

Trial Description

Title

Return-to-work experts in the inpatient treatment of patients with mental illness - a proof-of-concept study (RETURN)

Trial Acronym

RETURN

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with mental illness often find it difficult to return to work after an inpatient stay, and are at risk of losing their jobs. The aim of the study is to investigate how affected persons can be supported in this way already during a hospital stay, so that the return to work is as successful as possible afterwards.

Brief Summary in Scientific Language

Incapacity for work due to mental illness is a highly relevant subject and there is a social need to deal with actions, who maintain or restore the ability to work of persons with mental illnesses. The empirically well-documented salutogenetic aspects of work, i.e. the health-promoting aspects (e.g. social contacts, appreciation, daily rhythms, etc.), are brought to the fore in order to provide affected persons with the support they need to maintain work.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016037**
- Date of Registration in DRKS: **2018/12/21**
- 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**
-

DRKS-ID: **DRKS00016037**

Date of Registration in DRKS: **2018/12/21**

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.: **437/18 S-KK , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20-F29 - Schizophrenia, schizotypal and delusional disorders**
- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40-F48 - Neurotic, stress-related and somatoform disorders**
- ICD10: **F60-F69 - Disorders of adult personality and behaviour**

Interventions/Observational Groups

- Arm 1: **For the intervention wards, so-called return-to-work experts (RTW experts) will be established who will focus treatment on the workplace-related needs of patients treated on those wards and thus lead to better use of existing resources within the framework of work-related discharge management and thus to a more successful return to work.**
- Arm 2: **Test subjects of the control wards will act under “treatment as usual” (TAU) conditions.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Health care system**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

Control: **Active control (effective treatment of control group)**

Purpose: **Health care system**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Days at work within the 12 months period after discharge from hospital

Secondary Outcome

**number of patients returning to work,
sicknes days,
relapse rates
cost-benefit ratio of the intervention**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychiatrie und Psychotherapie der Technischen Universität München, München**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie der Ludwigs-Maximilians-Universität, München**
- Medical Center **kbo-Isar-Amper-Klinikum, Klinikum München-Ost, Haar bei München**
- Medical Center **kbo-Isar-Amper-Klinikum, Klinik Nord für Psychiatrie und Psychotherapie, München**
- Medical Center **kbo-Isar-Amper-Klinikum Fürstenfeldbruck, Fürstenfeldbruck**
- Medical Center **kbo-Lech-Mangfall-Klinik Agatharied, Agatharied**

- other **Max-Planck-Institut für Psychiatrie, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/01/10**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

- **Diagnosis of a mental illness [ICD-10 Chapter F2-4, F6**
- **In a permanent employment relationship (fixed employment contract, no minimal employment), in which they can be reintegrated**
- **Psychopathologically capable of reflecting on work in general and on their own work**

Exclusion criteria

- **Insufficient proficiency in German language**
- **Main diagnosis of an organic mental disorder (F0), substance abuse (F1) or an eating disorder (F5)**

Addresses

- **Primary Sponsor**

**Klinik für Psychiatrie und Psychotherapie des Klinikums rechts der Isar der
Technischen Universität München
Mr. Prof. Dr. Johannes Hamann
Ismaninger Str. 22
81675 München
Germany**

Telephone: **089/4140-0**

Fax: **089/4140 4898**

E-mail: **johannes.hamann at tum.de**

URL: [---]*

- **Contact for Scientific Queries**

Contact for Scientific Queries

**Klinik für Psychiatrie und Psychotherapie des Klinikums rechts der Isar der
Technischen Universität München**
Mr. Prof. Dr. Johannes Hamann
Ismaninger Straße 22
81675 München
Germany

Telephone: **089/4140-0**

Fax: **089/41406688**

E-mail: **return.psykl.med at tum.de**

URL: [---]*

■ Contact for Public Queries

**Klinik für Psychiatrie und Psychotherapie des Klinikums rechts der Isar der
Technischen Universität München**
Ms. Dr. Lina Riedl
Ismanginer Straße 22
81675 München
Germany

Telephone: **089/4140-0**

Fax: **089/41406688**

E-mail: **return.psykl.med at tum.de**

URL: [---]*

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.)**

Innovationsausschuss beim Gemeinsamen Bundesausschuss
Wegelystraße 8
10623 Berlin
Germany

Telephone: [---]*

Fax: [---]*

E-mail: **info at if.g-ba.de**

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

DRKS-ID: **DRKS00016037**

Date of Registration in DRKS: **2018/12/21**

Date of Registration in Partner Registry or other Primary Registry: [---]*

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.*