

Research paper

Managing suicidality within specialized care: A randomized controlled trial

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ABSTRACT

Background: Suicide prevention is a core task in mental health services. Our objective was to determine whether Collaborative Assessment and Management of Suicidality (CAMS) reduced suicidal thoughts and behaviors and mental health distress more effectively than treatment as usual (TAU) in a heterogeneous patient population within specialized mental health care services.

Methods: In this observer-blinded pragmatic randomized controlled trial participants who scored 13 or above on Beck's Scale for Suicide Ideation-Current (BSSI-C) were included from seven in- and outpatient units. Primary outcome was suicidal ideation (BSSI-C). Secondary outcomes were mental health distress measured by the Outcome Questionnaire-45, and suicidal behaviors measured by the Suicide Attempt Self-Injury Count. Patients were assessed at baseline and after 6 and 12 months.

Results: The final intent-to-treat analyses included 78 participants (mean age 35.9 years, SD = 14.5, 41 females). The majority were depressed (65%), had a secondary diagnosis (73%) and 32% suffered from borderline personality disorder or borderline traits. After 6 months, CAMS participants reported lower levels of suicidal ideation compared to TAU ($\beta = -4.29$, 95% CI = -8.32 to -0.27 , $p = .036$). Larger changes in mental health distress were observed for CAMS participants after 6 months ($\beta = -11.87$, 95% CI = -22.99 to -0.76 , $p = .036$) and 12 months ($\beta = -13.70$, 95% CI = -24.88 to -2.51 , $p = .017$).

Limitations: The modest sample size rendered the trial unable to detect small between-group differences.

Conclusions: CAMS reduced suicidal ideation and mental health distress more efficiently than TAU in a heterogeneous patient population within specialized care.

1. Introduction

Traditionally, suicidal thoughts and behaviors have been understood as symptoms and indicators of an underlying mental disorder (cf. Jobes, 2006; Pompili, 2010), most typically depression (Chesney et al., 2014). However, leading researchers have questioned whether treatment of the mental health disorder alone is an effective way to reduce the risk of suicide (De Leo, 2004; Linehan, 2008; Jobes, 2006; Pompili, 2010). Suicide specific treatment models may be effective in reducing suicide risk and suicidal behaviors (Meerwijk et al., 2016). It has been suggested, that opposed to focusing on the mental health disorder per se, treatment should target the pain and underlying reasons of why a person considers suicide (Pompili, 2018). Suicide specific treatment models explicitly address suicidal thoughts and behaviors. Phenomena such as mental pain and hopelessness transcend diagnostic categories and are tightly associated with suicidal thoughts and behaviors, both

independent from and in the context of a specific mental health disorder as e.g. depression (Ducasse et al., 2017; Verrocchio et al., 2016; Cuijpers et al., 2013). Together with listening to the patients' communications about suicide (Pompili et al., 2016), exploring these phenomenological factors in treatment might be a promising approach in suicide prevention.

In a metaanalysis of 32 RCTs, Calati and Courtet (2016) found that those adult patients who received psychotherapy were less likely to attempt suicide during follow-up compared to those who received pharmacological interventions, supportive interventions, telephone interviews or treatment as usual. In another systematic review and meta-analyses, Meerwijk et al. (2016) reported that psychotherapeutic interventions for people at risk for suicide that directly targeted suicidal thoughts and behaviors were more effective in reducing suicide attempts and suicide compared to interventions that only addressed these factors indirectly. In a recent systematic review, Zalsman et al. (2016)

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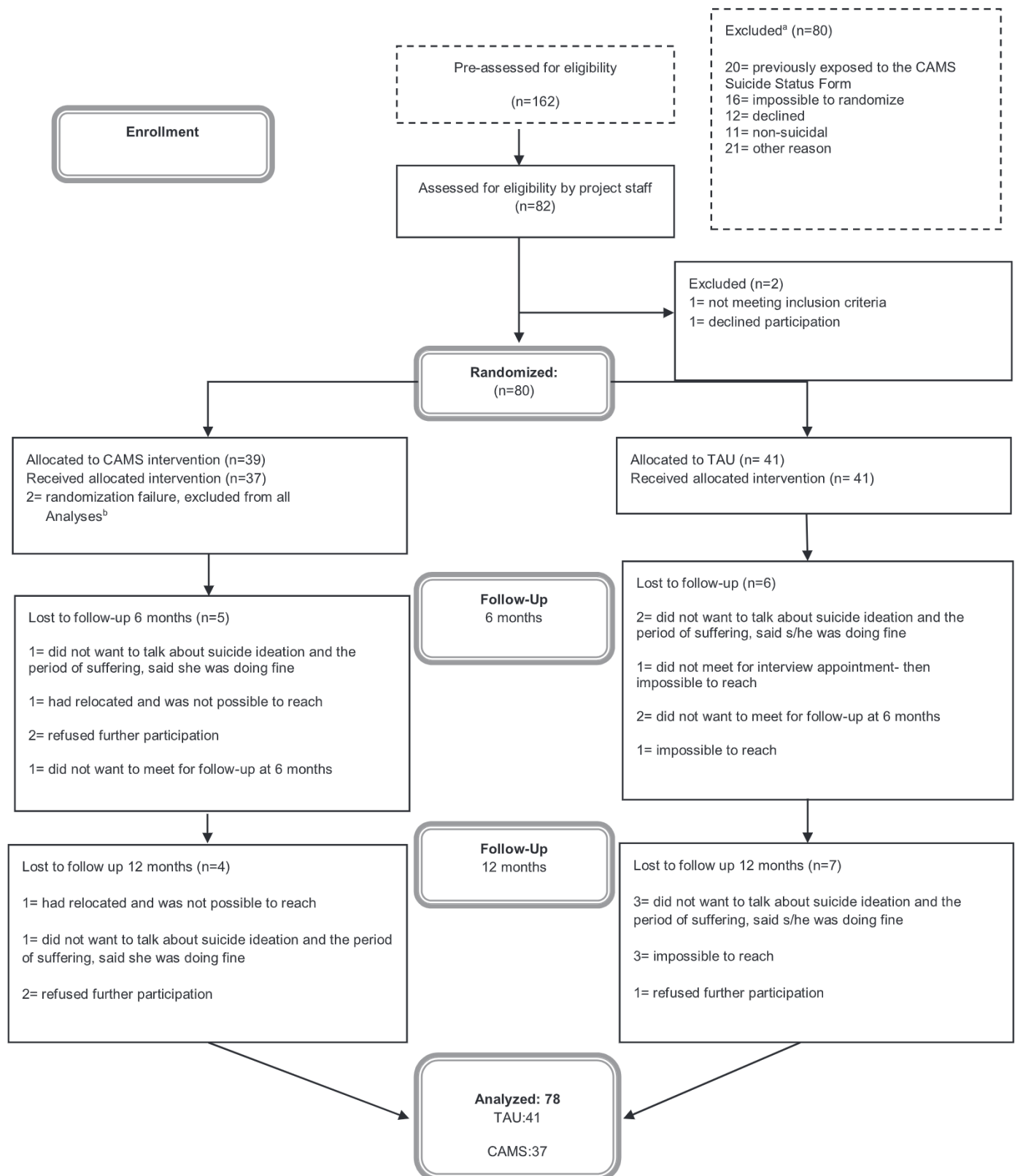


