows constantly reviewed materials and session outlines. We also made sure to carry out some informal test-runs with patients whose verbal feedback was used to revise session contents for the final intervention that is currently tested in a feasibility study.

2.6. Step 5 and 6: implementation and evaluation plan

After completing step 1–4, IM includes two additional steps consisting of setting up an implementation and evaluation plan (43). However, we decided to follow van Agteren and colleague's decision to exclude these steps in our current research (40) as this allowed us to provide a more detailed insight into our intervention development process. Nevertheless, the evaluation of the intervention is covered by the above mentioned feasibility study ([clinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT04874974) (74). We will give a brief overview of our ongoing pilot study in the future directions part of the discussion section.

3. Results

3.1. Step 1: logical model of the problem and needs analysis

To facilitate a deeper understanding of our initial project phase and literature research, we present the results of Step 1 in a narrative format that begins with a brief description of our development

context and population and progresses to the problem definition and the derivation of needs.

3.1.1. Development context and target population

MEBASp is part of a research initiative at the Max Planck Institute of Psychiatry in Munich, Germany, which aims to implement a clinic-wide mechanism-based treatment concept containing different group modules each focusing on a specific change mechanisms like emotion regulation or behavioral activation. By identifying individually relevant psychological processes and personal preferences of each patient on admission, the clinical team ensures a targeted treatment selection by combining indicated therapy modules (9, 75–77). In this context, our IM approach focused on the development of an intervention targeting change mechanisms found to be relevant in acute inpatients with positive and/or negative psychotic symptoms (according to ICD-10 criteria) treated in an (locked) acute psychiatric ward (78) (for a detailed research background on the concept see Supplementary Methods and [Supplementary Figure 1](#)). Based on the assumption of psychosis as an independent clinical trait (79), our target inpatient group covered the entire psychosis-spectrum as well as psychotic depression and psychotic bipolar disorder.

3.1.2. Defining the problem of acute inpatients with psychotic symptoms

In the course of our epidemiological assessment, we specified two main mental health problems for acute inpatients with psychosis (16, 25): (1) severe positive symptoms such as hallucinations and delusions and (2) resulting dangerous behaviors toward themselves and others making immediate (compulsory) hospitalization necessary. Our social assessment in turn revealed a tremendous negative impact of the severity of positive symptoms and crisis-associated hospitalization on patients' QoL (27, 80–82). Both are believed to contribute to the secondary activation of negative symptoms such as poor rapport (83) and comorbid disorders like mood and anxiety disorders (84) resulting in an increased chronification risk (85). Relevant contributing psychological processes in the development of negative symptoms thereby seem to be a demoralization due to patients' low expectancies for pleasure or success (64, 86),

TABLE 1 Expected cognitive, behavioral and environmental outcomes and performance objectives (PO) for MEBASp (Step 2).

Cognitive outcome 1: critically reflects on internal experiences	
PO 1.1.	Understands the cognitive model of CBT
PO 1.2.	Understands the negative consequences of cognitive biases on mental health
PO 1.3.	Considers multicausal explanations for situations and internal experiences
PO 1.4.	Gathers sufficient information before drawing decisions
PO 1.5.	Considers a variety of information when assessing someone
PO 1.6.	Formulates helpful alternatives for depression-inducing thought patterns
PO 1.7.	Knows positive activities to counteract depressed mood and low self-esteem
Behavioral outcome 2: reduces reactivity to internal experiences	
PO 2.1.	Understands the negative consequences of fusing with internal experiences (thoughts, delusions and hallucinations)
PO 2.2.	Understands that most internal experiences are produced by the mind and learned in the past
PO 2.3.	Actively perceives internal experiences without directly reacting to them
PO 2.4.	Differentiates between helpful and unhelpful internal experiences
PO 2.5.	Deploys various functional coping strategies in dealing with internal experiences
Environmental outcome 3: psychological therapy (PT) supports recovery of individual	
PO 3.1.	PT is accessible for acute patients with psychotic symptoms
PO 3.2.	PT is adapted in scope and complexity for acute patients
PO 3.3.	PT provides social support and enables exchange with fellow patients
PO 3.4.	PT normalizes and destigmatizes mental health problems
PO 3.5.	PT supports patients to apply functional coping strategies in everyday life

internalized stigma (87), a lack of participation and activities (88), and maladaptive coping responses such as social anhedonia and substance abuse to deal with aversive internal and external experiences (89).

Furthermore, our ecological assessment (see [Supplementary Table 2](#)) identified metacognitive deficits (90) to be the main determinant for pathogenetic cognitive processes associated with positive symptoms (first health problem). We also found associations of metacognitive deficits with negative symptoms and impaired processes discussed above (91). While metacognition is being broadly defined as “knowledge about knowledge” (92), it can be further distinguished into a knowledge (knowledge and beliefs about cognition), an awareness (conscious experience of and reflection about cognitive processes), a goal (setting goals on a

meta-level), and a strategy part (conscious application of functional strategies for goal achievement) (93). Patients with psychotic symptoms thereby seem to show deficits in all four components (94). Deficits in metacognitive knowledge and awareness moreover are believed to lead to cognitive distortions (e.g., jumping to conclusions, attributional biases, theory of mind deficits) (60), dysfunctional beliefs and expectancies (associated with a low self-esteem and negative symptoms) (10, 95) and a lack of cognitive insight into those cognitive biases (96). For instance, a lack of knowledge about common human cognitive biases, poor awareness of one’s own thoughts, and the inability to recognize distortions in conclusions could lead to misinterpreting a crackling sound on a phone line as proof of being watched (21). Delusional thoughts and hallucinations alone however, do not automatically result in distress and dysfunctional behavior making compulsory hospitalization necessary (second health problem). It seems to be the appraisal and behavioral reactivity toward the thought and voice contents that increases the probability of danger to self and others (97). Psychological processes linked with this problem are cognitive fusion with internal experiences and maladaptive coping strategies such as experiential avoidance, thought suppression and worry (66, 98–100). Explained in highly simplified terms, cognitive fusion describes a cognitive process in which a person is fully entangled with the verbal content of internal experiences, beliefs it to be true and reacts to the content (101). Consistent with metacognitive process models, cognitive fusion can be associated with a deficit in metacognitive goal setting and strategies leading to the increased reactivity to dysfunctional thought content (102). The idea of being surveilled may e.g., take on great importance due to dysfunctional metacognitive beliefs, such as that one’s thoughts are true and need to be acted on. Without being aware of own goals and values, one may turn to dysfunctional coping strategies like aggression, social withdrawal or excessive worrying, which in turn can escalate into mental crisis followed by a decrease in functioning (103). In summary, there is convincing evidence for the contribution of metacognitive deficits to both severe psychotic symptoms and subsequent crisis development (104).

Lastly, our policy assessment identified bio-social vulnerabilities and structural (health) system barriers that lead to environmental risk factors such as social conflicts (interpersonal), a general shortfall of psychosocial treatments (organizational), stigma and societal disadvantages (society) that all seem to additionally contribute to our overall problem (105–107). For a visualization of our problem theory see [Figure 2](#).

3.1.3. Determining the needs for development and implementation

Having a better understanding of our problem and the underlying impaired processes, we were now able to draw general implications for the implementation of the intervention itself.

Considering the severity of mental health problems and low QoL, we first of all determined a great need to generally expand and improve the psychotherapeutic offer for acute inpatients with psychosis. Although guidelines recommend psychological care already in the acute illness phase (3, 4), implementation rates on acute ward are still extremely low (28, 108, 109) resulting in a dissatisfaction among patients who criticize the predominant pharmacological and risk-focused treatment (27, 110). The demand

TABLE 2 Matrix of change for cognitive, behavioral and environmental outcomes showing the change objectives for each performance objective and change domain (Step 2).

	Key change domains			
	Increases knowledge about ... [Metacognitive and cognitive knowledge]	Raises awareness of ... [Metacognitive awareness and cognitive attention]	Builds up skills to ... [Behavioral and (meta-) cognitive strategies]	Changes beliefs to ... [Metacognitive beliefs]
Cognitive outcome 1: critically reflects on internal experiences [Cognitive insight]				
PO 1.1.	K1.1 Influence of thoughts on feelings and behavior	A1.1 Internal experiences	S1.1 Report on internal experiences [Introspection]	B1.1 Behavior is controllable
PO 1.2.	K1.2 Nature of cognitive distortions and their impact on mental health problems	A1.2 Selective attention/Attentional biases	S1.2 Anticipate consequences of internal experiences on behavior [Expectancy reasoning]	B1.2 Thoughts are prone to error
PO 1.3.	K1.3a Attribution types (internal, external, control possibility)	A1.3 Attributional biases (Self-serving bias/Pessimistic attributional style)	S1.3 Rationally analyze events [Attributional reasoning]	B1.3 Events are always multicausal
	K1.3b Dysfunctional attributional styles and their effect on mental health			
PO 1.4.	K1.4a Rationale behind premature decisions	A1.4 Jumping to conclusions (Arbitrary inference/Belief bias)	S1.4a Gather and process information	B1.4 Sufficient information is necessary for reasonable conclusions
	K1.4b Effect of JTC on mental health		S1.4b Actively challenge own conclusions and adjust if necessary [Information processing/ Interpretative reasoning/ Self-reflection]	
PO 1.5.	K1.5a Rationale behind theory of mind	A1.5 Hasty first impressions (Selective abstraction/Biased expectancy/Availability heuristic)	S1.5a Consider contextual information in social interactions	B1.5 Sufficient information is necessary to assess my opposite
	K1.5b Effect of distorted mentalizing on mental health		S1.5b Take different perspectives S1.5c Tolerate ambiguity [Cognitive shifting/ Interpretative reasoning/ Social reasoning]	
PO 1.6.	K1.6a Dysfunctional cognitive patterns	A1.6 Depressive-inducing thinking patterns (Catastrophizing/ Personalization/ Over-generalization)	S1.6 Come up with functional thoughts [Cognitive reappraisal]	B1.6 Depression and low self-esteem are influenceable
	K1.6b Effect of negative cognitive styles on mood and self-esteem			
PO 1.7.	K1.7 Importance of positive activities		S1.7 Pursue positive activities [Behavioral activation/Commitment]	B1.7 Positive activation is indispensable for my mental health

(Continued)

TABLE 2 (Continued)

	Key change domains			
	Increases knowledge about ...	Raises awareness of ...	Builds up skills to ...	Changes beliefs to ...
	[Metacognitive and cognitive knowledge]	[Metacognitive awareness and cognitive attention]	[Behavioral and (meta-) cognitive strategies]	[Metacognitive beliefs]
Behavioral outcome 2: reduces reactivity to internal experiences [Cognitive defusion]				
PO 2.1.	K2.1 Effects of maladaptive coping strategies (submission, control or avoidance) on thoughts		S2.1 Anticipate consequences [Expectancy reasoning]	B2.1 The problem is not the symptom, but how I react to it
PO 2.2.	K2.2a Biographical influences on thinking patterns		S2.2 To understand connections and concepts of psychological constructs [Information processing]	B2.2 Thoughts, delusions and hallucinations are merely words and pictures inside my head
	K2.2b Conceptualization of hallucinations as externalized loud thoughts			
PO 2.3.	K2.3a Rational behind mindfulness	A2.3 Internal and external stimuli in the present moment	S2.3 Allow distressing internal experiences to come and go [Mindfulness/ Acceptance]	B2.3a I can accept the presence of difficult internal experiences
	K2.3b Steps to mindfulness			B2.3b Internal experiences come and go
PO 2.4.	K2.4a Features and effect of helpful vs unhelpful internal experiences	A2.4a Internal experiences	S2.4 Select helpful internal experiences against the background of own goals [Goal-orientated action planning]	B2.4a The mind is not always my friend
PO 2.5.	K2.5a Difference between fusion and defusion	A2.4b Goals and values [Goal setting]	S2.5 Decenter from internal experiences [Self-regulation/Deliteralization/ Disidentification]	B2.4b I have the choice between reacting and not reacting to internal experiences
		A2.5a Internal experiences		B2.5 Internal experiences don't have the power to control my life
	K2.5b Defusion strategies	A2.5b Maladaptive coping strategies (Experiential avoidance/Thought suppression/Self-focused attention)		
	K2.5c Steps of defusion			

(Continued)

TABLE 2 (Continued)

	Key change domains			
	Increases knowledge about ...	Raises awareness of ...	Builds up skills to ...	Changes beliefs to ...
	[Metacognitive and cognitive knowledge]	[Metacognitive awareness and cognitive attention]	[Behavioral and (meta-) cognitive strategies]	[Metacognitive beliefs]
Environmental outcome 3: psychological therapy (PT) supports recovery of individual [Social support]				
PO 3.1.	K3.1a Importance of PT in the treatment of mental health problems	I3.1 Socially supported by psychotherapeutic relationship [Therapeutic alliance]	S3.1 Engage in therapy [Motivation]	B3.1 PT is important for my recovery process
	K3.1b Possibilities to access PT			
PO 3.2.	K3.2 Simple disturbance models and coping strategies		S3.2a Follow cognitively in psychotherapy sessions [Perceived competence]	B3.2 PT is comprehensible, helpful and even fun
			S3.2b Overcome difficulties encountered in therapy [Self-efficacy]	
PO 3.3.	K3.3 Possibilities to seek social support	I3.3 Comfortable within the group [Group conformity, Group identity, Group norms]	S3.3 Interact positively with fellow patients [Sense of belonging/ Collaborative problem solving]	B3.3 I am not alone with problems
PO 3.4.	K3.4 Recovery based model of illness	I3.4 Positive about self [Self-acceptance]	S3.4 Speak confidently about own illness [Self-confidence/Self-esteem]	B3.4 Having mental problems doesn't mean I am worthless
PO 3.5.	K3.5a Personal set of coping strategies to manage everyday life challenges	I3.5 Inspired by therapist model and fellow patients [Modeling]	S3.5 Practice new behavior outside of therapy session [Motivation/ Perceived competence/ Self-management]	B3.5 Behavior change is possible
	K3.5b Importance of practicing new behaviors			

PO, performance objectives (see Table 1). Change objectives are coded according to change dimensions: Knowledge (K), Awareness (A), Skills (S), Beliefs (B), Social influences (I). If suitable, change objectives were labeled with the appropriate change mechanism that can be found in the square brackets.

TABLE 3 Matrix with change methods/techniques and practical applications (Step 3).

Change objectives	Behavioral change techniques	Practical applications
Increase knowledge	Conscious raising; Persuasive communication; Discussion; Elaborating; Scenario-based risk information; Psychoeducation	Therapist-led information input (verbal; written; visual) e.g., on cognitive biases; group brainstorming and discussions
Raise awareness	Self-monitoring; Thought-monitoring; Introspective training; Using imagery/analogy; Behavioral experiments; Directing attention; Mindfulness training	Therapist-asked prompted questions (e.g., “Image a friend doesn’t call on your birthday; how would you feel?”); thought records; guided mindfulness exercises e.g., Leaves-on-a-river mediation; using metaphors to explain selective attention e.g., attention like a spotlight just focused on one information
Change beliefs	Belief selection; Persuasive communication; Active learning; Cognitive restructuring	Therapist-led summary at the end of each session (e.g., learning objective: “Always think through several possibilities that could contribute to a situation or event!”); Take-home rounds (“What was important for you today?”)
Improve skills		
– S1.1 Report internal experiences	Introspective training	Therapist-asked explorative questions (e.g., “What came into your mind when you saw this picture? How would you feel if your opposite doesn’t greet you?”); Entrance rounds (“On a scale of 1 to 10; how are you feeling today?”); mindfulness exercises
– S1.1/S2.1 Anticipate consequences	Conscious raising; Self-reevaluation	Therapist-led information input (verbal; written; visual); group brainstorming and discussions; therapy cards with prompting questions (e.g., “Even if I am right; Am I overreacting?”)
– S1.3 Rationally analyze	Arguments; Shifting perspective; Direct experience; Reattribution training; Cognitive restructuring; Critical reasoning	Therapist-led group exercises to contemplate on different causes of events (e.g., “People are laughing while you are talking. What might be the reason?”); sharing of personal examples in group
– S1.4a Gather information – S1.4b Challenge conclusions	Arguments; Shifting perspective; Direct experience; Decision making; Critical reasoning	Therapist-led group exercises to gather enough information before drawing conclusions (e.g., “A fellow patient doesn’t acknowledge you when you walk past each other. Did she ignore you on purpose?”); sharing of personal examples in group
– S1.5a Consider context – S1.5b Take perspectives – S1.5c Tolerate ambiguity	Environmental reevaluation; Arguments; Shifting perspective; Direct experience; Empathy training; Critical reasoning; Social cognitive training	Therapist-led group discussion on social cues for social reasoning; group exercises to gather enough information before drawing conclusions (e.g., “During an appointment; the doctor has a serious expression and an intense stare. Why?”); sharing of personal examples in group
– S1.6 Come up with functional thoughts	Deconditioning; Reframing	Therapist-led group exercises to come up with more helpful thoughts for different events (e.g., “You fail an exam and your mind immediately tells you that you are a failure. What would be a more helpful appraisal?”); sharing of personal examples in group
– S1.7 Pursue positive activities	Behavioral planning; Activity scheduling	Therapist-led group brainstorming on positive activities; participants choose one activity and schedule it for the upcoming week
– S2.2 Understand psychological constructs	Elaboration	Therapist-led information input on psychological formulation of psychotic symptoms and group discussion
– S2.3 Allow distressing internal experiences	Acceptance training; Mindfulness training	Therapist-led behavioral experiments to demonstrate counterproductive effect of thought avoidance e.g., Don’t-think-of-the-pink-elephant; mindfulness training e.g., mindfully-eating-a-raisin
– S2.4 Select internal experiences	Using imagery; Self-affirmation; Goal setting; Disputation	Therapist-led practical exercises and metaphors e.g., Bad-cup/Taking-your-mind-for-a-walk; functional disputation e.g., “Is this thought helpful?” and goal clarification (e.g., “What is important for you in this situation?”)
– S2.5 Decenter from internal experiences	Active learning; Using imagery; Counterconditioning; Planning coping resources; Training executive functions; Guided practice; Self-monitoring; Attentional training; Self-Instruction Training	Therapist-led practical defusion exercises e.g., Labeling-your-thoughts; group discussion and selection of individual techniques
– S3.1 Engage in therapy	Motivational interviewing; Participating problem solving	Therapist directly approaches new patients; explains advantages/disadvantages of PT; develops joint therapy goals
– S3.2a Follow cognitively – S3.2b Overcome difficulties	Cognitive training	Therapist ensures that contents are in a simple and comprehensive form; adapts each session according to cognitive level; challenges participants with exercises; includes fun activities
– S3.3 Interact with fellows	Interpersonal contact	Therapist ensures secure group framework (group rules and mediation in the case of problems); Therapist-led group discussions and reflections; encouragement of personal group exchange

(Continued)

TABLE 3 (Continued)

Change objectives	Behavioral change techniques	Practical applications
– S3.4 Speak about own illness	Interpersonal contact; Shifting perspectives; Reframing; Cooperative learning	Therapist holds an attitude of destigmatization; normalizes psychotic experiences; encourages sharing of personal experiences
– S3.5 Practice behavior	Behavioral rehearsal; Set homework tasks; Self-help	Therapist suggests homework assignments and gives space for debriefing
Encourage positive social influences		
– I3.1 Socially supported	Mobilizing social support/networks; Social support theory; Increasing stakeholder influence; Social skills training	Therapist shows empathy and understanding, regardless of dysfunctional behavior; repeatedly offers relationship despite initial rejection
– I3.3 Comfortable in group	Interpersonal contact; Participatory problem solving; Entertainment education; Forming coalitions,	Therapist ensures secure group framework; reinforces participation and group exchange
– I3.4 Positive about self	Verbal persuasion; Stereotype-inconsistent information; Reducing inequalities of class/race/gender and sexuality; Provide contingent rewards	Therapist praises participation; is open to different points of view and does not judge participant's internal experiences
– I3.5 Inspired by therapist and fellows	Modeling; Cooperative learning	Therapist encourages sharing of personal experiences; gets involved with personal examples e.g., "I know that feeling. My mind always tells me that I am not good enough."

Each change objectives can be found in the matrix of change (Table 2). Change objectives from the domains knowledge, awareness and beliefs were each combined into one major change objective due to overlap. Change objectives found in the dimension skills and social influences on the other hand were all treated separately. Behavioral change techniques are taken from IM's comprehensive taxonomy of BCTs (43, 69).

for psychosocial treatments that do not involve medication but aim to assist with recovery, on the other hand, is high (25).

The second need we derived was the necessity to adapt existing mechanism-based interventions to the specific characteristics of acute ward and inpatients with psychotic symptoms (25). Available concepts are often lengthy and quite complex in content and it has to be doubted if they can actually work efficiently in acute settings (6, 16, 28). Main limitations consist of short hospital stays (111) and patients' general difficulties to engage with traditional psychotherapy concepts due to treatment resistance (112, 113), high distrust levels toward the entire environment (114), emotional distress (115), severe cognitive deficits (116), and dual diagnoses (117). Despite the demanding patient clientele, therapists in acute settings are moreover challenged to provide psychological therapies with minimal resources (16). Staff shortage, economic pressure and administrative duties leave little room to offer individual therapy to each patient making group-based formats a cost-effective alternative to reach a large number of patients (118). Moreover, group interventions offer valuable opportunities for interpersonal skill development and peer support (26). Due to high patient turnovers, group therapies should be delivered in standalone formats with patients being able to already benefit when attending only one session or one module (118). Despite the economic and social benefits of group concepts, it is advisable to offer at least a minimum number of individual sessions to provide additional space for addressing personal needs and topics (119).

Thirdly, we formulated the need to consider both staff and patients' needs when planning the content of the intervention. While care taker priorities often focus on symptom and risk management, patients themselves name social circumstances and intra- and interpersonal symptom distress (e.g., unwanted internal states, sleep difficulties, lost sense of identity, social isolation, and stigma) as their main concerns (16, 25, 28, 120).

In summary, our findings suggest that an effective and feasible intervention for acute psychiatric inpatients should focus on key

mechanisms associated with changes in symptom severity and patients' symptom distress. A group concept is favored over individual sessions due to economic and social reasons, although additional individual sessions should be offered based on individual needs or demand. Therapy sessions should be simple, brief, flexible, low key, and able to be delivered stand-alone.

3.1.4. Examining existing practice

Beside Metacognitive Training (MCT), we identified two more mechanism-based therapies for psychosis focusing explicitly on impaired metacognitive processes linked to our first health problem (positive symptoms) (36): Metacognitive insight and reflection therapy (MERIT) and Metacognitive interpersonal therapy for psychosis (MIT-P). However, sufficient evidence was only available for Metacognitive Training (37–40) that furthermore recently provided an open-source transdiagnostic group format suitable for acute inpatients and acute settings (121). The concept of MCT by Moritz and Woodward was originally inspired by research on cognitive biases in psychosis (65) and aims to convey metacognitive knowledge and raise metacognitive awareness for dysfunctional thought patterns (60, 122). Compared to Metacognitive Therapy by Wells and Matthews, MCT not only focuses on general thinking mechanisms from a metacognitive perspective, but also on specific thoughts from a cognitive one by directly addressing thought contents (60). MCT's goals are implemented in a group therapy format that works with non-confrontational, educative and delusional-neutral material (21). Although MCT was originally developed for psychosis, it has been adapted for use in treating other disorders such as depression and personality disorders and can be applied in a transdiagnostic manner (60).

Our target processes cognitive fusion and maladaptive coping strategies related to our second health problem (dangerous behaviors and hospitalization) on the other hand are the main subject in the Acceptance and Commitment Therapy by Hayes (101) and the Metacognitive Therapy by Wells and Matthews

TABLE 4 Table giving an overview of the objective and core exercises for each session of MEBASp (Step 4).

