Trial Description

Title

Safety and feasibility of a new psychotherapeutic intervention for secured acute psychiatric wards – MCT-A

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

The aim of this study is to demonstrate the feasibility and safety of a new psychotherapeutic group intervention, which was developed specifically for the setting of acute psychiatric wards.
Psychotherapy is now recommended by international treatment guidelines for severe mental disorders such as schizophrenia or depression. However, suitable programs developed for patients with acute, severe symptoms, who are admitted to closed acute care wards, have been scarce up to now.
Therefore, the Metacognitive Training for Psychosis (MCT), which has been proven to be effective in previous studies, has been revised and adapted for the acute psychiatric context (MCT-A).
The MCT-A will be offered twice a week to all patients admitted to the acute psychiatric ward as an additional therapy offer to standard treatment.
Study participants take part in up to 7 modules (for 4 weeks). After each session, patients are asked to fill out a short feedback questionnaire on the respective session. After 2 and 4 weeks, subjective utility and satisfaction with the therapy, side effects and general changes compared to the start of therapy as well as adverse events related to the therapy are recorded. Before participation, sociodemographic data and expectations regarding the therapy are recorded. Before, during (after 2 weeks) and after the participation period (after 4 weeks) participants are also asked about their hope regarding their therapy, quality of life, current subjective symptom severity and self-stigmatization. At all 3 points in time current symptom severity is also assessed by doctors via external ratings.
We assume that participation in the group therapy is evaluated as positive afterwards, that there are few side effects and no worsening of symptoms, and that after participation the participants' hope and quality of life is increased and self-stigmatization is reduced compared to before participation.

Brief Summary in Scientific Language

Psychotherapy is now part of the treatment guidelines for patients with severe psychiatric disorders such as schizophrenia or depression (e.g. German guidelines: DGPPN, DGPs). Yet, pharmacological treatments are often the only therapeutic option offered in acute care units.
Metacognitive Training for Psychosis (MCT) is an easy-to-use group intervention that aims to reduce cognitive biases associated with the development and maintenance of psychotic symptoms. We developed a new version of MCT for the

**acute ward setting (MCT-A), which was adapted for patients with severe, particularly psychotic and depressive, symptoms.
In a pilot study, the intervention will be carried out twice a week on acute wards and examined for feasibility and acceptance.
Patients on secured acute psychiatric wards with a primary diagnosis of a severe psychiatric illness (F diagnosis according to the ICD-10), primarily a diagnosis of schizophrenia, schizotypal and delusional disorders, mood disorders, psychoactive substance use disorders or emotionally unstable personality disorders will be included. Exclusion criteria include inability to give informed consent/consent not given by legal guardian, a lack of German language skills, mental retardation and dementia. Since this is a pilot study on feasibility without effect sizes for group comparisons, no specific sample size calculation can be carried out. The aim is to include as many people as possible within a 9-month intervention period. We are aiming for a sample size of 40 complete cases with data for all three assessments.
Addendum January 4th, 2021: due to the Covid-19 pandemic which influences our recruitment rates we have decided to expand the recruitment period to a total of 18 months (without having accessed any of the data we have collected so far).
After each session, as well as after 2 and 4 weeks respectively, subjective utility of the intervention will be assessed.
Within the intervention period, adherence, reasons for non-participation and adverse events are recorded. Before (t0), during (after 2 weeks; t1) and after (4 weeks; t2) the intervention, hope regarding one's therapy, quality of life, self-stigmatization and current symptom severity (self- and external rating) are recorded. Before the intervention, sociodemographic data and expectations regarding therapy on the ward will be recorded. After the intervention, additional positive changes and reported side effects are assessed. In addition to descriptive evaluation, factors influencing participation rates and evaluation of the therapy program will be investigated.
A questionnaire on the subjective utility of the intervention serves as the primary endpoint. We expect the MCT-A to be evaluated as useful and meaningful.
Further hypotheses on secondary endpoints:
- The majority of participants give positive feedback at the end of each session.
- Participation in the MCT-A is not associated with adverse events (external rating: Unwanted Events- Adverse Treatment Reactions (UE-ATR) checklist) and contributes to symptom stabilization (self-rating: Brief Symptom Inventory, external ratings: Brief Psychiatric Rating Scale, Global Assessment of Functioning, Clinical Global Impression). Side effects are recorded and reported using an adapted version of the Questionnaire about Side Effects Psychosis and Internet.
- After participation in MCT-A, participants report a) more hope regarding their therapy (Questionnaire on Therapy Motivation-23, subscale Hope), b) higher quality of life (WHOQOL-100 Item G1.1), c) lower self-stigmatization (Self-Stigma of Mental Illness Scale - Short Form), compared to before the intervention
- Participation in the MCT-A is retrospectively evaluated by patients to be associated with explicit positive changes as well as with a reduction in stress (short form of the Bochum Change Questionnaire 2000).
Exploratory subgroup analyses will be carried out, for example, differences between disorders and specific effects of individual modules.**