Fig. 1. Flow chart.

(a) Cases “impossible to randomize” refers to those cases where it was not feasible to randomize due to structural conditions in the clinical units, e.g. the CAMS therapist was on sick leave/ vacation, or the therapists at the local unit had too high work load and did not have sufficient (work) capacity to enroll another potential patient. “Other reasons” refer to those situations where the potential participant was transferred to another clinical unit for treatment/ declined treatment altogether/ clinicians did not ask eligible participants for participation for various reasons (s/he forgot, s/he did not think participation in the trial was right for the patient and the like).

(b) Two cases were deleted due to failure in the allocation process. Here, the CAMS therapist was not informed about the CAMS project status of the participants and provided another treatment without CAMS treatment elements.

reported conflictual results for whether specific therapeutic models prevent suicide, suicide ideation and suicide behaviors. Among the models with some support from RCTs are Dialectical Behavior Therapy (DBT) for borderline patients (Linehan et al., 2006b, 2015), Cognitive Behavioral Therapy (CBT) for military personnel (Rudd et al., 2015) and previous suicide attempters (Brown et al., 2005), Mindfulness-based CBT for chronically depressed outpatients (Forkmann et al., 2014), the Attempted Suicide Short Intervention Program (ASSIP) for previous suicide attempters (Gysin-Maillart et al., 2016), and a brief psychodynamic intervention for patients who had self-poisoned (Guthrie et al., 2001).

The Collaborative Assessment and Management of Suicidality (CAMS) is a suicide-specific treatment model that has been indicated to reduce suicidal ideation and behaviors in several studies, across settings and diagnoses. In a retrospective uncontrolled trial from a military setting, Jobes et al. (2005) reported that CAMS participants resolved suicidality faster than those who were treated with usual care therapies. In another non-randomized trial, CAMS was evaluated as feasible and efficacious for managing suicidal risk in a real life clinical context when adopted to 42 patients treated at The Danish Centre of Excellence in Suicide Prevention (Nielsen et al., 2011). In a comparison trial from an inpatient setting, CAMS outperformed usual treatment at discharge, but not at 6 months follow-up, on both suicide-related variables and measures of general mental health, including depression severity, hopelessness and subjective well-being (Ellis et al., 2017). Three randomized controlled trials have been conducted and documented the CAMS model's effectiveness. Comtois et al. (2011) conducted a pilot trial from an outpatient crisis center setting, whereas in Denmark, CAMS was compared to a shortened version of DBT for suicidal patients with borderline traits (Andreasson et al., 2016). Recently CAMS was also reported to be effective, although not superior to enhanced care as usual (E-CAU), with a high risk sample of soldiers within a military outpatient treatment facility (Jobes et al., 2018).

Previous RCTs of CAMS have been conducted in specifically adopted treatment settings for selected populations: military treatment center for soldiers, crisis intervention center for acute problems in the homeless or the otherwise socially disadvantaged, and a specialized treatment center for suicide prevention. This is the first randomized controlled trial to investigate the effectiveness of CAMS as a transdiagnostic intervention delivered in a generic clinical setting within specialized mental health services. Here, people from the general population are referred for specialist treatment for a wide range of mental health disorders, including personality disorders, schizophrenia spectrum disorders, bipolar disorder, depressions, anxiety disorders, PTSD, and alcohol and drug addictions. We included a variegated set of participants from this generic setting, with relatively high levels of suicide ideation and overall morbidity, to be treated by ordinary therapists at outpatient clinics, ambulatory outpatient teams, and inpatient wards. This trial had the potential to establish CAMS as feasible and effective across a wide specter of mental health problems and across the range of typical treatment settings that meets the general population when moderate to high levels of suicidal problems and behaviors occur. If successful, treatment services within specialized mental health care may be rationalized and improved by employing a suicide specific treatment model for patients with increased risk of suicide. Primary aims were to investigate whether CAMS more successfully and statistically significantly reduced suicide ideation compared to Treatment as Usual (TAU) when measured at 6- and 12 months. Secondary aims were to examine treatment effects upon mental health distress and suicidal behaviors.

2. Materials and methods

2.1. Design

Patients were randomized to CAMS or TAU from two ambulatory

acute outpatient units, three inpatient units and two regular outpatient units at Division of Mental health and addiction, Vestre Viken hospital trust, Norway. The study protocol has previously been published (Ryberg et al., 2016). The study was approved by the Regional Committees for Medical and Health Research Ethics, Region South-East, Norway, 2014/465.

