PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Group Intervention for Improving Stigma Coping and Empowerment of People With Mental Illness (STEM)

Trial Acronym

STEM

URL of the trial

[---]*

Brief Summary in Lay Language

Main purpose of the study is to impart abilities to cope with the stigma of mental illness. Background: People with mental illness often suffer from stigmatization. People suffering the stigma often experience discrimination in different life domains, such as the family, the social network or the working place. In the framework of a psycho-educational group (which is a group therapy to impart knowledge about a mental illness and to impart abilities to cope with the illness and its consequences), abilities shall be learnt to cope with stigma and discrimination and to make decisions concerning the illness in a self-determined manner (empowerment). Potential study participants are patients of different psychiatric services (in-patient, out-patient, and day hospital) suffering from schizophrenia or depression. The following hypothesis will be tested: long-term improvement of quality of life will be higher in the interventional group in comparison to the control group.

Brief Summary in Scientific Language

People with mental illness suffer both from the burden of disease itself and from the social stigma related to mental illness, hence impeding their treatment (Sartorius et al. 2005, Link et al. 1999). Negative attitudes towards and discriminating behavior against people with mental illness negatively affect health care utilization, the course of disease, compliance, self-esteem, and social functioning (Sirey et al. 2001, Link et al. 2001, Perlick et al. 2001). Internalizing negative social stereotypes (self-stigmatization; Ritsher et al. 2003, Watson et al. 2007) impairs the quality of life and leads to social withdrawal (Rüesch 2005). Furthermore, self stigma is associated with lower empowerment (Ritsher et al. 2004), a poorer social network (Lysaker et al. 2007), lower compliance (Fung et al. 2008) and a higher extent of symptoms (Corrigan et al. 2006). The stigma of mental illness leads to an impaired pursuance of individual life goals, as job-related ambitions or living in a relationship (Rüesch 2005).
Current approaches targeting the stigma of mental illness primarily focus on education about mental illness in different target groups (e.g. Gaebel et al. 2003, 2004) and can be successful, if appropriately implemented (Gaebel et al. 2008).

Yet there is a lack of RCT-tested psychotherapeutic approaches which directly address patients with mental illness improving their skills of coping with stigma and discrimination. Therefore it is intended to develop, manualise, and to evaluate such a psychotherapeutic group intervention within a randomized clinical control group design.
In this context, group-based cognitive-behavioral psychotherapy has been proved as efficient therapeutic approach for patients with depression (cf. McDermut et al. 2006) and with schizophrenia (cf. Lawrence et al. 2006, Barrowclough et al. 2006) in different settings. Patients can serve each other as role models and will modify negative self-related cognitions, thus developing new cognitions supporting self-esteem (Corrigan et al. 2001). The following interventional effects should improve the patients' quality of life and also result in a reduction of frequency and length of inpatient stays and sickness-related absenteeism:
•improved skills to cope with negative stigmatizing experiences,

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004217**
- Date of Registration in DRKS: **2012/12/10**
- Date of Registration in Partner Registry or other Primary Registry: **2012/06/14**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **3748 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- Primary Registry-ID: **NCT01655368 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **F20-F29 - Schizophrenia, schizotypal and delusional disorders**
- ICD10: **F31.3 - Bipolar affective disorder, current episode mild or moderate depression**

ICD10: **F31.3 - Bipolar affective disorder, current episode mild or moderate depression**

- ICD10: **F31.4 - Bipolar affective disorder, current episode severe depression without psychotic symptoms**
- ICD10: **F31.5 - Bipolar affective disorder, current episode severe depression with psychotic symptoms**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F34 - Persistent mood [affective] disorders**
- ICD10: **F43.2 - Adjustment disorders**

Interventions/Observational Groups

- Arm 1: **The intervention consists of 8 group sessions psycho-education (duration approx. 60 minutes) and 3 sessions STEM module (stigma coping and empowerment) (duration approx. 90 minutes). The sessions usually are (depending of the health care setting) one to three times per week. A booster session will take place 6 weeks after the first 11 sessions.**
- Arm 2: **The control condition consists of 11 group sessions psycho-education (duration approx. 60 minutes). The sessions usually are (depending of the health care setting) one to three times per week. A booster session will take place 6 weeks after the first 11 sessions.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary endpoint is subjective quality of life assessed with the questionnaire WHOQOL-BREF (total score). This is a self-rating. The questionnaire is being assessed before intervention, directly after intervention, and 6 weeks, 6 and 12 months after intervention. Primary endpoint is the change between "before intervention" and after 12 months.