Session	Title, main objective and target change mechanism	Core exercises and metaphors
1.	Psychoeducation Objective: Understanding the cognitive model, awareness of problematic cognitive biases and over identification/reaction to them Target mechanism: Knowledge increase	Developing theory based on an everyday example (“Imagine your friend doesn’t call on your birthday”) and interactive group discussion Source: MCT for depression (72)
Module cognitive insight [Metacognitive knowledge and awareness]		
2.	Finding explanations Objective: Changing dysfunctional attributional patterns by understanding that multiple factors can lead to a scenario Target mechanism: Attributional reasoning	Contemplating different causes for everyday examples and discussing negative consequences of monocausal attributions Source: MCT for psychosis and MCT-acute (21, 121)
3.	Jumping to conclusions Objective: Avoiding premature first impressions, adjusting conclusion when new information emerges Target mechanism: Interpretative reasoning	Holding back and revising premature decisions with the help of various fragmented picture tasks where patients have to guess the object behind it Source: MCT for psychosis and MCT-acute (21, 121)
4.	To empathize Objective: Understanding that facial expressions can easily be misinterpreted, considering various information sources when assessing your opposite Target mechanism: Social reasoning	Trying to guess what a person may feel or intends to do by judging pictures of their faces and discussing everyday examples Source: MCT for psychosis and MCT-acute (21, 121)
5.	Mood and self-esteem Objective: Recognizing dysfunctional thinking styles, finding alternative views and engaging in positive actions Target mechanism: Cognitive reappraisal	Gathering symptoms of depression, finding more helpful thoughts for negative cognitive schemas in various everyday examples, collecting positive activities to counteract depressive mood and low self-esteem Source: MCT for psychosis and MCT-acute (21, 121)
Module cognitive defusion [Metacognitive goals and strategies]		
6.	Noticing thoughts Objective: Being more present in the moment, noticing inner and outer sensations and responding more consciously to them Target mechanism: Mindfulness	Practicing mindfulness for external (mindfully eating chocolate) and internal (observing thoughts) experiences, metaphors: “life on autopilot,” being a “distant observer” Source: ACT for psychosis (158)
7.	How our mind works Objective: Developing a different relationship toward thoughts by understanding that they mostly consist of automatic rules and judgments learned in our past, giving thoughts less power dictating our behavior Target mechanism: Goal-orientated action planning	Debunking thoughts by distinguishing between facts and appraisals (Bad Cup), noticing automaticity and uncontrollability of thoughts (“Mary had a little lamb” and “Don’t think of a pink elephant”) and acting contrary to thoughts (“Don’t do what your mind says”), metaphors: mind as a “production machinery” and “hard drive” with “data garbage” Source: ACT metaphors (159) and ACT for life (160)
8.	Helpful vs. unhelpful thoughts Objective: Distinguishing between helpful and unhelpful internal experiences and learning to act contrary to them without trying to avoid or control them Target mechanism: Disidentification	Classifying everyday thoughts in unhelpful and helpful thoughts, actively executing defusion in “Taking your mind for a walk,” metaphors: thoughts as “ankle cuffs” vs. “tools” Source: ACT for psychosis (158)
9.	Defusion techniques Objective: Learning to actively distance from internal experiences by using cognitive and behavioral strategies Target mechanism: Self-regulation	Trying out different defusion and detached mindfulness techniques e.g., “labeling thoughts,” “floating leaves on a stream” and “Attention training technique” and choosing one for the “instruction manual for the mind,” metaphors: mind as “parrot” always telling the same story, the little “mind monster” Source: ACT metaphors (159), ACT for psychosis (158), Metacognitive Therapy for anxiety and depression (122)

(122). In contrast to traditional CBT principles of disputation and restructuring, ACT focuses on transdiagnostic change mechanisms such as acceptance and cognitive defusion to modify patients’ relationship toward internal experiences changing their function on behavior (19). Defusion thereby refers to a decentering-related mechanism that operates through metacognitive goal clarification (e.g., asking yourself if this thought is helpful for your broader goals and values) and the use of mindfulness-based distancing strategies (123). Similar to defusion techniques, Well’s Metacognitive Therapy aims to reduce toxic thinking styles such as worry and threat monitoring believed to maintain

paranoid thoughts and hallucinations by changing dysfunctional metacognitive beliefs and practicing metacognitive strategies like detached mindfulness (124). Both ACT and Metacognitive Therapy share their transdiagnostic orientation and focus on metacognitive strategies and have demonstrated effectiveness in working with psychosis in smaller studies (18, 19, 59, 103, 124, 125). However, most studies were either conceptualized for individual therapy and/or outpatients (5–7) with most available concepts still rather unsuitable and demanding for group inpatient settings. For an overview and further description of differences between treatments and key change mechanisms see [Supplementary Table 3](#).

3.2. Step 2: intervention outcomes, change mechanisms, and logical model of change

Looking at each target area of our problem model, we formulated desired intervention outcomes and constructed a logical model of change (see [Figure 3](#)) linking outcomes and hypothesized mechanisms of change. As we were challenged to address the very diverse needs of our target population in one intervention, we made sure to come up with treatment goals applicable to a wide range of mental health problems. Following the ACT nomenclature, we therefore no longer speak of specific symptoms such as delusional thoughts or hallucinations, but group them together under the term distressing internal experiences (97).

Our overarching treatment goal was to encourage functional behavior and coping via improving *cognitive flexibility*. Cognitive flexibility thereby can be understood as the capacity to switch between cognitive processes in order to generate effective behavioral regulation and is determined by general metacognitive abilities (126). To achieve this objective, we aimed to raise patients' *cognitive insight* on cognitive distortions and hence the patients' capability to reflect on internal experiences on a meta-level (127, 128). Cognitive insight is linked to functional *metacognitive knowledge and awareness* and has been identified as a potential promising candidate mechanism for a decline of positive symptoms in psychosis and favorable treatment outcome in other disorders (127).

Furthermore, we aimed to reduce patients' reactivity to aversive internal experiences via promoting *cognitive defusion*, which is determined by functional *metacognitive goals and strategies*. Cognitive defusion has been found to generally improve functioning, reduce dysfunctional attitudes, anxiety, negative affect (102) and also post-traumatic-like symptoms (129) and sleep difficulties (130). It has also been found to mediate symptom distress in psychosis via reduced believability of thought and voice content (131), and changes in *metacognitive beliefs* and *coping skills* (18).

Lastly, our intervention was supposed to support patients' recovery by providing positive *social support* and with this foster peer group relationships, and a strong therapeutic alliance found to be essential ingredients for treatment success (132, 133). Overall, we hoped that our identified transdiagnostic change mechanisms and outcomes would support patients in a wide range of needs and topics, thus improving their mental health and QoL in the long term and prevent or at least mitigate further relapses.

We then divided all intervention outcomes into performance objectives (PO) (see [Table 1](#)), which we subsequently linked to our overarching change dimension via change objectives in our change matrix (see [Table 2](#)).

3.3. Step 3: evidence-based change methods

All change objectives were assigned to change techniques and practical applications in our matrix of change methods (see [Table 3](#)). The main change methods in our intervention blueprint consisted of therapeutic techniques fostering knowledge increase,

introspection, perspective-taking and cognitive/behavioral regulation (69). As we faced the challenge to translate a complex set of change objectives and methods into very simple and comprehensible end applications for a group format, we made sure to come up with lots of interactive information sharing and fun exercises inspired by techniques used in existing mechanism-based interventions such as MCT, ACT and Metacognitive Therapy (see Step 1). For the change objective "Patient is able to allow distressing internal experiences" we for example planned to integrate a mindfulness training by performing simple guided exercises such as the "Leaves-on-a-river" from the ACT for psychosis manual (134).

3.4. Step 4: intervention outline

3.4.1. Transdiagnostic conceptualization

Although our intervention development aims to target mainly change mechanisms behind psychotic symptoms and crisis development through symptom distress, the identified underlying impaired processes are interrelated with several other disorders (see [Supplementary Table 2](#)). Metacognitive deficits (135), cognitive distortions (61), a lack of cognitive insight (136), and cognitive fusion (137) for example play an important explanatory role among others in anxiety, mood, personality disorders, and substance abuse (138). Cognitive insight, cognitive defusion, social support, cognitive flexibility, and in turn improved metacognitive skills are considered to function as transdiagnostic mechanisms of change in therapy (123, 139–141). Hence, our transdiagnostic concept allows us to address not only the different needs of our patients with psychotic and comorbid diagnosis, but also patients with diagnoses other than psychosis. Given the heterogeneous patient composition of acute ward, a transdiagnostic mindset and approach might be an especially valuable treatment component (24).

3.4.2. Modules and sessions

Our final intervention comprised a 5-week group therapy program consisting of three short treatment modules and a total of nine sessions.

Module I (Psychoeducation) gives a brief introduction into the rationale of the therapy and the targeted change mechanisms. The terms cognitive distortions and cognitive fusion and their role in the development of general psychological problems are explained in a simple language and with the help of examples and small exercises. The importance of cognitive insight and cognitive defusion for mental health is made clear.

Module II (Cognitive Insight) consists of four sessions and aims to raise cognitive insight by explaining and illustrating different cognitive biases and demonstrating their negative consequences on mental health. The treatment module includes materials and interventions adapted from the MCT for psychosis, MCT for depression and MCT for acute psychiatric settings (MCT-acute) and focuses on the change domains metacognitive knowledge and awareness.

Module III (Cognitive Defusion) with another four sessions aims to change the function internal experiences have on the patient's behavior by strengthening adaptive coping strategies. Exercises are assembled from various ACT and Metacognitive

therapy manuals and cover the change domains metacognitive goals and strategies. An overview of the intervention's contents and sources for used materials can be found in [Table 4](#).

All sessions follow the same general procedure: entrance round with mood poll, brief introduction to the program and group rules, experience-based exercises and group discussions, linking therapy content to mental health problems, transferring knowledge into every-day life, take-home message and closing round.

3.4.3. Delivery format and framework

We propose group therapy takes place twice a week with each session lasting between 40 and 60 minutes depending on the group's cognitive capacity. To ensure a maximum of flexibility for patients with brief treatment duration and attendance preferences, all modules are independent from each other and each session can be delivered stand-alone. Information is presented on simple PowerPoint slides with plain language, short inputs and illustrating imagery makes participation possible even for patients with pronounced cognitive impairments. Simple metaphors, concrete and personally relevant experience-based exercises and "touchable" therapy material (e.g., bringing dark sunglasses to demonstrate the information filter of our mind) make contents additionally easy to understand and create a relaxed atmosphere (97). All patients receive a patient workbook with short session summaries, exercises and optional homework assignments. Two therapy-cards in pocket size summarize the most important points of each module. See [Figure 4](#) for therapy content examples. Due to high levels of distress and occasionally hostile and suspicious behaviors, group sizes are kept small with a maximum of seven participants. Group sessions can be carried out by a clinical psychologist, psychiatrist, trained nurse or an occupational therapist, as little prior knowledge is required because of its simple conceptualization and available therapy manual. Next to group therapy, we advise all patients receive psychosocial treatment-as-usual (see Supplementary Methods) and additional individual psychotherapy sessions.

3.4.4. Therapeutic attitude

The therapists general therapeutic attitude should be empowering trying to support patients to pursue their valued goals despite symptoms of serious mental illness (28, 97). They should moreover try to create an open, acceptance-based and destigmatizing atmosphere (142). The therapists' process-oriented stance, which sees psychotic symptoms as extreme manifestations of normal human cognitive distortions and dysfunctional strategies, can thereby foster rapid alliance building (21). Self-disclosure by therapists is strongly recommended at this point, as it allows them to convey to patients that they too are often "victims" of their own cognitive biases (97). Thereby, they work in accordance to key features of third-wave therapies that place therapists on an equal level to patients in the sense of "you cannot teach what you cannot do" (9) (p. 369). A focus on mechanisms of change rather than symptom disputation moreover reveals room for change and returns a sense of control to patients (10).

Group attendance is voluntary, however, participants should be personally approached before each session to encourage participation (28). During sessions, patients have the possibility to leave the group if they feel uncomfortable as well as the

option to return. Contents of psychotic thoughts and experiences can be talked about openly without being judged as wrong, right or even pathological (142). Therapy sessions should not be rushed and therapists should give enough time for discussion and exchange between the participants. They can promote involvement by directly approaching patients with simple questions and thus encouraging socially anxious participants. Following the transdiagnostic concept of the intervention, disease-related language is rarely used (143).

4. Discussion

The current research aimed to develop a novel mechanism-based therapy for acute inpatients with psychotic symptoms using Intervention Mapping as a structured development framework to improve the intervention's scientific foundation, reporting standards and potential reproducibility. To our knowledge, this is the first research for this specific setting and patient group, which has attempted to do so.

MEBASp is a low-threshold transdiagnostic and modularized group therapy that focuses on symptom and distress reduction and responds to a central priority of health care services to develop, test and offer effective and needs-oriented care for acute inpatients with psychosis (5–7). We believe that our underlying intervention model and format will be able to meet the complex needs of those patients and the settings they are treated in due to several reasons.

Firstly, our intervention directly targets hypothesized change mechanisms instead of specific symptom content and hence follows a current promising paradigm shift in intervention science toward process-based treatments (13, 75, 144). We believe that our mechanism focus will not only allow us to optimize patients' treatment outcomes (13), but will be especially helpful when working with acute (involuntary) inpatients. As suggested by Moritz and Woodward (21), MEBASp operates through a non-confrontational and symptom-neutral "backdoor" approach (p. 623) that could be beneficial to address a transdiagnostic spectrum of patients and diverse needs, foster rapid alliance building, motivate resistant patients, lower drop-out rates, and enhance recovery rather than illness elimination (6, 16, 19, 145). By combining evidence-based mechanisms and procedures from various theories and therapy schools into one approach, we moreover refocus on key questions of why and how interventions work best for patients instead of if they align or differ from specific therapy approaches (75).

Our intervention's overarching emphasis on transdiagnostic metacognitive change mechanisms (cognitive insight and cognitive defusion) furthermore fits in a new generation of treatments promoting recovery from serious mental illnesses including psychosis (104, 138). The concept of metacognition thereby is believed to serve as a valid candidate for filling the gap between simplistic biological treatment models and psychosocial ones (104). A main benefit of metacognitive treatment models is the promotion of overall wellbeing beyond the positive symptom reduction achieved through psychopharmaceuticals, an aspect considered to be essential when working in psychiatric inpatient care (27). However, authors criticize that existing

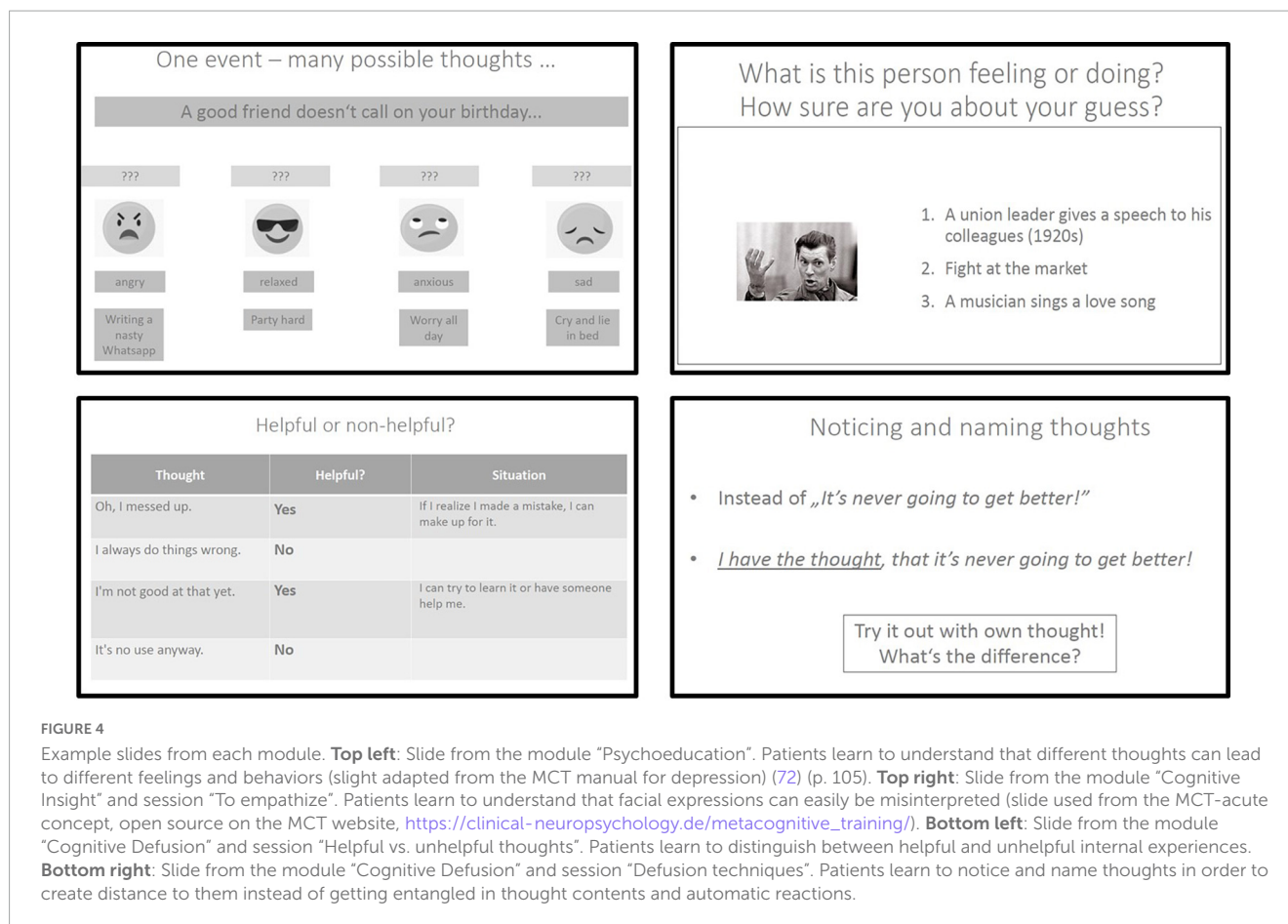


FIGURE 4

Example slides from each module. **Top left:** Slide from the module “Psychoeducation”. Patients learn to understand that different thoughts can lead to different feelings and behaviors (slight adapted from the MCT manual for depression) (72) (p. 105). **Top right:** Slide from the module “Cognitive Insight” and session “To empathize”. Patients learn to understand that facial expressions can easily be misinterpreted (slide used from the MCT-acute concept, open source on the MCT website, https://clinical-neuropsychology.de/metacognitive_training/). **Bottom left:** Slide from the module “Cognitive Defusion” and session “Helpful vs. unhelpful thoughts”. Patients learn to distinguish between helpful and unhelpful internal experiences. **Bottom right:** Slide from the module “Cognitive Defusion” and session “Defusion techniques”. Patients learn to notice and name thoughts in order to create distance to them instead of getting entangled in thought contents and automatic reactions.

treatments only cover certain aspects of the larger construct of metacognition (see **Supplementary Table 3**) (93) and call for intervention development that incorporate all four metacognitive domains into hybrid approaches (104). Due to our modularized treatment concept, MEBASp is actually able to enclose the whole spectrum of metacognitive mechanisms into one intervention. Patients therefore not only benefit from a broad range of hypothesized positive treatment effects when attending all three modules, but already profit when attending only one or two (76).

Despite an underlying change theory seeming complex at first sight, we moreover believe that we managed to adapt the intervention for the inpatient context. MEBASp is brief, flexible, experience oriented, low-key and easy to learn for therapists and thus takes into account key treatment elements proposed by competence frameworks in working with acute patients (26, 58). The modularized approach moreover allows to combine and integrate different independent treatment modules and therewith ensures high flexibility and goodness-of-fit to patient needs and preferences (146). All procedures taken from in- and outpatient concepts are simplified and adapted for a crisis-focused setting addressing both priorities of symptom (cognitive insight) and distress reduction (cognitive defusion) (25). On top of that, the group-based design permits high therapy frequency and dose, is cost-effective, resource saving and offers opportunities for peer social support and interpersonal skill development (147).

4.1. Advantages to the IM approach

Although the research base on process-oriented care is growing, authors do not yet provide a standardized method on how to construct evidence-based problem models, choose adequate sets of change mechanisms, procedures and change measures (13, 148). In this context, IM offers different structured elements to overcome those challenges. The PRECEDE-model allowed us the synthetization of multi-level data and an in-depth understanding of our situation necessary for identifying evidence-based change mechanisms (31). Building matrices of change and change procedures represented a valuable method to ensure our change mechanisms were precisely defined (148) and got effectively linked to therapeutic applications (75). In doing so, we could refer back to IM-associated extensive frameworks such as the Theoretical Domains Framework (68) and the taxonomy of behavior change methods (69) that clearly close the gap of comparable compositions in the literature (144). Thereby, IM per se works according to principles of mechanism-based therapies by being “theory agnostic,” flexibly combining evidence-based concepts from across paradigms and thus creating synergistic effects between different approaches (149). Lastly, the detailed mapping of all change mechanisms and procedures in an intervention blueprint reflects the underlying complexity of our intervention and allows the derivation of matching outcome measures to monitor change in future studies (as described in the future direction sections) (148).

4.2. Limitations

There are several limitations to the current research. First, the mechanism and procedure selection were based on considerations and decisions made by our development team in each step of the IM framework. A different working group could have created a different needs analysis and chosen a different treatment focus, change methods and practical applications (see for example the CRISIS-, the WIT- or the OASIS-study) (150–152). Nevertheless, thanks to our detailed documentation of each decision step, potential differences become transparent and are made objectifiable.

Second, we encountered an excessive concept overlap in the literature (148). Cognitive defusion for example shares significant variance with constructs such as deliteralization, decentering, distancing and detached mindfulness (102). Moreover, the concept of metacognition is also somewhat “blurry” making it difficult to separate accurately what is a metacognitive and what a purely cognitive change mechanism (153). A central source integrating processes, mechanisms and procedures and using a common language and conceptualization would have made our selection much easier and the final intervention potentially more comparable with other mechanism-based treatments.

Thirdly, the complex set of mechanisms underlying the intervention could be seen as a challenge. From a clinical perspective, an intervention focusing on trying to change such a variety of mechanisms might be an overload for acute inpatients. Along with this, our mechanism-based group will naturally not provide the appropriate content and format for all patients due to varying needs and preferences. In addition to alternative therapy options (see [Supplementary Figure 1](#)), further research should investigate which patients can particularly benefit to make appropriate therapy offers.

Fourthly, due to time and resource constraints and in consideration of protecting the wellbeing of our vulnerable target population, we did not conduct codesign activities during the first development stage. This decision may have limited the intervention prototype’s suitability and acceptability for patients. Although we relied on pre-existing qualitative data and plan to integrate codesign activities in the second stage of the development process (feasibility study), future research should explore appropriate and sensitive ways to involve patients already in the first development stage.

Finally, although we found the detailed approach of IM helpful in creating our intervention and followed most of its steps, the overall development process was time consuming and took up a lot of resources. If teams thus require rapid intervention development, a more pragmatic approach such as the 6SQuID (“Six steps in quality intervention development”) (154) might be favored over IM.

4.3. Implications and future directions

Our mechanistic treatment design enables us to conduct necessary research to determine whether our proposed mechanisms are capable of producing therapeutic change (13). A single-arm feasibility study investigating the impact of MEBASp is

currently in progress ([clinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT04874974) (74). The study includes a mixed methods evaluation to assess the feasibility and test key change mechanisms of our logical model of change. Next to primary outcome measures such as trial entry rate, patient engagement and satisfaction, the study includes metacognitive measures e.g., the Beck Cognitive Insight Scale (155) and the Cognitive Fusion Questionnaire (156). Intensive involvement of participants through codesign activities such as feedback questionnaires, feedback rounds and interviews moreover ensures the revision of the intervention prototype will be in accordance to patients’ needs and preferences (157). If feasible and acceptable, future research will further investigate on the effects of change mechanisms by involving a control condition and performing mediation analyses in a larger scale study. Our ultimate goal is to individualize treatment allocation by matching patients to the treatment module most likely to produce change and fit with personal preferences (see [Supplementary Figure 1](#)). The allocation process could in the long term involve e.g., moderation studies, complex network approaches and ecological momentary assessments (75).

