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Research paper

Reducing short term suicide risk after hospitalization: A randomized controlled trial of the Collaborative Assessment and Management of Suicidality

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ABSTRACT

Background: This study compared the "next day appointment" (NDA) use of the Collaborative Assessment and Management of Suicidality (CAMS) to treatment as usual (TAU) for individuals discharged from the hospital following a suicide-related crisis. We hypothesized that CAMS would significantly reduce suicidal thoughts and behaviors as well as improve psychological distress, quality of life/overall functioning, treatment retention and patient satisfaction.

Methods: Participants were 150 individuals who had at least one lifetime actual, aborted, or interrupted attempt and were admitted following a suicide-related crisis. There were 75 participants in the experimental condition who received adherent CAMS and 75 participants who received TAU. Suicidal thoughts and behaviors, psychological distress, and quality of life/overall functioning were assessed at baseline and at 1, 3, 6, and 12 months post-baseline. Treatment retention and patient satisfaction were assessed at post-treatment.

Results: Participants in both conditions improved from baseline to 12 months but CAMS was not superior to TAU for the primary outcomes. A small but significant improvement was found in probability of suicidal ideation at 3 months favoring TAU and amount of suicidal ideation at 12 months favoring CAMS. CAMS participants experienced less psychological distress at 12 months compared to baseline.

Limitations: The study was limited by only one research clinic, lower than expected recruitment, and imbalance of suicidal ideation at baseline. Conclusions: All participants improved but CAMS was not more effective than TAU. The NDA clinic was feasible and acceptable to clients and staff in both conditions and future research should investigate its potential benefit.

1. Introduction

1.1. The challenges of suicide risk

In 2019, 47,511 Americans died by suicide (Drapeau and McIntosh, 2020); 1,400,000 attempted suicide and 12,200,000 had *serious* suicidal thoughts (Substance Abuse and Mental Health Services Administration [SAMHSA], 2021). In response, national policy calls for accessible evidence-based treatments that: a) prevent suicidal behavior; b) increase clinician confidence/willingness to work with suicidal risk; and c) are feasible, trainable, adaptable, and flexible across care systems (Grumet et al., 2019).

Risk for suicide following discharge from inpatient care is clear (Chung et al., 2017) and finding providers who see recently discharged

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patients is difficult (Baraff et al., 2006; Olfson, 2012). Post-discharge outpatient care is recommended within 24–72 h, and not later than 7–30 days post-discharge (National Action Alliance for Suicide Prevention, 2019; NCQA, 2020c). However, only a fraction of discharged psychiatric inpatients (28–48 %) and emergency department patients (ED; 29–46 %) are seen by 7 days (NCQA, 2020b, 2020a). A study of youth admitted to inpatient care who received outpatient care within 7 days of discharge had reduced suicide risk at six months (Fontanella et al., 2020). Some systems use "urgent care" or "next-day appointment" (NDA) clinics to ensure care transition and follow-up. Cohort studies in Denmark and the United Kingdom (UK) suggest suicide intervention clinics may reduce suicide, deliberate self-harm, and overall mortality (Bickley et al., 2013; Erlangsen et al., 2015; Oquendo and Courtet, 2014). Moreover, in the United States with the advent of the National Suicide Prevention Lifeline 3-digit number (988), the need for rapid suicide-focused outpatient stabilization and NDA's for inpatients and ED patients post-discharge will likely increase exponentially (Jobes, in press).

1.2. The Collaborative Assessment and Management of Suicidality (CAMS)

Only a handful of replicated randomized controlled trials (RCTs) of suicide-focused treatments (with independent replications) exist (Jobes et al., 2015) including CAMS. CAMS is a suicide-focused therapeutic framework that is guided by the collaborative use of the Suicide Status Form (SSF) which is a multi-purpose assessment, treatment planning, tracking, and clinical outcome tool (Jobes, 2016). The SSF is a procedural "roadmap" with different versions for the first session, all interim care, and the final outcome-disposition session. Every CAMS session begins with the patient completing the "SSF Core Assessment" (i.e., rating psychological pain, stress, agitation, self-hate, hopelessness, and overall risk of suicide) and ends with a suicide-focused treatment plan that includes crafting or reviewing the CAMS Stabilization Plan (Tyndal et al., 2021) and the identification and subsequent treatment of patient-identified "suicidal drivers" (e.g., hopelessness, financial issues, trauma, or a relationship crisis). Theoretically agnostic, patient-centered, and used across populations/settings (Jobes et al., 2018), CAMS creates therapeutic change via collaborative assessment and treatment interventions focused on suicidal drivers using all available interventions (e.g., CBT, insight-work, behavioral activation, mentalization, teaching skills, etc.) such that the patient is able to recover and learn to manage any suicidal thoughts, feelings, and behavioral impulses that may arise. Towards the end of CAMS (modal response is 6–8 sessions) there is an overt emphasis on creating hope and a life worth living. There are ten published open trials and five published randomized controlled trials supporting this use of CAMS (Jobes, in press). A recent meta-analysis of 9 CAMS clinical trials showed significant impact on suicidal ideation, overall symptom distress, treatment acceptability, and hope/hopelessness relative to control care and is therefore a "well-supported intervention" as per CDC criteria (Swift et al., 2021).

