Collaborative Assessment and Management of Suicidality (CAMS) compared to Enhanced Treatment as Usual (E-TAU) for suicidal patients in an inpatient setting: Study protocol for a randomized controlled trial

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Study protocol

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Abstract

Background: The Collaborative Assessment and Management of Suicidality (CAMS) is a therapeutic framework that has been shown to reduce suicidal ideation and overall symptom distress. CAMS has not been previously evaluated in a standard acute inpatient mental health care setting with only short treatment times for suicidal patients. In this randomized controlled trial (RCT) we investigate, if CAMS is more effective than Enhanced-Treatment as Usual (E-TAU) in reducing suicidal thoughts and behaviors. As secondary outcomes we are also investigating depressive symptoms, symptom relief in general, and quality of the therapeutic relationship. Methods/design: The trial is designed as a single-center, two-armed, parallel group observer-blinded randomized clinical effectiveness trial. We aim to recruit and randomize 60 participants with different diagnoses, who are admitted as inpatients due to acute suicidal thoughts or behavior in the Clinic of Psychiatry and Psychotherapy, Ev. Hospital Bethel in Bielefeld, Germany. The duration of treatment will vary depending on patients' needs and clinical assessments between 10 and a maximum of 40 days. Patients are assessed at 4 time points (admission, discharge, 1 month, and 5 months after discharge). The primary outcome measure is the Beck Scale for Suicide Ideation. Other outcome measures are included, such as severity of psychiatric symptoms, depression, reasons for living, and the therapeutic relationship. Discussion: This effectiveness study is being conducted on an acute ward in a psychiatric clinic where patients have multiple problems and diagnoses. Treatment times are rather short and therapists have a high workload. The results of this study can be generalized to a typical hospital setting and similar results should be expected if CAMS is implemented in other psychiatric systems.

Background

In Germany, approximately 10,000 people die each year as a result of suicide—that are 28 suicides per day or 1 suicide every 52 minutes [1]. Well over 100,000 people attempt suicide every year in Germany. Suicidality is linked in over 90% to the presence of a psychiatric illness or acute crisis and is omnipresent in the inpatient psychiatric setting [2, 3]. Nevertheless, there are surprisingly few empirically evaluated interventions and guidelines for the treatment of suicidal patients [4, 5], particularly within inpatient settings.

Traditional treatment approaches mainly aim to treat the underlying mental disorders, but remarkably few clinical treatments have been proven to be effective for specifically treating suicide risk through randomized controlled trials [6]. There is extensive support from randomized controlled trials for Dialectical Behavioral Therapy (DBT) for borderline patients [7, 8], Brief Cognitive Behavioral Therapy (BCBT) for military personnel [9] and Cognitive Therapy for Suicide Prevention (CT-SP) for suicide attempters [10] and Mindfulness-based Cognitive Behavioral Therapy (MBCT) for chronically depressed outpatients [11]. Due to time, economic and personnel limitations, however, these treatments are rarely directly accessible and only effective after a certain period of therapy. In the case of acute risk of suicidal risk, however, immediately effective interventions are needed. Leading suicidologists repeatedly have questioned whether treatment focusing on the mental disorder is an effective way to reduce the risk of

suicide [12, 13, 14]. They have proposed that it might be necessary to deal with suicidal risk as an independent syndrome with the aim of treating them quick and effectively - irrespective of the underlying disorder. The establishment of research criteria for suicidal behaviour disorders in the DSM–5 takes this idea into account. In a systematic review and meta-analyses, Meerwijk et al. reported that psychotherapeutic interventions that directly target suicidal thoughts and behaviours are more effective in reducing suicide attempts and suicide than interventions that only address these factors indirectly [15]. Consequently, in the current suicidal treatment research, there is a great effort to develop effective treatment approaches that quickly and directly engage the issue of suicidal risk independent of diagnoses.

The CAMS framework (Collaborative Assessment and Management of Suicidality) focuses on the difficulties and challenges in the treatment of patients with acute suicidal thoughts or behaviour by explicitly making suicidal risk the focus of therapy [13]. CAMS is a semi-structured therapeutic framework in which the therapist and the patient jointly initiate an intervention process to explicitly reduce suicidality. CAMS emphasizes active collaboration between the patient and the therapist and aims at enhancing the patient's motivation to live. To date, CAMS is supported by a range of clinical trial studies including eight correlational nonrandomized published trials [13] and four published randomized trials [16, 17, 18, 19]. So far, results are promising and suggest that CAMS is superior to other approaches and leads to a rapid and sustained reduction of suicidal ideation, overall symptom distress, and related risk factors such as depression and hopelessness. The impact of CAMS on self-harm and suicide attempts is promising but limited thus far [16]. The usefulness of CAMS in longer and private inpatient settings has already been previously demonstrated [20, 21]. Ryberg et al. showed CAMS to be effective in a context with a broad standard psychiatric sample among inpatients and outpatients [19]. To confirm and generalize the results to a broader population and to show that CAMS is superior to other approaches, further research is necessary, in particular randomized controlled trials with comparable treatment doses of CAMS and TAU in inpatient contexts with a standard psychiatric sample in the public health system and a very short treatment duration. To date, no CAMS studies have been carried out in German-speaking countries.

Methods

Aim of the Trial

The primary aim of the current study is to investigate whether CAMS reduces suicidal ideation and suicidal behaviour more than Enhanced Treatment As Usual (E-TAU) in suicidal inpatients. Secondary aims are to investigate effects of CAMS and E-TAU upon the general symptom burden, depression, reasons for living and the therapeutic relationship. Furthermore, we plan to test the influence of various moderating variables upon outcome, including diagnosis group (borderline personality disorder in particular), number of previous suicide attempts, treatment duration, number of therapeutic sessions, and baseline level of distress (see [22] for more information on moderators of CAMS).

Trial Design

In our pragmatic randomized controlled trial at the Clinic of Psychiatry und Psychotherapy, Ev. Hospital Bethel, Germany, CAMS is being compared with E-TAU within an inpatient crisis setting. The trial is designed as a single-center, two-armed, parallel-group, observer-blinded randomized clinical effectiveness trial. We expect to examine 144 patients of the Clinic of Psychiatry and Psychotherapy of the EvKB who are admitted to the ward due to acute suicidal behaviour (thoughts or actions) in order to reach the target sample size of 60 patients. After screening and randomizing, the study participants will be followed for about 6 months at four checkpoints t_1, t_2, t_3, t_4.