4.4. Conclusion

Our research demonstrates the importance of a) developing needs-oriented and mechanism-based interventions for acute inpatients with psychotic symptoms and b) using a structured development methodology to ensure their scientific foundation and replicability. Our rigorous and evidence-based intervention design focuses on addressing metacognitive change mechanisms associated with both acute symptoms and crisis development and adapts to key components required to deliver psychotherapy in psychiatric inpatient settings. It therefore has the potential to positively impact a neglected patient group. However, a pilot study is required to assess the intervention for safety, feasibility and preliminary effectiveness.

Data availability statement

The original contributions presented in this study are included in the article/[Supplementary material](#), further inquiries can be directed to the corresponding author.

Author contributions

EG, SL, PF, FP, SE, and JK-B: research objectives, project methodology, needs-analysis, guidance of process and clinical input, review intervention prototype, and manuscript write-up. EG: theoretical framework for intervention, material development and beta testing with patients. All authors contributed to the article and approved the submitted version.

Funding

This research was funded by the Max Planck Institute of Psychiatry and the Alfred Golombek Foundation.

Acknowledgments

We thank the team and the patients of the acute closed ward of the Max Planck Institute of Psychiatry that gave their informal and very valuable feedback on the intervention's prototype. We also thank Prof. Steffen Moritz (University Clinic Hamburg), who provides Metacognitive Training therapy material free of charge and open source, and thereby makes a major contribution to the advancement of research in the field of psychosis and other disorders.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsy.2023.1160075/full#supplementary-material>

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Supplementary Material

Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: An Intervention Mapping approach

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Table of Contents

1 Supplementary Methods. Background to the intervention development context3

2 Supplementary Table 1. Synthesis of primary qualitative studies, qualitative metasynthesis, and competence frameworks used for the problem definition and needs analysis of MEBASp (Step 1).....4

3 Supplementary Table 2. Impaired transdiagnostic processes in (acute) psychosis and other disorders (Step 1).....6

4 Supplementary Table 3. Existing mechanism-based therapies for psychosis focusing on impaired metacognitive and cognitive processes (Step 1).....8

5 Supplementary Figure 1. Mechanism-based group therapy concept on the locked acute ward9

1 Supplementary Methods. Background to the intervention development context

1. Clinic-wide mechanism-based group concept

Our intervention development project was conducted as a part of the MoMenT ("Modularized and Mechanism-based PsychoTherapy") treatment concept (<https://www.psych.mpg.de/psychotherapie>) at the Max Planck Institute of Psychiatry in Munich, Germany. Within a pilot phase, various brief group therapy modules each focusing on a transdiagnostic change mechanism e.g. emotional regulation or behavioral activation were developed. On admission, the clinical team identifies patient's preferences and therapy goals and change mechanisms potentially relevant for treatment success and creates an individually targeted therapy plan combining different group modules. For a patient with depression for example, the clinicians' team might identify repetitive negative thinking as a main causing and maintain mechanism for recurrent depressive episodes. Moreover, the patient reports a severe anhedonia and lack of positive activities. A possible treatment plan could therefore include the group module "mindfulness training" and "Activity group (behavioral activation)". In the long run, the aim is to personalize treatment and thus optimize patients' outcomes (1–3). A feasibility study for selected therapy modules is currently in preparation.

2. "Acute" mechanism-based group concept

To meet the unique treatment needs of psychiatric inpatients on the acute closed ward, a small subproject group was responsible for creating an adapted "acute" mechanism-based concept (4). The first version of our mechanism-based concept focused on change mechanisms such as distress tolerance, impulsivity reduction, behavioral activation, information processing, and self-management (5). Using these mechanisms, we developed a transdiagnostic Skillstraining, a Resource group, a Psychoeducation group, and a Crisis-competence group (as shown in Supplementary Figure 1). All group interventions were adapted to a crisis-focused setting, designed to be brief, easy to understand, and focused on coping (4). As there were still limited treatment options available for inpatients with acute psychotic symptoms (6), we decided to develop a fifth mechanism-based group (as shown in Supplementary Figure 1). However, since there was little existing evidence for concepts tailored to this patient population and setting (6), the intervention design was accompanied by a rigorous scientific process described in our current work (7).

2 Supplementary Table 1. Synthesis of primary qualitative studies, qualitative metasynthesis, and competence frameworks used for the problem definition and needs analysis of MEBASp (Step 1)

Study	Participants and context	Aim	Results
Patient experiences of psychiatric inpatient care: a systematic review of qualitative evidence (5)	11 qualitative studies involving inpatients with different diagnoses from Sweden and the UK	Examine patients' experience of psychiatric inpatient care	<i>Themes regarding needs for treatment:</i> inclusive care, positive relationships with staff, supporting therapeutic environment
Acute inpatients' experiences of stigma from psychosis: A qualitative exploration (8)	25 acute inpatients from the UK	Examine patients' subjective experiences of stigma	<i>Stigmatizing themes:</i> stigmatising environment, stigmatised person, stigma interactions
The therapeutic needs of psychiatric inpatients with psychosis: A qualitative exploration of patient and staff perspectives (9)	12 acute inpatients and 12 multidisciplinary team members from the UK	Examine patient and staff perspectives on priorities regarding psychological treatment	<i>Patient themes:</i> importance to consider social environment and trauma, managing intra- and interpersonal consequences of psychosis, inflexible treatment and dominant pharmacological approach <i>Staff themes:</i> multidisciplinary collaboration, treating complexity and symptom management, restrictive practices preventing quality treatment
Sources of Distress in First-Episode Psychosis: A Systematic Review and Qualitative Metasynthesis (10)	33 qualitative studies involving inpatients and outpatients from Europe, Canada, New Zealand, South Africa, and USA	Increase understanding of self-reported sources of distress	<i>Intrapersonal distress:</i> unwanted internal states, conflicts, lost sense of identity, poor health conditions e.g. sleep difficulties <i>Interpersonal distress:</i> traumatic life experiences, distressing contact with health professionals and relatives, stigma
Key Components for the Delivery of Cognitive Behavioral Therapies for Psychosis in Acute Psychiatric Inpatient Settings: A Delphi Study of Therapists' Views (11)	45 psychological therapists working in psychiatric inpatient care in the UK	Gain consensus on how CBTp should be delivered in acute inpatient settings	<i>Requirements on CBTp:</i> normalizing, taking into account patients' perspectives, reducing distress, recovery-oriented, flexible session content and delivery, adapting to restrictive environment
Psychologists' Perspectives on the implementation of Psychological Therapy for Psychosis in the Acute Psychiatric Inpatient Setting (12)	12 psychological therapists working in psychiatric inpatient care in the UK	Explore adaptations required to deliver psychological therapies to acute inpatients	<i>Crisis-focused psychological interventions:</i> distress reduction, crisis formulation, crisis-focused change mechanisms e.g. mindfulness, normalization and behavioral activation, standalone group interventions <i>Working with the wider system:</i> informed team work, feedback,

The role of psychology in a multidisciplinary psychiatric inpatient setting: Perspective from the multidisciplinary team (13)	12 interdisciplinary staff members working in psychiatric inpatient care in the UK	Examine interdisciplinary team's view on the role of psychology within acute psychiatric settings	discharge planning, supporting family system <i>Environmental adaptations:</i> working alongside the medical model, brief interventions, flexible sessions and contents, creative interventions <i>Benefits from psychological treatments:</i> psychological formulation, delivering group and individual interventions, development of insight and coping strategies, treating interpersonal and intrapersonal difficulties
Acute Mental Health Inpatient Competence Framework: Adults and older adults (14)	Expert Reference Group including patients, carers, clinicians and academics in the UK	Provide guidance to staff working in acute inpatient settings	<i>Necessary integration into overall concept:</i> no first line treatment, develop balance to medical model, feedback and supporting the staff team, no clear understanding what psychology does <i>Psychosocial interventions:</i> reduce crisis, increase patient's safety, improve functioning, adapt interventions to crisis setting, provide group-based interventions to offer opportunities for coping, interpersonal skill development, and peer support, provide family interventions
A competence framework for psychological interventions with people with psychosis and bipolar disorder (15)	Expert Reference Group including patients, carers, clinicians and academics in the UK	Provide guidance to staff working with people with psychosis and Bipolar Disorder	<i>Psychosocial interventions for psychosis:</i> psychoeducation, normalisation, symptom-specific competences focusing on delusions, hallucinations, negative symptoms and trauma, family interventions

Notes: CBTp = Cognitive Behavioral Therapy for psychosis. Search for qualitative studies involving acute inpatients with psychotic symptoms was conducted using the database Medline and search terms: patient OR inpatient AND psychosis AND mental OR psychiatr* AND hospital OR admission AND qualitative OR interview OR focus group AND experience* (5). All study abstracts were screened to assess the relevance and fit for the current intervention development context.

3 Supplementary Table 2. Impaired transdiagnostic processes in (acute) psychosis and other disorders (Step 1)

Process domain	Impaired process	Associated with		
		Positive symptoms	Negative Symptoms	Other disorders
Metacognition	Dysfunctional metacognitive beliefs about worry (16)	x AH		Anxiety, PTSD, Somatoform, Eating, Mood, Sleep disorders (17)
	Negative beliefs about uncontrollability/danger/superstition (16)			
	Diminished self-reflectivity (18,19)	x AH/D	x	Autism spectrum disorders (20), Psychopathy (21)
	Deficits in self-monitoring (22)	x AH/D	x	
	Deficits at basic metacognitive levels (23)		x	Personality disorders (24)
	Deficits in metacognitive capacity (25)		x	OCD (25)
Cognition	Higher cognitive confidence (16)	x AH		
	Limited cognitive insight (26)	x AH/D	x	Mood disorders (27)
	Cognitive distortions (reasoning biases such as JTC, attributional biases, biased expectancy, deficits in Theory of mind, confirmation biases) (28)	x D	x	Anxiety, Somatoform, Mood, Eating, Sexual, Impulse control disorders (2)
	Low outcome expectancies (for pleasure/success) (29)		x	Panic disorders, Social Phobia, Eating disorders, Somatoform, Substance abuse, Mood disorders, GAD, PTSD (2)
	Low perceived competence (29)		x	
	Impaired source monitoring(30)	x AH		
	High levels of general worry (31)	x D		Across all disorders (32)
	Deficits in social cognition (33,34)	x AH/D	x	MDD (35), Autism spectrum disorders (36)
	Cognitive fusion (37,38)	x AH/D		OCD (39), Mood, Anxiety disorders (40)
	Dysfunctional coping strategies (41)	x AH/D	x	Across all disorders (42)
Memory	Vague and less vivid memory recollection (43)	x AH/D	x	Mood, Anxiety and Eating disorders (2)
	Overconfidence in (false) memory (44,45)	x AH/D	x	Depressive disorders (46)
Attention	Selective attention (29)	x AH/D	x	Anxiety, Somatoform, Sexual, Sleep, Mood, Eating, Substance-related disorders (2)
Affective	Lower self-esteem (34,47)	x AH/D	x	Mood, Eating, Substance-related disorders (48)

Supplementary Material

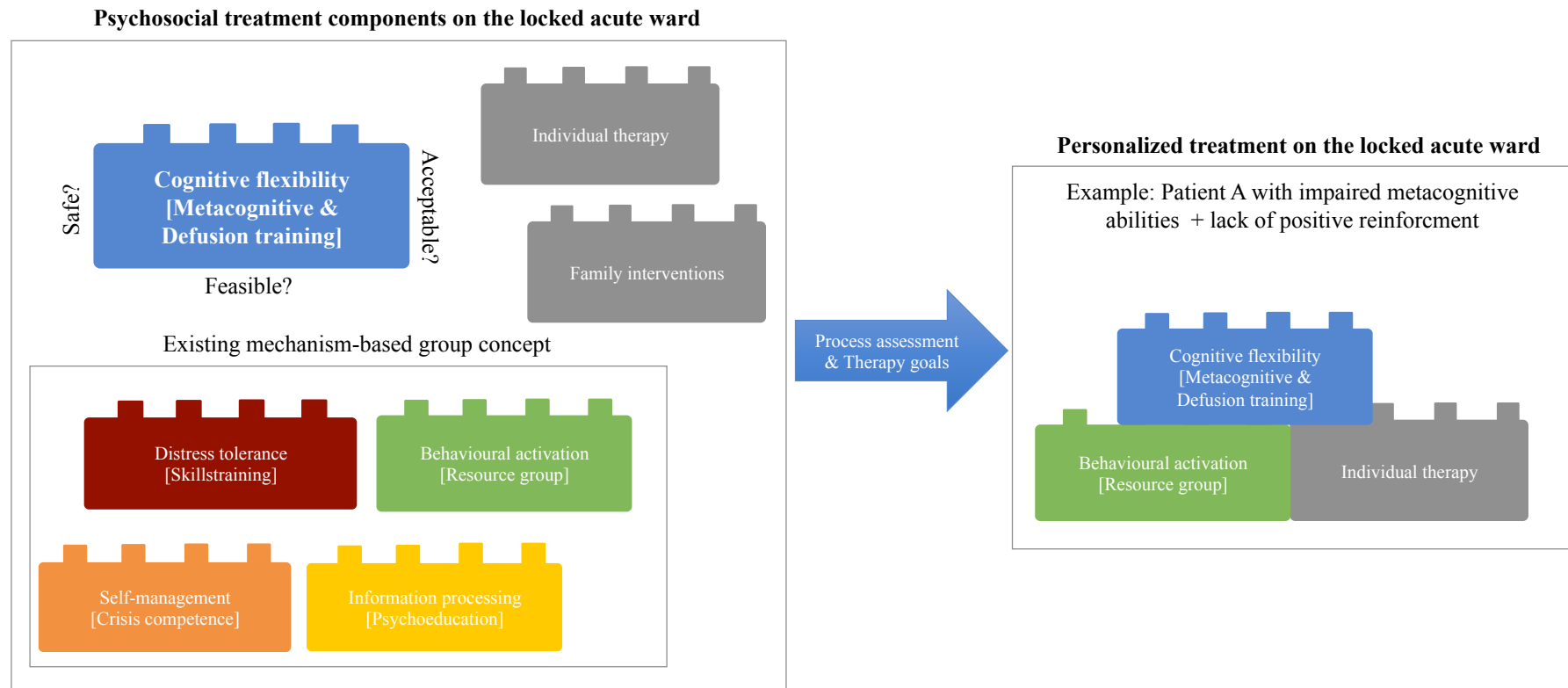
	High emotional reactivity (49)	x AH/D	x	Mood, Anxiety disorders (50)
Beliefs	Negative self-concepts		x	BPS (34,51), Anxiety (52), Mood disorders (53)
	Defeatist beliefs (54)		x	Bipolar (55), Personality disorders, MDD (56)
	Dysfunctional acceptance beliefs (34)		x	
Behavior regulation	Incapability to endure ambiguity (57)	x D		
	Less empathic (18)		x	Personality (antisocial, Borderline, Narcissist), Autistic spectrum, Mood disorders (58)
	Safety behavior (59)	x AH/D	x	Anxiety, Somatoform, Sleep, Mood, Eating, Substance-related disorders, OCD, PTSD (2)
	Dysfunctional coping strategies (41,60)	x AH/D	x	Across all disorders (42)
Social influences	Unsupportive environments (61)	x AH/D	x	
	Trauma and social adversity (63)	x AH		Across all disorders (62)
	Social alienation (64)	x AH/D	x	

Key. AH = Auditory Hallucinations; BPS = Borderline personality disorder; D = Delusions; GAD = Generalized anxiety disorder; JTC = Jumping to conclusions; MDD = Major depressive disorder; Mood disorders = Depressive and Bipolar disorders; OCD = Obsessive compulsive disorder; PTSD = Post-traumatic stress disorder

4 Supplementary Table 3. Existing mechanism-based therapies for psychosis focusing on impaired metacognitive and cognitive processes (Step 1)

	Target mechanism of change	Procedure	Evidence-base for psychosis	Suitable for acute patients	Group format (acute settings)
Metacognitive and cognitive processes					
Metacognitive Training (MCT)	Metacognitive knowledge and awareness, Cognitive restructuring	Raising awareness for cognitive biases and changing the way patients deal with them	Three meta-analyses (65–67)	Current pilot testing of version for acute wards (68)	Available for acute setting
Metacognitive insight and reflection therapy (MERIT)	Metacognitive awareness	Helping patients to make sense of self and others	Two RCTs (69,70)	Limited, since complex	No group format available
Metacognitive interpersonal therapy for psychosis (MIT-P)	Metacognitive awareness	Promoting understanding of relationship between emotional distress and symptoms	Three case studies (71–73)	Limited, since complex	No group format available
Cognitive fusion and maladaptive coping strategies					
Acceptance and Commitment Therapy (ACT)	Metacognitive awareness, metacognitive goals and strategies (acceptance/mindfulness/cognitive defusion/values)	Changing the function of thought and voice contents on behavior	One systematic review containing 11 RCTs (74)	Past testing of versions for acute ward (75–77)	Available (not for acute settings)
Mindfulness-based interventions for psychosis	Metacognitive knowledge, awareness and strategies	Developing mindfulness skills and making sense of crisis	Two feasibility randomized controlled trials (78,79)	Tested with inpatients, but not explicitly acute	Available (not for acute settings)
Metacognitive Therapy	Metacognitive knowledge and strategies	Challenging beliefs and training functional coping with thoughts	Two case studies (80,81), one case series (82) and one open trial (83)	Limited, since complex	Available, but only for depression (not for acute settings)

5 Supplementary Figure 1. Mechanism-based group therapy concept on the locked acute ward



Notes: Psychosocial treatment components present the targeted change mechanism with the name of the respective group/treatment module in square brackets. Existing mechanism-based groups on the locked acute ward include a) a transdiagnostic Skillstraining (in total three sessions covering psychoeducation on tension regulation, testing of different stress-tolerance-skills, development of emergency plans and skill chains), b) a transdiagnostic Resource group (in total three sessions covering psychoeducation on depression upward- and downward-spiral, development of positive activities and resources, day and week planning), c) a transdiagnostic Crisis-Competence group (in total four sessions covering crisis formulation, early warning signs and coping strategies, emergency plan and discharge planning, and d) a transdiagnostic Psychoeducation group (in total three sessions covering information on diathesis-stress-model, medication, and treatment options). All groups were adapted from existing group manuals (84–87) to fit the acute inpatient setting. Each group session lasts 50 minutes and takes place weekly. Inpatients are able to participate in two group therapies with the option for individual therapy. The experimental mechanism-based group therapy (in blue) was specifically designed for inpatients with acute psychotic symptoms and takes place twice a week with a total of nine sessions. The ultimate goal of the mechanism-based concept is to individually tailor treatment for acute inpatients by allocating them to the group therapies most likely to target individually relevant change mechanisms and personal preferences.

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6. Publication II

European Archives of Psychiatry and Clinical Neuroscience
<https://doi.org/10.1007/s00406-023-01690-y>

ORIGINAL PAPER



Targeting metacognitive change mechanisms in acute inpatients with psychotic symptoms: feasibility and acceptability of a modularized group intervention

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Received: 11 May 2023 / Accepted: 26 August 2023
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Abstract

Emerging evidence suggests the usefulness of psychological interventions targeting metacognitive change mechanisms in patients experiencing psychosis. Although many of these patients are treated in acute psychiatric contexts, only few studies have adapted such interventions for acute inpatient settings. The present study aimed to assess the feasibility, acceptability, and preliminary clinical outcomes of a novel modularized group intervention focusing on different aspects of metacognitive change mechanisms. In particular, the intervention aims to reduce patients' acute symptoms by enhancing cognitive insight and to relieve distress via cognitive defusion (i.e. coping). A sample of 37 participants with acute psychosis received up to nine sessions of the intervention. Baseline and post-intervention assessments were conducted for general psychopathology, psychotic symptoms, global functioning, and symptom distress. Measures of change mechanisms were assessed before and after the respective treatment module. Participants' experiences were explored in feedback questionnaires and interviews. Recruitment, retention, and attendance rate met the pre-set feasibility benchmark of 80%. The intervention was well received by participants, who emphasised the group's clear structure, positive atmosphere, and helpful contents. Response rates were high and linear mixed models revealed significant medium-to-large time effects on all clinical outcomes. As expected, increase in hypothesised change mechanisms cognitive insight and decrease in cognitive fusion was found. However, the uncontrolled design limits interpreting clinical effects. The study provides evidence that an intervention based on a metacognitive model is feasible and acceptable for acute inpatients with psychosis. Positive results on clinical outcomes and change mechanisms warrant further exploration in a randomized controlled trial.

Keywords Acute inpatient setting · Acute psychosis · Mechanism-based · Metacognition · Modularized · Group therapy · Intervention

Introduction

Psychotic spectrum disorders (PSDs), such as schizophrenia and psychotic mood disorders, affect around 3.5% of the global population [1] and are considered to be among the top 25 contributors to disability worldwide [2]. They are also among the mental illnesses associated with the highest

economic costs for health care services, partially due to repeated hospitalisations [3, 4]. Internationally, as much as two-thirds of the current psychiatric inpatient population are experiencing psychosis [5], also being the group most frequently subject to involuntary admissions [6].

During acute crises, patients with PSDs can pose high risks to themselves and others, requiring treatment in acute psychiatric inpatient wards (also known as secure, locked or acute wards) [7]. In contrast to open wards, where inpatients are treated after their most severe symptoms have subsided, acute psychiatric inpatient wards often focus primarily on psychopharmacological treatment rather than psychological interventions, resulting in on-going patient dissatisfaction [8]. The lack of psychotherapeutic activity moreover contrasts with treatment guidelines, which recommend

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psychological interventions for psychosis already in the acute treatment stage [9, 10] to improve patients' functioning and support recovery [11, 12]. Interestingly, recent systematic reviews and meta-analyses report heterogeneous findings for guideline-recommended cognitive behavioural therapy for psychosis (CBTp) in acute psychiatric inpatient settings [13–15]. However, promising evidence supports the efficacy of third-wave therapies like Acceptance and Commitment Therapy (ACT) and CBT approaches integrating third-wave components, such as Metacognitive Training (MCT) [13–15].

Disorder-specific CBTp protocols aim to change the appearance and nature of psychotic symptoms [16]. In contrast, third-wave therapies focus on how individuals process and manage experiences while encouraging a mindful and accepting attitude towards them [17]. They also often directly focus on targeting transdiagnostic change mechanisms that are thought to positively impact treatment outcomes [18]. In this context, change mechanisms rely on psychological processes found to be responsible for the onset and maintenance of disorders [17]. In the case of psychosis, third-wave approaches have a particular interest in various aspects of impaired metacognitive processes and associated metacognitive change mechanisms [19, 20]. More precisely, approaches try to enhance patients' critical awareness of own thoughts (“thinking about thinking”) [21] in order to change immediate thought-related reactions [19]. MCT, for example, aims to promote patients' cognitive insight via raising metacognitive awareness and knowledge for cognitive biases [22] and has demonstrated significant effectiveness in reducing positive symptoms [16, 23, 24]. ACT on the contrary, although not categorized specifically as a metacognitive therapy, also incorporates several metacognitive elements. Key ACT concepts such as mindfulness, acceptance, cognitive defusion (ACT term for cognitive distancing), and value commitment [25], are associated with metacognitive awareness and functional metacognitive goals and strategies [26–28]. With regard to acute inpatients with PSDs, ACT-based interventions have been shown to reduce general psychopathology and rehospitalisation rates [11, 29, 30].