1.3. Current study

Given the need for evidence-based service following hospital discharge, we conducted a treatment development study to determine how CAMS needed to be adapted to be feasible and acceptable in our university affiliated community mental health center (CMHC). We made two adaptations - adding the availability of case management and determining the level of severity that this brief outpatient treatment could manage (i.e., patients who could be discharged from the hospital for 24 h prior to starting CAMS rather than a direct referral during the hospital stay or immediately after leaving the hospital). We then conducted a small randomized controlled trial (RCT) with patients discharged for 1–7 days following an acute hospital admission in which we compared CAMS to the treatment as usual (TAU) – standard NDA services provided in the CMHC (Comtois et al., 2011). Satisfaction was higher for CAMS which also showed better treatment retention. At 12 months follow-up, CAMS had significantly better and sustained reductions in suicidal ideation, overall symptom distress, and increased hope.

The present study replicates this pilot study using a pre-specified well-powered RCT with a primary outcome of suicide events (i.e., suicide attempt or death or acute hospitalization to prevent suicide). We predicted that among recently discharged patients being seen for NDA, CAMS compared to standard NDA treatment (TAU) would result in (a) significant reduction in suicide events, (b) significant reductions in suicidal ideation and other mental health markers, and (c) significant improvement of treatment retention, patient satisfaction, and therapist satisfaction and acceptability.

2. Materials and methods

2.1. Participants

Patient was recruited from 08/19/16 to 11/14/18 primarily from two university medical centers with four inpatient, two consultation-liaison, and two ED services. Study treatment was conducted in a research clinic modeled closely on the same CMHC as the pilot study; where the PI and study clinicians provide care.

Inclusion criteria: a) inpatient or ED admission for suicidal risk, b) past month suicide attempt (including interrupted or self-aborted attempts), c) no appropriate outpatient mental health appointment within two weeks, d) an NDA as an appropriate disposition plan, and e) consent to study procedures. Exclusion criteria: a) under age 18, b) insufficient English to participate, c) too psychotic or manic, aggressive, or cognitively impaired, d) patient not stable enough to be discharged 24 h before the NDA, e) court-ordered to outpatient treatment, or f) lived too far away. Although extensive outreach was conducted in hospitals, EDs, and crisis centers in the metropolitan area, we had difficulty identifying sufficient participants. With funder and Data Safety Monitoring Board (DSMB) pre-approval, inclusion criterion (b) was expanded from past month to lifetime suicide attempt.

2.2. Treatment conditions

2.2.1. Experimental condition: Collaborative Assessment and Management of Suicidality (CAMS)

CAMS (Jobes, 2006, 2016) is a suicide-focused intervention for decreasing suicidal ideation and behaviors while increasing hope and reasons for living. CAMS includes weekly individual therapy and a weekly therapist consultation team. The CAMS condition was delivered according to the CAMS source manual, *Managing Suicidal Risk: A Collaborative Approach*, 2nd Ed. (Jobes, 2016). Dr. Jobes conducted CAMS training via online training and live role-playing. Initial and ongoing adherence checks were done on digital recordings using the CAMS Rating Scale (CRS-3R) by members of Dr. Jobes' laboratory. Additional supervision was provided following non-adherent sessions.

2.2.2. Comparison condition: treatment as usual (TAU)

A central goal of the study was to determine whether the implementation of CAMS was an improvement over standard NDA care. Accordingly, the treatment-as-usual (TAU) comparison condition followed the CMHC's standard policies and procedures for brief, crisis oriented services, which entails an intake followed by 1–11 visits with a clinician (mean 4.5 visits) and medication management, if needed, ending in a referral to another provider for primary care follow-up or additional mental health or substance abuse treatment. The focus of CMHC treatment is best-practice pharmacotherapy plus assistance to resolve the suicidal crisis using case management and psychotherapy as appropriate. To match CAMS, consultation and supervision for TAU occurred in weekly meetings led by the study psychiatrist.

Table 1
Demographic and clinical characteristics.