Individuals who are screened positive for the trial and who are committed to take part in the study are asked to complete a set of questionnaires (t_1) on the admission day or on the workday following the admission day (see Figure 2 below for an overview of all measures). Then, the patient is randomized and informed about his group membership and the respective intervention begins on the following day. A second examination (t_2) is carried out between 10 and 40 days later at the day before discharge. Another follow-up appointment will be arranged for 4 weeks after discharge (t_3). 5 months after the end of their treatment, patients will receive the examination instruments again by mail (t_4). Please see Figure 1 for a schematic overview of the time flow of the trial.

Figure 1: Overview of the examination procedure. CAMS = Collaborative Assessment and Management of Suicidality; E-TAU = Enhanced Treatment as Usual

Outcomes of the Trial

Primary Outcome

Suicidal Ideation

Beck Scale for Suicide Ideation (BSS)

The primary outcome in the trial is the change in suicidal ideation severity from baseline measure (t_1) to post assignment ($t_{2)}$ and the follow-up assignments (t_3 and t_4). Suicidal Ideation are measured at each assessment by the *German Version of the Beck Scale for Suicide Ideation* (BSS; [23]). The Beck Scale for Suicidal Ideation is a self-report instrument for assessing the patient's severity of suicidal tendencies. For this purpose, 21 statements on a likert scale ranging from 0 to 2 are evaluated as self-assessments and the frequency and seriousness of previous suicide attempts are reported. The statements containing content such as the wish to live, wish to die, frequency of ideation, perceived capability to carry out an attempt, and extent of actual preparation. The responses of 19 Items are summed up to create an index of suicidal ideation ranging from 0 to 38, with higher scores reflecting greater ideation. The scale has been found to be a valid and reliable measure of suicidal ideation for use with psychiatric patients,

including test-retest reliability and internal consistency scores above.90 [24]. The BSS is widely used in suicide research and has demonstrated predictive validity for suicide attempts and deaths by suicide [25]. The BSS is administered at all study time points.

Secondary Outcomes

Depression

Beck Depression Inventory-II (BDI-II)

The BDI-II is a 21-items self-report inventory of depressive symptomatology used to measure depression [26]. It is one of the most widely used research instruments for this purpose and has demonstrated good psychometric properties for use with an inpatient population [27]. Each item is rated on a Likert scale from 0 to 3, with higher scores indicating more severe levels of depressive symptoms. Previous studies have reported BDI-II means of 12.75 in a nonclinical student sample [28] and of 21.02 in an inpatient sample [29].

General Symptom Burden

Symptom Checklist–18-Mini (SCL–18-Mini)

The SCL–18-Mini is a self-report questionnaire that measures the current extent of the general symptom burden with 18 items [30]. On a Likert scale from 0 (not at all) to 4 (very much), patients should indicate how much they have suffered from various complaints in the last 7 days. 3 subscales (somatisation, depression, anxiety) and an overall index for mental stress can be calculated. There are very good coefficients for the internal consistency (Cronbach's Alpha). The results for convergent, discriminant and differential validity are satisfactory to good.

Reasons for Living

Brief Reasons for Living Inventory (deutsche Version) (B-RFL)

The B-RFL is a 12-items form of the *Reasons for Living Invent*ory, a self-report inventory on which patients rate how important each item would be for living if a suicide is contemplated. Inventory Items should be rated on a Likert Scale of 1 (not at all important as a reason of not killing myself) to 4 (very important as a reason of not killing myself), with higher scores indication more or more important reasons to live [31, 32].

The importance of family and children, religious values, beliefs in the own capabilities and the value of living in general as well as fears one may have about what others would think and about the actual pain involved in a suicidal act may be important considerations when someone thinks about contemplating suicide. The B-RFL possesses good psychometric properties and was as good as either the Beck Depression Inventory (BDI) or the Beck Hopelessness Scale (BHS) in predicting suicidality [33, 34]. The

Brief Reasons for Living Inventory, which has not yet been published in German, has been translated from English into German. In order to check and guarantee the linguistic and content-related correctness, a back-translation into English was carried out by a native speaker.

Therapeutic relationship

German Version of the Scale to Assess the Therapeutic Relationship in Community Mental Health Care, Patient-Version (D-STAR-P)

The therapeutic relationship should be measured with the patient-version of the D-STAR. The D-STAR-P is a 12-items self-report questionnaire with three subscales: Positive Collaboration, Positive Clinician Input and Nonsupportive Clinician Input. Loos et al. (2011) found the psychometric properties to be acceptable [35]. The feasibility and internal consistency of the D-STAR-P was good with also good convergent validity.

Suicidality

Suicide Status Form (SSF; CAMS condition only)

Administration of the *Suicide Status Forms* (initial, tracking and outcome versions) is an integral part of the CAMS method and is administered in a collaborative process with the patient, as described in the CAMS treatment manual [13]. The SSF is a multifaceted instrument, which is used in the course of the CAMS program for risk assessment, treatment planning and session documentation, as well as for outcome measurement. Five items asking for subjective ratings (0–5) of negative states: psychological pain, stress, agitation, hopelessness and self-hate. This set of variables has shown good validity and reliability with suicidal inpatients [36]. The first three variables (pain, stress and agitation) are based on Shneidman's cubic model of psychic pain that lies at the heart of his formulation of the suicidal experiences [37]. The SSF also obtains patient's sense of hopelessness, based on the work of Aaron Beck and self-hate, derived from Baumeister's work conceptualizing suicide as an escape from the pain of self-loathing [38, 39]. The SSF is divided into four sections to assess the current risk of suicide and to plan treatment. Based on the answers in the first two sections A and B, Section C discusses and defines possible treatment goals and steps with the patient.

Additional Measures

In addition to the outcome measures described above, sociodemographic data (including age, gender, education and current living situation) are recorded for all examination times. Furthermore, a short medical anamnesis will take place. This information is gathered in order to describe the characteristics of the study sample.

Exploratory Measures

In order to generate hypotheses for forthcoming studies and to improve our inpatient treatments, the following exploratory outcome is assessed:

Components of inpatient treatment

Questionnaire to assess the factors subjectively experienced as helpful in the context of inpatient crisis intervention

The questionnaire for the evaluation and assessment of the impact factors of crisis treatment was prepared by us at our own discretion. Patients should describe on 14 items how helpful they found offers of inpatient treatment, such as therapeutic sessions, contact with other patients, pharmacotherapy, the setting of the clinic, the help of the social worker etc., for their stabilisation. Inventory Items should be rated on a Likert Scale of 1 (not helpful at all) to 6 (extremely helpful), with higher scores indication more satisfaction with the treatment. In addition, they should award a grade for inpatient treatment and estimate their health before and after treatment.