While altering cognitive responses to experiences instead of directly challenging them seems to be especially helpful in treating acute psychotic symptoms [31], existing evidence has to be approached with caution [13–15]. Apart from the current small evidence base and methodological shortcomings, most of the metacognitive interventions for psychosis that have been studied were originally developed for outpatients [32–35] or for inpatients with mild to moderate symptoms [22] and were not tailored to fit the unique characteristics of acute psychiatric settings and inpatients [13, 36]. These include restrictive environments, high economic pressure, brief admissions, and acutely unwell patients likely to pose high risks, have multiple disorders, cognitive

difficulties and low motivation for treatment [7]. Given the urgent need to improve acute inpatient care, yet a remaining substantial research gap, studies are needed to investigate the feasibility and effectiveness of adapted interventions [37].

Therefore, the present research aimed to examine the feasibility and acceptability of a novel modularized and mechanism-based treatment, while evaluating preliminary clinical outcomes and alterations in potential change mechanisms. More precisely, the current study extended our previous work [36] on designing an adapted metacognitive treatment using Intervention Mapping [38] as suggested by best practice guidelines on complex intervention development [39]. Specifically, the novelty of the intervention (see Supplementary Material and our previous work for details) [36] is that it (1) focuses directly on underlying transdiagnostic metacognitive change mechanisms (cognitive insight and cognitive defusion) rather than on specific symptom content, thus following a current paradigm shift towards mechanism-based psychotherapeutic treatments [18, 40, 41], (2) combines and integrates different existing evidence-based therapeutic approaches in a hybrid and modularized approach allowing for tailored treatments and greater flexibility [42, 43], (3) is delivered in a group format to take advantage of social support and optimal resource use [44, 45], and (4) adapts all therapeutic elements to be brief, flexible and low-key to meet the needs of acute inpatients with PSDs [37].

We hypothesised that (1) feasibility and acceptability measures would exceed the 80% benchmark necessary to proceed to a fully powered effectiveness randomized controlled trial (RCT) [46]. Furthermore, we assumed that (2) participants would show significant improvements (compared to baseline) on general psychopathology, positive and negative symptoms, symptom distress, symptom severity, and functioning, and that (3) targeting metacognitive treatment mechanisms would lead to positive changes, as evidenced by increased cognitive insight and decrease in cognitive fusion (i.e. greater cognitive defusion from internal experiences).

Materials and methods

Procedure and participants

Between May 2021 and February 2022, we recruited a total of $N=37$ participants from the acute psychiatric inpatient ward of the Max Planck Institute of Psychiatry in Munich, Germany for the study. Within this period, nine group therapy cycles were conducted. After a standardized screening process, eligible participants were briefed about the study's procedures and written informed consent was obtained. Enrolment into the group therapy was possible at the beginning of each module. The screening procedure and

all rater-based assessments were either conducted by a clinical psychologist or psychiatrist in training. Inclusion criteria were: (1) aged between 18 and 70; (2) diagnosed with a PSD (ICD-10 codes F20-39); and (3) able to give informed consent. Exclusion criteria were: (1) severe neurological or internal concomitant diseases; (2) $IQ < 80$, severe learning disability, brain damage or pervasive developmental disorder; and (3) missing eligibility for psychotherapy because of missing language skills, hostile or uncooperative behaviour. Our sample size of $N = 37$ participants exceeded the suggested benchmark of $N = 20$ participants required to evaluate the feasibility, acceptability and preliminary effectiveness of a group therapy intervention [47], also for studies with PSDs [48–50]. Following guidelines on conducting feasibility studies, we employed a non-randomised exploratory pre-post design closest to a Phase II early clinical trial [51, 52] (see Fig. 1), suitable for assessing and maximizing the intervention's potential effectiveness for future research [39]. Outcome measures were taken at baseline (timepoint T_0), before and after each therapy module (timepoints T_1 , T_2 , T_3 , T_4 , T_5) and post intervention (timepoint T_6). Rehospitalisation data was examined up to 12 months after completion (timepoint T_7). Our study received approval from the ethics committee of the Medical Faculty at Ludwig Maximilian University Munich (PNO-21-0025) and was pre-registered in ClinicalTrials.gov (TRN04874974-2021.04.26).

Modularized metacognitive group intervention

We designed the metacognition-focused and modularized group therapy as an experimental group in addition to the already existing mechanism-based therapy concept of the acute psychiatric inpatient ward (see Supplementary Methods 1 and Supplementary Fig. 1 for an overview) [36]. The five-week group intervention consisted of nine stand-alone sessions (two per week) divided into three modules targeting various metacognitive and social change mechanisms, with the overall goal of enhancing cognitive flexibility

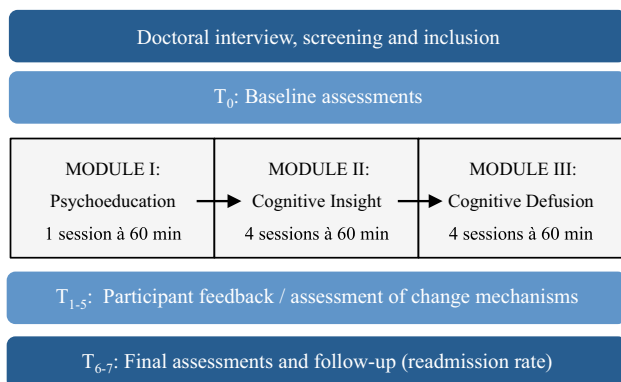


Fig. 1 The study and intervention design

(see Supplementary Fig. 2 for underlying therapy model). Modules I and II aimed to enhance attentiveness to internal experiences by promoting metacognitive awareness and knowledge and hence cognitive insight for cognitive distortions. Module III focused on reducing distress and automatic relational responses through cognitive defusion and thereby strengthen metacognitive goals and strategies. Module I contains mainly psychoeducational material and exercises on metacognition (cognitive biases and dysfunctional coping strategies), adapted in a transdiagnostic way from the Metacognitive Training for depression [53]. Therapy contents for Module II were adapted from the “acute version” of the Metacognitive Training for psychosis by Moritz and Woodward [22, 54]. Module III includes adapted exercises from the Metacognitive Therapy by Wells and Matthews [35] and the Acceptance and Commitment Therapy by Hayes [34]. A description of sessions' contents can be found in Supplementary Table 1. To address the specific characteristics of acute inpatients with psychotic symptoms, such as low illness insight, treatment resistance [55], severe cognitive deficits [56], and comorbid diagnoses [57], we designed the contents to be transdiagnostic, experiential, and easy-to-comprehend. Information was presented on simple PowerPoint slides, group sizes were kept small with no more than seven participants, and each session lasted a maximum of 60 min. Sessions were carried out by a psychotherapist trained in CBT who adopted an empowering and self-disclosing therapeutic attitude [58]. Due to the naturalistic study design, participants were allowed to participate in one other group therapy, received weekly individual psychotherapy sessions and additional routine care (described in Supplementary Methods 2) within the acute inpatient setting. Any other interventions participants were involved in were documented. Risk assessments and evaluations were conducted regularly during group sessions and team meetings with medical staff. Pre-specified adverse events included: symptom aggravation, new symptoms, treatment misuse, increased suicidality, and negative impact on work or social network. The assessments were documented using standardized checklists proposed by Linden [59]. In case of a serious adverse event (attempted suicide) related to the intervention, the termination of the study was determined.

Outcome measures

Primary outcomes consisted of measures operationalized to assess the feasibility and acceptability of the intervention and study evaluation design. Secondary outcomes included multiple clinical measures that were used to evaluate the preliminary effectiveness of the intervention. Demographic information was collected at baseline via a self-reported questionnaire, supplemented by the clinical record. Baseline medication and any changes during the course of the

study were recorded using participant's medical records. Table 1 presents an overview of all study instruments and the sequence of their administration at each of the timepoints.

Primary outcome measures

Using the CONSORT extension to pilot and feasibility studies [60] feasibility data included: (1) eligibility rate, (2) consent rate, (3) trial entry rate, (4) completion and missing data rate, (5) retention rate, (6) dropout rate, (7) patient engagement, and (8) adverse events. Acceptability, subjective effectiveness and participants' treatment satisfaction with each module and the whole intervention was measured with a five-point Likert scale self-report questionnaire (see Supplementary Methods 3) adapted from Moritz and Woodward [61]. Additionally, all participants were invited to give general feedback on the group therapy and study conditions in semi-structured interviews conducted at study completion (see Supplementary Methods 4). Following guidelines on evaluating pilot studies [46, 62], feasibility and acceptability criteria were benchmarked a priori with a traffic light system on recruitment, retention and attendance rate as well as patients' overall treatment satisfaction: red (not feasible < 60%), yellow (modify intervention and

protocol $\geq 60\% < 80\%$), and green (continue without modifications > 80%) [63–65].

Secondary clinical outcome measures

General psychopathology as well as negative and positive symptoms were rated with the Positive and Negative Syndrome Scale (PANSS), a clinician-administered 30-item semi-structured interview [66]. On the three different scales (positive, negative and global symptom scale), items are scored on a seven-point Likert scale between 1 (not present) and 7 (severe). The PANSS demonstrates strong internal consistency, indicated by a Cronbach's $\alpha=0.73$ and a high inter-rater reliability (between 0.83 and 0.87) [67].

Symptom distress was measured with the Psychotic Symptom Rating Scale (PSYRATS), a 17-item clinician-administered semi-structured interview. On two different subscales (auditory hallucinations and delusions), different dimensions (e.g. controllability, severity and intensity of distress and disruption) of hallucinations and delusions are rated between 0 (not present) and 4 (highest possible distress). The PSYRATS is reported to have a good internal consistency with a high inter-rater reliability (between 0.79 and 1.00) [68].

Table 1 Measurements across each timepoint

Time point	Baseline	Intervention					Post-intervention	Follow-up
	T ₀	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆	T ₇
WEEK	0	1	2	3	4	5	5	12 months
Demographics	X							
Treatment regime	X						X	
Primary outcome measures								
General feasibility measures	X	X	X	X	X	X	X	
Participant feedback questionnaire		X		X		X	X	
Semi-structured interview							X	
Secondary outcome measures								
Positive and Negative Syndrome Scale	X						X	
Psychotic Symptom Rating Scale	X						X	
Global Assessment of Functioning	X						X	
Clinical Global Impression Scale	X						X	
World Health Organization Disability Assessment Schedule	X						X	
Beck Cognitive Insight Scale			X	X				
Cognitive Fusion Questionnaire					X	X		
Readmission rate								X

Note. General feasibility measures included: eligibility rate, consent rate, trial entry rate, completion and missing data rate, retention rate, dropout rate, attendance rate and adverse events. Participant feedback questionnaires were handed out after each module and rated the participants' subjective satisfaction with the corresponding module. Insights from therapy and suggestions for improvement were interrogated from selected participants in semi-structured interviews after completing the whole intervention

The level of functioning was assessed using the Global Assessment of Functioning (GAF), a clinician-administered rating scale. The GAF scale considers both symptoms and functionality, and its scores range from 1 (indicating a risk of self-harm or harm to others) to 100 (suggesting the absence or minimal presence of symptoms). It demonstrates a good internal consistency with Cronbach's $\alpha=0.70$ [69, 70], but has been criticised for its weak inter-rater reliability [71].

Symptom severity and treatment response to the intervention was rated on the Clinical Global Impression (CGI) rating scales, a one-item clinician-administered assessment [72]. On the severity scale (CGI-S), the severity of an individual's illness is evaluated relative to the clinician's past experience on a seven-point Likert scale from 1 (not at all ill) to 7 (among the most extremely ill patients). The improvement scale (CGI-I) quantifies the individual's improvement or worsening since the start of the intervention from 1 (very much improved) to 7 (very much worse) [73]. The CGI is one of the most widely used rating scales in mental health trials and several studies demonstrated its validity by linkage to rating scales such as the PANSS [74].

Disability and functional impairment were estimated using the World Health Organization Disability Assessment Schedule 2.0 (WHODAS-2.0), a 12-item self-report questionnaire [75]. The six disability dimensions (social, cognitive, society, self-care, household, and mobility) of the International Classification of Functioning (ICF) [76] serve as subscales in the questionnaire. These are rated using a five-point Likert scale (1 = no disability to 5 = very strong disability). The WHODAS shows good reliability (Cronbach's $\alpha=0.89$) [77, 78]. As suggested in the literature, inpatients with psychosis tend to overestimate their functioning [79], so we introduced an additional rater-corrected WHODAS score when a participant lacked the insight to answer the questions objectively. Following the approach of Gspandl et al. [80] and the DSM-5's WHODAS-2.0 Clinician Administration guide [81], we used information from proxy respondents such as family members and carers, as well as clinical judgement, to record a question-by-question "corrected" score alongside the participant's self-reported "raw" score.

The hypothesised metacognitive change mechanism of cognitive insight was determined using Beck's Cognitive Insight Scale (BCIS), a 15-item self-report questionnaire. The BCIS contains two subscales, self-reflection and self-certainty regarding one's thoughts and experiences, which are rated using a four-point Likert scale from 0 (do not at all agree) to 3 (agree completely). It presents acceptable internal consistency with Cronbach's $\alpha=0.60$ – 0.68 [82].

To assess the potential change mechanism of cognitive defusion, the Cognitive Fusion Questionnaire (CFQ) was used. The seven-item self-report questionnaire measures the extent to which an individual's behaviour is influenced by

thoughts (cognitive fusion), using a seven-point Likert scale ranging from 1 (never true) to 7 (always true). Previous studies have demonstrated its high internal consistency (Cronbach's $\alpha=0.89$ – 0.93) [83, 84].

Rehospitalisation rates (to the same unit or psychiatric hospital) during the follow-up period were monitored exploratory using internal patient chart records.

Data analysis

In line with the CONSORT guidelines on reporting pilot and feasibility studies [60], we focused the analysis on descriptive statistics for feasibility and acceptability measures using frequencies and percentages. Thematic analysis [85], a systematic approach to organize, encode, and analyse patterns (themes) within qualitative data, was employed for the semi-structured interviews. Changes in dosages of psychotropic medication from baseline to post-intervention were compared by computing dose equivalents [86] and conducting parametric (paired t-tests) or non-parametric (Wilcoxon's signed ranks) tests depending on the data's distribution.

Intraclass Correlation Coefficients (ICC) for all secondary outcomes (0.25–0.67) provided evidence for a nested data structure [87, 88], so we used linear mixed models (LMMs, for details see e.g. [89]) via the maximum likelihood method to estimate participants' changes on secondary clinical measures (i.e., post–pre treatment comparison) [90]. In all our LMMs, the measurement occasions of the outcomes were represented as a binary-coded time variable with 0 (i.e., baseline measure before treatment) and 1 (i.e., post-intervention measure). The time variable was added as a fixed effect on the within-participant level, while participants' ID was treated as a random effect [91, 92]. All our LMMs controlled for potential confounders by including the covariates sex, age, psychotherapeutic treatment dosage (group and total), and medication change scores (antipsychotic and antidepressant), that we selected based on previous research findings [93].

For investigating clinically significant changes over treatment time, we referred to the recommended criteria of 25% and 50% of improvement indicated by percentage of PANSS total scores reduction from baseline and to the CGI-improvement scale cut-offs [94, 95]. Finally, for exploratory rehospitalisation rates, we calculated the proportion of participants readmitted to the same unit or hospital within the follow-up period. All statistical analyses were conducted using R Software, version 4.1.2 [96].

Results

Baseline demographic and clinical characteristics and changes in the participants' medication regime are shown in Tables 2 and 3. There were no significant differences

in the antipsychotic medication dosages between baseline and post-intervention. However, we found significant changes for antidepressants and benzodiazepines.

Feasibility and acceptability

The study's CONSORT chart is illustrated in Fig. 2. In terms of feasibility, the eligibility and consent rates were 75.8% and 78.7% respectively, while the trial entry rate was 100%. The completion rate for all clinical assessments and between-module feedback questionnaires was high at 99.4%. All participants attended at least one module, resulting in a dropout rate of 0%. 33 of the 37 participants completed all three modules leading to an overall retention rate of 89.2%. Session attendance was consistently high with 86.5% of participants attending at least six sessions, i.e. two thirds of the total intervention. Five participants experienced a total of seven adverse events over the course of the study. These included one negative impact on work, one appearance of new symptoms and five symptom deteriorations. None was related to the intervention.

Participants' acceptability and satisfaction with the group intervention was high (see Table 4), with 85.2%, 91.9%, 91.4% and 80% of the participants rating their treatment satisfaction for Modules I, II, III, and the overall treatment respectively with the highest possible rating (applies to a great extent or applies exactly). Illustrative open-ended feedback quotes (see Table 4) on each module and on the group therapy as a whole further support participants' satisfaction with and positive insights gained from the group therapy. Greater details concerning attendance data, complete presentation of the qualitative feedback on the questionnaires, participation in supplementary treatments and therapy content of individual therapies can be found in Supplementary Tables 2–5.

25 of the 37 participants agreed to participate in the voluntary semi-structured feedback interview following study completion. Regarding positive group aspects, topics included helpful therapy contents, e.g. defusion techniques, and supporting environment, e.g. positive group atmosphere (see Supplementary Fig. 3). Themes identified for insights through therapy were gains in metacognitive abilities, e.g. thought awareness and recontextualisation (see Supplementary Fig. 4). Themes related to intervention deficiencies included e.g. tight session schedules and too few practical exercises (see Supplementary Fig. 5). Lastly, themes concerning the study and group setup comprised e.g. shortening session duration (see Supplementary Fig. 6). Examples of participants' quotes and identified codes that support themes can be found in Supplementary Table 6 and 7.

Table 2 Demographic and clinical characteristics of participants ($N=37$)

Baseline characteristic	F_N (%); M (SD)
Sex	
Male	16 (43.24%)
Female	21 (57.75%)
Age (years)	45.43 (15.09)
Ethnicity	
Caucasian	32 (86.49%)
Hispanic	0 (0%)
African German	2 (5.41%)
Asian German	3 (8.11%)
Family Status	
Single	16 (43.24%)
Partnership/Married	15 (40.54%)
Separated/Divorced/Widowed	6 (16.22%)
With children	17 (45.94%)
Years of education	
Low (≤ 10 years)	16 (34.24%)
Middle (≥ 12 years)	15 (40.54%)
High (≥ 15 years)	6 (16.22%)
Occupation	
Unemployed	16 (43.22%)
In retirement	7 (18.92%)
Student	4 (10.81%)
Employed	10 (27.03%)
Primary diagnosis	
F20-29 (Psychosis-spectrum disorders)	29 (78.38%)
F30-39 (Psychotic mood disorders)	8 (21.62%)
Psychotic symptoms (self-report)	
Delusions only	15 (40.54%)
Hallucinations only	2 (5.41%)
Delusions + Hallucinations	20 (54.05%)
Duration of illness (psychosis) in years	7.39 (9.29)
Refractory status	12 (32.43%)
Number of comorbid psychiatric diagnoses	
0	21 (56.76%)
1	9 (24.32%)
2	4 (10.81%)
3	3 (8.11%)
Number of previous hospitalisations	5.54 (4.59)
Type of hospital admission	
Involuntary	7 (18.91%)
Voluntary	30 (81.08%)
Previous psychotherapeutic experience	
None	4 (10.81%)
Received (In- and/or outpatient)	33 (89.19%)
Therapy motivation (self-report from 0 to 100%)	83.92 (24.58)

Note. Refractory status was assessed using Kane's criteria on treatment-resistant schizophrenia [123]. Comorbid diagnoses included ICD diagnoses from F06 ($n=2$), F10 ($n=2$), F12 ($n=5$), F13 ($n=2$), F17 ($n=3$), F19 ($n=1$), F32 ($n=1$), F42 ($n=2$), F44 ($n=1$), F45 ($n=1$), F60 ($n=1$), F84 ($n=2$), F90 ($n=2$) and Z73 ($n=1$)

Table 3 Participants' medication regime at baseline and post-intervention

Type, number and mean dose equivalent	Baseline <i>n</i> (%)	Post-intervention <i>n</i> (%)	<i>t</i>	<i>V</i>	<i>p</i>
Antipsychotics					
0	1 (2.70%)	2 (5.41%)			
1	21 (56.76%)	17 (45.94%)			
2	6 (16.22%)	11 (29.73%)			
≥3	9 (24.32%)	7 (18.92%)			
Mean dose equivalent in mg ^a (SD)	14.26 (11.75)	16.02 (7.83)	0.99		0.163
Antidepressants					
0	23 (62.16%)	20 (54.05%)			
1	12 (32.43%)	12 (32.43%)			
≥2	2 (5.41%)	5 (13.51%)			
Mean dose equivalent in mg ^b (SD)	9.99 (14.98)	17.90 (23.23)		108	0.003
Mood stabilizers					
0	34 (91.91%)	36 (97.30%)			
1	3 (8.11%)	1 (2.70%)			
Benzodiazepines					
0	21 (56.76%)	25 (67.57%)			
1	16 (43.24%)	12 (32.43%)			
Mean dose equivalent in mg ^c (SD)	1.12 (1.71)	0.43 (0.82)		16.5	0.004

Note. Table format adapted from Boege et al. [63]

For normally distributed data, parametric tests were used. For skewed distributions non-parametric Wilcoxon tests were used

^aDosages converted to Olanzapine equivalent

^bDosages converted to Fluoxetine equivalent

^cDosages converted to Lorazepam equivalent

Secondary clinical outcomes

The results of the LMMs (see Table 5) revealed significant medium-to-large post-intervention reductions from baseline for all secondary clinical outcomes, except for the self-rated WHODAS measuring disabilities and functional impairments. More precisely, we found reduced general psychopathology ($b = -17.03$, 95% CI: -23.78 , -10.27 , $d = -0.93$), positive ($b = -6.59$, 95% CI: -8.64 , -4.53 , $d = -1.24$) and negative symptoms ($b = -3.05$, 95% CI: -5.02 , -1.08 , $d = -0.53$), symptom distress ($b = -12.07$, 95% CI: -16.88 , -7.26 , $d = -0.99$), symptom severity ($b = -1.04$, 95% CI: -1.56 , -0.53 , $d = -0.97$) and increased levels of global functioning ($b = 19.72$, 95% CI: 14.89 , 24.56 , $d = 1.58$). We also found a post-treatment reduction for the adjusted WHODAS-score ($b = -5.26$, 95% CI: -7.94 , -2.57 , $d = -0.67$). Regarding hypothesised change mechanisms, we found a significant post-module reduction in self-certainty after Module II ($b = -1.64$, 95% CI: -2.84 , -0.45 , $d = -0.45$) and in cognitive fusion after Module III ($b = -4.52$, 95% CI: -8.24 , -0.81 , $d = -0.43$). Time effects on secondary clinical outcomes were not alternatively explained by differences in sex, age, psychotherapeutic treatment dosage,

or medication change since we controlled for these covariates in our LMMs.

Analyses of clinically significant change in means of relative changes in PANSS total scores from baseline are shown in Table 6 [94]. At post-intervention, 75% of the refractory and 36% of the non-refractory participants fulfilled the response criteria. According to responder cut-off definitions on the CGI-improvement scale (at least minimally better) [94], 91.9% of the participants responded to the treatment. At 12-month follow-up, 16.2% of the participants were readmitted to our hospital one or more times (up to three times).