	CAMS (N = 75)	TAU (N = 75)	Total (N = 150)
Age in years, Mean (SD)	33.51 (12.27)	34.09 (12.54)	33.80 (12.36)
N (%)			
Gender			
Male	37 (49.3)	35 (46.7)	72 (48.0)
Female	28 (37.3)	34 (45.3)	62 (41.3)
Transgender/non-binary	10 (13.3)	6 (8.0)	16 (10.7)
Ethnicity			
White or European American	47 (62.7)	47 (62.7)	94 (62.7)
African American, Black, or of African descent	4 (5.3)	2 (2.7)	6 (4.0)
Native American or Alaska Native	–	1 (1.3)	1 (0.7)
Asian American or of Asian descent	7 (9.3)	4 (5.3)	11 (7.3)
Hawaiian Native or Other Pacific Islander	–	2 (2.7)	2 (1.3)
Latinx	2 (2.7)	3 (4.0)	5 (3.3)
Biracial or multiracial	15 (20.0)	16 (21.3)	31 (20.7)
Marital status			
Single, never married	57 (76.0)	49 (65.3)	106 (70.7)
Married	7 (9.3)	8 (10.7)	15 (10.0)
Separated	3 (4.0)	3 (4.0)	6 (4.0)
Divorced	7 (9.3)	15 (20.0)	22 (14.7)
Widowed	1 (1.3)	–	1 (0.7)
Sexual orientation			
Heterosexual	43 (57.3)	40 (53.3)	83 (55.7)
Gay/lesbian/homosexual	9 (12.0)	12 (16.0)	21 (14.0)
Bisexual	11 (14.7)	15 (20.0)	26 (17.3)
Other	11 (14.7)	8 (10.7)	19 (12.7)
Unknown	1 (1.3)	–	1 (0.7)
Education			
Less than high school diploma or GED	9 (12.0)	4 (5.3)	13 (8.7)
High school graduate or GED	16 (21.3)	13 (17.3)	29 (19.3)
Some college, associate's degree, or technical training	33 (44.0)	41 (54.7)	74 (49.3)
Bachelor's or graduate degree	17 (22.7)	17 (22.7)	34 (22.7)
Employment			
Unemployed	26 (34.7)	29 (38.7)	55 (36.7)
Disabled or retired	12 (16.0)	16 (21.3)	28 (18.7)
Employed <20 h per week	4 (5.3)	6 (8.0)	10 (6.7)
Employed 20–39 h per week	15 (20.0)	13 (17.3)	28 (18.7)
Employed 40 or more hours per week	18 (24.0)	11 (14.7)	29 (19.3)
Annual income			
None	3 (4.0)	5 (6.7)	8 (5.3)
Less than $5000	6 (8.0)	7 (9.3)	13 (8.7)
$5000–$9999	9 (12.0)	4 (5.3)	13 (8.7)
$10,000–$24,999	14 (18.7)	22 (29.3)	36 (24.0)
$25,000–$49,999	18 (24.0)	14 (18.7)	32 (21.3)
$50,000 or more	10 (13.3)	12 (16.0)	22 (14.7)
Unknown	15 (20.0)	11 (14.7)	26 (17.3)
Lifetime suicide attempts			
Any, N (%)[a]	70 (93.3)	72 (97.3)	142 (95.3)
If any			
Mean (SD)	5.25 (10.85)	13.21 (61.70)	9.26 (44.47)
Median (IQR)	2 (1–4)	2 (1–4)	2 (1–4)
Areas of functional impairment[b]			
Mean (SD)	2.72 (1.47)	2.80 (1.36)	2.76 (1.41)
Psychiatric illness	74 (98.7 %)	70 (93.3 %)	144 (96 %)
Substance abuse	322 (42.7 %)	37 (49.3 %)	69 (46 %)
Cognitive limitations (from any cause)	4 (5.3 %)	7 (9.3 %)	11 (7.3 %)
Medical illness or severe pain	31 (41.3 %)	25 (33.3 %)	56 (37.3 %)
Lack of housing	8 (10.7 %)	15 (20.0 %)	23 (15.3 %)
Insufficient funds for basic needs	8 (10.7 %)	15 (20.0 %)	23 (15.3 %)
Domestic violence, violent environment, or recent severe trauma	12 (16 %)	6 (8.0 %)	18 (12.0 %)
	2 (2.7 %)	0	2 (1.3 %)
Lack of communication (<2 type of contact information)			
Lack of transportation/lives far away	4 (5.3 %)	8 (10.7 %)	12 (8.0 %)
Lack of social support/no one to turn to	13 (17.3 %)	10 (13.3 %)	23 (15.3 %)
Legal problems	6 (8.0 %)	7 (9.3 %)	13 (8.7 %)
Lack of mental health insurance	9 (12.0 %)	10 (13.3 %)	19 (12.7 %)

[a] Eight participants without a lifetime attempt were included on the basis of an interrupted or aborted attempt.
[b] Each area was evaluated using a combination of baseline data, referral information from the inpatient clinician, and a review of the medical record. Inclusion criterion of appropriate for an NDA at discharge was based on having <7 areas of impairment; Matching categories for randomization was 1–2 (mild), 3–4 (moderate), and 5–6 (severe) areas of impairment.

Because TAU can vary more than is desirable under research conditions, to maximize internal validity, TAU therapists offered at least one session per week for at least four weeks because four is the minimum number of sessions to complete CAMS. TAU providers had no CAMS training; non-fidelity to CAMS in TAU was rated with CRS-3R during training and the final study months.