We have kept the set of research measures at a minimal level in order not to overstrain the highly stressed patients without losing meaningful and thoroughness. Completion of the baseline and the follow up questionnaires (t_1, t_2, t_3, t_4) will take patients approximately 20–30 minutes each. The test batteries are handed over by the responsible therapist and are administered by the research assistant.

Study Center

The treatments are taking place at the Clinic of Psychiatry and Psychotherapy, Ev. Hospital Bethel in Bielefeld, Germany. The clinic is responsible for the public health care of the city of Bielefeld with over 330,000 inhabitants. The study is being carried out on a crisis ward with 22 beds, where approximately 600 inpatient treatments are performed annually with a mean duration of stay of 13 days (range 1 to 60).

Study Sample

Subject Inclusion and Exclusion Criteria

Included are patients with acute suicidal thoughts or behaviours who fluently speak and read the German language and who are able to agree to participate in the study and to record this by a written informed consent. Most patients are expected to suffer from affective and/or anxiety disorders and/or personality disorders. We only treat inpatients. The consent, legal capacity and cognitive capacities are clinically examined. Even clinical doubts about self-determination lead to exclusion from the study.

Patients are also excluded who are chronically suicidal and have been treated in an inpatient psychiatric setting for a total of more than 12 weeks within the last 12 months, or who have been admitted more

than 6 times during this period, or who have received inpatient integration assistance. In addition, patients with a psychotic disorder during the last 12 months, an eating disorder with BMI < 16 and/or a current substance dependency are excluded. Substance abuse or previous substance dependence are not exclusion criteria. Patients who are currently suffering from psychotic symptoms as part of an underlying depressive disorder are also excluded, as are patients with developmental disabilities, dementia or an organically conditioned mental disorder. Also excluded are patients who, at the time of admission, have already planned further long-term inpatient or day patient treatment to continue after the crisis therapy without being discharged in the meantime, as well as patients who have to be treated on our crisis ward for longer than 40 days. However, the duration of the treatment must be at least 10 days in order to ensure that patients receive the treatment to a sufficient extent (at least three sessions following the admission interview). The exclusion criteria are established at the time of admission (t_1) and validated through the diagnostic interview few days later. Patients who are accommodated in the clinic against their own's will according to the Law of aid and protective measures for mental illnesses (PsychKG) from the federal state of North Rhine-Westphalia or the care law do not take part in the study.

Subject Retention

In the context of suicidal crises, spontaneous improvements or treatment discontinuations often occur, e.g. because the life conditions of the patients have spontaneously changed. Nevertheless, we make every reasonable effort to maintain every randomized participant in the study.

A telephone appointment between the end of treatment and the post-operative session should serve to maintain contact with the patients and to make an appearance for the post-operative session (t_3) more likely.

Subject Withdrawal Criteria and Procedures

In the informed consent procedure, participants are informed from their therapists that they can withdraw their consent from study participation at any time without giving reasons and without any negative consequences. However, clinical staff will ask participants to share their reasons for withdrawal in order to identify any adversities or difficulties experienced by subjects during the trial. Withdrawn participants have the opportunity to continue a regular crisis therapy on the ward if this appears to be indicated.

In addition, participants can be withdrawn from the trial by the investigators, if an exclusion-criteria is found after inclusion either during the screening-process or by clinical assessment, for example, if a patient develops psychotic symptoms during the course of treatment. The participant is then excluded from the trial and continue with a regular treatment in the clinic.

Procedures

Recruitment and Eligibility Screening

The recruitment of the study patients will be carried out consecutively according to the admission of the patients to the ward. The patients are referred from the psychiatric ambulance of the hospital, from general practitioners or from somatic wards after suicide attempts and patients can also self-refer to the clinic. As soon as there are indications in the admission interview for inpatient crisis treatment on the ward that a patient fulfils the inclusion criteria he or she is informed verbally and in writing about the study at the same or the following working day.

Diagnostic Procedures

With a summary of all available information, the current psychiatric diagnoses are made by at least one psychiatrist and one psychologist in the first admission interview. These diagnoses are checked in the course of treatment few days after inclusion by an independent research assistant with help of a structured clinical interview. The research assistant is a Psychologist (B.Sc.) who has been trained in the diagnostic SCID-interviews. After conducting the clinical diagnostic interview, the research assistant discusses and clinically validates the diagnostic conclusion with the therapist. All diagnostic data will be recorded directly on Case Report Forms and are considered to be source data.

Diagnosis

Structured Clinical Interview for DSM-IV Axis I & Axis II

SCID- I & SCID-II

The SCID-I is a diagnostic instrument based on diagnostic criteria for Axis I disorders found in the *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition (DSM-IV-TR; [40, 41, 42]). The SCID has been demonstrated to have good reliability with kappa values ranging from.04 to.84, with a mean of.61 for all disorders across a large number of samples. Test-retest reliabilities for disorders in psychiatric patients range from.54 to.84 with a mean of.73. In addition, the *Structured Clinical Interview for DSM-IV Axis II* was used to identify participants with personality disorder given the higher suicide risk for personality disorders, especially for the borderline personality disorder [43]. The SCID interviews will be conducted after the baseline assessment within the first days of study treatment.

Intelligence

Mehrfach- Wortschatz-Intelligenztest (MWT-B)

The Mehrfach-Wortschatz-Intelligenztest [44] is used to measure the general intelligence level according to a simple and reliable scheme using verbal material. Patients are asked in each of the lines to find out if any of the words presented actually exist and to cross it out. In each line, according to the multiple-choice principle, there is one word known in common or scientific language among four fictitious new

constructions. The total of 37 items are arranged according to the level of difficulty. The total number of correctly marked lines is compared with the performance of a representative sample of German-speaking adults aged 20 to 64 (n = 1,952). Then standards (IQ, standard value and percentile rank) can be determined.

See Figure 2 for an overview of the procedures of the clinical trial including enrolment, diagnostic and interventions.

Figure 2: Displayed are the standard protocol items (SPIRIT) for the clinical trial including enrolment, diagnostic assessments and interventions.

Interventions

Collaborative Assessment and Management of Suicidality (CAMS)

In brief terms, CAMS is a suicide-focused psychotherapeutic approach that targets suicidality as the primary focus of all assessment and treatment.

CAMS is based on the assumption that suicidal thoughts and actions are less a symptom of a disease than an intrapersonal logical and comprehensible response to psychological stress and suffering because basic needs are not met. Suicidality can be a great challenge for the therapeutic relationship if it creates an opposing dynamic (patient versus therapist) - a struggle to determine whether suicide is an option or not. CAMS is intended to circumvent this dynamic and enables the patient to constructively deal with his own suicidal tendencies in a non-combative and collaborative therapeutic dynamic.