2.2. Participants

This study recruited participants from publicly funded specialized psychiatric care centers in Norway in the period February 2015 to November 2016 (Fig. 1), with the last follow-up interview being conducted in November 2017. In this setting, patients are prioritized for treatment after a balanced assessment of three core elements; anticipated benefits, cost effectiveness and the severity of the condition (Ottersen et al., 2016). Conditions assessed as less severe, or with less prosperity of change, receive treatment at other arenas. Included were newly referred patients aged 18 and above, with ongoing suicidal ideation, whose symptom severity and/or complexities qualified for treatment in specialized care. To be included, we required a score of 13 or above on the Beck's Scale for Suicide Ideation- Current (BSSI-C) combined with a positive response on the question of current suicide intention, to ensure clinical relevancy. Excluded were patients who were; unable to provide an informed consent (e.g., due to intellectual disability or dementia, active hallucinations), had poor Norwegian language acquisition, diagnosed with a developmental disorder (e.g. Asperger syndrome or Autism) or previously been exposed to CAMS treatment components (Ryberg et al., 2016). Altogether 43 therapists participated in the trial. CAMS therapists were eight psychologists and one psychiatrist, with four of these having more than 10 years of clinical experience. TAU therapists were 15 psychologists, four residents, six psychiatrists and nine psychiatric nurses. Among these, 19 had more than 10 years of clinical experience. TAU therapists from acute ambulatory teams worked interdisciplinarily and shared the role of appointed therapist. This is reflected by the diversity of therapists in TAU.

2.3. Interventions

CAMS is a semi-structured therapeutic framework characterized by its humanistic values, empathic stance, and patient-centered focus (Michel and Jobes, 2011). Suicidal thoughts and behaviors are the main therapeutic foci, and patient and therapist collaboratively work on assessing and deactivating the patient-defined “drivers” or underlying reasons for why the patient considers suicide (Jobes, 2006). During the CAMS treatment, the patient and therapist work in team to try to understand what increases suicide risk and why.

Central therapeutic tools and characteristics that permeates the process in CAMS therapy includes a systematic and collaborative use of the multi-purpose assessment, treatment-planning, and tracking tool called the Suicide Status Form (SSF), systematic use of a stabilization plan and an agreed upon overarching treatment plan where the suicidal drivers are addressed and evaluated every session. Every session is started by the patient and therapist filling out the SSF formula. Here, the patient rates him/herself on a Likert scale from 1–5 on suicidal markers for psychological pain, stress, agitation, hopelessness, and self-hate in addition to making a subjective assessment of suicide risk. In the first session, the patient is prompted to also give a qualitative description for each suicidal marker, (e.g. what specifically makes him/her feel hopeless or agitated). Additionally, the patient is asked to rank these items on the SSF from the least important to the most important. “Suicidal drivers” are the reasons the individual patient feels compelled to consider suicide. These drivers can be direct (e.g. specific situations, thoughts or behaviors that increase mental pain) or they can be indirect (e.g. traumas in the past that make the patient vulnerable). The CAMS structured stabilization plan is compiled during the first session, and

modified in every consecutive interim CAMS session. In this trial, we used a stabilization plan that addressed limiting access to lethal means, warning signs for rising suicidal thoughts and behaviors, coping strategies, ways to reduce isolation, a list of people to contact before and during crisis, and potential hindrances for attending interim consultation sessions. A typical treatment course of CAMS has weekly sessions of 50–60 min. CAMS treatment is developed as a framework for people at risk for suicide with current intentional suicidal thoughts and behaviors. The strict focus upon suicidal thoughts, suicidal behaviors and “drivers” of suicide is kept until the patient no longer is suicidal (as operationalized by three consecutive sessions where s/he rates her/himself with a score of 2 or less on overall risk while also effectively managing suicidal thoughts and feelings in the absence of any suicidal behaviors). In this pragmatic trial, the cessation criterion was adjusted in some cases, because it was not feasible to e.g. prolong days in inpatient care ($n = 3$) on the basis of a self-ratings on the SSF. When a CAMS course was finalized, the patient was either discharged or continued in treatment, however focusing on other mental health problems.

TAU was an active intervention of high-quality standard care (Ryberg et al., 2016). The TAU intervention was represented by the diversity of orientations practiced within specialized care in Norway today. None of the clinical units had implemented a structured and unified treatment approach. In Norway, health care services is, however, not “uncontrolled.” Treatment is governed by central legislations and national guidelines, influencing both arms of the trial. Here, best practice summarizations of treatment for a range of mental health disorders are provided, including psychosis, depression, bipolar disorder and addiction, in addition to a separate guideline for suicide prevention (The Norwegian Directorate of Health and Social Affairs, 2008). Usual suicide preventive procedures include systematic suicide risk assessments, procedures to ensure safe transitions at discharge, and compilation of a crisis plan. A typical outpatient treatment course is weekly 45 min sessions for an unspecified duration of time. In times of crises, increased frequency of sessions is typical to prevent unnecessary hospitalizations.

Number of treatment sessions was not pre-defined but decided in each case for both treatment conditions. However, we were able to extract critical information about the magnitude of health care utilization provided during the 12 months follow-up period (treatment sessions, inpatient stays) from the Electronic Patient Registry (EPJ). This information was later compared between CAMS and TAU.

Non-manualized pharmacotherapy was available to both groups.

2.4. Measures

2.4.1. Primary outcome

Beck's Scale for Suicide Ideation - Current (BSSI-C) is a 19 item questionnaire that measures a patient's suicidal ideation at its worst point during the past 2 weeks (Beck et al., 1997). Items are scored on a Likert scale ranging from 0 to 2, with a total score of 38. BSSI-C is a reliable measure with test-retest reliability and internal consistency above 0.90 and acceptable test-retest reliability (Beck et al., 1997).