2.2.3. Both conditions

Study clinicians were licensed mental health counselors working in the CMHC with comparable years of training and experience (TAU mean years was 15.67 [SD 14.5]; CAMS mean years was 15 [SD 8.12]). Clinicians were given dedicated research time in their CMHC schedule to participate (resulting in more frequent sessions and more time for tracking no-shows than occurred in the rest of their CMHC schedule). Medications were provided by participants' existing prescriber or by the study psychiatrist using standard CMHC procedures. Most participants saw the study psychiatrist for at least one session (TAU = 69, CAMS = 68). Study treatment was conducted until the "suicide crisis resolved." CAMS ended when participants were able to manage their suicidal thoughts/feelings/behaviors for three consecutive sessions after the initial session, per CAMS criteria (Jobes, 2016). TAU ended when the "crisis was resolved" as per clinician judgement.

2.3. Measures

2.3.1. Suicide events

Suicide deaths were determined via medical examiner and state death data. Suicide attempts were determined using the valid and reliable Suicide Attempt Self-Injury Count (SASI-Count) (Linehan and Comtois, 1996; Linehan et al., 2006). This measure is the short form of the Suicide Attempt Self-Injury Interview (SASII) that utilizes standardized ratings and clear behavioral definitions. The SASI-Count inquires about suicide attempts and non-suicidal self-injury by method, which improves recall, and is lower participant burden than the SASII and other measures which assess the details of each attempt one at a time. The Treatment History Interview (THI; Linehan and Heard, 1987) evaluated acute hospitalizations to prevent suicide.

2.3.2. Beck Scale for Suicide Ideation

The Beck Scale for Suicide Ideation (BSS; Beck and Steer, 1993) is the self-report version of the Scale for Suicide Ideation (Beck et al., 1997; Beck et al., 1979), and is a valid and reliable measure of suicidal ideation (Beck et al., 1988; Healy et al., 2006; Pinninti et al., 2002) that was reliable in this sample ($\alpha = 0.89$). Given that suicidal ideation was not the primary measure nor an inclusion criterion for this study, the lower burden self-report form was selected to reduce participant burden at the baseline assessment.