Discussion

Given the significant individual and economic burden associated with exacerbations of psychotic disorders and hospitalisation, improving inpatient treatment is a critical concern for healthcare services [37]. An important contribution in this respect is the development of interventions targeting mechanisms of therapeutic change [97, 98] that are moreover adapted to the specific needs of acute inpatients [99]. The present study is the first exploratory study conducted within an acute psychiatric inpatient ward that investigates

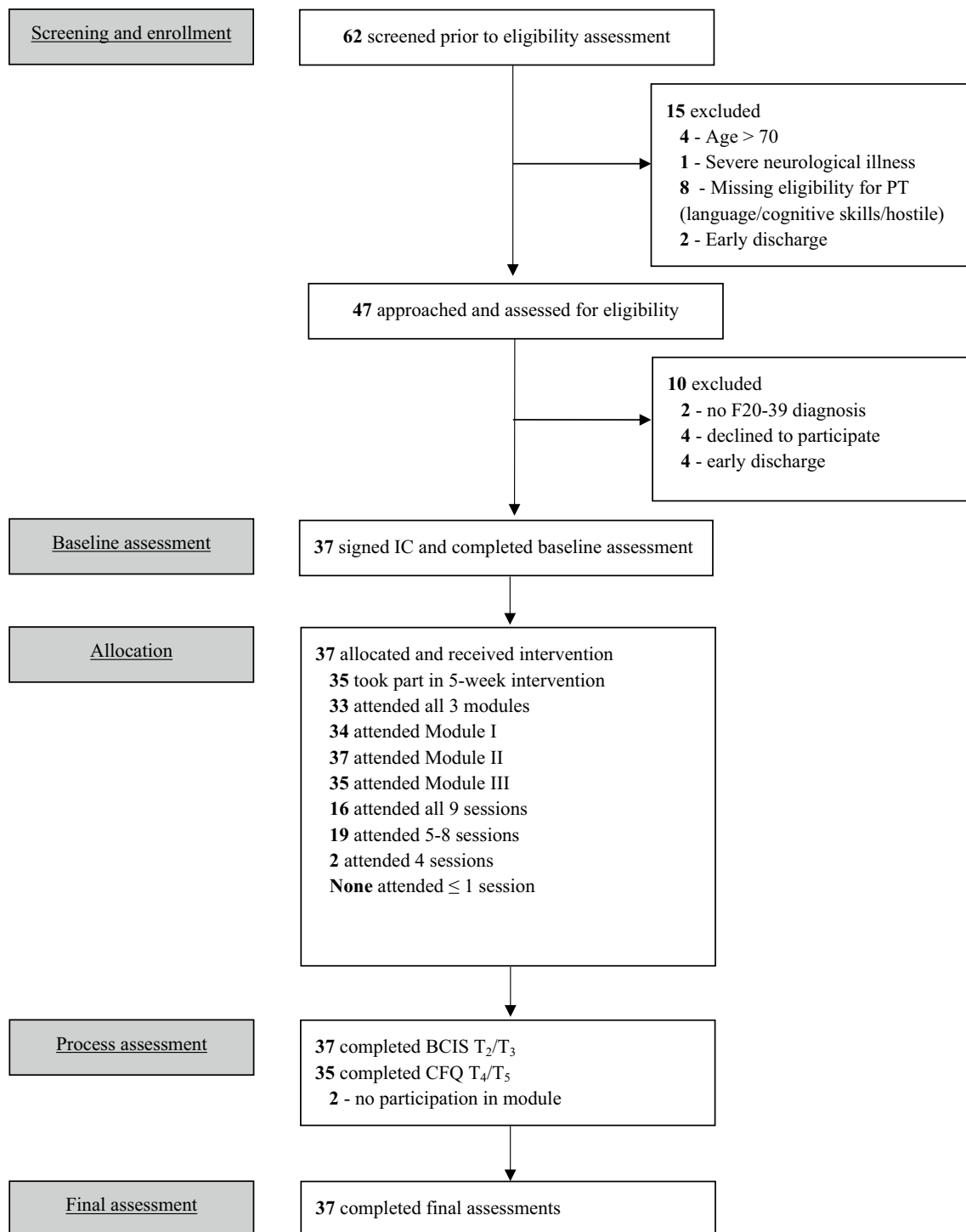


Fig. 2 CONSORT flow diagram of the recruitment, assessment and treatment process. Feasibility measures were defined as: 1) eligibility rate (proportion of those eligible to participate as a percentage of those screened); 2) consent rate (proportion of those who signed the informed consent as a percentage of those who were approached to participate); 3) trial entry rate (proportion of those who consented and completed baseline measures); 4) completion and missing data rate (proportion of assessments completed at each time point including screening, baseline, intervention and final meeting and reasons

for missing data); 5) retention rate (proportion of those who began the treatment and completed all three modules); 6) dropout rate (patients you entered the trial, attended at least one therapy session and dropped out before completing at least one module); 7) patient engagement (proportion of those attending at least two thirds of the intervention, i.e. six sessions, as well as the reasons for non-attendance); and 8) adverse events (any unwanted events related to the intervention)

Table 4 Participants' quantitative and qualitative feedback on each module and the overall treatment

Numeric items 1–12	Module Psychoeducation (n = 34)	Module Cognitive Insight (n = 37)	Module Cognitive Defusion (n = 35)	Overall treatment (n = 35)
	M (SD) [%] Positive appraisal ^a	M (SD) [%] Positive appraisal ^a	M (SD) [%] Positive appraisal ^a	M (SD) [%] Positive appraisal ^a
1. Useful and helpful	3.26 (0.90) [82.4]	3.35 (0.92) [83.78]	3.23 (0.97) [82.86]	3.37 (1.03) [88.57]
2. Understandable contents	3.35 (0.81) [85.29]	3.54 (0.73) [91.89]	3.39 (0.83) [80.00]	3.34 (0.91) [85.71]
3. Applicable in everyday life	2.74 (1.02) [64.71]	2.94 (1.17) [65.57]	3.71 (0.94) [57.14]	2.80 (1.13) [60.00]
4. Coping ideas	2.44 (1.21) [61.76]	2.84 (1.19) [59.46]	3.85 (1.21) [68.57]	2.74 (1.34) [60.00]
5. Clear rationale	3.03 (0.94) [76.47]	3.35 (0.92) [83.78]	3.26 (1.16) [82.86]	3.34 (1.00) [82.86]
6. Fun sessions	2.62 (1.18) [64.71]	2.84 (1.21) [64.86]	2.88 (1.02) [68.57]	2.89 (1.11) [68.57]
7. Boring sessions	1.38 (1.3) [23.53]	1.32 (1.31) [21.62]	1.36 (1.32) [22.86]	1.29 (1.38) [20.00]
8. Group format	3.15 (0.97) [76.47]	3.32 (1.06) [83.78]	3.47 (0.61) [91.43]	3.26 (1.04) [85.71]
9. Comfort in group	3.15 (1.08) [76.47]	3.24 (1.01) [78.38]	3.18 (0.97) [80.00]	3.09 (1.09) [80.00]
10. Important for treatment	2.68 (1.15) [61.76]	2.76 (1.23) [67.57]	2.91 (0.97) [65.71]	2.74 (1.20) [60.00]
11. Recommendation for others	3.12 (0.95) [79.41]	3.35 (0.98) [83.78]	3.53 (0.99) [82.86]	3.26 (1.22) [85.71]
12. Overall satisfaction	3.26 (0.79) [85.29]	3.46 (0.84) [91.89]	3.43 (1.01) [91.43]	3.31 (1.11) [80.00]
Categorical items 13–14	N (missing n)	N (missing n)	N (missing n)	N (missing n)
13. Number of sessions	34 (2) n (%)	37 (1) n (%)	35 (2) n (%)	35 (1) n (%)
Too few	1 (3.15%)	5 (13.88%)	3 (9.09%)	1 (2.94%)
Just right	29 (90.62%)	29 (80.55%)	25 (75.76%)	28 (82.35%)
Too many	2 (6.25%)	2 (5.55%)	5 (15.15%)	5 (14.71%)
14. Duration of sessions	N (missing n)	N (missing n)	N (missing n)	N (missing n)
Too short	34 (0) n (%)	37 (1) n (%)	35 (0) n (%)	35 (0) n (%)
Just right	2 (5.88%)	3 (8.33%)	3 (8.57%)	2 (5.71%)
Too long	27 (79.41%)	27 (75.00%)	25 (71.43%)	26 (74.29%)
	5 (14.70%)	6 (16.66%)	7 (20.00%)	7 (20.00%)

Table 4 (continued)

Open feedback items 15–16	Example quotes Module Psychoeducation	Example quotes Module Cognitive Insight	Example quotes Module Cognitive Defusion	Example quotes overall treatment
15. Insights from the module	<p>“This gave me motivation to fight.” (P56)</p> <p>“I can change something about the way I think and therewith, I can change my problems.” (P80)</p>	<p>“Strengthened self-worth.” (P70)</p> <p>“Careful with JTC, wait until you know what the other wants.” (P53)</p> <p>“Not to cling to thoughts and go into the thought trap.” (P77)</p>	<p>“One should get help when having problems.” (P90)</p> <p>“Notice my thoughts actively and distinguish whether they are helpful or not and how much they influence my behaviour.” (P33)</p> <p>“I don’t have to control my thoughts, thoughts are thoughts and not facts.” (P58)</p>	<p>“The group helped me to see that many fight against the same problems and that there are many ways to cope with them.” (P22)</p> <p>“Taking metacognitive perspective, balancing thoughts, not taking decisions with too few information.” (P47)</p>
16. Ideas for improvement	<p>“Thoughts versus voices.” (P80)</p> <p>“Skills and how to stop thoughts.” (P20)</p>	<p>“How to handle incomplete information, decision aids for accepting things.” (P24)</p> <p>“I need more tips on how to train my memory. I know this doesn’t fit with the problems of the others.” (P16)</p>	<p>“Some things were too fast.” (P58)</p> <p>“Discuss thoughts during acute psychosis.” (P49)</p>	<p>“Personal topics and examples.” (P53)</p> <p>“Talking about topics in individual session to recognize what helps me.” (P20)</p>

Note. The feedback questionnaires use a five-point Likert scale ranging from 0 (does not apply at all) to 4 (applies exactly) for items 1–12. For items 13–14, participants decide between three levels of a rating scale. Item 15 and 16 are open-ended questions. Example quotes are represented in this table and marked with the corresponding participant number. A more detailed table with all quotes can be found in the Supplementary Material (Supplementary Table 3)

^aPositive appraisal: The pooled relative number of participants that answered the item with 3 (applies to a large extent) and 4 (applies exactly)

Table 5 Effect of time on secondary outcome measures using linear mixed models

Secondary outcome measures	Min–Max	Baseline M (SD)	Post-intervention M (SD)	Time Coefficient ^a <i>b</i>	SE	95% CI	<i>p</i>	Cohen's <i>d</i> ^b
PANSS total score	30 to 210	82.32 (18.81)	62.24 (17.92)	– 17.03	12.00	[– 23.78, – 10.27]	<0.001	– 0.93
PANSS-positive scale	7 to 49	20.35 (5.89)	13.73 (4.68)	– 6.59	3.61	[– 8.64, – 4.53]	<0.001	– 1.24
PANSS-negative scale	7 to 49	20.08 (6.09)	15.84 (5.50)	– 3.05	3.73	[– 5.02, – 1.08]	0.008	– 0.53
PANSS-global scale	16 to 112	41.89 (10.03)	32.68 (9.45)	– 7.39	7.86	[– 11.68, – 3.09]	0.004	– 0.76
PSYRATS total score	0 to 68	22.62 (13.46)	10.94 (10.72)	– 12.07	8.29	[– 16.88, – 7.26]	<0.001	– 0.99
PSYRATS-Delusions scale	0 to 24	14.48 (4.75)	7.89 (6.00)	– 5.84	3.19	[– 7.68, – 3.99]	<0.001	– 1.08
PSYRATS-Auditory hallucinations scale	0 to 44	8.13 (13.18)	3.05 (7.78)	– 6.23	7.78	[– 10.63, – 1.83]	0.014	– 0.58
GAF	1 to 100	34.94 (12.55)	56.19 (12.40)	19.72	8.54	[14.89, 24.56]	<0.001	1.58
CGI-severity scale	1 to 7	5.73 (0.83)	4.59 (1.26)	– 1.04	0.98	[– 1.56, – 0.53]	0.001	– 0.97
WHODAS total score	12 to 60	32.54 (10.40)	28.28 (8.66)	– 1.91	5.23	[– 5.09, 1.28]	0.279	– 0.20
WHODAS-cognitive scale	2 to 10	5.70 (2.39)	4.89 (2.21)	– 0.42	1.41	[– 1.26, 0.41]	0.359	– 0.18
WHODAS-society scale	2 to 10	6.76 (2.28)	6.08 (2.19)	0.00	1.57	[– 0.90, 0.91]	0.996	0.00
WHODAS-social scale	2 to 10	5.59 (2.58)	4.76 (1.88)	– 0.58	2.10	[– 1.73, 0.57]	0.359	– 0.26
WHODAS total score-rater-adjusted	12 to 60	36.67 (8.20)	29.38 (7.57)	– 5.26	4.54	[– 7.94, – 2.57]	0.001	– 0.67
Potential change mechanisms		Pre-module	Post-module					
BCIS composite score	– 18 to 27	3.76 (7.21)	4.13 (5.44)	0.73	3.58	[– 1.42, 2.89]	0.536	0.11
BCIS-self-reflectiveness	0 to 27	12.70 (5.04)	12.16 (3.71)	– 0.91	2.95	[– 2.63, 0.81]	0.339	– 0.21
BCIS-self-certainty	0 to 18	8.94 (3.99)	8.03 (3.24)	– 1.64	1.99	[– 2.84, – 0.45]	0.017	– 0.45
CFQ	7 to 49	27.86 (10.69)	24.31 (10.34)	– 4.52	6.24	[– 8.24, – 0.81]	0.033	– 0.43

Note. BCIS: Beck Cognitive Insight Scale; CGI: Clinical Global Impression; CI: Confidence interval; CFQ: Cognitive Fusion Questionnaire; GAF: Global Assessment of Functioning; SE: Standard error of random effects; PANSS: Positive and Negative Syndrome Scale; PRSYRATS: Psychotic Symptom rating scale; WHODAS: World Health Organization Disability Assessment Schedule. The BCIS was measured before and after Module II (Cognitive Insight), the CFQ was assessed before and after Module III (Cognitive Defusion). All other measures were taken at baseline and after completing the whole intervention. For the WHODAS scores, a rater-adjustment was introduced as participants partly overestimated their functioning [80]

^aAdjusted time coefficient representing mean differences between post-intervention scores and baseline scores. All LMMs controlled for the covariates sex, age, psychotherapeutic treatment dosage (group and total) and medication changes in antidepressants and antipsychotics, included as random effects in the LMMs

^bAdjusted effect sizes were calculated as the square root of the adjusted post-baseline mean difference divided by the pooled standard deviation estimates

Table 6 Percentage changes from baseline in PANSS total scores as responder rates

	<0 reduction (i.e. increase) <i>n</i> (%)	0–24% PANSS reduction <i>n</i> (%)	25–49% PANSS reduction <i>n</i> (%)	50–74% PANSS reduction <i>n</i> (%)	75–100% PANSS reduction <i>n</i> (%)
Refractory participants (N=12)	0 (0)	2 (16.7)	7 (58.3)	2 (16.7)	1 (8.3)
Non-refractory participants (N=25)	1 (4.00)	8 (32.00)	7 (28.0)	5 (20.0)	4 (16.0)

Note. Table format adapted from Leucht et al. [94]

PANSS: Positive and Negative Syndrome Scale. Refractory status was assessed using Kane's criteria on treatment-resistance schizophrenia [123]

the feasibility, acceptability, and clinical outcomes of a mechanism-based and modularized group intervention targeting metacognitive change mechanisms in acute psychosis.

Results from the trial suggest that our group intervention was both feasible and acceptable, meeting the desired criteria for feasibility trials as outlined in guidelines [46, 100]. Despite COVID-19 pandemic-related challenges such as temporary closed wards and group format limitations, we recruited 37 participants within nine months, exceeding our pre-set recruitment target of 20 patients. Retention and attendance rates were both above the 80% benchmark, with overall satisfaction ratings exactly reaching the 80% acceptability target. The low dropout and missing data rates, and participants' positive feedback in the questionnaires and interviews, further indicate high commitment and satisfaction with the treatment. Despite high symptom burden among participants with PANSS total scores comparable to average inpatients with acute psychosis [101, 102], there were no related adverse events, indicating the intervention's safety. Overall, our study results on feasibility and acceptability align with previous research, indicating that group psychological interventions are feasible, safe, and acceptable for inpatients with PSDs in acute care settings [16, 63, 103, 104]. This adds to the growing evidence contradicting the idea that psychotherapy is neither feasible nor helpful for this specific patient population [63].

Our LMMs moreover revealed promising results with medium-to-large effect sizes supporting hypothesised improvements on all secondary clinical measures. The decrease in negative symptoms is particularly noteworthy, as they greatly impair the functioning of those affected and have been reported to be resistant to pharmacotherapy and psychosocial treatments [105]. Participants in our study had significantly lower rehospitalisation rates compared to the average readmission rate of 50% within a year [106]. However, it's important to note that this interpretation is limited, as we only had access to readmission data from our hospital and not from other hospitals where patients may have been admitted during the follow-up period. The response rates in terms of PANSS reduction and CGI improvement moreover exceeded those of sole antipsychotic drug trials [102, 107], further supporting the potential clinical benefit of our mechanism-based intervention and meriting exploration in a larger scale study. Our findings are also consistent with above mentioned studies, which, next to demonstrating positive feasibility and acceptance, likewise presented preliminary encouraging results on clinical outcomes such as PANSS and WHODAS [16, 63, 103, 104].

Furthermore, our findings on assumed change mechanisms add support to the proof-of-concept of our underlying metacognitive treatment model. The post-Module-II improvements on cognitive insight measured with BCIS thereby are consistent with previous studies reporting

immediate small post-intervention effects on self-certainty scores, with positive effects on self-reflectiveness showing only at the six-month follow-up [108, 109]. This suggests a previously discussed "sleeper" effect of MCT [110], that needs further exploration in future research studying long-term effects of cognitive insight [82, 108]. Significant post-Module-III reductions of cognitive fusion on the other hand are comparable to previous research reporting medium effect size changes in CFQ scores after four weeks of mindfulness-based group therapy for inpatients with PSDs [63]. Literature moreover discusses the mediating role of cognitive defusion in increasing psychological flexibility and thus fostering effective coping necessary for reducing symptom believability, subjective symptom severity, and psychosis-related distress in acute inpatients [111–113]. In summary, findings on potential change mechanisms underlying the respective modules were promising, but further exploration through mediation analyses in a randomized controlled trial is necessary before making viable statements [40, 114, 115].

Strengths and limitations

The major strengths in our study included the adherence to a pre-registered trial protocol, pre-set feasibility benchmarks, the use of well-validated qualitative and quantitative assessments (rater and self-report), the detailed assessment of psychotropic medication, and use of complementary treatment elements to control for potential confounding variables. Moreover, the broad inclusion criteria (e.g. no restriction on substance abuse or ECT) allowed capturing a diverse range of patients that were actively involved in the intervention refinement through codesign activities during the whole study period [116]. In addition, the use of a contextualized, flexible (modularized) and targeted (change mechanisms) treatment approach allowed for individualized and tailored interventions, increasing the potential for positive treatment outcomes in acute inpatients with psychosis [36]. Finally, our LMM analyses captured the nested structure of our data and delivered more valid standard error estimates than common analysis of variance. In addition, we controlled for several confounders in our LMMs making our results on time effects on the outcome variables more reliable and unbiased, despite the small sample size.

As an exploratory phase II study, there are several methodological limitations to consider. Firstly, the lack of a control group and the absence of restrictions on additional treatment modalities make it difficult to reliably estimate the intervention's effectiveness. Despite controlling for covariates, preliminary clinical outcomes need to be viewed with caution since the intervention's effectiveness cannot be conclusively determined yet. Secondly, the assessments and therapy were mainly carried out by the same researchers. While assessments were strictly conducted according to

protocol, this could have led to biases. Nevertheless, there was consistency in the effects observed between rater-based and self-report measures. Thirdly, the small sample size limits the statistical power of our LMMs, although it can be considered sufficient to answer the question of feasibility and acceptability. Fourthly, no follow-up measurements were included to test lasting treatment effects on secondary clinical outcomes and change mechanisms. Fifthly, the overall positive feedback given in the open-ended sections in the modules' feedback questionnaires and the semi-structured interviews may be the result of a selection bias, as only patients who were already specifically "motivated" may have chosen to answer and/or to participate. Lastly, participants' personal therapy goals (see Supplementary Table 5) did not always match group contents. However, personal topics were discussed in individual sessions and treatment personalization will be subject to further research.

Future research should adjust therapy contents and the study's framework according to participants' feedback and feasibility measures, including bigger sample sizes, blinded assessments, randomization, and an active control condition not focusing on the targeted change mechanisms to explore the treatment's internal validity [115, 117] (see Supplementary Table 8 for planned adjustments). To provide further proof-of-concept for the metacognitive-based treatment model, additional mechanism measures should be added, such as direct measures of cognitive biases e.g. jumping to conclusion (JTC) bias [118] and theory of mind (ToM) impairments [119], along with mediation analyses and follow-up timepoints (also including information on readmissions to other hospitals) to examine the effects of change mechanisms [114, 115, 117, 120, 121]. The ultimate goal is to identify moderators of outcome to ensure the intervention is matched to the patient's need and personal therapy goals, hence providing personalized treatment [42, 122] (for further details see Supplementary Table 8).

Conclusion

Overall, the current results indicate that it is feasible and acceptable to conduct a mechanism-based and modularized group intervention focusing on metacognitive change mechanisms in acute psychiatric settings. The encouraging preliminary outcomes on clinical measures and change mechanisms moreover support the metacognitive treatment model. Further evaluation of the intervention and change mechanisms is warranted.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00406-023-01690-y>.

Acknowledgements The authors would like to thank the team of the acute psychiatric inpatient ward at the Max Planck Institute of

Psychiatry, who made a significant contribution to the successful implementation of the study. They also extend their gratitude to all study participants, whose valuable feedback greatly influenced the development process of the intervention. We also thank all co-therapists, especially Britta Maier, Leah Just, Dr. Rachele Sanfelici, and Dr. Romana Stoeckl, who provided coverage during vacations or illness to ensure continuous group therapy sessions. Finally, the authors would like to acknowledge the work of Prof. Steffen Moritz's research group, who provided valuable support as well as charge-free therapy materials used in the present study.

Author contributions EG, SL, SE and JKB conceptualized the intervention and study design. EG conducted the study with the support and supervision of JKB, SL, PF and SE. EG and CL organized the database, and performed data analysis, JKB supervised data analysis. EG and CL wrote the first draft of the manuscript. SL, PF, FP, SE and JKB carefully reviewed and edited the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

Funding Open Access funding enabled and organized by Projekt DEAL. This study was funded by the Max Planck Institute of Psychiatry and the Alfred Golombek Foundation.

Data availability Data contributing to the results are included in the article/Supplementary Material. Additional inquiries can be directed to the corresponding author.

Declarations

Conflict of interest The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics approval and consent to participate The study was conducted in accordance with the principles of the Declaration of Helsinki and received approval from the ethics committee of the Medical Faculty at Ludwig Maximilian University Munich (PNO-21-0025). All participants provided their written informed consent to participate in this study.

