***PLEASE NOTE:*** *This study has been imported from ClinicalTrials.gov without additional data checks.*

## Trial Description

### Title

**Randomized-controlled Trial of Aftercare-Coordination by Phone for Patients With Depression and Anxiety Subsequent to an Inpatient Treatment.**

### Trial Acronym

**[---]***

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**The primary objective of this study is to test in a randomized controlled trial if aftercare-coordination by phone subsequent to inpatient treatment is an effective aftercare approach in the treatment of depression and anxiety.**

### Brief Summary in Scientific Language

**Depression and anxiety are among the most prevalent mental health problems and are associated with a high risk of chronification. Despite the large capacities in the German health care system only a small percentage of these patients receive treatment. Relevant barriers on the pathways of patients are communication und coordination difficulties between different services and providers.The aftercare subsequent to an inpatient treatment represents one of these interfaces. Here the aim is to consolidate the treatment outcomes and to minimize the so called rebound-effect, the reduction of the positive treatment effects after the inpatient treatment. Although evidence-based treatments for depression and anxiety disorders exist, treatment effects often decrease after treatment due to the lack of an integration of different steps in care. The method of a case management-based aftercare coordination by phone could be a promising approach to overcome the interface between inpatient treatment and aftercare: case management is a patient-centered and**

**situation-based approach which comprises systematic tracking and support of patients by a case-manager. Primary goal is to coordinate and integrate services across treatment settings. This approach can help to maintain and even improve longterm treatment outcomes.**

## Organizational Data

- DRKS-ID: **DRKS00005857**
- Date of Registration in DRKS: **2014/08/22**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/22**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

## Secondary IDs

- Primary Registry-ID: **NCT02044913 (ClinicalTrials.gov)**
- Sponsor-ID: **0421-FSCP-Z202 (Universitätsklinikum Hamburg-Eppendorf)**
- Other Secondary-ID: **0421-FSCP-Z202**

## Health condition or Problem studied

- Free text: **Depression, Anxiety**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F34.1 - Dysthymia**
- ICD10: **F40.0 - Agoraphobia**
- ICD10: **F40.1 - Social phobias**
- ICD10: **F41.0 - Panic disorder [episodic paroxysmal anxiety]**
- ICD10: **F41.1 - Generalized anxiety disorder**

## Interventions/Observational Groups

- Arm 1: **Behavioral: Phonebased Aftercare-Coordination**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

### Primary Outcome

**- Measure of the symptom severity - Beck Depression Inventory (BDI); time frame: Change in the BDI from the beginning of the intervention to follow up (6 months after termination of the intervention)**

### Secondary Outcome

**- Measure of health related quality of life - Short Form 8 Health Survey (SF-8), Measure of health related quality of life (EQ-5D); time frame: Change in the SF-8 and EQ-5D from the beginning of the intervention to follow up (6 months after termination of the intervention)**
**- Proportion of patients who get routine outpatient aftercare treatment at follow up (6 months after the intervention); time frame: 6 months after termination of the intervention**
**- Patient-rated acceptance and satisfaction with the intervention; time frame: Approximately 3 months (end of intervention); Patients rate their acceptance of the intervention and their satisfaction using non-standardized items.**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- **University Medical Center Hamburg-Eppendorf, Centre of Psychosocial Medicine, Department of Medical Psychology, Hamburg**

## Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/03/31**
- Target Sample Size: **152**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

### Inclusion Criteria

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

### Additional Inclusion Criteria

**- Depressive disorder (F32.x; F33.x; F34.1) and/or Anxiety disorder (F40.0; F40.1, F41.0; F41.1) according to ICD-10**

### Exclusion criteria

**- Concurrent outpatient psychotherapeutic treatment which will be continued after the inpatient rehabilitation treatment.**

**- No knowledge of the German language**

**- Risk of suicide**

**- Acute psychosis or psychotic symptoms**

## Addresses

- **Primary Sponsor**

  **Universitätsklinikum Hamburg-Eppendorf**

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

**Primary Sponsor**

**Universitätsklinikum Hamburg-Eppendorf**

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

- **Contact for Scientific Queries**

**University Medical Center Hamburg-Eppendorf, Centre of Psychosocial Medicine, Department of Medical Psychology**
**Dr. phil. Hanne Melchior**

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

- **Contact for Public Queries**

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Fax: **[---]***
E-mail: **l.kivelitz at uke.de**
URL: **[---]***

## Sources of Monetary or Material Support

- **[---]***

**Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor**

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

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

## Trial Publications, Results and other documents

*The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.*

*- Translation on version: 2*

*- Last processed date by ClinicalTrials.gov: 2014/11/27*

** 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.*