Within the CAMS, patient and therapist should work together as focused as possible on patient-defined suicidal “drivers” which are those problems that cause the patient to consider suicide. The “common” in CAMS shows itself both content wise and figuratively: Immediately at the beginning of the CAMS intervention, the therapist asks the patient to be allowed to sit next to the patient to fill in the suicide status form (SSF) during the survey (“I want to see it through your eyes”, [13]), so that both can work side by side and together.

CAMS treatment follows a pre-defined structure, where the SSF serves as a multipurpose assessment and treatment planning tool. The continuous monitoring and work on reducing individual reasons for being suicidal and developing alternative solutions and perspectives over the course of the sessions ensures high-quality suicide-focused treatment and is associated with detailed documentation. A typical treatment course in our study is characterized by employing two sessions weekly of 30–60 minutes duration. Every session is initiated by filling out the SSF in a side-by side manner. In the first session, approximately 20 minutes are used to fill out the first part of the SSF as part of a “core assessment”. During the interim sessions, approximately five minutes are used to fill out this part of the SSF. A problem-specific treatment plan addressing the patient’s suicidal drivers is jointly developed during the first

session and routinely evaluated in each following CAMS session. Furthermore, as part of CAMS-guided care, a stabilization plan is developed during the first CAMS session and evaluated and improved during every consecutive session in order to increase the patient's coping skills. Following the first assessment, various suicidal "drivers" are identified and treated during the CAMS course. Ongoing CAMS care consists of developing adequate coping skills and helping the patient identify and cope with their drivers of suicidality in a problem-focused way. In CAMS, suicidal drivers are divided in two categories; direct and indirect drivers. Direct drivers are thoughts, feelings, or behaviours that increase specific suicidal risk. Indirect drivers are factors that themselves do not produce suicidal states but instead increase the vulnerability and may lead to the activation of direct drivers (e.g. unemployment, economic difficulties). The CAMS approach does not require any therapeutic orientation and does not prescribe precise interventions as to how exactly suicidal drivers should be treated, so that the therapist chooses the concrete interventions on his or her own.

There are no mandatory homework assignments during a CAMS course of care. The duration of CAMS-guided care is dependent on the treatment progress and varies between patients. The treatment is concluded when the clinician and the patient agree that the acute danger of a suicidal act is eliminated, adaptive coping skills are developed while the patient scores him/herself below 3 on subjective suicidal risk rating (on a 5-point scale) and that they are managing any suicidal thoughts or feelings while remaining behaviorally stable which can lead to planning a discharge from the inpatient setting. We will analyse all cases who have received between 4 and 9 CAMS sessions including the initial session.

Enhanced- Treatment as Usual (E-TAU)

In addition to the ward's standard therapy services, which CAMS patients also receive, patients in the TAU condition also receive supportive, behavioural-therapeutic conversations similar to the number of CAMS sessions (at least three and up to nine 30–60-minute sessions during treatment and one post-operative session). There is no predefined manual for the TAU treatment. In addition to establishing a viable therapeutic relationship and acute relief, diagnostic, psychoeducation and initial therapeutic steps, the planning of further treatment of the underlying disease or life problem plays an important role. Depending on the current risk situation, the aim is to promote the patient's safety, to encourage the patient to reflect and to build up confidence and motivation for treatment and the effecting of changes. Depending on the problem areas described by the patient, the practitioners independently determine the focal points and contents of the therapeutic sessions together with the patients. The therapists are free to choose methods and strategies to promote self-control and the use of social support as well as to learn strategies for emotional stabilisation.

An overview of the various modules of crisis intervention in E-TAU can be found in Figure 3. To increase experimental internal validity, TAU in this study was "enhanced" (i.e., E-TAU). Patients in E-TAU receive as many treatment sessions as CAMS Patients, approximately 2 per week, so the treatment dose is

comparable in both conditions. Thus, E-TAU was designed to balance and minimize threats to both the internal and external validity of the study.

Figure 3: Diagram showing contents of E-TAU treatment.

Standard Inpatient Care (SIC)

SIC contains all non-specific therapy elements that are identical for both intervention groups. In addition to the individual psychotherapeutic sessions described above, there are also occasionally supportive consultations with the nursing staff. Longer individual nursing contacts due to crisis situations should be documented in number and length. A daily morning meeting takes place for all patients. Depending on the patient's stability and wishes, an individual therapy plan is designed so that the patient can participate in additional offers such as body and movement therapy, Jacobson relaxation, music therapy, occupational therapy and offers from clinical social work and pastoral care. Weekly team meetings serve to exchange information on each individual patient between all the professional groups involved, and weekly visits by a senior physician also take place. The interventions are embedded in the context of a therapeutic environment that offers continuous care, supervision and plenty of opportunities for spontaneous contact with fellow patients.

Choice of comparator

The aim of this trial is to test the efficacy of CAMS for suicidal inpatients on an acute crisis ward. For this purpose, it is necessary to compare CAMS as provided on the ward with the efficacy of the treatment that would be available without this module, i.e. a TAU condition. So far, no data exists regarding the efficacy of TAU in this understudied population. As described above, TAU in this study was "enhanced" (i.e., E-TAU), which means that the treatment dose is comparable in both conditions, to increase experimental internal validity.

Medications and Treatments permitted/not permitted during the intervention

In both groups, patients receive medication according to their underlying disease and current symptoms, which is measured according to the clinical experience of the senior physician according to international guidelines. Benzodiazepines and medication on demand can also be used. All medication and changes in medication are recorded in both groups. We expect that medications are equally represented in both arms as per randomization.

In the follow-up investigations, it is also assessed whether and, if so, which follow-up treatments the patients receive, e.g. outpatient psychotherapeutic or psychiatric treatment as well as any partial inpatient or inpatient treatment.

Measures taken to minimize/avoid bias, including randomization and blinding

Randomization

Patients who meet the inclusion criteria and agree to participate in the study are randomly assigned to one of the two therapy arms either CAMS (36 subjects) or TAU (36 subjects). Randomization is performed by an independent practitioner by throwing the dice immediately after the patients have agreed to participate in the study and returned the completed questionnaires (1–3 = CAMS, 4–6 = E-TAU).

Blinding

Due to the behavioral nature of the intervention, neither participants nor therapists and therapy interpreters can be blinded. However, the diagnostic examination is performed by an independent clinician who is blinded for the study group and we tried to keep the group membership confidential from the treatment team and from other patients and study participants, e.g. there was no documentation about the group membership in the patient file. Participants are instructed not to reveal any information related to the group they have been assigned to or regarding the therapeutic process.