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Online Supplementary Material

Targeting metacognitive change mechanisms in acute inpatients with psychotic symptoms: Feasibility and acceptability of a modularized group intervention

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Table of Contents

SUPPLEMENTARY METHODS	3
SUPPLEMENTARY METHODS 1. BACKGROUND TO THE MECHANISM-BASED GROUP THERAPY CONCEPT FOR THE ACUTE PSYCHIATRIC INPATIENT WARD.....	3
SUPPLEMENTARY METHODS 2. ROUTINE CARE ON THE ACUTE PSYCHIATRIC INPATIENT WARD OF THE MAX-PLANCK-INSTITUTE OF PSYCHIATRY IN MUNICH, GERMANY	4
SUPPLEMENTARY METHODS 3. FEEDBACK QUESTIONNAIRE FOR THE MODULE DEFUSION	5
SUPPLEMENTARY METHODS 4. SEMI-STRUCTURED INTERVIEW CONDUCTED AT THE END OF THE INTERVENTION WITH SELECTED PARTICIPANTS	6
SUPPLEMENTARY FIGURES	7
SUPPLEMENTARY FIGURE 1. MECHANISM-BASED GROUP THERAPY CONCEPT ON THE ACUTE PSYCHIATRIC INPATIENT WARD	7
SUPPLEMENTARY FIGURE 2. PROBLEM MODEL OF SEVERE PSYCHOTIC SYMPTOMS, DANGER TO SELF AND OTHERS AND HOSPITALISATION	8
SUPPLEMENTARY FIGURE 3. UNDERLYING THERAPEUTIC MODEL OF THE MECHANISM-BASED GROUP INTERVENTION.....	9
SUPPLEMENTARY FIGURE 3. THEMATIC ANALYSIS OF THEMES AND SUB-THEMES FOR “POSITIVE GROUP ASPECTS” IN THE SEMI-STRUCTURED INTERVIEWS	10
SUPPLEMENTARY FIGURE 4. THEMATIC ANALYSIS OF THEMES AND SUB THEMES FOR “INSIGHTS FROM GROUP THERAPY” IN THE SEMI-STRUCTURED INTERVIEWS	11
SUPPLEMENTARY FIGURE 5. THEMATIC ANALYSIS OF THEMES AND SUB THEMES FOR “NEGATIVE GROUP ASPECTS” IN THE SEMI-STRUCTURED INTERVIEWS	12
SUPPLEMENTARY FIGURE 6. THEMATIC ANALYSIS OF THEMES AND SUB THEMES FOR “STUDY SETUP” IN THE SEMI-STRUCTURED INTERVIEWS	13
SUPPLEMENTARY TABLES	14
SUPPLEMENTARY TABLE 1. OVERVIEW OF INTERVENTION’S OBJECTIVES AND CORE EXERCISES	14
SUPPLEMENTARY TABLE 2. PARTICIPANTS’ ATTENDANCE RATES AND REASONS FOR NON-ATTENDANCE ..	16
SUPPLEMENTARY TABLE 3. PARTICIPANTS’ QUALITATIVE FEEDBACK ON THE FEEDBACK QUESTIONNAIRES OF EACH MODULE AND THE OVERALL INTERVENTION.....	17
SUPPLEMENTARY TABLE 4. PARTICIPATION IN SUPPLEMENTARY TREATMENTS ADDITIONALLY TO THE EXPERIMENTAL GROUP THERAPY	19
SUPPLEMENTARY TABLE 5. CONTENT OF INDIVIDUAL PSYCHOTHERAPY SESSIONS DURING THE STUDY PERIOD	20
SUPPLEMENTARY TABLE 6. TRANSCRIPT NOTES OF INDIVIDUAL QUOTES SUPPORTING THE THEMATIC ANALYSIS FOR EACH QUESTION IN THE SEMI-STRUCTURED INTERVIEW.....	24
SUPPLEMENTARY TABLE 7. CODES IDENTIFIED FOR EACH PARTICIPANT FOR THE THEMATIC ANALYSIS OF THE SEMI-STRUCTURED INTERVIEW	26
SUPPLEMENTARY TABLE 8. RECOMMENDATIONS FOR FUTURE RESEARCH.....	30
REFERENCES	33

Supplementary Methods

Supplementary Methods 1. Background to the mechanism-based group therapy concept for the acute psychiatric inpatient ward

The experimental mechanism-based group therapy for inpatients with acute psychosis was part of an already established modular and mechanism-based psychosocial group therapy concept on the acute psychiatric inpatient ward. The existing concept thereby covered the change mechanisms of distress tolerance, impulsivity reduction, behavioural activation, information processing, and self-management, which have been identified as relevant treatment targets in acute psychiatric settings [1, 2]. Based on this selection and with reference to evidence-based treatment manuals, we implemented four group modules, including a transdiagnostic Skillstraining, a transdiagnostic Resource Group, a transdiagnostic Psychoeducation Group and a transdiagnostic Crisis-Competence-Group (see Supplementary Figure 1). All group modules were adapted to a crisis-focused setting by being brief, easy to understand and coping-oriented [3].

Due to the lack of available treatments specifically tailored for inpatients with acute psychotic symptoms [4], a new mechanism-based group was developed (see Supplementary Figure 1). As there was limited evidence available for existing concepts in this patient population and setting, a rigorous scientific process was followed during the intervention design [5] and feasibility study [6], which we described in our previous [7] and current work. Our target inpatient group for the design and evaluation study encompassed the entire psychosis-spectrum, including affective disorders with psychotic symptoms and comorbid diagnosis. However, we ensured that the group was also designed using transdiagnostic principles to allow for future expansion to other patient populations.

Our feasibility study resembles an early Phase II clinical trial with the aim of testing the feasibility, acceptability and safety of the novel intervention with a small amount of diverse participants [8, 9]. Given that the group treatment is feasible and safe, we plan to further study the effect of hypothesized change mechanisms with the help of mediation analyses in Phase III and IV studies. Moreover, our goal is to further evaluate which patients will particularly benefit from the concept by studying moderators [10]. Therewith, our ultimate goal is to personalize treatment and optimize outcomes by a) identifying patients' relevant change mechanisms right on admission, b) creating a treatment plan that combines interventions targeting various key change mechanisms, and c) offering treatment in different therapeutic modes e.g. individual and group therapy to meet patients' needs (see Supplementary Figure 1) [11–13].

Supplementary Methods 2. Routine care on the acute psychiatric inpatient ward of the Max-Planck-Institute of Psychiatry in Munich, Germany

1) Target patient group and treatment mission

24 available beds for individuals with severe symptoms and acute crises. The treatment spectrum covers all diagnoses with a particular focus on psychosis-spectrum disorders. Treatment goals include detailed differential diagnostic assessment, medication adjustment, crisis intervention, reinforcement of coping strategies, family involvement, psychosocial counselling and referral, and discharge management. Psychiatric detention may be ordered to protect patients from danger to themselves or others.

2) Staffing on the acute psychiatric inpatient ward

- Two to three nurses each shift (morning, day, night)
- One senior physician and three residents
- One psychologist trained in CBT
- One social worker, one occupational therapist
- Work for different wards: Nutritionist, physiotherapist, internist, and sports therapist

3) Treatment options on the acute psychiatric inpatient ward

- Neurological assessment (i.e. MRI, Computed tomography, lumbar puncture)
- (Psychotropic) medication
- Electroconvulsive therapy
- Transcranial magnetic stimulation
- Physician's consultation (25 minutes per week)
- Senior physician rounds (15 minutes per week)
- Individual psychotherapy (25 to 50 minutes per week)
- Group psychotherapy (50-100 minutes per week)
- Social counseling
- Occupational therapy
- Sports therapy
- Optional: Nutritional counseling and physical therapy

Supplementary Methods 3. Feedback questionnaire for the Module Defusion**Feedback questionnaire Module *Defusion***

Study-ID: _____ Date: _____

How did you experience the last four therapy sessions on the Defusion module? Please indicate how much the following 16 statements apply to you according to the rating scale shown below. Please edit all statements, even if some of the content may not seem entirely appropriate to you.

0 = Does not apply at all; 1 = Applies to a small extent; 2 = Applies to some extent; 3 = Applies to a great extent; 4 = Applies exactly

1. I found the Defusion module useful and helpful.	0	1	2	3	4
2. I was able to understand the contents of the module well.	0	1	2	3	4
3. I can apply the contents of the module well in my everyday life.	0	1	2	3	4
4. The module has given me suggestions on how to cope with my complaints.	0	1	2	3	4
5. The objectives of the module are clear to me.	0	1	2	3	4
6. I had fun in the sessions.	0	1	2	3	4
7. I would rather spend my time elsewhere than in group therapy.	0	1	2	3	4
8. I think it is good that the therapy takes place in the group.	0	1	2	3	4
9. I felt comfortable in the group.	0	1	2	3	4
10. After this module I think that this form of therapy is promising for my treatment.	0	1	2	3	4
11. I would recommend this module to other patients.	0	1	2	3	4
12. Overall I am satisfied with the Defusion module.	0	1	2	3	4

13. What do you think about the number of sessions in the Defusion module (4 sessions)?

- a) Too few b) just right c) too many

14. What do you think about the duration of the sessions (60 min.)?

- a) Too short b) just right c) too long

15. What did you personally take away from the Defusion module?

16. Which topics that you find important have not been taken into account enough?

Supplementary Methods 4. Semi-structured interview conducted at the end of the intervention with selected participants

Semi-structured interview to explore patients' subjective experience of the group therapy

Main questions

(Prompts are in italics)

- 1) Can you tell me about what you liked about our group therapy?
 - *What was it like taking part?*
 - *Did you feel comfortable in the group?*
 - *Did you like the setting and kind of exercises?*
 - *Did the main topic of the group appeal to you?*

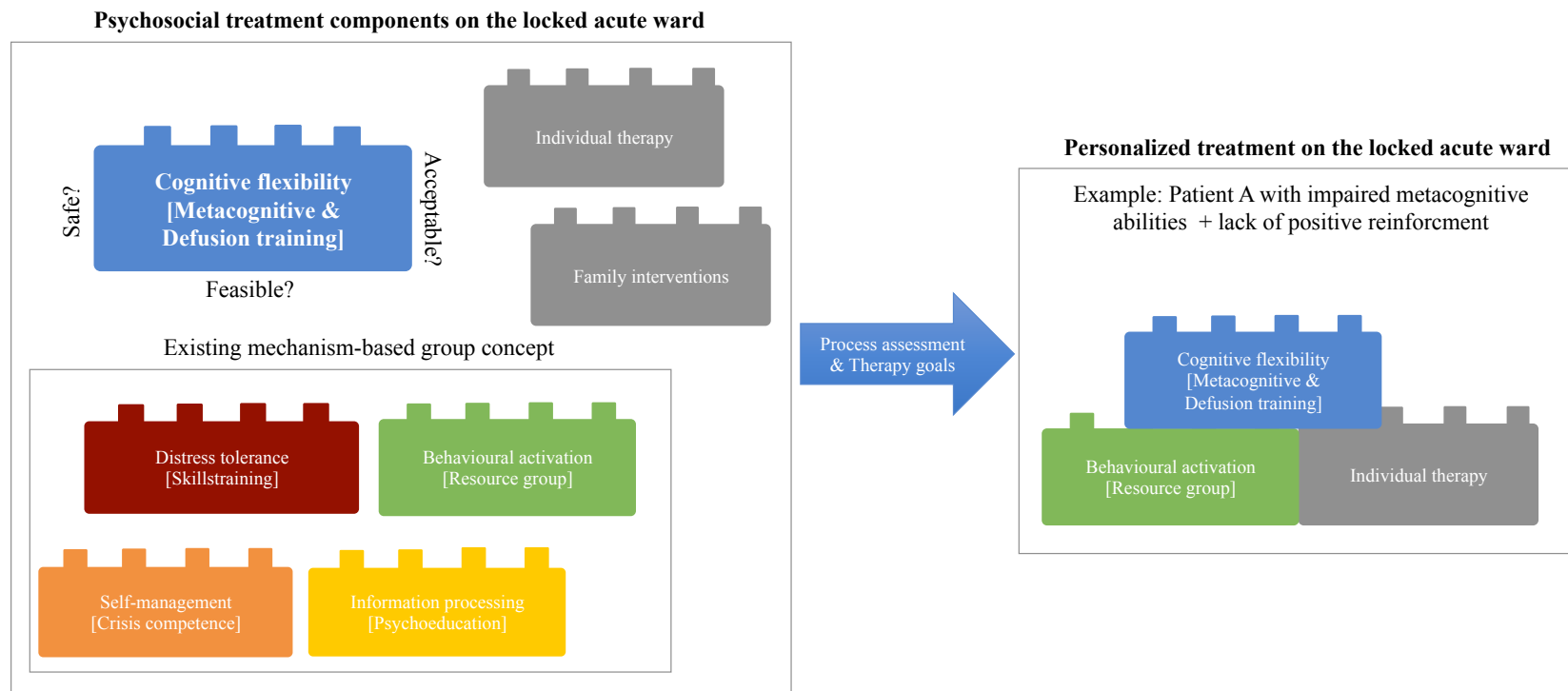
- 2) What insights and strategies for dealing with your thoughts will you take away from the group?
 - *What have you learned in general about your thoughts?*
 - *Are there any particular exercises you liked?*
 - *Are you already using new strategies in dealing with your thoughts?*

- 3) Was there anything you didn't like about the group?
 - *Did you have difficulties following the topics?*
 - *Did you have difficulties joining the exercises?*
 - *Would you rather have participated in a different group?*

- 4) How do you evaluate the framework of the group therapy?
 - *How do you rate the frequency and duration of the group sessions?*
 - *How do you rate the frequency and effort of the questionnaires?*
 - *Any suggestions for the future? Anything else you would like to add?*

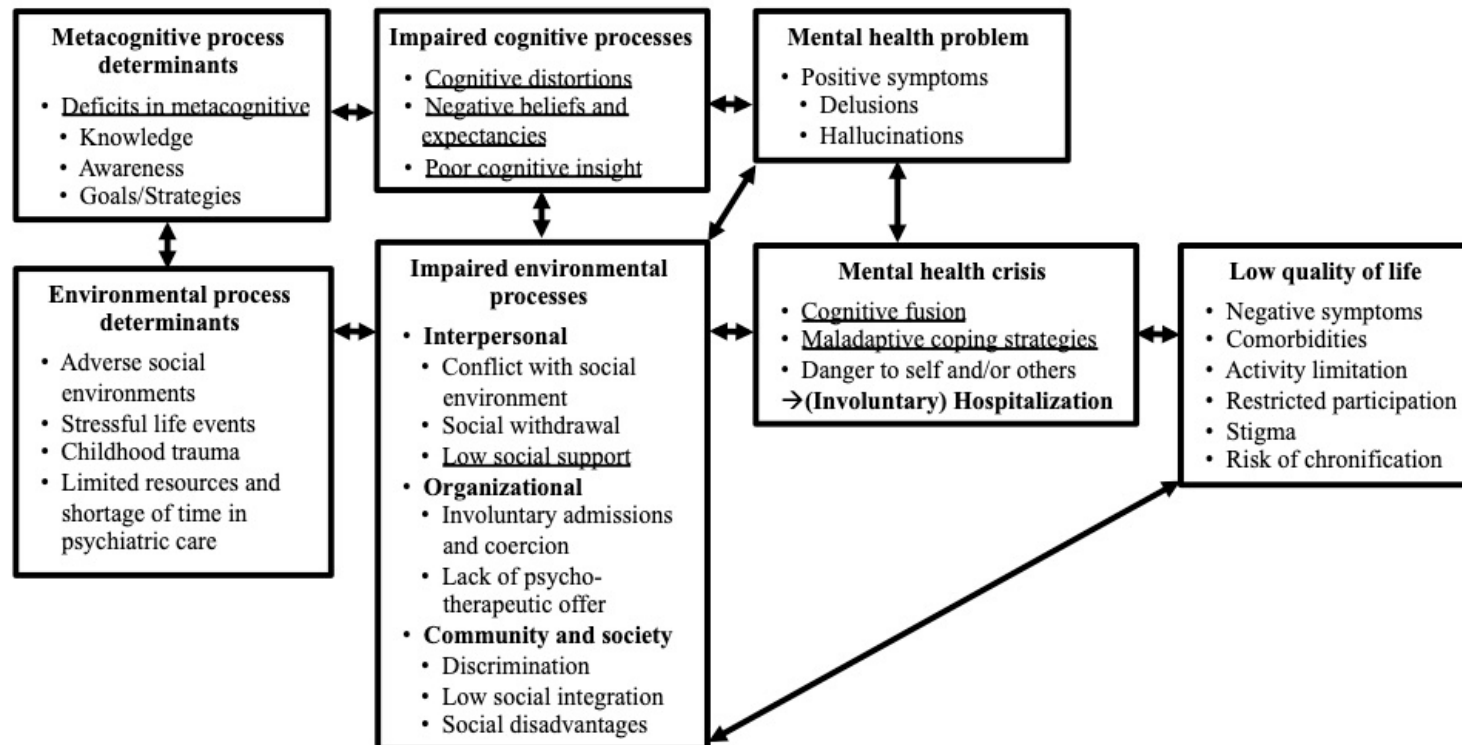
Supplementary Figures

Supplementary Figure 1. Mechanism-based group therapy concept on the acute psychiatric inpatient ward



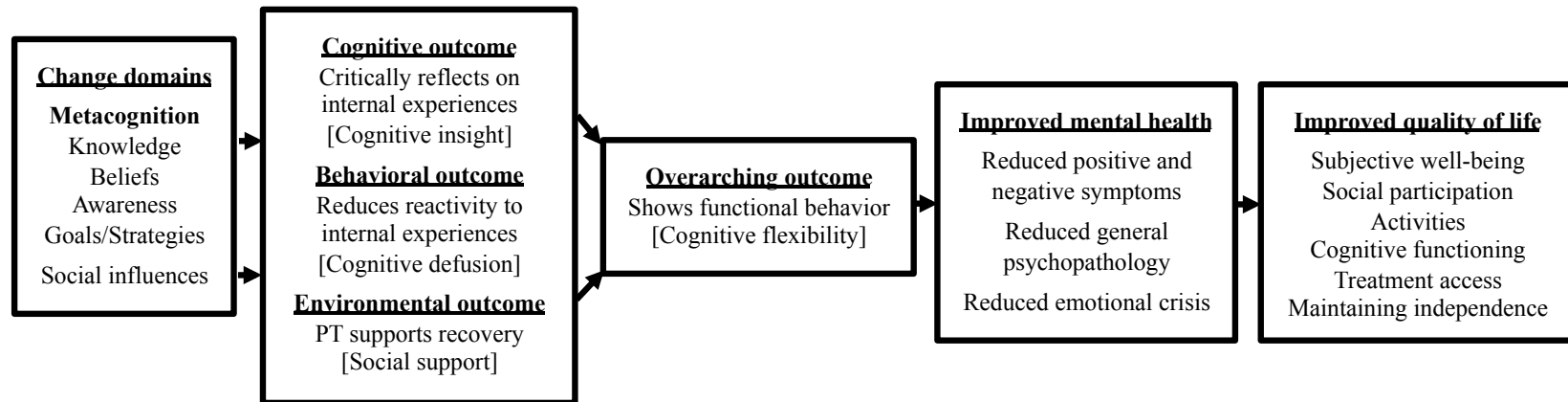
Note. Reprinted from “Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: An Intervention Mapping approach” [7]. Psychosocial treatment components present the targeted change mechanism with the name of the respective group/treatment module in square brackets. Existing mechanism-based groups on the acute psychiatric inpatient ward include a) a transdiagnostic Skillstraining (in total three sessions covering psychoeducation on tension regulation, testing of different stress-tolerance-skills, development of emergency plans and skill chains), b) a transdiagnostic Resource Group (in total three sessions covering psychoeducation on depression upward- and downward-spiral, development of positive activities and resources, day and week planning), c) a transdiagnostic Crisis-Competence Group (in total four sessions covering crisis formulation, early warning signs and coping strategies, emergency plan and discharge planning, and d) a transdiagnostic Psychoeducation Group (in total three sessions covering information on diathesis-stress-model, medication, and treatment options). All groups were adapted from existing group manuals [14–17] to fit the acute inpatient setting. Each group session lasts 50 minutes and takes place weekly. Inpatients are able to participate in two group therapies with the option for individual therapy. The experimental mechanism-based group therapy (in blue) was specifically designed for inpatients with acute psychotic symptoms and takes place twice a week with a total of nine sessions. The ultimate goal of the mechanism-based concept is to individually tailor treatment for acute inpatients by allocating them to the group therapies most likely to target individually relevant change mechanisms and personal preferences.

Supplementary Figure 2. Problem model of severe psychotic symptoms, danger to self and others and hospitalisation



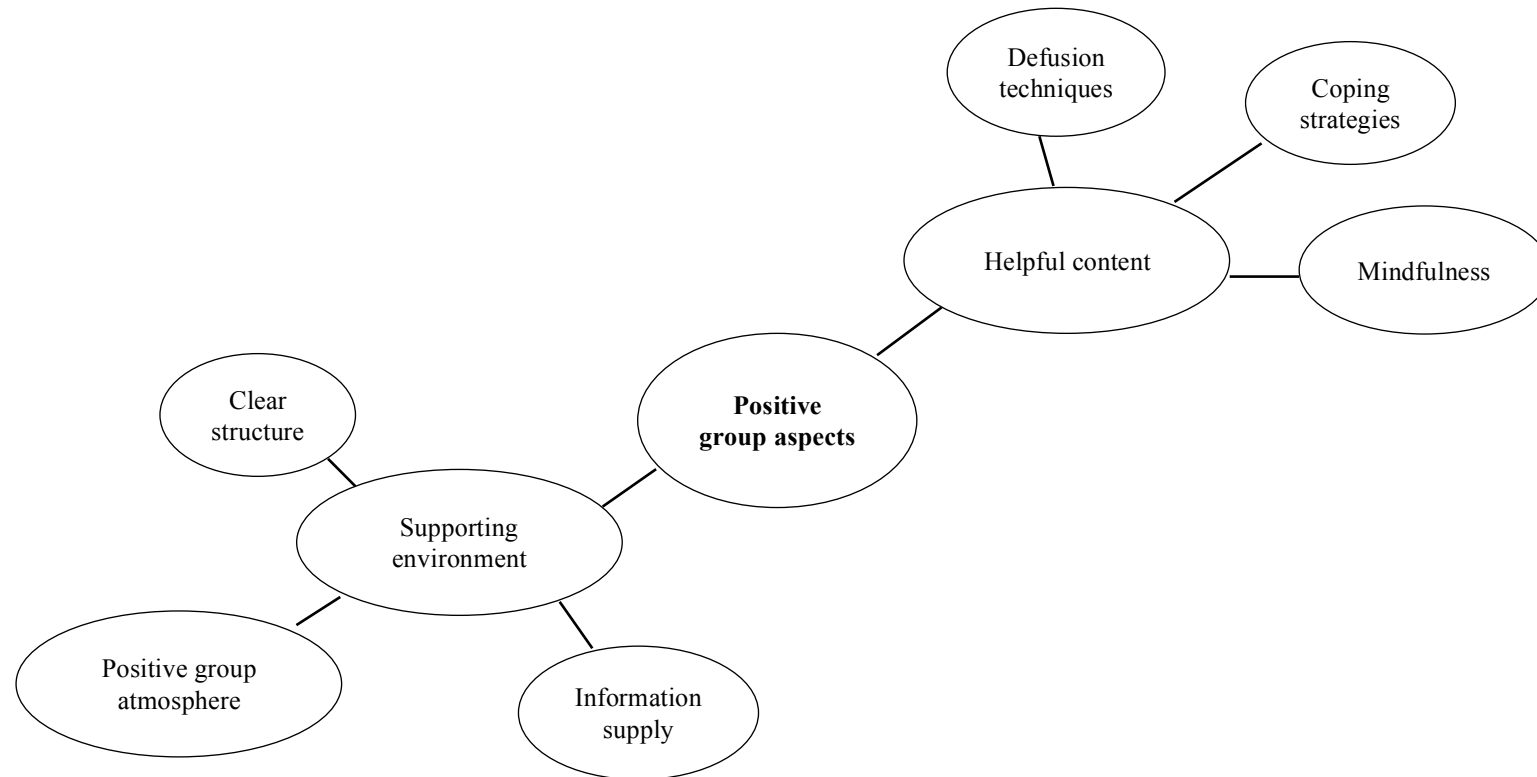
Note. Reprinted from “Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: An Intervention Mapping approach” [7]. Logical model of the problem of severe psychotic symptoms, danger to self and others, (involuntary) hospitalization and a resulting low quality of life. The model has a focus on psychological and social factors in the development of acute psychosis and does not consider biological factors e.g. genetics [18–22]. It moreover does not map the moderating or mediating relationships between variables, but rather aims to visualize the variability of factors and impaired processes that contribute to the main problems. Impaired processes that were identified as target areas for the underlying therapeutic model are underlined.