2.4.2. Secondary outcomes

The *Outcome Questionnaire - 45 (OQ-45)* is a 45-item questionnaire designed to measure overall mental health distress. OQ-45 is sensitive to change and correlates well with other measures of distress (Lambert et al., 1996). The inventory was recently validated in a Norwegian sample, demonstrating high reliability and an internal consistency of 0.93 (Amble et al., 2014).

The *Suicide Attempt Self-Injury Count (SASIC)* is a short version of the interview *Suicide Attempt Self-Injury Interview (SASII)* (Linehan et al., 2006a). SASIC counts previous suicide attempts and non-suicidal acts, incidents of self-inflicted injuries by method, and degree of suicidal intent for the suicidal behavior (Linehan, 1996).

Ratings on the Count version of the SASI is the same as the Interview version, which has been reported to have good psychometric properties including internal consistency of 0.85 (Linehan et al., 2006). We provided the Lifetime version at baseline and the Recent form at follow-up.

BSSI-C and SASIC were translated into Norwegian according to conventional procedures.

2.4.3. Descriptive measures

The Mini International Neuropsychiatric Interview (MINI) was administered to identify clinical conditions that correspond with diagnosis described in the ICD-10 (Sheehan et al., 1998). Additionally, the SCID-II interview for DSM-IV Axis II Borderline Personality Disorder (BDP) was administered (First et al., 1997). Substance abuse was assessed at baseline with the Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) and the Drug Use Disorders Identification Test (DUDIT) (Berman et al., 2005; Nesvåg et al., 2010; Voluse et al., 2012). Both instruments have an overall reliability above 0.80 and convergent validity, sensitivity and specificity above 85% (Nesvåg et al., 2010; Voluse et al., 2012).

The OQ-45, AUDIT and DUDIT were self-administered, while the BSSI-C and the SASIC were provided in an interview. BSSI-C, SASIC and OQ-45 were applied at baseline and at 6- and 12 months while AUDIT, DUDIT and SASIC were administered at baseline only.

To prevent that the baseline screening was too extensive, we administered the MINI after 3 sessions/weeks (Ryberg et al., 2016).

2.5. Procedures

Local staff and research assistants identified and recruited participants (Ryberg et al., 2016). Patients were allocated to treatment group by using a stratified four-block randomization procedure with treatment unit as the stratification variable. An independent statistician at the Norwegian Institute of Public Health performed the procedure, and the allocation order was secluded in closed envelopes and stored in a locked file cabinet. After the research assistant completed the baseline interview, and after she assured that the participant fulfilled all inclusion criteria, she opened the envelope and disclosed the treatment allocation to the patient. Five research assistants performed the patient interviews. Research assistants who screened at 6 and 12 months were blinded for treatment conditions, and patients were instructed not to tell which intervention they received. No participant disclosed this information.

All CAMS therapists attended a two-day CAMS training course followed by adherence training, and were provided relevant literature (Dr. Jobes' “Managing Suicidal Risk; a Collaborative approach (2005)” and an unpublished CAMS treatment manual). Even though CAMS is a therapeutic framework that can be incorporated across different schools of treatment, a therapist needs to adhere to the model's main conceptual domains emphasizing a collaborative approach, empathic stance, and focus on suicide drivers, along with using SSF and the CAMS Stabilization Plan. The CAMS Rating Scale (CRS) has been developed to assess a therapist's adherence to and competence with using the model. The CRS has been found to have high inter-rater reliability and internal consistency (Corona, 2017). It consists of three main sections, where a 7 point Likert Scale is used to rate the CAMS therapist, ranging from poor performance (score of 0) to satisfactory performance (score of 3) and to excellent performance (score of 6). Within the CRS, Part 1 evaluates the clinician's adherence to the CAMS philosophy in terms of collaborative skills and ability to maintain the suicide-specific focus. Part 2 assesses how the clinician manages to follow the framework and structure of CAMS, such as the use of SSF in the beginning of each session and revising the stabilization plan. Part 3 provides an assessment of the clinician's overall adherence to the CAMS framework, the patient's receptiveness of the CAMS focus, and a sense of the clinician's confidence in the model. CAMS therapists provided videotapes of three CAMS training sessions with real patients, with the exception of two therapists

Table 1
Baseline characteristics.