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00020551**
- Date of Registration in DRKS: **2020/02/04**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **LPEK-0108 , Universitätsklinikum Hamburg-Eppendorf (UKE), Lokale Psychologische Ethikkommission am Zentrum für Psychosoziale Medizin (LPEK)**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20-F29 - Schizophrenia, schizotypal and delusional disorders**
- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F60-F69 - Disorders of adult personality and behaviour**
- ICD10: **F10-F19 - Mental and behavioural disorders due to psychoactive substance use**
- ICD10: **F40-F48 - Neurotic, stress-related and somatoform disorders**
- ICD10: **F50-F59 - Behavioural syndromes associated with physiological disturbances and physical factors**
- ICD10: **F90-F98 - Behavioural and emotional disorders with onset usually occurring in childhood and adolescence**
- ICD10: **F00-F09 - Organic, including symptomatic, mental disorders**

Interventions/Observational Groups

- Arm 1: **Participation in the group intervention MCT-A over 4 weeks (7 modules in total, 2 per week each); participation in pre-, interim and post-assessment**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***

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Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Overall satisfaction with and subjective utility of the intervention (self-generated questionnaire); measured after 2 and after 4 weeks, i.e. when participants have participated in up to 4 and up to 7 modules respectively.

Secondary Outcome

- Abbreviated version of the Questionnaire about Side Effects Psychosis and Internet (QueSPI; Rüegg, Moritz, Berger, Lüdtke & Westermann, 2018): Side effects of the intervention; reported after 2 and 4 weeks

- UE-ATR checklist: Number of adverse events associated with the intervention; continuously documented by members of the research team during the intervention period

- Subscale Hope of the questionnaire on therapy motivation-23: Hope regarding therapy; before, during (after 2 weeks) and after the intervention (after 4 weeks)

- Brief Symptom Inventory: Subjective symptom severity; before, during and after the intervention

- Self-Stigma of Mental Illness Scale - Short Form: self-stigmatization; before, during and after the intervention

- Brief Psychiatric Rating Scale, Global Assessment of Functioning, Clinical Global Impression: externally assessed symptom severity; before, during and after the intervention

- Abbreviated version of the Bochum Change Questionnaire 2000: changes compared to before the start of therapy; after the intervention

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**
- Medical Center **Asklepios Klinik Nord - Psychiatrie Wandsbek, Hamburg**
- Medical Center **Psychiatrische Klinik Lüneburg, Lüneburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/02/23**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Presence on a secured, closed acute psychiatric ward; diagnosis of a severe psychiatric illness (F diagnosis according to ICD-10)

Exclusion criteria

Inability to give informed consent / no consent from the legal guardian, lack of German language skills, mental retardation, and dementia

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2021/09/01**
- Number of Participants in Germany after Recruiting complete: **77**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **77**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*