Supplementary Figure 3. Underlying therapeutic model of the mechanism-based group intervention



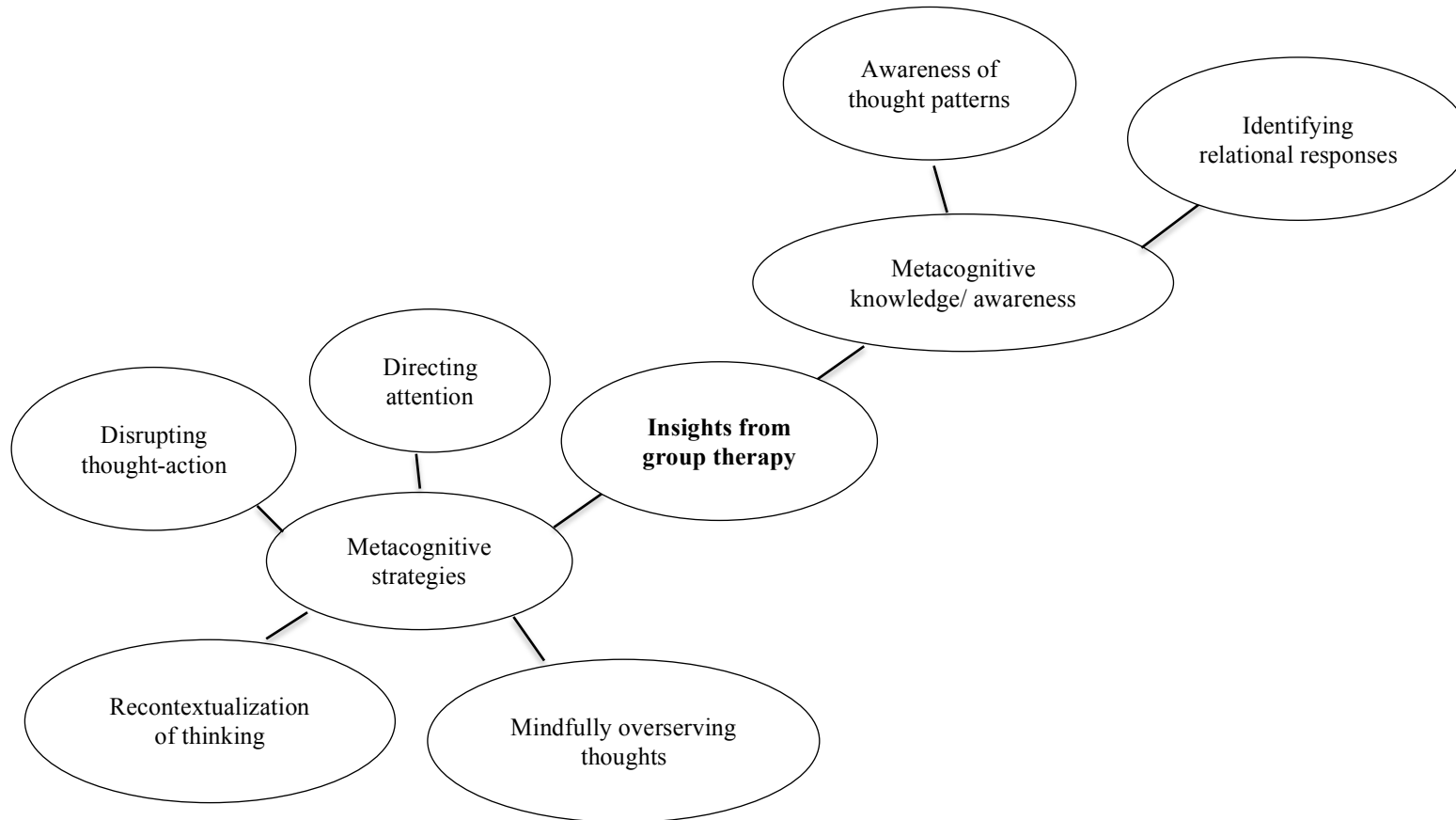
Note. Reprinted from “Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: An Intervention Mapping approach” [7]. Underlying therapeutic change model showing what change is needed to manage severe psychotic symptoms acute crises. It points out the metacognitive change domains and belonging change mechanisms expected to influence the cognitive, behavioural and environmental outcomes that are in turn believed to improve mental health and quality of life. Hypothesized underlying target change mechanisms are put into square brackets. Regarding different psychotic symptoms, the intervention employs a cognitive perspective with auditory hallucinations being viewed as intrusive thoughts amplified and externalized through cognitive dissonance [23]. Hence, both delusional thoughts and hallucinations are referred to as distressing internal experiences, which generally creates a destigmatizing and normalizing therapy language [24].

Supplementary Figure 3. Thematic analysis of themes and sub-themes for “positive group aspects” in the semi-structured interviews

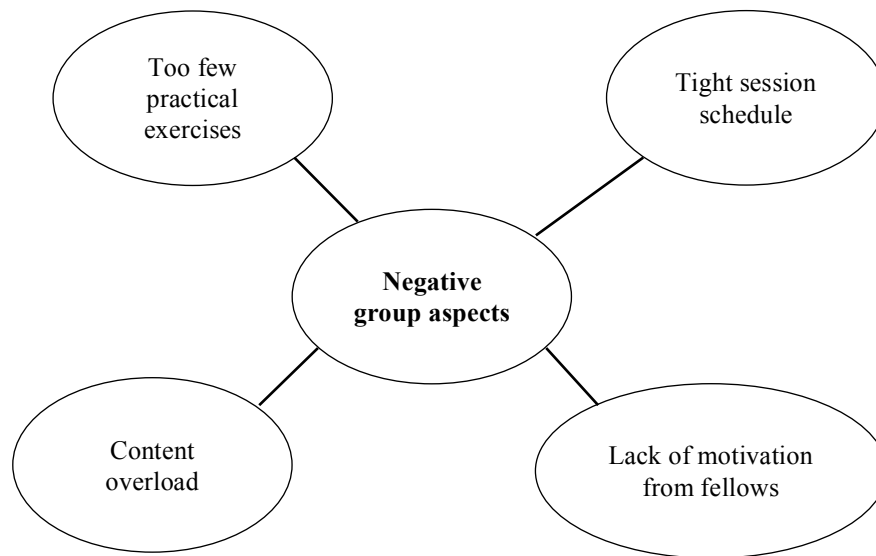


Note. Thematic analysis for participants’ answers on the question “Can you tell me about what you liked about our group therapy?” in the semi-structured interview (see Supplementary Methods 4) revealed two themes with subthemes (see Supplementary Tables 6 and 7). Topics included helpful therapy contents (Defusion techniques, Coping strategies and Mindfulness) and supporting environment (Clear structure, Positive group atmosphere, and Information supply).

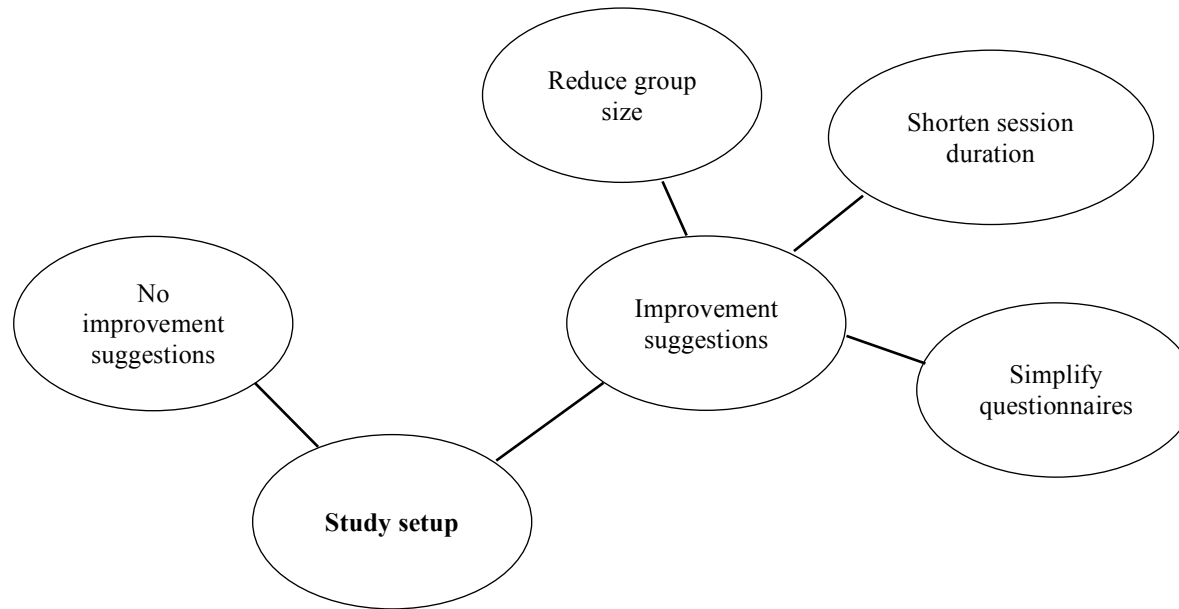
Supplementary Figure 4. Thematic analysis of themes and sub themes for “insights from group therapy” in the semi-structured interviews



Note. Thematic analysis for participants’ answers on the question “What insights and strategies for dealing with your thoughts will you take away from the group?” in the semi-structured interview (see Supplementary Methods 4) revealed themes and subthemes on metacognitive knowledge and awareness (Awareness of thought patters and Identifying relation responses) and metacognitive strategies (Directing attention, Mindfulness, Disrupting thought-action and Recontextualization) (see Supplementary Tables 6 and 7).

Supplementary Figure 5. Thematic analysis of themes and sub themes for “negative group aspects” in the semi-structured interviews

Note. Thematic analysis for participants’ answers on the question “Was there anything you didn’t like about the group?” in the semi-structured interview (see Supplementary Methods 4) included tight session schedules, partial content overload, too few practical exercises and a lack of motivation from fellow participants (see Supplementary Tables 6 and 7).

Supplementary Figure 6. Thematic analysis of themes and sub themes for “study setup” in the semi-structured interviews

Note. Thematic analysis for participants’ answers on the question “How do you evaluate the framework of the group therapy?” in the semi-structured interview (see Supplementary Methods 4) comprised reducing group size, shortening session duration, and simplifying feedback questionnaires (see Supplementary Tables 6 and 7).

Supplementary Tables

Supplementary Table 1. Overview of intervention's objectives and core exercises

Session	Title, main objective and target change mechanism	Core exercises and metaphors
1	<p>Psychoeducation <u>Objective:</u> Understanding the cognitive model, awareness of problematic cognitive biases and over identification/reaction to them <u>Target mechanism:</u> Knowledge increase</p>	<p>Developing theory based on an everyday example (“Imagine your friend doesn’t call on your birthday”) and interactive group discussion <u>Source:</u> MCT for depression [25]</p>
Module Cognitive Insight [Metacognitive knowledge and awareness]		
2	<p>Finding explanations <u>Objective:</u> Changing dysfunctional attributional patterns by understanding that multiple factors can lead to a scenario <u>Target mechanism:</u> Attributional reasoning</p>	<p>Contemplating different causes for everyday examples and discussing negative consequences of monocausal attributions <u>Source:</u> MCT for psychosis and MCT-acute [26, 27]</p>
3	<p>Jumping to conclusions <u>Objective:</u> Avoiding premature first impressions, adjusting conclusion when new information emerges <u>Target mechanism:</u> Interpretative reasoning</p>	<p>Holding back and revising premature decisions with the help of various fragmented picture tasks where patients have to guess the object behind it <u>Source:</u> MCT for psychosis and MCT-acute [26, 27]</p>
4	<p>To empathize <u>Objective:</u> Understanding that facial expressions can easily be misinterpreted, considering various information sources when assessing your opposite <u>Target mechanism:</u> Social reasoning</p>	<p>Trying to guess what a person may feel or intends to do by judging pictures of their faces and discussing everyday examples <u>Source:</u> MCT for psychosis and MCT-acute [26, 27]</p>
5	<p>Mood and self-esteem <u>Objective:</u> Recognizing dysfunctional thinking styles, finding alternative views and engaging in positive actions <u>Target mechanism:</u> Cognitive reappraisal</p>	<p>Gathering symptoms of depression, finding more helpful thoughts for negative cognitive schemas in various everyday examples, collecting positive activities to counteract depressive mood and low self-esteem <u>Source:</u> MCT for psychosis and MCT-acute [26, 27]</p>
Module Cognitive Defusion [Metacognitive goals and strategies]		
6	<p>Noticing thoughts <u>Objective:</u> Being more present in the moment, noticing inner and outer sensations and responding more consciously to them <u>Target mechanism:</u> Mindfulness</p>	<p>Practicing mindfulness for external (mindfully eating chocolate) and internal (observing thoughts) experiences, metaphors: “life on autopilot”, being a “distant observer” <u>Source:</u> ACT for psychosis [28]</p>
7	<p>How our mind works <u>Objective:</u> Developing a different relationship towards thoughts by understanding that they mostly consist of automatic rules and judgments learned in our past, giving thoughts less power dictating our behaviour <u>Target mechanism:</u> Goal-orientated action planning</p>	<p>Debunking thoughts by distinguishing between facts and appraisals (Bad Cup), noticing automaticity and uncontrollability of thoughts (“Mary had a little lamb” and “Don’t think of a pink elephant”) and acting contrary to thoughts (“Don’t do what your mind says”), metaphors: mind as a production machinery and hard drive with data garbage <u>Source:</u> ACT metaphors [29] and ACT for life [30]</p>
8	<p>Helpful vs. unhelpful thoughts <u>Objective:</u> Distinguishing between helpful and unhelpful internal experiences and learning to act contrary to</p>	<p>Classifying everyday thoughts in unhelpful and helpful thoughts, actively executing defusion in “Taking your</p>

<p>them without trying to avoid or control them <u>Target mechanism:</u> Disidentification</p>	<p>mind for a walk”, metaphors: thoughts as ankle cuffs vs. tools <u>Source:</u> ACT for psychosis [28]</p>
<p>9 Defusion techniques <u>Objective:</u> Learning to actively distance from internal experiences by using cognitive and behavioural strategies <u>Target mechanism:</u> Self-regulation</p>	<p>Trying out different defusion and detached mindfulness techniques e.g. “labeling thoughts”, “floating leaves on a stream” and “Attention training technique” and choosing one for the “instruction manual for the mind”, metaphors: mind as parrot always telling the same story, the little “mind monster” <u>Source:</u> ACT metaphors [29], ACT for psychosis [28], Metacognitive Therapy for anxiety and depression [31]</p>

Note. Reprinted from “Developing a mechanism-based therapy for acute psychiatric inpatients with psychotic symptoms: An Intervention Mapping approach” [7].

Supplementary Table 2. Participants' attendance rates and reasons for non-attendance

Session	1	2	3	4	5	6	7	8	9
Attendance N (missing n)	36 (2)	37 (5)	37 (1)	37 (4)	37 (5)	35 (4)	35 (5)	35 (5)	35 (8)
Attendance rate (%)	94.4	86.5	97.3	89.2	86.5	88.6	85.7	85.7	77.1
Reason for non-attendance, n									
Lack of motivation	1	1			1	1	1	1	1
Non-capable		1	1	1	2		1	2	4
Isolation room	1								
Other appointment		3		2	2	2	2	2	2
Disorganized				1		1	1		1

Note. The N for attendance refers to all participants who hypothetically could have participated in the session, i.e., still participated in the study in the corresponding module (see Consort Flow Diagram). 36 of the 37 participants were in the study for Module I (Session 1), 37 for Module II (Session 2-6), and 35 for Module III (Session 6-9). The mean group therapy dose received by participants was 465.4 minutes ($SD = 93.2$), corresponding to eight sessions.

Supplementary Table 3. Participants' qualitative feedback on the feedback questionnaires of each module and the overall intervention

Item	Psychoeducation	Cognitive Insight	Cognitive Defusion	Overall
Feedback provided on insights from the modules, N (missing n)	34 (7)	37 (8)	35 (11)	35 (16)
Unspecific answers (example quotations)	<p>“The therapist was very caring.” (P20)</p> <p>“This gave me motivation to fight.” (P56)</p> <p>“More fun in life, skills for healing.”(P37)</p>	<p>“More inner calmness.” (P30)</p> <p>“Strengthened self-worth.” (P70)</p> <p>“The construct of every session.” (P64)</p>	<p>“Allow myself more rest, want to stop drinking that much coffee.” (P30)</p> <p>“One should get help when having problems.” (P90)</p>	<p>“Very helpful for the future.” (P77)</p> <p>“New experiences on with other people.” (P05)</p> <p>“Nothing.” (P46)</p> <p>“Interest and motivation.” (P89)</p>
Specific answers (example quotations)	<p>“Thoughts influence behaviour.” (P61)</p> <p>“I can change something about the way I think and therewith, I can change my problems.” (P80)</p> <p>“Learning how to deal with thoughts is important.” (P44)</p>	<p>“I will focus more on myself.” (P26)</p> <p>“Careful with JTC, wait until you know what the other wants.” (P53)</p> <p>“My judgment is influenced by emotional factors. In order to not harm myself, I must not decide hastily and under pressure, but evaluate calmly. Keyword thinking traps.” (P66)</p> <p>“Not to cling to thoughts and go into the thought trap.” (P77)</p>	<p>“One can learn to treat thoughts differently.” (P49)</p> <p>“Notice my thoughts actively and distinguish whether they are helpful or not and how much they influence my behaviour.” (P33)</p> <p>“I don't have to control my thoughts, thoughts are thoughts and not facts.” (P58)</p>	<p>“I learned how to differentiate between helpful and not helpful thoughts.” (P96)</p> <p>“I can steer my thoughts.” (P28)</p> <p>“The group helped me to see that many fight against the same problems and that there are many ways to cope with them.” (P22)</p> <p>“Taking metacognitive perspective, balancing thoughts, not taking decisions with too few information.” (P47)</p>
Feedback provided on missing topics in the modules, N (missing n)	34 (26)	37 (27)	35 (12)	35 (30)
Unspecific answers (example quotations)	<p>“The interior of my pockets.” (P28)</p> <p>“There were too few participants.” (P39)</p>	-	<p>“Some things were too fast.” (P58)</p>	<p>“Personal topics and examples.” (P53)</p> <p>“Talking about topics in individual session to recognize what helps me.” (P20)</p>

Specific answers (example quotations)	“Thoughts versus voices.” (P80) “Skills and how to stop thoughts.” (P20)	“How to handle incomplete in- formation, decision aids for ac- cepting things.” (P24) “I need more tips on how to train my memory. I know this doesn't fit with the problems of the oth- ers.” (P16) “We only talked about thoughts, I would be interested also in audito- ry hallucinations, do we handle them just the same way as thoughts?” (P80)	“Discuss thoughts during acute psychosis.” (P49) “How do I differentiate between helpful and not helpful if thoughts are very complex?” (P24)	“Social competencies.” (P08)
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Supplementary Table 4. Participation in supplementary treatments additionally to the experimental group therapy

Supplementary treatments (multiple therapies possible), n (%)	37 (100)
Individual psychotherapy	37 (100)
Other group therapy	26 (72.9)
Occupational therapy	37 (100)
Sports therapy	28 (75.7)
Electroconvulsive therapy	5 (13.5)

Note. Participants were able to take part in one other group therapy module besides the experimental group intervention. Supplementary group therapies included a transdiagnostic Skillstraining, a Resource Group, a Psychoeducation Group and a Crisis-competence Group (see Supplementary Methods 1). All participants received individual sessions. The accumulated mean therapy dose including group therapy and individual sessions resulted in a total therapy dose of 711.3 minutes (SD = 103.55) during the study period.

Supplementary Table 5. Content of individual psychotherapy sessions during the study period

ID	Individual therapy dose (minutes)	Therapy goals	Topics and therapeutic techniques related to group	Topics and therapeutic techniques not related to group	Homework
P41	250	1. Tension regulation 2. Value exploration	1. Defusion techniques 2. Value commitment	1. Crisis formulation 2. Skillstraining	1. Skillstraining
P89	300	1. Distancing to thoughts 2. Behavioural activation	1. Identifying unhelpful thoughts 2. Defusion techniques	1. Crisis formulation 2. Behavioural activation 3. Emotion regulation 4. Trauma exploration	1. Defusion techniques
P53	400	1. Grief management 2. Value exploration	1. Acceptance 2. Defusion techniques 3. Value commitment	1. Crisis formulation 2. Psychoeducation depression 3. Behavioural activation	1. Grief exposition 2. Defusion techniques 2. Positive activities
P26	250	1. Stress management 2. Distancing to thoughts	1. Psychoeducation psychosis 2. Defusion techniques	1. Crisis formulation 2. Behavioural activation	None
P49	250	1. Stress management	-	1. Crisis formulation 2. Stress management 3. Relapse prevention	1. Stress management
P33	300	1. Psychoeducation 2. Stress management	1. Psychoeducation psychosis 2. Defusion techniques	1. Crisis formulation 2. Relapse prevention	1. Stress management
P64	250	1. Distancing to thoughts 2. Behavioural activation	1. Acceptance 2. Defusion techniques	1. Crisis formulation 2. Behavioural activation 3. Relaxation techniques	1. Defusion techniques 2. Relaxation techniques
P03	300	1. Distancing to voices 2. Value exploration	1. Thought disputation 2. Defusion techniques 3. Value commitment	1. Crisis formulation 2. Motivational interviewing 3. Behavioural activation	1. Defusion techniques
P77	200	1. Distancing to thoughts 2. Emotion regulation	1. Defusion techniques	1. Crisis formulation 2. Emotion regulation 3. Relaxation techniques	1. Defusion techniques 2. Relaxation techniques
P37	150	1. Tension regulation	-	1. Crisis formulation 2. Skillstraining 3. Relapse prevention	1. Organization further treatment
P83	250	1. Distancing to thoughts 2. Emotion regulation	1. Defusion techniques 2. Acceptance	1. Crisis formulation 2. Skillstraining	1. Defusion techniques 2. Skillstraining

Supplementary Material

P08	250	1. Distancing to thoughts 2. Emotion regulation	1. Psychoeducation psychosis	3. Social competencies 4. Behavioural activation 1. Crisis formulation 2. Stress management 3. Social competencies	3. Behavioural activation 1. Relapse prevention
P58	200	1. Distancing to thoughts	1. Psychoeducation psychosis 2. Defusion techniques	1. Crisis formulation	1. Defusion techniques
P24	200	1. Stress management	1. Acceptance	1. Crisis formulation 2. Emotion regulation 3. Trauma exploration	-
P96	200	1. Social competencies 2. Behavioural activation	1. Defusion techniques 2. Acceptance	1. Crisis formulation 2. Biographical work 3. Diagnostic clarification	1. Behavioural activation
P30	200	1. Value clarification 2. Behavioural activation	1. Defusion techniques 2. Value commitment	1. Crisis formulation 2. Social competencies	1. Problem solving techniques
P74	350	1. Tension regulation 2. Value clarification	1. Defusion techniques 2. Acceptance 3. Value commitment	1. Crisis formulation 2. Skillstraining 3. Behavioural activation	1. Defusion techniques 2. Skillstraining
P61	250	1. Illness acceptance 2. Emotion regulation	1. Thought disputation 2. Defusion techniques 3. Value commitment	1. Crisis formulation 2. Emotional exposition	1. Behavioural activation
P28	300	1. Psychoeducation 2. Sleeping hygiene 3. Distancing to thoughts	1. Psychoeducation psychosis 2. Thought disputation 3. Defusion techniques	1. Crisis formulation 2. Sleep hygiene	1. Thought disputation 2. Defusion techniques
P80	250	1. Distancing to thoughts 2. Behavioural activation	1. Thought disputation	1. Crisis formulation 2. Motivational interviewing 3. Relapse prevention	1. Relapse prevention
P06	250	1. Improving self-esteem	1. Value exploration 2. Defusion techniques	1. Crisis formulation 2. Diagnostic clarification	1. Defusion techniques
P93	250	1. Distancing to thoughts 2. Emotion regulation	1. Thought disputation 2. Defusion techniques	1. Crisis formulation 2. Emotional exposition 3. Behavioural activation	1. Defusion techniques 2. Behavioural activation
P46	250	1. Value commitment	1. Psychoeducation psychosis	1. Crisis formulation 2. Trauma exploration	-