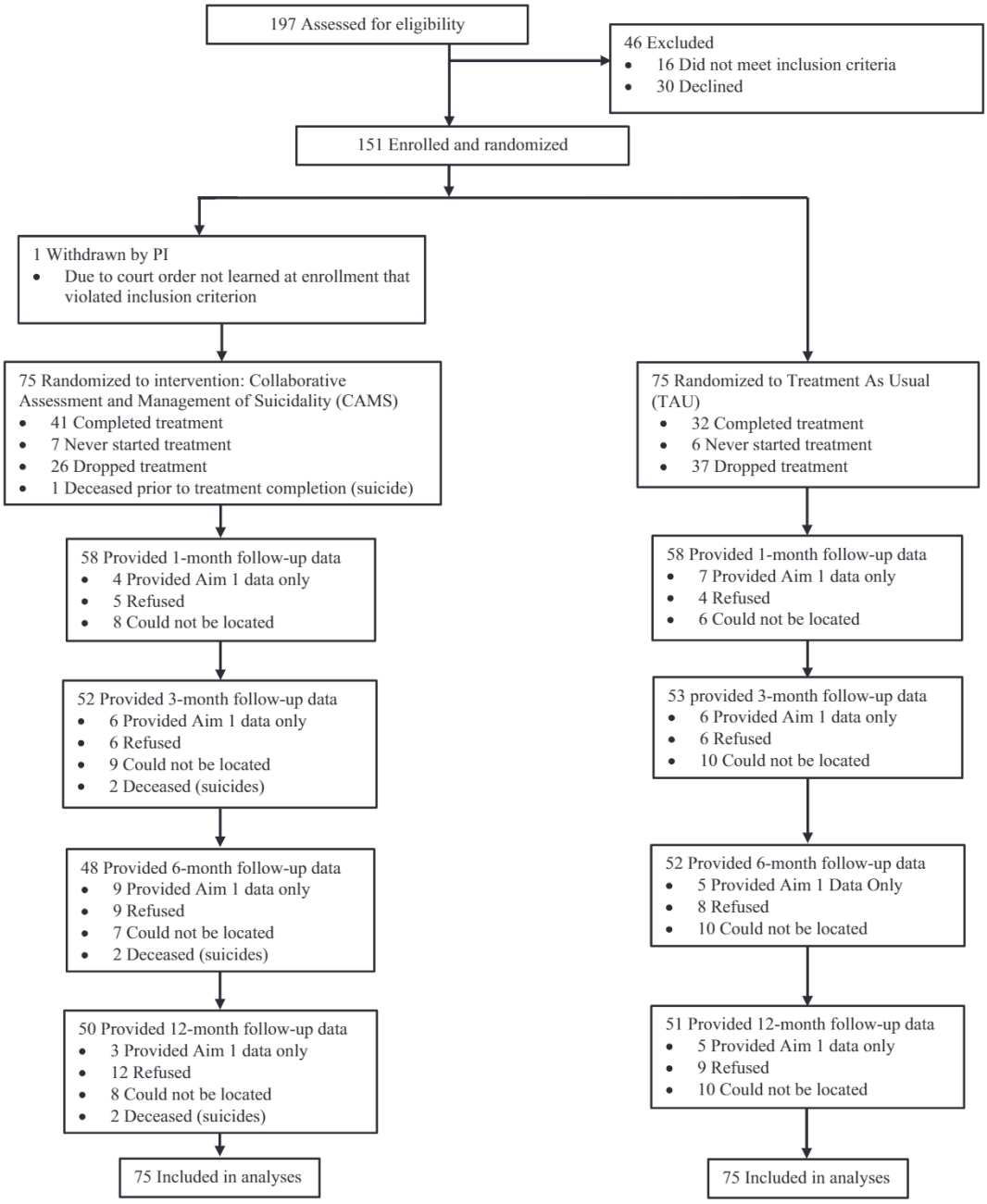

Fig. 1. ITT CONSORT chart.

2.3.3. Outcome Questionnaire-45.2

The Outcome Questionnaire-45.2 (OQ-45; Lambert, 2004; Lambert and Finch, 1999) is a 45-item questionnaire, measuring key areas of psychological distress including symptom distress (SD), interpersonal problems (IP), and social role functioning (SR) subscales and a total score. The OQ-45 shows good validity and reliability with adult patients with psychiatric-related diagnoses (Umphress et al., 1997) and was reliable in this sample ($\alpha = 0.94$).

2.3.4. EQ-5D

The EQ-5D (The EuroQol Group, 1990) is a psychometrically validated, self-administered measure of quality of life/overall functioning (Devlin and Brooks, 2017; Schrag et al., 2000) that was reliable in this sample ($\alpha = 0.71$).

2.3.5. Treatment evaluation

The Client Satisfaction Questionnaire (CSQ; Attkisson and Greenfield, 2004; Attkisson and Zwick, 1982) is a widely used 8-item questionnaire to assess participants' satisfaction with treatment (Gaston and Sabourin, 1992; Larsen et al., 1979; Nguyen et al., 1983; Sheppard, 1993; Urben et al., 2015) that was reliable in this study ($\alpha = 0.95$). A therapist version was developed for this study via slight modification of item wording (e.g., instead of "Have the services you received helped you deal more effectively with your problems?", the therapist responded to the item "Did the services you provide help the patient deal more effectively with his or her problems?") that was also reliable ($\alpha = 0.96$). Therapists completed the CSQ for each client along with an acceptability item: "knowing what you know now, how likely would you choose the treatment approach you used for this client for a client comparable to this client in the future?" from 1 = very likely to 7 = very unlikely.

Table 2
Treatment characteristics.

	CAMS (N = 75)	TAU (N = 75)	Total (N = 150)
Number of sessions, Mean (SD)	10.71 (7.99)	12.76 (8.53)	11.73 (8.30)
Client satisfaction, Mean (SD)	26.81 (6.08)	25.36 (5.92)	26.10 (6.02)
Therapist satisfaction, Mean (SD)	23.48 (5.66)	21.22 (5.65)	22.33 (5.74)
Therapist acceptability, Mean (SD)	5.90 (1.67)	5.14 (1.29)	5.51 (1.53)
N (%)			
Received at least 4 sessions	50 (66.7 %)	46 (61.3 %)	96 (64.0 %)
CAMS adherence[a]	85 %	0 %	N/A
Medication classes – received at least 1[b]			
Antidepressant	49 (79.0 %)	49 (75.4 %)	98 (77.2 %)
Mood stabilizer	21 (33.9 %)	28 (43.1 %)	49 (38.6 %)
Antipsychotic	15 (24.2 %)	23 (35.4 %)	38 (29.9 %)
Antianxiety	27 (43.5 %)	28 (43.1 %)	55 (43.3 %)
Stimulant	1 (1.6 %)	2 (3.1 %)	3 (2.4 %)
Addiction Medicine	6 (9.7 %)	12 (18.5 %)	18 (14.2 %)
Ketamine	1 (1.6 %)	0	1 (0.8 %)
Not taking any psychiatric medication	12 (19.4 %)	6 (9.2 %)	18 (14.2 %)
If taking any medication, Mean (SD) medication classes	2.94 (1.38)	3.17 (1.59)	3.06 (1.49)
Range			

[a] Based on 101 CAMS sessions and 4 sessions/TAU clinician during the training phase of the study and 2 sessions/TAU clinician during the final three months of the study.

[b] Number (valid percent). Medication data was missing for 14 (18.6 %) CAMS and 10 (13.3 %) TAU at follow-up assessments (i.e., medications were prescribed by providers outside of study).

2.3.6. CAMS Rating Scale Revised

Therapist adherence to CAMS was done using the CAMS Rating Scale Revised (CRS-3R). Items are rated on 7-point scales ranging from 0 ("poor") to 6 ("excellent"). Intra-class Correlation Coefficients (ICCs) range from 0.96 to 0.99 (Corona, 2014).