	<i>n</i> -valid	Total	CAMS ^b	TAU ^b
Gender, females, <i>n</i> (%)	78	41 (53)	19 (51)	22 (54)
Age, mean (SD)	78	35.9 (14.5)	38.4 (15.3)	33.7 (13.6)
History				
Previous hospitalizations in psychiatric care, <i>n</i> (%)	78	26 (33)	13 (35)	13 (32)
Previous outpatient treatment course	77	47 (60)	21 (57)	26 (63)
Previous suicidal behavior, <i>n</i> (%)	78	54 (69)	27 (73)	27 (66)
Habitual self-harmers, ^a <i>n</i> (%)	78	12 (15)	8 (22)	4 (10)
Previous suicide attempt with high intention, <i>n</i> (%)	78	41 (53)	22 (60)	19 (46)
Previous stays at intensive care units due to severe self-harm or suicide attempt, <i>n</i> (%)	78	28 (36)	16 (43)	12 (30)
Use of medication				
Antiepileptics, <i>n</i> (%)	78	5 (6)	4 (11)	1 (2)
Antipsychotics, <i>n</i> (%)	78	6 (8)	3 (8)	3 (7)
Hypnotics/sedatives, <i>n</i> (%)	77	15 (20)	4 (11)	11 (27)
Antidepressants, <i>n</i> (%)	76	24 (32)	14 (38)	10 (24)
Overall/any, <i>n</i> (%)	75	37 (49)	19 (51)	18 (44)
Diagnoses				
Addiction, F10-F19, <i>n</i> (%)	78	6 (8)	2 (5)	4 (10)
Bipolar disorder, F31, <i>n</i> (%)	78	5 (6)	3 (8)	2 (5)
Depression, F32-F34, <i>n</i> (%)	78	51 (65)	22 (60)	29 (71)
Anxiety, F40-F41, <i>n</i> (%)	78	4 (5)	2 (5)	2 (5)
PTSD, F43.1, <i>n</i> (%)	78	7 (9)	5 (14)	2 (5)
Other, <i>n</i> (%)	78	5 (6)	3 (8)	2 (5)
At least one secondary diagnosis F10-F40, <i>n</i> (%)	78	57 (73)	26 (70)	31 (76)
Concurrent Borderline personality disorder (BPD), F60.3, <i>n</i> (%)	78	12 (15)	5 (14)	7 (17)
Three or more concurrent BPD traits, <i>n</i> (%)	78	13 (17)	6 (16)	7 (17)
BPD/ BPD traits, <i>n</i> (%)	78	25 (32)	11 (30)	14 (34)
Level of care at baseline				
Inpatient units, <i>n</i> (%)	78	24 (31)	11 (30)	13 (32)
Acute ambulatory units, <i>n</i> (%)	78	38 (49)	19 (51)	19 (46)
Regular outpatient units, <i>n</i> (%)	78	16 (21)	7 (19)	9 (22)
Symptom distress				
Problems related to alcohol (AUDIT), Median/ Mean (SD)	78	6/ 8.8 (8.3)	7/ 9.2 (7.7)	5/8.5 (9.0)
Problems related to illicit drugs (DUDIT) Median/ Mean (SD)	78	.00/ 2.3 (5.6)	.00/2.6 (5.5)	.00/2.0 (5.7)
Suicide ideation (BSSI-C), Mean (SD)	78	24.2 (4.8)	24.9 (4.2)	23.5 (5.2)
Mental health distress (OQ-45), Mean (SD)	77	101.0 (17.8)	102.5 (20.0)	99.8 (15.9)

^a "Habitual self-harmers" were defined as participants who reported 100 or more lifetime episodes of non-suicidal self-harm behaviors.

^b We did not observe statistical differences between the two groups on baseline measures.

who provided two videos. These tapes were rated for adherence by three people in the research group (first author, one psychologist and one of the research assistants). We required an average score of 3 or above on part 3 (overall rating) on the CRS, before the therapist was defined "adherent" and ready to participate in the trial. Adherence scores ranged from 4 to 6 with an average of 4.9 (SD = 0.62). A detailed description of both CAMS training and adherence procedures are provided in the study protocol (Ryberg et al., 2016).

Patients were not offered reimbursements or payment for their participation in the trial.

2.6. Statistical analyses

The initial power calculation was based on the following assumptions (Ryberg et al., 2016): (a) a four points group difference on the BSSI-C at follow up, (b) equal sample sizes, (c) a standard deviation of 7 on BSSI-C, (d) an alpha level of 0.05, and (e) one-sided confidence intervals because previous studies had indicated that CAMS was superior

to TAU (Comtois et al., 2011; Ellis et al., 2012). Based on these premises, we would achieve 82% power to detect differences at 6 and 12 months by including 80 participants. We assumed 20% drop-out rate and our desired sample size was defined as 100. The trial was conducted during a time of large re-organizational changes in the hospital, leading to feasibility challenges (Ryberg et al., 2016). Recruitment was slower than anticipated, and the trial closed at 80. We did not perform post hoc analyses to support this decision.

Differences in central tendencies at baseline and outpatient sessions during the trial were tested with either Independent sample *t* test or Mann-Whitney *U* test. Differences in proportions and proportions of patients with inpatient stays during the trial were tested by Pearson's chi-square tests or Fisher exact tests.

Primary analyses included differences in suicidal ideation, mental health distress and suicidal behaviors at 6 and 12 months. Secondary analyses included changes over time in suicidal ideation and mental health distress from baseline to 6 months and from baseline to 12 months. Analyses of primary and secondary outcome variables and psychotropic medication at 6 months, 12 months and changes from baseline to 6 and 12 months were performed by using mixed models. Mixed effects linear or logistic regressions for approximately normally distributed and binary outcome variables were used to fit three data points per patient (baseline, 6 months and 12 months). In mixed model analyses all available data are incorporated in the analyses, and likelihood estimation is a valid way for handling missing data in randomized controlled trials (Sullivan et al., 2017). Fixed factors were time, treatment condition, and interaction between treatment condition and time. The patient identifier was specified as a random variable. Restricted maximum likelihood estimation method (reml) was used in all mixed effects estimations. Before performing the mixed effect logistic regression analyses, the SASIC variables were dichotomized (specific self-harm episode vs no specific self-harm episode) due to a general low prevalence of episodes with a minor set of cases with extremely high frequencies.

Sensitivity analyses for the complete cases were conducted for BSSI-C and OQ-45 scores at 6 months using the Mann-Whitney *U* test and the Independent sample *t* test, respectively. Effect sizes are reported as unstandardized regression coefficients for interaction effects between group and time in the mixed analyses, and, second, as Cohen's *d* for mean improvement in symptoms over time (Table 3). Differences in proportions of participants who deteriorated on the primary measure (BSSI-C) were calculated by estimating a reliable change index (Jacobson and Truax, 1991). Statistical analyses were intention to treat, with the exception of two cases that were deleted due to randomization failure and miscommunication between project staff and therapist (Fig. 1).

The level of significance was set at 0.025 for a one-sided test and 0.05 for a two-sided test. If the difference between the groups was statistically significant at the two-sided test, it would also be true for the one-sided test scenario. Only two-sided *p*-values are reported, and the level of significance was set at 0.05. For sub-variables from SASIC, a Bonferroni corrected significance level of $p < .003$ was pre-decided. Analyses were conducted in IBM SPSS version 23 and version 25 and STATA/SE version 15.