Trial Monitoring

There are regular appointments with the supervisors once a month with the main purpose to observe the progress, the well-being of the patients and to identify problems in conducting the study and to solve problems together. Supervisors have access to all documents (e.g. assessments, audiotapes of therapy sessions, therapy session sheets) to check diagnostic accuracy, consistency with data entered, and adherence to treatment.

Treatment fidelity

The therapists in CAMS and TAU are a licensed psychotherapist and a psychologist (Msc.). The assignment to the therapist is consecutive, i.e. the clinician who conducted the admission interview will also be responsible for further treatment. Potential effects of the therapists will be analysed during the evaluation. We have trained CAMS therapists with help of the E-learning training by David Jobes, which both therapists have completed before the start of the study. Additionally, both have worked intensively with the CAMS manual of David Jobes. The application of the Suicide Status Form (SSF) was practiced by each therapist with at least 3 patients before the start of the study, so that the therapists have internalized the contents and acquired sufficient adherence to the CAMS framework. In the event of difficulties, David Jobes provides consultation.

Every fourth treatment session of the therapists is supervised. Each therapy session is audiotaped, and the therapists are rated for adherence according to the CAMS Rating Scale (CRS) by an external evaluator so treatment adherence to CAMS should be ensured [45]. The supervisors also monitored the E-TAU sessions using the CRS to ensure and verify that clinicians were not doing CAMS in these sessions. The CRS is an observer rating scale and consists of three parts and 14 items in total. Part I covers the treatment philosophy, part 2 the clinical/ session framework and part 3 the overall rating. The items were rated on a 6-point scale from 0 = poor to 6 = excellent. The use of the CRS therefore serves to confirm the difference in treatment groups with regard to the fact that the same therapists are treating both groups. We discussed the problem of the CAMS therapists being also the TAU therapists and the question if how the therapy is influenced by the knowledge about the other therapy arm. But in fact, despite the risk of contamination, if difference is there between the groups, from our view there is even more proof because the clinicians serve as their own controls.

Treatment feasibility

The feasibility of the measures is assessed on the basis of dropout rates and the satisfaction with the assigned procedure is also measured. A therapy drop out is defined if the treatment is terminated before the conclusion of at least 3 sessions.

Measures taken to avoid attrition bias

In order to prevent an attrition bias we try to examine patients even after a discontinuation of the study participation further and we carry out the analysis according to the Intention to treat method. In order to estimate the extent of a possible bias, the participants who remain in the study are compared with those who drop out prematurely. And as we expect difficulties in collecting follow-up data for which patients are expected to return to the clinic after discharge, we offer them a small expense allowance of 10 Euros for their travel expenses in order to avoid a systematic drop-out.

Data Handling and Quality Control

In our role as data producers, our clinic is responsible for handling of the data generated in our institution according to the General Data Protection Regulation (GDPR). Data storage and transfer will be conducted exclusively in an encrypted manner. Three different kinds of data will be produced at the centers: (1) Personal data including names and contact information, (2), pseudonymized screening, diagnostic and therapy process data, and (3) source data (e.g., audios of assessments and therapy sessions, therapy session sheets). A separate code list with a unique identifier for each participant links the personal data to the pseudonymized data. The code list is stored at the clinic by the data custody and will be deleted at the end of the project duration, thus, at the end of the project the pseudonymized data will become anonymized data. We will transfer the pseudonymized encrypted data to a secured server accessible only for authorized staff. Checks for completeness as well as range checks will be conducted to ensure data

integrity. Statistical analyses will be conducted by independent collaborators. Direct access to trial documents, including source data, is provided for trial-related monitoring and reviews by the ethical committee or regulatory authorities if requested following the guidelines of the GDPR. All individuals who are authorized to perform the aforementioned reviews are bound to confidentiality.

Statistics

Power Analysis and Sample Size Calculation

An a priori power analysis by using G*Power was carried out to determine the sample size [46]. On the basis of the available literature, we expect an average effect size (comparison of CAMS versus TAU with regard to the reduction of suicidal tendencies) of Cohen's d = 1. Here we refer to the study by Ellis (2015), which is rather comparable [21]. The author reports a pre-post effect size of d = 1.72 for CAMS (measured by the BSS) and of d = 0.71 for TAU. Although the interaction effect was not reported we assume it to be about d = 1.

Taking into account a probability of α error = 5 % (one-sided) and a power of 1 - β = 80 %, the total sample size of 48 participants, i.e. 24 per group. For compensating participants who withdraw their consent we plan 30 subjects per group. Assuming that after the first diagnostic examination 50% are not eligible for inclusion into the study due to non-existent inclusion criteria or exclusion criteria and 20% discontinue treatment in the course of the study or are excluded due to further inpatient treatment, it is to be expected, that 144 patients have to be interviewed, of whose 72 patients (36 per group) are randomly assigned to CAMS intervention (36 subjects) and a TAU (36 subjects), respectively, in order to achieve the targeted number of N = 2 x 30 in the intent to treat sample.

Data Analyses

Statistical Analyses

The analysis of this study will be calculated as a mixed-effects model with the BSS total symptom score as the outcome variable. Mixed models are especially suited for longitudinal studies as they can deal with a correlated data structure and can analyze all cases and data points, even if missing values occur in the course of the trial. In detail, participants will be modeled as a random factor, while time and intervention (CAMS vs. TAU) as well their interaction will be modeled as fixed factors. The hypothesis that CAMS is superior to TAU in the treatment of suicidal patients will be evaluated by the significance test of the interaction effect time × intervention.

In case of a significant interaction effect, two planned general linear hypotheses will be calculated as post-hoc tests for linear mixed effect models in order to test between-group differences at t_2 and t_3. P-values will be adjusted for multiple comparisons following the Holm procedure.

We will perform an intention-to-treat analyses, that is, all trial participants will be analyzed as randomized, even if they discontinue treatment or are unavailable for one or both of the follow-up interviews. The between-group effect size (Cohen's d) will be calculated at each follow-up assessment (t_2 and t_3).

Continuous secondary outcome measures (BDI-II, SCL–18-Mini, B-RFL, D-STAR-P) are analyzed in the same way. In absence of a valid cut-off score for clinically significant change or treatment response of the BSS, the number of subjects with clinically significant improvement as well as worsening based on the reliable change index (RCI) will be compared between groups using $\chi 2$ –tests or Fisher's exact tests. For this purpose, the RCI will be calculated based on the pre-treatment scores of the study sample. We will use two-tailed tests for statistical significance with alpha set at $P<0.05$. Effect strength will be determined with Cohen's d. All calculations will be performed using SPSS 20.0 computer software [47].