2.4. Procedures

Study staff tracked admissions at both university medical centers to identify potential participants along with referrals from inpatient/emergency/consultation-liaison clinicians. Interested individuals were approached by study staff to conduct informed consent. After confirming eligibility, prior to discharge, participants completed baseline assessment and were randomized. Staff provided the participant and referring social worker a referral card with NDA date, time, therapist name, and directions to the clinic. A minimization randomization strategy was used (Freedman and White, 1976; Pocock, 2013; Pocock and Simon, 1975; White and Freedman, 1978), matching on identified gender, single or multiple suicide attempts, and mild, moderate, or severe functional impairment (see Table 1), which was programmed by the UW Institute for Translational Health Services to prevent foreknowledge of treatment assignment by research staff.

Blind outcome assessments were conducted at 1, 3, 6, and 12 months. Post-treatment assessment of patient satisfaction was conducted separately by unblinded assessment staff. Interviews were in-person or over the phone (based on participant preference). The University of Washington Risk Assessment Protocol (UWRAP) developed by Marsha Linehan, Ph.D. and the PI managed risk during assessments. Participants received $30 for each assessment plus an incentive between $25 for completing two follow-up assessments to $100 for completing all four. Study procedures were approved by two universities' Institutional Review Boards and an independent DSMB.

2.5. Statistical analyses

Power and sample size in the present design was selected to achieve power of 0.80 for the primary treatment effect on suicide events (i.e., suicide death, suicide attempt, or acute hospitalization to prevent suicide) (Hypothesis 1). Based on a prospective clinical epidemiology study of usual care conducted at the study site (Comtois et al., 2015), we estimated a 40 % rate of re-attempt or hospitalization to prevent suicide over the following year and considered a 50 % reduction in suicide events in CAMS relative to TAU to be a clinically meaningful reduction. Power analysis conducted prior to study initiation with these assumptions indicated the study would be powered at 0.80 at the proposed sample size of 200 (100 per arm).

An intent-to-treat approach was used for all analyses; all participants randomized in the RCT were included in final analyses. For the primary suicide attempt outcome, data was too sparse for planned hurdle models so binary logistic regression was used to test the association between treatment condition (CAMS = 1, TAU = 0) and the presence-absence of a suicide event across the entire one-year follow-up period. Logistic regression models were adjusted for recent (i.e., past-year) suicide events and lifetime suicide attempts. Differences in treatment dropout were tested using a Chi-squared test of independence.

To assess the outcome of suicidal ideation (i.e., BSS), generalized linear mixed models (GLMMs) were employed. GLMMs are types of multilevel models that allow for non-normal outcomes. Suicidal ideation is bounded at zero and we expected many observations of zero. Further, there is not a fixed duration of the treatment for this study, and because the pattern of change was highly nonlinear and different between treatments in pilot data, we fitted a main effect of CAMS, assessment point, and their interaction via a hurdle model. This two-part model is appropriate for over-dispersed count data with many observations of zero. In the first part of the model (i.e., Logistic Regression [LR] portion), the association between each variable and the likelihood of 1 or more counts of the outcome is assessed. Next, the association between each variable and the number of counts of the outcome, if any, is tested. A GLMM assuming normally distributed residuals (i.e., Gaussian) was used to evaluate the OQ-45 and EQ-5D. In the GLMMs, each outcome variable was regressed on treatment (CAMS vs. TAU), time, and the treatment by time interaction in separate GLMM models. The time variable was divided into four planned contrasts: (a) month one vs. baseline; (b) month three vs. baseline; (c) month six vs. baseline; and (d) month 12 vs. baseline. The treatment effects were evaluated by examining the magnitude and statistical significance of the treatment by time interactions. Difference in patient satisfaction at post-treatment was tested using an independent samples *t*-test. All tests, as prespecified in our funded application, were two-tailed without correction factors and tested a priori hypotheses. Since the GLMM approach utilizes all available data, including from participants with both complete and partial data, missing data should not bias outcome analyses as the rate of missing data was comparable across treatment conditions.

3. Results

3.1. Participant characteristics

The CONSORT chart (Fig. 1) shows the intent-to-treat sample of 150 participants (see Table 1) and outcome assessment completion rates. Mean age was 33.8 years (SD 12.4); ranging from 18 to 79 years. Half (48.0 %) of participants identified as male, 41.3 % as female, and 10.7 % as transgender/non-binary. Two-thirds identified as White/European American (62.7 %), 20.7 % as biracial/multiracial, 7.3 % as Asian American or of Asian descent, 4.0 % as African American, Black, or of African descent, 3.3 % as Latinx, 1.3 % as Hawaiian Native or Other Pacific Islander, and 0.7 % as Native American or Alaska Native—representative of the surrounding county (The Office of Economic and Financial Analysis, 2017). There were no significant differences