3. Results

Among 162 participants considered for participation, 78 were included and successfully randomized (Fig. 1). At baseline, the participant group was characterized by high levels of suicide ideation and mental health distress (Table 1). Two thirds (65%) fulfilled the criteria for a depressive disorder (F32-F34). Most participants (73%) qualified for at least one secondary diagnosis where anxiety related problems were the most common (28%). Nearly a third had a full borderline personality disorder (BDP) or at least three BDP traits. The majority (69%) had previously harmed themselves and more than half had

Table 2

Use of psychotropic medication and the prevalence of suicidal or self-harm behavior at 6- and 12 months.

Proportion with use of psychotropic medication	6 months		β (95% CI) ^a	p^a	12 months		β (95% CI) ^a	p^a
	CAMS	TAU			CAMS	TAU		
Antiepileptics n (%)	3 (8)	1 (2)	1.22 (–2.13 to 4.57)	.475	4 (11)	1 (2)	1.78 (–1.46 to 5.03)	.280
Antipsychotics n (%)	5 (14)	3 (7)	0.60 (–1.50 to 2.69)	.574	6 (16)	4 (10)	0.71 (–1.12 to 2.62)	.464
Antidepressants n (%)	12 (32)	13 (32)	–0.20 (–1.83 to 1.42)	.806	13 (35)	8 (20)	1.22 (–.46 to 2.90)	.155
Hypnotics n (%)	4 (11)	9 (22)	–1.18 (–3.00 to 0.58)	.187	3 (8)	4 (10)	–0.39 (–2.44 to 1.67)	.710
Overall n (%)	17 (46)	17 (41)	–1.02 (–1.67 to 1.47)	.898	16 (43)	12 (29)	0.65 (–0.90 to 2.20)	.412
Proportion with suicide attempts^b and Non Suicidal Self-Injurious behaviors (NSSI)								
Suicide attempt ^c n (%)	3 (8)	5 (12)	4.92 (–1.15 to 2.13)	.555	2 (5)	3 (7)	0.35 (–1.61 to 2.31)	.725
NSSI ^b	7	6	0.37 (–1.10 to 1.84)	.619	3	8	–1.15 (–2.82 to 0.52)	.175

^a Estimations derived from mixed binary logistic regression analyses.^b All categories of self-harm and suicide related behaviors from the SASIC interview (intoxications, burning, strangulations, jumping, shooting, ingesting, asphyxia, drowning, smashing, stabbing and other events (e.g., scratching) was also examined separately in chi square tests at 6 and 12 months. None of these episodes or categories was significantly different in CAMS and TAU.^c Here suicide attempt is defined as any episode of suicide related behavior performed with a high intention to die, or an ambivalent intention to die.

attempted suicide (with high intent) during their life-time. Nearly a third (33%) had been hospitalized in psychiatric care, and 60% had at least one previous outpatient treatment course. About 50% used psychotropic medications, most frequently antidepressants.

During the year of follow-up, participants in both groups averagely met for 16.1 outpatient treatment sessions. TAU participants averagely received 14.6 sessions (SD = 11.9). CAMS participants met for 17.8 sessions (SD = 13.2), whereas 7.9 of these were CAMS sessions (SD = 5.2). The difference was not significant ($p = .27$).

During the trial, six CAMS participants and seven TAU participants were admitted for additional inpatient care ($p = .92$). We observed no difference in the use of psychotropic medications in CAMS and TAU at 6 and 12 months (Table 2).

3.1. Suicide ideation

In the mixed effects models, in accordance with our primary hypothesis, we observed a significant treatment effect for CAMS compared to TAU at 6 months ($\beta = -4.29$, 95% CI = -8.32 to -0.27 , $p = .036$), but not at 12 months ($\beta = -2.82$, 95% CI = -6.85 to 1.20 , $p = .168$). In secondary analyses, CAMS participants reported significantly larger changes in suicidal ideation from baseline to 6 months ($\beta = -5.65$, 95% CI = -10.49 to -0.80 , $p = .023$, $d = 1.20$) with a trend in the same direction from baseline to 12 months ($\beta = -4.18$, 95% CI = -9.03 to 0.67 , $p = .090$, $d = 0.89$) compared to TAU participants. We performed sensitivity analysis on complete cases, where also a superior and significant treatment effect for CAMS compared to TAU was observed at 6 months ($U = 406.5$, $p = .048$). There were no differences upon deterioration in suicidal ideation (2 vs 0 patients at 6 months/ 1 vs 1 at 12 months in TAU and CAMS, respectively). See Fig. 2 for longitudinal changes in suicidal ideation, and Table 3 for detailed estimates.

3.2. Suicide attempts and self-harm

There were no differences in proportions of patients who attempted suicide (suicide behavior performed with high or ambivalent intent to die). Also, we observed no differences in the two groups in terms of episodes of Non Suicidal Self-Injurious behaviors (NSSI) (Table 2).

3.3. Mental health distress

In mixed effects model analyses for OQ-45, measuring level of mental health distress, we observed no differences between CAMS and

TAU at 6 months ($\beta = -10.03$, 95% CI = -22.76 to 2.70 , $p = .121$) or 12 months ($\beta = -11.86$, 95% CI = -24.64 to 0.93 , $p = .069$). In sensitivity analyses for complete cases at 6 months, likewise, no difference was observed between CAMS and TAU ($t(67) = 1.475$, $p = .145$). However, in secondary analyses, we did observe significant group differences upon changes in mental health distress both from baseline to 6 months ($\beta = -11.87$, 95% CI = -22.99 to -0.76 , $p = .036$, $d = 0.66$) and from baseline to 12 months ($\beta = -13.70$, 95% CI = -24.88 to -2.51 , $p = .017$, $d = 0.76$) in favor of the CAMS treatment condition. See Fig. 3 for longitudinal changes in mental health distress, and Table 3 for detailed estimates.