Interim analyses before the completion of the investigations are not intended. Any potential deviations from the original statistical plan as defined in the study protocol will be described in protocol amendments as well as in the final study report.

Dissemination policy

Dissemination of trial results

The trial results will be disseminated to the scientific community by publications in international peer-reviewed journals. The results regarding the primary outcome of the trial will be published regardless of the direction and statistical significance of the effect.

In addition, we expect that this trial can inform the regular health care system (clinics, psychotherapists in outpatient clinics) about the effect of short-term therapy for suicidal patients and improve the quality of care. As there is a lack of methodological sound RCTs for suicidal patients we expect that this trial can have a major impact on the guidelines for the treatment of suicidal patients.

Safety and Ethical Aspects of the Trial

Safety

CAMS previously has been shown to be an effective treatment model. In a pilot study from 2012, Ellis and colleagues found that CAMS was successfully implemented and accepted by both patients and clinicians within the frameworks of an inpatient settings and Ryberg and colleagues (2019) showed that CAMS was successfully implemented within a very broad psychiatric sample with a high symptom load which is probably comparable to our sample [19, 20]. On this basis we expect that CAMS most probably will be acceptable and feasible to the patients and therapists within our clinic. Psychological stress caused by the examination of the causes of suicidal tendencies within the treatment is possible. Negative emotions

will occur in all suicidal patients, this is immanent to the symptoms and treatment situation. The team at the ward, on which the study is conducted, is specialized in the treatment of this group of patients. In the event of an increase in psychological stress, patients in emergency situations have nursing staff on the ward and doctors on duty outside regular working hours available at all times for supportive interventions. In an emergency, safety measures can also be initiated in an inpatient context. Patients would be excluded if therapists were given the impression that CAMS or E-TAU treatment is harmful to the patient.

In the case of suicides in the course of treatment and study participation that may occur in such a high-risk group, these are documented by the therapists.

Ethics

The trial has been approved by the Ethical Committee of the Medical Department of the University of Münster in Germany on 6 March 2017. Research on a vulnerable group of patients requires several ethical considerations to be discussed and addressed, especially when it comes to suicidal patients, who are excluded from most treatment studies. The major problem in the field of suicide treatment is that most clinically administered treatments are not supported by randomized controlled trial investigations.

If we look at the results of previous CAMS clinical trials, there is no reason to believe that CAMS will have a more negative effect than TAU, rather the opposite. The main intention of the study is to evaluate whether CAMS is more effective than E-TAU. If our hypotheses are supported, our goal is to contribute to the use of CAMS for future inpatients in our own and other clinics. It is important to stress that all suicidal patients will receive treatment during the study, whether this is CAMS or E-TAU. Patients in the study receive twice as many therapeutic consultations as it is assured to other patients on the ward who do not participate in the study. The increased amount of therapeutic consultations in both conditions should motivate patients to participate in the study and ensure that they receive a sufficient number of treatment sessions even in the short treatment periods to make a valid comparison between CAMS and TAU possible and appropriate.

We will not offer a control group who receives no treatment or postponed treatment. Participation is voluntary, and the patients are informed of their possibility to withdraw from the study at any time. The patients attending the project are not offered any remuneration, such as payments of gifts for their participation in the trial. Therefor we expect little to no other motives for participation, except general openness, hope for an improvement of complaints and interest.

Data protection and security

During the trial, sensitive data on the mental health status will be collected in the assessments on the Case Report Forms. The Case Report Forms will be pseudonymized, that is, the name of the participant will be replaced by a code. A separate code list will be only available in paper and will link the participant

codes with the name and contact information for the purpose of contact for the follow-up assessments. This code list will be always locked securely and stored separately from the study records by the data custody. Furthermore, other source data (e.g. therapy session sheets, audio tapes of therapy sessions) which cannot be pseudonymized, are of sensitive nature as they might reveal the identity of the participant. All participant information will be stored in locked filing cabinets. Study records which contain names (e.g., informed consent forms, contact sheets) as well as data which might allow the identification of the participant (e.g. audio-tapes) will be stored separately from the Case Report Forms (both physically and electronically).

All team members of the centers who have contact with the sensitive data, including the clinicians who conduct diagnostic interviews and treatments are bound to confidentiality. The only exceptions are in the event of an acute risk of self-harm or harm to other persons, which would require immediate actions and/ or mandatory reporting.

Discussion

For our study, we decided to focus on effectiveness of CAMS. As a result, pragmatic considerations guided our decisions for the development and implementation of the study. Within effectiveness studies it should be investigated, and it is crucial whether an intervention can work within normal practice. The patients seeking our help in the mental health system often have multiple problems. By making ongoing suicidality the main inclusion criteria and trying to keep the inclusion criteria very broad, we expand the applicability of the results from the trial. To enhance the feasibility in the trial process for the patients, we decided to use a rather short test battery.

The trial is a single centre trial and can therefore be considered as a pilot trial for multicentre trials in the future. In order to obtain external validity, we need multicentre trials.

However, we expect some challenges during the implementation of the study. The main concerns are associated with the setting and recruitment. The ward where the study is carried out is an acute crisis ward with numerous very short treatments and a high fluctuation of patients, which can create great restlessness and make the additional work for the therapists in the study in everyday life difficult.

Because the inclusion criteria are very broad, we will invite as many patients as possible to participate in the study. There is no preselection. Randomization should reduce the risk of a selection bias. We will also include patients with longer histories of inpatient psychiatric treatments who seem to express suicidal thoughts as “crying for help” in order to receive support, which is sometimes difficult to distinguish from suicidal tendencies. These patients are generally regarded as very difficult to treat. However, we will also include these patients in the study to see if the treatment supports these patients as well. The inclusion of these “chronic” patients may, of course, reduce the effects of the study.

Due to the multiple illnesses of the patients in our clinic, we expect in particular many patients to have personality disorders and special needs and expectations in the treatment, which may cause problems

during the treatment in adhering to the manual or can lead to increased treatment discontinuations.

Finally, it is possible that despite the broad inclusion criteria, many patients of the ward meet exclusion criteria, and recruitment may therefore take longer than initially assumed. Intent to treat-analyses should reduce the bias introduced by missing data.