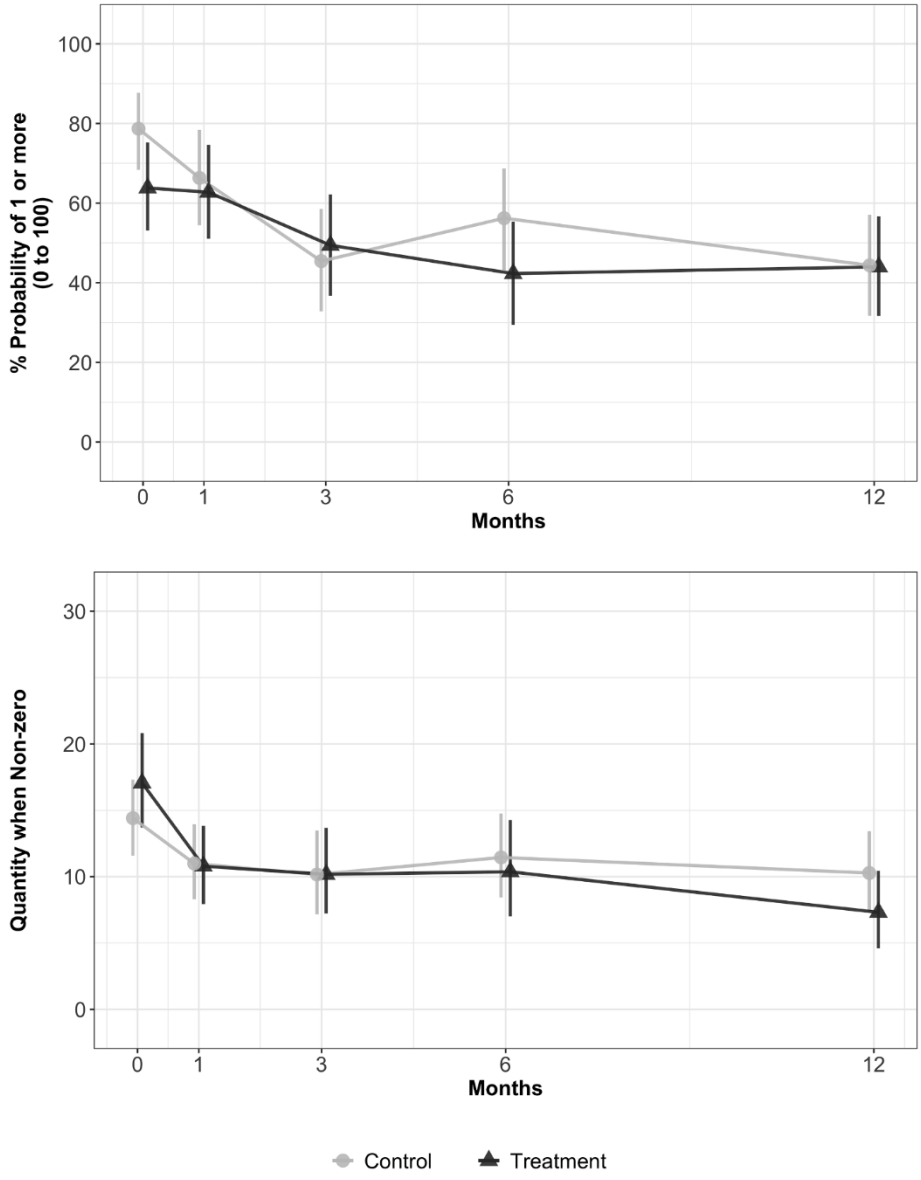

Fig. 2. Plots of hurdle model of suicidal ideation – probability of any and quantity when non-zero.

Table 3
Continuous outcome measures across time points.

	CAMS					TAU				
Timepoint	0	1	3	6	12	0	1	3	6	12
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)
BSS	10.93 (10.98)	6.59 (8.03)	5.17 (7.23)	4.82 (7.75)	3.60 (5.84)	11.35 (9.89)	7.54 (8.13)	5.44 (8.0)	6.76 (8.18)	5.87 (8.69)
OQ-45	86.43 (27.17)	79.50 (26.88)	74.32 (29.66)	72.54 (29.85)	64.52 (25.80)	83.79 (26.35)	76.28 (26.16)	67.11 (29.30)	72.12 (27.04)	67.58 (26.75)
Symptom distress subscale	53.61 (18.02)	48.80 (19.16)	45.51 (19.81)	43.42 (18.73)	39.06 (17.39)	51.91 (17.10)	46.97 (17.82)	40.98 (18.36)	11.75 (5.51)	42.42 (18.08)
Interpersonal relations subscale	19.93 (6.56)	18.78 (6.38)	16.92 (6.88)	17.27 (8.53)	14.88 (6.09)	18.12 (6.35)	17.02 (6.36)	14.49 (7.72)	15.08 (7.13)	14.04 (6.73)
Social role subscale	13.44 (5.63)	12.88 (5.22)	11.89 (5.35)	11.85 (5.50)	10.58 (4.89)	13.76 (5.80)	12.29 (5.51)	11.64 (5.64)	11.75 (5.51)	11.12 (5.02)
EQ5D	0.674 (0.202)	0.726 (0.164)	0.736 (0.141)	0.776 (0.162)	0.807 (0.147)	0.697 (0.187)	0.722 (0.157)	0.751 (0.135)	0.745 (0.159)	0.776 (0.133)

Table 4
Hypothesis 1 suicidal behavior[a].