4. Discussion

After 6 months, CAMS participants experienced less suicidal ideation as well as larger improvements from baseline in this measure compared to TAU participants ($d = 1.20$). After 12 months, improvements in CAMS remained at the same level as after 6 months whereas patients in TAU partly had caught up, with the difference between the treatments groups no longer being significant ($d = 0.89$). Moreover, general mental health distress was reduced in both CAMS and TAU over time, where CAMS participants experienced superior reductions from baseline to both 6 ($d = 0.66$) and 12 months ($d = 0.76$) follow-up.

Despite not reaching the desired sample size of 100 participants, we observed significant differences between CAMS and TAU in the primary measure (at 6 months). This was probably due to lower attrition rates and larger differences on the BSSI-C scale than anticipated in the power analyses. We observed a significant effect for changes (secondary analyses) but not for levels (primary analyses) in mental health distress. This may be explained by (a) results being around the critical value of $p = .05$ (either significant or significant at trend level). Small changes in Beta values had large effects on p -values, (b) statistical modeling and (c) the power analyses was not set out to estimate a sample size for changes of symptoms. The significant improvement in both groups reflects that the TAU intervention was also moderately effective, in addition to possible improvements over time in both CAMS and TAU due to other causes than therapy (e.g. spontaneous improvements). Given the seriousness of high suicide risk and of providing the best possible treatment method, combined with the ease and low cost of learning the CAMS intervention, the moderate to large effect sizes we identified provide an argument to implement CAMS in similar mental health systems as ours. The CAMS approach may serve as a first step intervention in the acute phase of a suicide crisis, while diagnosis-specific, tailored interventions may be introduced either in parallel or as a

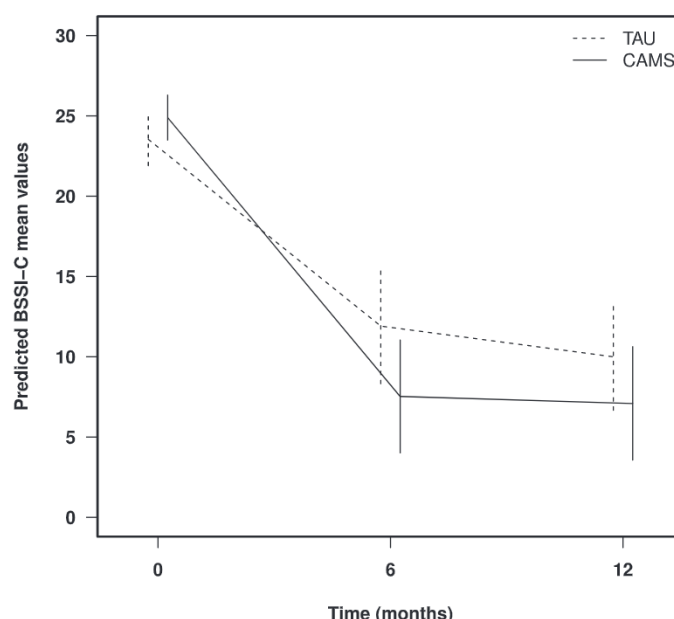


Fig. 2. Longitudinal changes in suicidal ideation.

(a) Changes in suicidal ideation as measured by the BSSI-C over time, presented with error bars for 95% confidence interval.

(b) Changes in suicidal ideation from baseline to 6 months are significantly larger in CAMS compared to TAU, $p = .023$.

second step in the treatment of people with mental health related disorders and increased risk of suicide.

Our results are largely consistent with three previous RCT studies of CAMS. In a small-scale randomized feasibility trial, CAMS was compared to E-CAU in an outpatient crisis intervention setting for the socially disadvantaged. Superior effects were observed upon suicidal ideation and mental health problems (Comtois et al., 2011). The present trial overcame some of the limitations reported in the pilot (Comtois et al., 2011), by providing a more balanced number of therapy sessions in CAMS and TAU, lower drop-out rates, and a larger sample. Also in line with our findings, Jobes and colleagues reported from a rigorous RCT that both CAMS and enhanced usual care reduced suicide ideation and mental health distress in a high risk population of military veterans (Jobes et al., 2018). The two groups were observed to respond equally well on all outcomes at one, three, 6 and 12 months follow up, except that the CAMS group reported superior improvements in suicidal ideation after three months. In a Danish RCT of patients with borderline traits, CAMS was as effective as a shortened version of DBT upon

suicide attempts and self-harm, suicidal ideation, hopelessness, and depression (Andreasson et al., 2016). Regarding suicidal behaviors, the superiority of CAMS is more ambiguous. One characteristic of RCTs on CAMS, including ours, is a relatively low prevalence of non-suicidal self-injurious behaviours (NSSI) and suicide attempts during follow up. Thus, the trials likely have been underpowered to detect differential treatment effects upon these behaviors. The CAMS approach is designed to treat suicide thoughts and behaviors in the context of suicide intent. For this reason, it is not surprising that CAMS treatment is not superior to TAU on NSSI, as these behaviors are associated with different (but overlapping) motivations compared to intentional suicide acts. As compared to prior evaluations of CAMS, our study is noteworthy by being carried out in a generic clinical setting within specialized mental health care. This speaks to the high generalizability of our findings to the type of clinical setting where suicidal patients typically receive mental health care in many countries. Results from this study combined with previous findings from selected and specific patient populations strengthen the evidence base for CAMS' applicability and effectiveness