Trial Status

Version	Author	Date	Reason for Revision
0.1	M. Santel	1 March 2019	1st draft version sent to participating authors for review
0.2	M. Santel	24 May 2019	2nd draft version with integrated feedback from all co-authors sent to all co-authors again
1.1	M.Santel	29 May 2019	1st version sent for review

Date: 29 May 2019

The trial opened by recruiting the first patient on 8 March 2017 and is still recruiting. Recruitment is terminated when the targeted number of 30 patients in each treatment group has been reached. Recruitment is expected to be completed in autumn 2019.

List Of Abbreviations

In the following abbreviations are listed as used within this study protocol:

BCBT: Brief Cognitive Behavioral Therapy BDI-II: Beck-Depression-Inventory-II; BSS: Becks Scale for Suicidal Ideation; B-RFL: Brief Reasons for Living Inventory; CAMS: Collaborative Assessment and Management of Suicidality; CBT: Cognitive Behavioral Therapy; CRS: CAMS Rating Scale; CT-SP: Cognitive Therapy for Suicide Prevention; DBT: Dialectical Behavior Therapy; DSM: Diagnostic and Statistical Manual of Mental Disorders; D-STAR: German Version of the Scale to assess the Therapeutic Relationship in Community Mental Health Care; E-TAU: Enhanced Treatment As Usual; EvKB: Evangelical Hospital Bethel; GDPR: General Data Protection Regulation; MBCT: Mindfulness-based Cognitive Behavioral Therapy; MWT-B: Mehrfach-Wortschatz-Intelligenztest; RCI: Reliable Change Index; RCT: Randomized Controlled Trial; SCID-I & SCID-II: Structured Clinical Interview for DSM-IV, Axis I & Axis II; SCL–18-Mini: Short version of the Symptom Checklist; SIC: Standard Inpatient Care; SSF: Suicide-Status-Form; SPSS: Statistical Package for the Social Sciences; TAU: Treatment As Usual.

Declarations

Ethical Approval and consent for participate

The trial has been approved by the Ethical Committee of the Medical Faculty of the University of Münster, Germany (reference number: 2016–620-f-S).

Participation requires the provision of informed consent, and participants sign a written declaration on consent before they are enrolled in the trial. Patients will be removed from the trial if he or she during trial period presents acute suicidal thoughts or loses the ability to understand the research process or the concept of informed consent.

According to scientific conventions, the volunteers are fully informed about the study in written and verbal form and document their voluntary participation. The examination can be discontinued at any time by the volunteers without giving reasons and does not have any negative consequences for the patients regarding their treatment.

To ensure anonymity, all questionnaire data are collected pseudonymously, i.e. in a form not identified by name by assigning consecutive code numbers. The pseudonymised data are archived in the research department and destroyed after ten years or if consent is withdrawn.

Availability of data and material

The datasets generated during the current study are not publicly available because the data collection is still ongoing, and the data sets are not yet complete, but data are available upon reasonable request from the corresponding author.

Competing interests

The authors declare that they have no competing interests. Dr. Jobes receives grant support from the National Institute of Mental Health (NIMH), Department of Defense, Veterans Affairs, the American Foundation for Suicide Prevention in the United States. He receives book royalties from Guilford Press and American Psychological Association Publications. He is a founder and co-owner of CAMS-care, a training and consultation company.

Funding

Financing is provided entirely by the clinic’s own funds.

Authors contributions

MS was responsible for the study conception and writing the manuscript, critically reviewing it as well as conducting the trial. MD is the trial sponsor and participated in the conception of the trial and critically revised the manuscript, FN participated in designing the trial and revised the manuscript critically, KHF and MB participated in the conception of the trial and were responsible for the supervision of the therapists and critically reviewed the manuscript. DJ participated in the conception of the trial and critically reviewed the manuscript. All authors have read the manuscript and its content. TB was responsible for the study conception, the design of the trial and critically reviewed the manuscript.

Name and address of the trial sponsor

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Appendicies

Appendix 1—Full questionnaire set

Appendix 2—Full CAMS Material

Appendix 3—Informed Consent Forms (for editor only)

Appendix 4—SPIRIT Checklist

Appendix 5—Consent of the Ethical Committee (for editor only)