Supplementary Material

P16	200	1. Value commitment	1. Thought disputation	1. Crisis formulation 2. Self care	-
P86	300	1. Distancing to hallucinations 2. Stress management	1. Defusion techniques	1. Crisis formulation 2. Biographical work	-
P05	200	1. Psychoeducation 2. Behavioural activation	1. Psychoeducation psychosis	1. Crisis formulation	-
P39	200	1. Behavioural activation 2. Grief management	-	1. Crisis formulation 2. Grief exposition	1. Grief work
P20	250	1. Distancing to thoughts	1. Psychoeducation psychosis 2. Thought disputation	1. Crisis formulation	1. Thought disputation
P11	150	1. Distancing to hallucinations	1. Defusion techniques	1. Crisis formulation 2. Behavioural activation	1. Defusion techniques
P90	250	1. Distancing to thoughts 2. Psychoeducation	1. Psychoeducation psychosis	1. Crisis formulation 2. Stress management 3. Resource activation	1. Social competencies
P22	250	1. Distancing to thoughts 2. Psychoeducation	1. Psychoeducation psychosis 2. Thought disputation	1. Crisis formulation 2. Behavioural activation 2. Stress management	1. Behavioural activation
P44	350	1. Illness acceptance 2. Behavioural activation	1. Psychoeducation psychosis	1. Crisis formulation 2. Social competencies 3. Emotion regulation 4. Behavioural activation	1. Behavioural activation
P66	250	1. Distancing to thoughts	1. Thought disputation 2. Defusion techniques	1. Crisis formulation 2. Psychoeducation depression	1. Defusion techniques 2. Behavioural activation
P47	250	1. Distancing to thoughts 2. Distancing to voices	1. Defusion techniques	1. Crisis formulation 2. Stress management	1. Defusion techniques
P70	200	1. Psychoeducation 2. Distancing to thoughts	1. Psychoeducation psychosis 2. Defusion techniques 3. Value clarification	1. Crisis formulation 2. Relapse prevention	1. Defusion techniques
P56	200	1. Psychoeducation 2. Distancing to thoughts	1. Psychoeducation psychosis 2. Acceptance	1. Crisis formulation	-

Supplementary Material

P02	200	1. Psychoeducation 2. Distancing to thoughts	1. Thought disputation 2. Defusion techniques	1. Social competencies	1. Thought disputation
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Supplementary Table 6. Transcript notes of individual quotes supporting the thematic analysis for each question in the semi-structured interview

ID	Transcript notes of quotes			
	Like	Insights	Dislike	Study and group setup
P33	Good examples, felt taken serious, practical exercises and theory, Taking your mind for a walk	Don't take every thought serious, Understanding how mind works	Nothing	Reduce group size, Offer group in the morning
P64	Exciting topics, techniques how to deal with thoughts	Thoughts are not always helpful, letting the mind talk, letting thoughts pass, willingness	Sometimes too slow	Too many questionnaires
P03	Interesting topics, defusion, mindfulness	Setting priorities, take decisions according to values	Nothing	Everything fine
P77	Clear structure, comprehensible, great group, great examples	Detecting thought patterns, treating myself different in the future, slowing down, being mindful, thinking first	Sometimes too fast	Everything fine
P37	Good structure, reflecting on thoughts	Reflecting own thoughts, accepting negative thoughts, focusing on positive thoughts, noticing thoughts	Sometimes too slow	Reduce group size
P08	Very good group	Knowing what thoughts are, meta-perspective, staying focused, stopping autopilot	Lack of commitment from some participants	Everything fine
P58	Helpful techniques	Unhelpful vs. helpful thoughts, fact vs. appraisal	Complicated terms, too fast, too many topics	Everything fine
P24	Clear structure, exchange with patients, motivation through therapist, pictures and examples	Defusion techniques	Topics treated too superficial, more time needed, more information on illness needed, more examples on psychosis	Some questionnaires redundant
P96	Good structure, different modules	Looking at things from a different angle, unhelpful vs. helpful thoughts	Breaks in the middle needed	Everything fine
P30	Felt comfortable in group, defusion	Don't remember anything	Nothing	Was ok
P61	Interesting topics, felt comfortable in group, new ways of dealing with thoughts, feeling enthusiastic	Mindfulness, defusion techniques, imagination exercises	Nothing	Everything fine
P28	Information supply, looking down on thoughts	Butterfly exercise, distancing from thoughts	Nothing	Everything fine

Supplementary Material

P06	Clear structure	Don't take thoughts so serious, focusing on important goals, defusion techniques	Sometimes too slow, topics too easy	Everything fine
P46	Interesting topics, clear structure, good offers, good treatment	Forgot things right away	Nothing	Everything fine
P16	Good examples, great therapist, other patients in group, structure of the group	Don't take every thought serious	Sometimes too slow, more examples and exercises needed	Everything fine
P86	Group in general, good topics, good exercises	Problems remembering stuff	More time needed, more practical exercises needed	Everything fine
P05	Good topics, exchange with others, talking openly	Nice memories	Nothing	Everything fine
P39	General satisfaction with group	Learning to rethink	Lack of commitment from some participants	Everything fine
P20	Practical exercises, exchange with others	Learning new coping mechanisms, using defusion techniques	Too much theory, more exercises needed	Questionnaires hard to answer
P22	Sharing with others, coping strategies	Talking about problems earlier, defusion techniques, monster metaphor, asking for help right away	Sometimes hard to open up	Questionnaires hard to answer
P66	Empathic therapist, sharing with others, simple exercises, great group	Recognizing thinking patterns, distancing from thoughts, directing attention, butterfly metaphor	More time for sessions needed, more focus on therapy projects	Everything fine
P47	Mindfulness, talking openly, exchange in the group	Therapy cards, act vs. appraisals Collecting enough information before taking a decisions	Sometimes too long	Everything fine
P70	Exchange with others, recognizing variety of viewpoints	Defusion techniques, butterfly metaphor	Nothing	Group should be longer than 60 minutes, more groups per week
P02	Liked all topics	Recognizing emotions in others, defusion techniques, mindfulness	Group time too late	Shorter sessions

Supplementary Table 7. Codes identified for each participant for the thematic analysis of the semi-structured interview

ID	Codes Like	Codes Insights	Codes Dislike	Codes Setup
P33	<ol style="list-style-type: none"> 1. Good examples 4. Felt taken serious 2. Practical exercises and theory 3. Walking your mind 	<ol style="list-style-type: none"> 1. Don't take every thought serious 2. Understanding how mind works 	Does not apply	<ol style="list-style-type: none"> 1. Reduce group size 2. Offer group in the morning
P64	<ol style="list-style-type: none"> 1. Exciting 2. Techniques how to deal with thoughts 	<ol style="list-style-type: none"> 1. Thoughts are not always helpful 2. Letting the mind talk 3. Letting thoughts pass 4. Willingness 	1. Sometimes to slow	1. Too many questionnaires
P03	<ol style="list-style-type: none"> 1. Interesting topic 2. Defusion 3. Mindfulness 	<ol style="list-style-type: none"> 1. Setting priorities 2. Make decisions according to values 	Does not apply	Does not apply
P77	<ol style="list-style-type: none"> 1. Clear structure 2. Comprehensible 3. Great group 4. Great examples 	<ol style="list-style-type: none"> 1. Detecting thought patterns 2. Treating myself different in the future 3. Slowing down 4. Being mindful 5. Think first, act then 	1. Sometimes too fast	Does not apply
P37	<ol style="list-style-type: none"> 1. Good structure 2. Reflecting thoughts 	<ol style="list-style-type: none"> 1. Reflect thoughts 2. Accept negative thoughts 3. Focus on positive thoughts 4. Notice thoughts 	1. Sometimes to slow	1. Reduce group size
P08	<ol style="list-style-type: none"> 1. Very good group 	<ol style="list-style-type: none"> 1. Knowing what thoughts are 2. Metaperspective 3. Stay focuses 4. Stop autopilot 	1. Lack of commitment from participants	Does not apply

Supplementary Material

P58	<ol style="list-style-type: none"> 1. Helpful techniques 	<ol style="list-style-type: none"> 1. Unhelpful vs. helpful thoughts 2. Fact vs. appraisal 	<ol style="list-style-type: none"> 1. Complicated terms 2. Too fast 3. Too many topics 	Does not apply
P24	<ol style="list-style-type: none"> 1. Clear structure 2. Exchange with patients 3. Motivation through therapist 4. Pictures and examples 	<ol style="list-style-type: none"> 1. Defusion techniques 	<ol style="list-style-type: none"> 1. Topics too superficial 2. More time needed 3. More information on illness needed 4. More examples on psychosis 	<ol style="list-style-type: none"> 1. Some questionnaires redundant
P96	<ol style="list-style-type: none"> 1. Good structure 2. Different modules 	<ol style="list-style-type: none"> 1. Look at things from a different angle 2. Unhelpful vs. helpful thoughts 	<ol style="list-style-type: none"> 1. Breaks in the middle needed 	Does not apply
P30	<ol style="list-style-type: none"> 1. Comfortable in group 2. Defusion 	Does not apply	Does not apply	Does not apply
P61	<ol style="list-style-type: none"> 1. Interesting 2. Comfortable in group 3. New ways of dealing with thoughts 4. Feeling enthusiastic 	<ol style="list-style-type: none"> 1. Mindfulness 2. Defusion techniques 3. Imaginations 	Does not apply	Does not apply
P28	<ol style="list-style-type: none"> 1. Information 2. Looking down on thoughts 	<ol style="list-style-type: none"> 1. Butterfly exercise 2. Distance to thoughts 	Does not apply	Does not apply
P06	<ol style="list-style-type: none"> 1. Clear structure 	<ol style="list-style-type: none"> 1. Don't take thoughts so serious 2. Focus on important goals 3. Defusion techniques 	<ol style="list-style-type: none"> 1. Sometimes too slow 2. Too easy 	Does not apply

Supplementary Material

P46	<ol style="list-style-type: none"> 1. Interesting topics 2. Clear structure 3. Good offers 4. Good treatment 	<ol style="list-style-type: none"> 1. Forgot things right away 	Does not apply	Does not apply
P16	<ol style="list-style-type: none"> 1. Good examples 2. Great therapist 3. Patients in group 4. Structure of the group 	<ol style="list-style-type: none"> 1. Don't take every thought serious 	<ol style="list-style-type: none"> 1. Sometimes to slow 2. More examples and exercises 	Does not apply
P86	<ol style="list-style-type: none"> 1. Group 2. Good topics 3. Good exercises 	<ol style="list-style-type: none"> 1. Problems remembering stuff 	<ol style="list-style-type: none"> 1. More time needed 2. More practical exercises 	Does not apply
P05	<ol style="list-style-type: none"> 1. Good topics 3. Exchange with others 2. Talk openly 	<ol style="list-style-type: none"> 1. Nice memories 	Does not apply	Does not apply
P39	<ol style="list-style-type: none"> 1. General satisfaction 	<ol style="list-style-type: none"> 1. Learning to rethink 	<ol style="list-style-type: none"> 1. Lack of commitment from participants 	Does not apply
P20	<ol style="list-style-type: none"> 1. Practical exercises 2. Exchange with others 	<ol style="list-style-type: none"> 1. Coping mechanisms 2. Using inner assistant 	<ol style="list-style-type: none"> 1. Too much theory 2. More exercises needed 	<ol style="list-style-type: none"> 1. Questionnaires hard to answer
P11	Does not apply	Does not apply	Does not apply	Does not apply
P22	<ol style="list-style-type: none"> 1. Sharing with others 2. Coping strategies 	<ol style="list-style-type: none"> 1. Talk about problems 2. Defusion techniques 3. Monster metaphor 4. Consulting help right away 	<ol style="list-style-type: none"> 1. Sometimes had to open up 	<ol style="list-style-type: none"> 1. Questionnaires hard to answer
P66	<ol style="list-style-type: none"> 1. Empathic therapist 2. Sharing with others 3. Discreet 4. Great group 	<ol style="list-style-type: none"> 1. Recognizing patterns 2. Distancing from thoughts 3. Directing attention 4. Butterfly metaphor 	<ol style="list-style-type: none"> 1. More time for sessions 2. More focus in therapy projects 	Does not apply

Supplementary Material

P47	<ol style="list-style-type: none"> 1. Mindfulness 2. Talking openly <p>Exchange in the group</p>	<ol style="list-style-type: none"> 1. Therapy cards 2. Fact vs. appraisals 3. Enough information for decisions 	<ol style="list-style-type: none"> 1. Sometimes too long 	<p>Does not apply</p>
P70	<ol style="list-style-type: none"> 1. Exchange with others 2. Recognizing variety of viewpoints 	<ol style="list-style-type: none"> 1. Defusion techniques 2. Butterfly metaphor 	<p>Does not apply</p>	<ol style="list-style-type: none"> 1. Group should be longer than 60 min 2. More groups per week
P02	<ol style="list-style-type: none"> 1. Liked topics 	<ol style="list-style-type: none"> 1. Recognizing emotions in others 2. Defusion techniques 3. Mindfulness 	<ol style="list-style-type: none"> 1. Group time too late 	<ol style="list-style-type: none"> 1. Shorter sessions

Supplementary Table 8. Recommendations for future research

Observation	Recommended change(s)
Recruitment and retention	
<ul style="list-style-type: none"> • Eligibility rate: 75.8% • Consent rate: 78.7% • Trial entry rate: 100% • Completion rate: 99.4% • Retention rate: 89.2% 	Increase the eligibility rate by screening all admitted patients with PSDs. Involve entire clinician team in screening. Expand study to participants from other acute psychiatric inpatient wards to ensure adequate pool of participants
Participants were only recruited from one ward	Include different wards in the same hospital and different recruitment sites across Germany
Eligibility criteria	
Missing eligibility for psychotherapy was not clearly defined making the inclusion/exclusion decisions after screening challenging	Clearly operationalize eligibility for psychotherapy (e.g. scores on the PANSS ≥ 5 in hostility and uncooperative and ≥ 6 in suspiciousness) [32] in a future RCT still keeping in mind the acute setting and research question
Outcome measures	
The WHODAS turned out to be unsuitable as a sole self-report measure for inpatients with acute psychosis, as they tended to over-estimate their functioning at baseline [33, 34]. No significant correlations were found between the self-report and rater-adjusted WHODAS-2.0 scores and GAF at baseline ($r = 0.056$, 95% CI = -0.27, 0.37, $p = 0.739$; $r = -0.26$, 95% CI = -0.54, 0.07, $p = 0.115$). However, both self-report and rater-adjusted WHODAS-2.0 scores and GAF post-intervention were significantly correlated with a much larger correlation associated with rater-adjustment ($r = -0.34$, 95% CI = -0.60, -0.01, $p = 0.042$; $r = -0.67$, 95% CI = -0.82, -0.45, $p < 0.001$)	Identify additional quality of life assessments such as the Recovering Quality of life that are more suitable for the target group [37]
The CGI was too unspecific to measure treatment success given the specific psychopathology (positive and negative symptoms) of the target group [35]	Use the CGI-Schizophrenia Scale in order to assess more specific treatment effects [38]
Outcome measures mostly focused on symptom change with few focusing on the overarching treatment goals of recovery or crisis reduction [36]	Include recovery oriented outcome measures like the Beck Hopelessness Scale or the Process of Recovery Questionnaire [39], experiences of crisis in psychosis [36] or Self-stigma of mental illness scale [11]
Psychological mechanisms were only measured by two process outcomes (BCIS and CFQ), making it difficult to make sophisticated statements about the hypothesized therapeutic mechanisms	Add additional mechanism measures e.g. the Cognitive bias questionnaire for psychosis [40] and the Acceptance and Action questionnaire [41] to distinguish between correlated and overlapping treatment processes. Also add direct measures of cognitive biases e.g. using the BADE procedure to measure the jumping to conclusion (JTC) bias [42]
Modules' feedback questionnaires were hard to answer for some participants and some questions were found to be redundant	Shorten and simplify feedback questionnaires on modules, eliminate redundant questions
Outcome measures were rated by clinicians involved in the overall treatment of the patients	Make sure assessments are completed by research assistants blind to treatment allocation or not involved in the patient's treatment
Assessment time points	
Baseline diagnostic measures e.g. PANSS were only taken at the beginning and end of the treatment, no progression diagnostic in between took place	Make sure to continuously assess outcome measures in order to map treatment effects over the entire treatment period

Mechanism measures were taken immediately after the respective module with no time for patients to progress or practice therapy contents

Make sure to assess process measures weekly but also in various follow up assessment

No follow up measures were taken

Establish follow-up measurements e.g. 6, 12, and 24 months month after treatment completion to account for long-term effects, and also collect data on readmissions to other hospitals

External delivery framework

Overall retention rate was high at 89.2% for all three modules, but shortening the intervention's duration would allow everyone to participate in all the content.

Shorten total amount of sessions to five with one psychoeducative session and two sessions in Module II and Module III

According to participants, therapy sessions took too long with 60 minutes and contained too much theoretical information

Shorten contents down to the basics and reduce therapy lengths to a maximum of 40 minutes. Make sure to allow for time buffer

According to participants, sessions contained too many examples and exercises for the given time

Shorten number of examples and practical exercises down to the most helpful (according to participants' feedback)

Depending on the group composition, disturbances and unrest occurred that could not be solved by one therapist alone

If possible, let two therapists conduct the therapy sessions

Mostly clinical psychologist trained in CBT conducted the group therapy

Train co-therapists from related professions such as occupational therapy or nursing. Properly manualise the group concept

According to participants, group sizes were sometimes too large. The average number of patients attending a session was 6, but due to the naturalistic setting of the study, 20 sessions out of 81 sessions over the entire study period were held with more than 6 patients.

Limit group size to a maximum of seven patients as suggested in the literature [27]. High therapy demand could for example be met by a second parallel group

According to participants, the meaning of group-specific terms like metacognition, fusion and defusion was hard to understand

Simplify therapy language and avoid using specialized terms by e.g. replacing metacognition with "thought distance" or "thinking about thinking" and defusion with "detachment"

Therapy contents were partly too theoretical with participants benefitting most from exercises and practical examples

Shorten theoretical input to a minimum and focus on practical exercises. Make sure examples fit the current crisis situation and are transferable into patients' everyday life

Complementary individual sessions were not always coordinated with group contents

Create a consistent approach for one-on-one sessions to make them comparable between participants

There was no restrictions for participants to take part in complementary psychosocial treatments

For the study period, limit participation to the group intervention and individual sessions

Therapy contents

Disorder related language was rarely used. Nevertheless, participants frequently asked about the role of psychotic symptoms and found it helpful to receive information

Include more psychoeducative information about symptoms of psychosis and give room for discussion and exchange

Module "Cognitive Insight" with four sessions was found to be lengthy with overlapping topics and examples (e.g. attribution styles and jumping to conclusions). Patients struggled to transfer given examples to their

Shorten amount and content of sessions e.g. to two sessions and include only examples found most helpful for participants. Make sure to include relevant psychosis-related examples next to "neutral" ones and encourage

own psychotic experiences

Module “Cognitive Defusion” with four sessions was found to include too much theory compared to the amount of practical exercises. Participants reported difficulty in grasping the metacognitive concept, which treats delusions and hallucinations on par with “normal thoughts”

Therapy contents and therapeutic attitude clearly differed from the primary medical treatment focus of acute psychiatric inpatient wards making a unified treatment approach difficult. As a result, patients partly received contradictory information on treatment goals e.g. symptom reduction vs. symptom acceptance

Treatment fidelity

Sessions followed a manual, but were not audio recorded to ensure therapist’s adherence to the treatment model

Health economics

The costs of training, intervention delivery and analysis were integrated into routine clinical care and only sufficient to conduct a feasibility study

Statistical analysis

Given the small sample size, statistical analysis only included pre-post evaluations to test for preliminary effectiveness. No mediation analysis was included to test the effect of mechanisms of change

Study design for a future research

The study design was uncontrolled

Assessments were non-blinded

Sample size was small

sharing personal experiences

Shorten theoretical input to a minimum and focus on practicing and revising exercises with patients’ own examples. Make sure to give enough psychoeducative information about the classification of psychotic experiences from a metacognitive philosophy

Provide trainings for the whole treatment team to integrate psychological thinking, formulation and hypothesizing in the treatment plan. Make sure to educate the whole team about the treatment model behind the group intervention and frequently exchange in interdisciplinary team meetings [43]

Audio record group and individual sessions to ensure treatment fidelity

Calculate costs relevant for a randomized controlled pilot study and a subsequent fully powered trial involving multiple sites. Aim to build up research cooperations and raise research funds

In a larger scale study, include analysis of moderators and mediators to account for change mechanism effects

Set up control arm to test the specificity of change mechanisms in the experimental group intervention [44–46]

Make sure raters and therapists are different researchers and ensure raters are blinded to treatment allocation

Ensure pilot trial sample size is sufficiently large to achieve medium effect sizes e.g. with at least 15 participants per treatment arm [47]

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Acknowledgments

“As well as being one of the worst things that can happen to a human being, schizophrenia can also be one of the richest learning and humanizing experiences life offers.”

Mark Vonnegut (American paediatrician and author of The Eden Express: A Memoir of Insanity)

I owe a large part of my enthusiasm for research and the energy to overcome the ups and downs of this doctoral thesis to one group - the many wonderful patients I have been privileged to accompany over the years and whose needs and voices I want to make visible through my work. What I have been able to learn as a therapist and what I have received back in appreciation has been worth every effort. Thank you for these enriching encounters!

I would also like to thank my supervisor and first TAC member, Susanne Lucae, for her continued guidance and mentorship. I appreciate the valuable insights and guidance you have provided regarding clinical work, research and my personal path. As my second TAC member, I want to thank Peter Falkai for sharing his great expertise on psychosis and support in strategic questions concerning my work and career. As my third TAC member, I want to thank Frank Padberg for offering his enormous knowledge in the field of psychotherapy research.

Thank you, Johannes, for your incredible supervision and mentoring! Without your support, this project would not have been possible. You believed in me at all times, even when I questioned everything. Thank you for all your enthusiasm and vision.

During my time at the Max Planck Institute, I have been privileged to meet and be supported by many inspiring colleagues. Thank you Samy for your clinical guidance and advice. Thank you, Leah and Sarah, for the countless motivating conversations and valuable research input.

Sophia, Anja, Mari, Alma, Lea und Lu. Ihr seid die Freundinnen, die man sich nur wünschen kann. Danke für die vielen aufbauenden Gespräche und wunderbaren Ablenkungen vom Schreibtisch. Ich weiß, ich kann mich immer auf euch verlassen!

Carlo, meine Gelassenheit und Ruhe. Danke, dass du meine Launen mit deiner Geduld und deinem Humor auffangen kannst. Ohne deine Liebe und Fürsorge hätte ich nicht so lange durchgehalten. Ich bin froh, dich an meiner Seite zu wissen!

Mama und Papa. Danke für eure bedingungslose Liebe und Unterstützung, egal in welcher Lebensphase. Ich weiß, zu euch kann immer kommen. Die viele Arbeit der vergangenen Jahre hat mir gezeigt, wie wichtig ihr mir als Familie seid!