Table 3

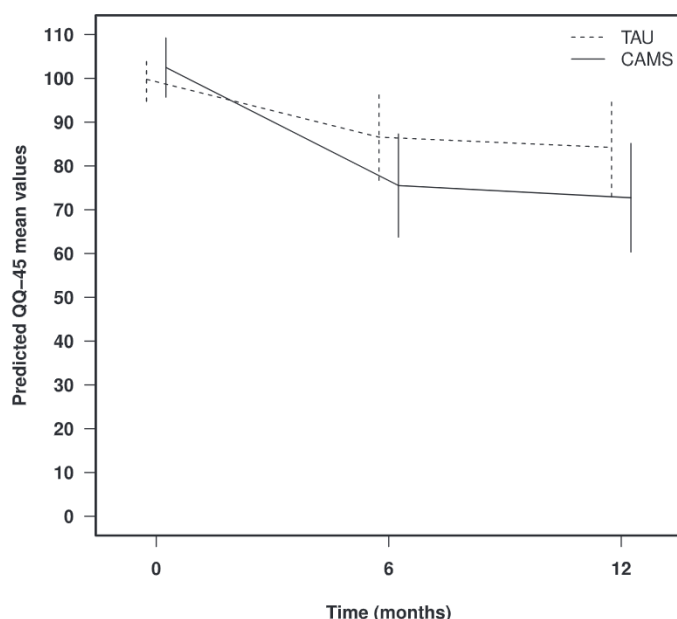
Changes in suicidal ideation and symptom distress from baseline to follow up.

CAMS $n = 37$	Mean difference (95% CI)	p^a	Effect size ^b
BSSI-C baseline-6months	17.3 (14.00–20.62)	<.001	4.14
BSSI-C baseline-12 months	17.8 (14.44–21.10)	<.001	4.26
OQ-45 baseline-6 months	26.2 (17.98–34.43)	<.001	1.32
OQ-45 baseline-12 months	29.1 (20.76–37.41)	<.001	1.46
TAU $n = 41$	Mean difference (95% CI)	p^a	Effect size^b
BSSI-C baseline-6 months	11.6 (8.10–15.18)	<.001	2.24
BSSI-C baseline-12 months	13.6 (10.1–17.1)	<.001	2.62
OQ-45 baseline-6 months	14.3 (6.65–21.93)	<.001	0.90
OQ-45 baseline-12 months	15.4 (7.75–23.03)	<.001	0.97
Total $n = 78$	Mean difference CAMS vs TAU (95% CI)	p^a	Effect size^c
BSSI-C baseline-6 months	–5.65 (–10.49 to –0.80)	.023	1.20
BSSI-C baseline-12 months	–4.18 (–9.03 to 0.67)	.090	0.89
OQ-45 baseline-6 months	–11.87 (–22.99 to –0.76)	.036	0.66
OQ-45 baseline-12 months	–13.70 (–24.88 to –2.51)	.017	0.76

^a Estimations derived from linear mixed model including pairwise comparisons.

^b The mean improvement from baseline to 6 months and from baseline to 12 months, divided by the pooled standard deviation at baseline.

^c The mean difference in changes in symptom distress between the two treatment conditions from baseline to 6 months and from baseline to 12 months, divided by the pooled standard deviation at baseline.



across settings and diagnosis. According to our knowledge, comparison trials where two active suicide specific treatment models have been contrasted are generally lacking in the literature and should be a priority for future research. Also, the CAMS framework relies heavily on the common factors of psychotherapy (Wampold and Imel, 2015). Dismantling studies should explore whether the effective treatment ingredients in CAMS are specific factors such as the strict suicide focus, common factors such as the empathic stance and collaborative approach, or a combination of such factors.

4.1. Limitations

Aspects which increased external validity and generalizability, may at the same time have diminished study effects; (a) broad inclusion criteria with a heterogeneous patient population across several treatment units, (b) the large pool of therapists, and (c) treatment fidelity not being monitored after the initial adherence training. The diversity of therapist characteristics (e.g. level of experience or education) may have been a confounder. As a pragmatic trial conducted within a naturalistic setting, choices made may have had consequences for the experimental rigor and interpretation of results (e.g. not predefining the magnitude of treatment dosage, being pragmatic about cessation criteria in CAMS, the relative modest amount of applied measures and measurements). The modest sample size, combined with not reaching the amount of participants required by the power analysis, may have rendered the trial underpowered. CAMS may be an effective treatment intervention due to different reasons; by its suicide specific focus reducing suicidal ideation, or by more general effective treatment components which reduced mental health distress, which in turn reduced suicidal ideation. We had not pre-contemplated such a possibility and the trial was underpowered to test it. Controlling for the effect of changes in mental health functioning would probably remove the observed treatment effect of CAMS, however with a large risk of making a statistical type II error.”

5. Conclusion

This study was conducted within the frames of specialized mental health care services in Norway, where patients from different treatment settings and geographic locations participated. CAMS improved treatment outcome on suicide ideation and mental health distress more rapidly and in a sustained manner when compared to TAU under these

Fig. 3. Longitudinal changes in mental health distress.

(a) Changes in symptom distress as measured by the OQ-45 over time, presented with error bars of 95% confidence interval.

(b) Changes in mental health distress from baseline to 6 months are significantly larger in CAMS compared to TAU, $p = .036$.

(c) Changes in mental health distress from baseline to 12 months are significantly larger in CAMS compared to TAU, $p = .017$.

varying conditions, suggesting that CAMS may have general beneficial effects across diagnoses and settings when suicidal thoughts and behaviors are part of the presenting problem. Focusing on the underlying reasons for suicidal thoughts and behaviors may effectively, and more successfully compared to usual treatment, reduce both levels of suicidal ideation and mental health distress.

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Contributors

R.F. was the project leader who designed the study. W.R. and R.F. conducted and managed the study, while W.R. wrote the first draft of the manuscript. W.R. conducted the statistical analyses in companionship with P.H.Z., L.M.D. and R.F. Interpretation, preparation, and writing up the final manuscript including approval of the final version of the manuscript was done in joint companionship with all authors W.R., R.F., L.M.D., P.H.Z. and N.I.L.

Declaration of interest

None.

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