Secondary Outcome

Secondary endpoint is "internalized stigma" assessed with the questionnaire ISMI (total score). This is a self-rating. The questionnaire is being assessed before intervention, directly after intervention, and 6 weeks, 6 and 12 months after intervention. Main research question is the change between "before intervention" and after 12 months.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **LVR Klinikum Düsseldorf - Kliniken der Heinrich-Heine-Universität Düsseldorf (stationär), Düsseldorf**
- University Medical Center **LVR Klinikum Düsseldorf - Kliniken der Heinrich-Heine-Universität Düsseldorf (teilstationär), Düsseldorf**
- Medical Center **Klinik für Psychiatrie und Psychotherapie (stationär), Aachen**
- Medical Center **Klinik für Psychiatrie und Psychotherapie (teilstationär), Aachen**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (stationär), Göttingen**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (teilstationär), Göttingen**
- Medical Center **Oberhavel Kliniken GmbH, Klinik Hennigsdorf (stationär), Hennigsdorf**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (ambulant), Hamburg**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (stationär), Köln**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (teilstationär), Köln**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (stationär), Marburg**
- University Medical Center **LVR Tagesklinik- und Ambulanzzentrum (TAZ) (teilstationär), Düsseldorf**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie, LMU (stationär), München**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie, LMU (teilstationär), München**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (stationär), Tübingen**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie (teilstationär), Tübingen**

- Medical Center **Oberhavel Kliniken GmbH, Klinik Hennigsdorf (teilstationär), Henningsdorf**
- other **Reha-Zentrum Seehof der DRV (stationär, Reha), Teltow bei Berlin**
- other **Psychiatrisches und psychotherapeutisches Rehazentrum Grundstein (stationär, Reha), Tübingen**
- Medical Center **AHG-Klinik (stationär, Reha), Waren**
- Medical Center **Mittelrhein-Klinik Bad Salzig der DRV (stationär, Reha), Boppard-Bad Salzig**
- Medical Center **MediClin Bliestal Kliniken, Fachklinik für psychosomatische Medizin (stationär, Reha), Blieskastel**
- Doctor's Practice **Düsseldorf**
- Doctor's Practice **Düsseldorf**
- Doctor's Practice **Berlin**
- Doctor's Practice **Berlin**
- University Medical Center **LVR-Klinikum Düsseldorf – Kliniken der Heinrich-Heine Universität (ambulant) , Düsseldorf**
- Doctor's Practice **Berlin**
- University Medical Center **LVR Tagesklinik- und Ambulanzzentrum (TAZ) (ambulant), Düsseldorf**
- other **Berolina Klinik, Fachklinik für Psychosomatik, Psychotherapie, Verhaltenmedizinische Orthopädie (VMO) und für Neurologie, Löhne / Westf.**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/09**
- Target Sample Size: **512**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Age: 18-65 years
ICD-10 diagnosis F2, F31.3-F31.5, F32-F34, F43.2
Patients who would participate at a psycho-educational group
written informed consent
being capable of consenting (evaluated by the rater)

Exclusion criteria

Poor capability of German language (reading, understanding, and speaking is not sufficient, evaluated by the rater)
Acute psychotic or dissociative states

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Bildung und Forschung Dienstsitz Bonn
  Heinemannstr. 2
  53175 Bonn
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/06/26**

Trial Publications, Results and other documents

- Paper **Gaebel W, Zäske H, Hesse K, et al. Promoting stigma coping and empowerment in patients with schizophrenia and depression: results of a cluster-RCT. Eur Arch Psychiatry Clin Neurosci. 2019 Sep 13. doi: 10.1007/s00406-019-01064-3. [Epub ahead of print]**

** 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.*