Figures

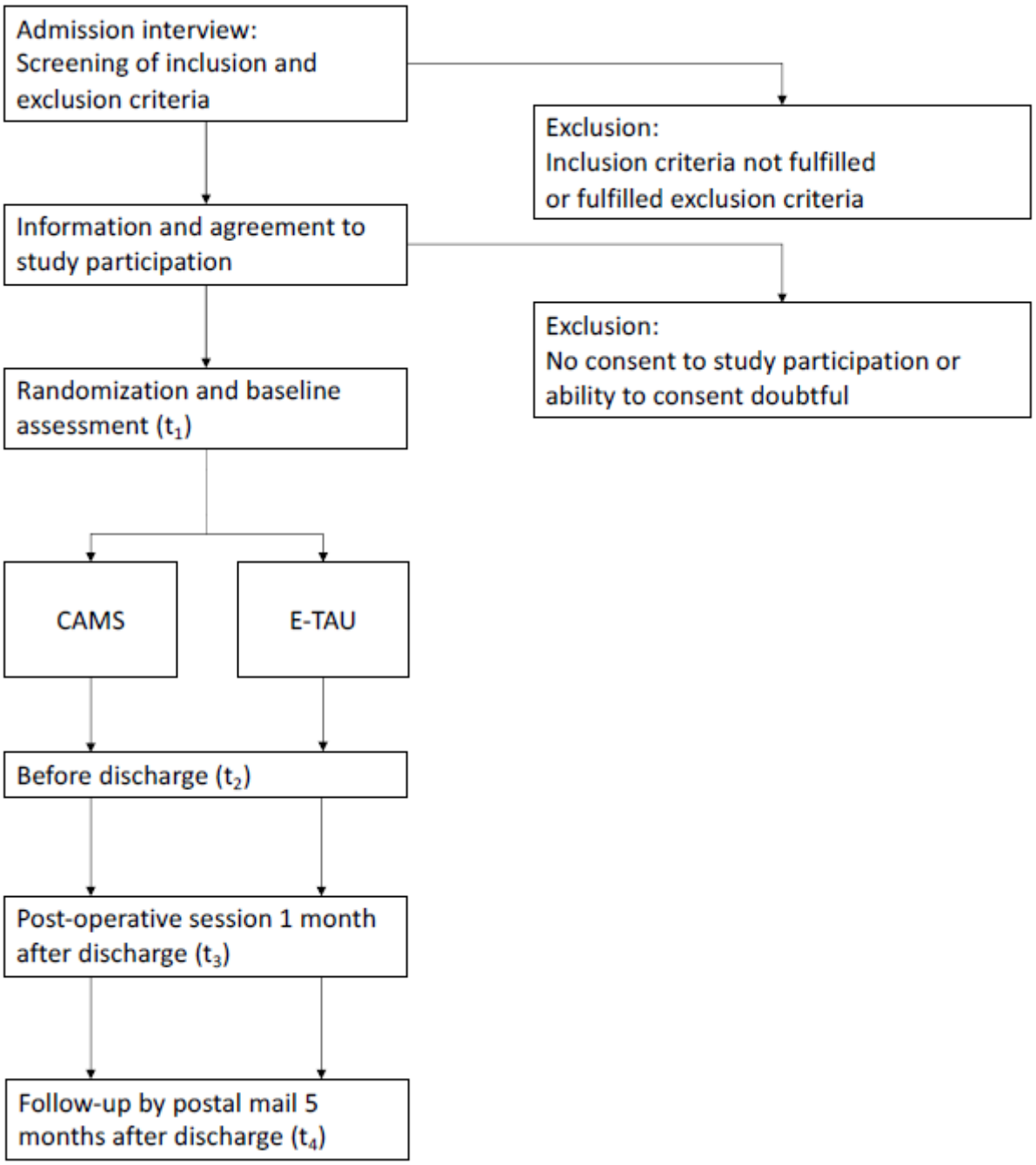

Figure 1

Overview of the examination procedure. CAMS = Collaborative Assessment and Management of Suicidality; E-TAU = Enhanced Treatment as Usual

		STUDY PERIOD				
	Enrolment	Allocation		Post-allocation		
TIMELINE	t_0 screening	t_1 baseline after admission	R (immediate randomi-zation at t_1)	t_2 before discharge (about 1-4 weeks after t_1)	t_3 1 month after discharge	t_4 5 months after discharge (per postal service)
ENROLMENT						
Eligibility screen	X					
Informed consent	X					
INTERVENTIONS						
CAMS + SIC			◆—	—◆		
E-TAU + SIC			◆—	—◆		
ASSESSMENTS						
MWT-B		X				
SCID I & SCID II		X				
BSS		X		X	X	X
BDI-II		X		X	X	X
SCL-18-Mini		X		X	X	X
Brief RFL		X		X	X	X
D-STAR-P				X	X	
Questionnaire for the evaluation and assessment of the impact factors of crisis therapy				X	X	
Short medical anamnesis		X		X		

Figure 2

Displayed are the standard protocol items (SPIRIT) for the clinical trial including enrolment, diagnostic assessments and interventions.

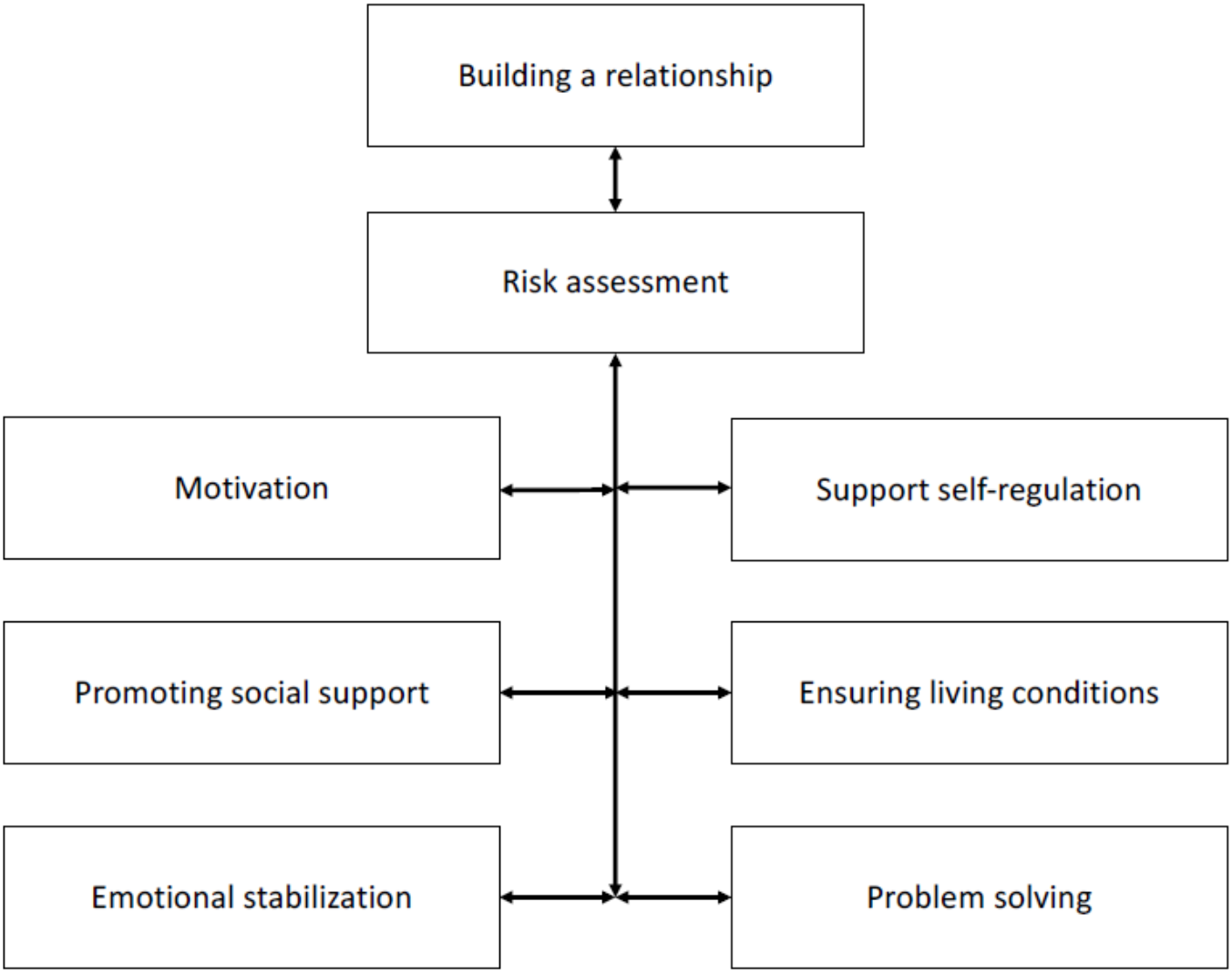

Figure 3

Diagram showing contents of E-TAU treatment.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- renamed9e08d.pdf
- CAMSStudienmaterialgesamt.pdf
- SPIRITCheckliste.pdf