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

Trial Description

Title

Evaluation of CAMS versus TAU with suicidal patients - An inpatient RCT
CAMS = Collaborative Assessment and Management of Suicidality

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In Germany, approximately 10.000 people die each year as a result of a suicide - 28 suicides per day or 1 suicide every 52 minutes.
In a psychiatric treatment setting, the subject of suicidal tendencies is omnipresent and patients with acute suicidal thoughts or after suicide attempts are admitted and treated in a hospital as standard. Nevertheless, there are hardly any scientifically investigated interventions and guidelines for the treatment of suicidal patients. Furthermore, on the part of the practitioners, due to the urgency of the topic, there is often great unease and fear in dealing with suicidal patients. However, in view of the acute threat posed by suicidal tendencies, immediate and effective interventions are needed, so that it makes sense to deal with suicidal tendencies, regardless of the underlying psychiatric disease, with the aim of understanding them and being able to treat them so effectively.
The "Collaborative Assessment and Management of Suicidality" (CAMS) is a suicide prevention approach developed by David A. Jobes in the USA as an attempt to adequately address the various difficulties and challenges in the treatment of suicidal patients by making suicidal behaviour explicitly the subject of therapy. CAMS can be understood as a "therapeutic framework programme" in which an intervention process to change the causes and reasons for suicidal thoughts is initiated and treatment errors are reduced.
The present study is the first study about CAMS in Germany and is intended to test the effectiveness of CAMS (originally developed for the outpatient context) in the setting of a crisis intervention ward. For this purpose, 60 patients admitted to hospital on the basis of acute suicidal thoughts or actions are included in this study and randomly assigned to one of the two treatment conditions (CAMS or the usual inpatient crisis therapy (TAU)). Both therapy arms receive the same dose of therapeutic consultation. Changes in suicidal tendencies and other associated disorder patterns (depressive symptoms, general symptom load, reasons for life, therapeutic relationship, satisfaction with treatment) are registered at the time of admission, at the end of treatment and 4 weeks and 5 months after treatment using standardized questionnaires.

Brief Summary in Scientific Language

The aim of this RCT study is to investigate the efficacy of a structured intervention for suicide prevention, the "Collaborative Assessment and Management of Suicidality" (CAMS) (CAMS + SIC) (SIC = standard inpatient care) compared to a "Treatment As Usual" (TAU + SIC) of hospitalized patients with suicidal thoughts or behavior at the time of admission.

Main hypothesis:
We assume that the suicidality of suicidal patients after an intervention with CAMS will decrease significantly more than after an intervention with TAU.

Side hypotheses:
a. We assume that CAMS in suicidal patients leads to a significantly greater reduction in depressiveness and overall symptom burden in suicidal patients and to an increase in reported causes for life than after TAU.
b. We assume that the therapeutic relationship and satisfaction with inpatient treatment is significantly better evaluated by the patients after CAMS than after TAU.

CAMS is a new procedure in Germany for a relatively difficult to treat and so far not systematically treated group of patients with a high risk potential. The applied procedure can fill a gap in the treatment of acute suicidal patients. If CAMS is effective, patients could therefore be better treated and future suicide attempts and, hopefully, suicides could be reduced in number and stationary readmission could be prevented. Furthermore, the establishment of the method could also reduce insecurity on the part of therapists in the treatment of suicidal patients and facilitate their access to long-term effective treatment.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00013727**
- Date of Registration in DRKS: **2018/01/12**
- 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.: **2016-620-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40-F48 - Neurotic, stress-related and somatoform disorders**
- ICD10: **F60-F69 - Disorders of adult personality and behaviour**
- Free text: **Suicidal patients with various underlying diseases**

Interventions/Observational Groups

- Arm 1: **Collaborative Assessment and Management of Suicidality (CAMS) in the context of individual therapeutic consultations (CAMS + SIC) (SIC = Standard Inpatient Care). The inpatient treatment time ranges from 10 to 40 days with at least 3 and up to 10 therapeutic sessions of 30-50 minutes during the course of treatment.**

- Arm 2: **Control Group: Treatment As Usual (TAU) in the context of therapeutic consultations (TAU + SIC) (SIC=Standard Inpatient Care). The inpatient treatment time ranges from 10 to 40 days with at least 3 and up to 10 therapeutic sessions of 30-50 minutes during the course of treatment.**

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

**Change in suicidal tendencies measured with the Beck Scale for Suicide Ideation (BSS).
The assessment is carried out at the time of admission (pre), on discharge from treatment (post), 4 weeks after treatment (FU-1) and 5 months after treatment (FU-2).
We also assess suicidal behavior by self-report.**

Secondary Outcome

**Changes in the extent of depressiveness (BDI-II) and general symptom burden (SCL-18-Mini), indication of reasons for life (Brief-RFL-I), evaluation of the therapeutic relationship (D-STAR-P) and satisfaction with inpatient crisis treatment (own questionnaire).
The assessment is carried out at the time of admission (pre), on discharge from treatment (post), 4 weeks after treatment (FU-1) and 5 months after treatment (FU-2).**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Evangelisches Klinikum Bethel (EvKB), Klinik für Psychiatrie und Psychotherapie, Bielefeld**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/03/08**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

**acute suicidal thoughts or actions (within the last 7 days)
largely fluent German language
Agreement to participate**

Exclusion criteria

**- chronic suicidal patients (for our study defined as: within the last 12 months in total more than 12 weeks of in-patient treatment or inpatient treatment in the last 12 months more than 6 admissions)
- lawful accommodation based on Psych-KG or BGB (German Civil Code)**

- currently psychotic symptoms (also in the context of a depressive illness) and patients who have suffered from psychosis within the last 12 months
- Eating disorder with BMI < 16
- current substance dependency (substance abuse and previous substance dependency are no exclusion criteria!)
- patients with diagnosed reduced intelligence
- patients who receive inpatient integration assistance, i. e. live in assisted residential care
- Patients with an organically caused mental illness
- planned inpatient or partial inpatient treatment immediately afterwards
- patients who are already aware that they will only stay for a very short time for crisis intervention (study patients must have at least 10 days of inpatient treatment to ensure that the treatment can be carried out to a sufficient extent)

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/06/04**

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.*