Variable	b	SE_b	OR	95 % CI	*p*
Suicidal behavior[b]					
Intercept	−0.90	0.34	0.41	0.21 to 0.79	.008**
Suicidal behavior at baseline	0.19	0.10	1.21	0.99 to 1.47	.048*
CAMS condition	−0.05	0.41	0.95	0.43 to 2.12	.893
Attempted suicide					
Intercept	−1.63	0.39	0.20	0.09 to 0.42	<.001***
Lifetime count of suicide attempts	0.05	0.04	1.05	0.97 to 1.14	.181
CAMS condition	0.52	0.47	1.68	0.67 to 4.23	.274

[a] 42 (28 %) participants were missing; CAMS 21 (28 %); TAU 19 (25 %).
[b] Suicidal behavior was defined as suicides, suicide attempts, or acute hospitalizations to prevent suicide.
* $p < .05$.
** $p < .01$.
*** $p < .001$.

between conditions except the number (but not presence or absence) of lifetime suicide attempts which was significantly higher in TAU (OR = 0.38, 95 % CI, 0.27–0.54; $p = .000$).

3.2. Treatment characteristics

Treatment characteristics are shown in Table 2. Participants received an average of approximately twelve sessions (about a third did not attend four sessions without between-group differences). The majority were taking at least one psychiatric medication. CAMS clinicians were adherent to CAMS and TAU clinicians were not.

3.3. Suicide events (Hypothesis 1)

Logistic regressions were calculated to evaluate the association between CAMS and suicide events, defined as suicide deaths, suicide attempts, or acute hospitalizations to prevent suicide. 38.9 % of CAMS and 37.5 % of TAU participants had a suicide event throughout 12-month follow-up. As demonstrated in Table 4, there was no association between CAMS treatment condition (OR = 0.95, $p = .893$) and the presence-absence of a suicide event during the follow-up period, above and beyond the effect of past history of suicide events (OR = 1.21, $p = .048$).

3.4. Suicidal ideation (Hypothesis 2)

Measurements of suicidal ideation (BSS) at each follow-up time point were compared to baseline via a series of hurdle models (see Table 5). In the logistic regression portion of the model, there was a significant imbalance in treatment conditions at baseline, such that TAU participants were more likely to report any SI at baseline. In addition to significant effects of time, overall CAMS was not more effective than TAU.

There was only one significant treatment by time interaction, which indicated that participants in the TAU condition improved faster than CAMS participants from baseline to 3 months. As demonstrated in Fig. 2, this is relative to the higher odds of any suicidal ideation at baseline, which was significantly higher in TAU than in CAMS. In the counts portion of the model, evaluating the severity of suicidal ideation, if any, at baseline, there was not a statistically significant imbalance between conditions. There was a significant effect of time at 1, 3, and 12 months. There was one significant treatment by time interaction at 12 months, which indicated that CAMS participants had a statistically significant decrease in the severity of their suicidal ideation at 12 months compared to baseline (see Fig. 2).

3.5. Psychological distress and quality of life/overall functioning (Hypothesis 2)

Overall, there were no significant differences between conditions for psychological distress (OQ-45) nor quality of life/overall functioning (EQ-5D)—refer to Table 3, 6 and 7. OLS regressions evaluated the effect of CAMS on psychological distress, as indicated by the Outcomes Questionnaire 45 (OQ-45), including the total and subscale scores. There was no significant effect of CAMS treatment on OQ total scores, the interpersonal relations (IP), or social role (SR) subscales. However, there was a significant treatment by time interaction, such that CAMS treatment had a statistically significant effect on the symptom distress (SD) subscale, as shown in Fig. 3.

3.6. Treatment evaluation (Hypothesis 3)

54.7 % of CAMS participants and 42.7 % of TAU completed treatment, which was not a statistically significant difference ($\chi^2(1) = 2.16$, $p = .142$). As shown in Table 2, there was no significant difference on satisfaction on the participant CSQ ($t = -1.21$, $p = .226$). While study therapists in both conditions rated satisfaction and acceptability of the treatment they provided highly, CAMS vs. TAU therapists reported higher satisfaction on the therapist CSQ ($t = -2.33$, $p = .021$) and were more likely to choose their treatment for a future client ($t = -2.94$, $p = .003$).

Potential harm in this study was evaluated by the DSMB. There were no serious adverse events reported in either study condition other than

Table 5
Hypothesis 2 suicidal ideation negative binomial hurdle model.

	LR portion					Count portion				
Variable	b	SE_b	OR	95 % CI	*p*	b	SE_b	RR	95 % CI	*p*
Suicidal ideation (BSS)										
Intercept	2.51	0.55	–	–	<.001***	2.56	0.10	–	–	<.001***
CAMS condition	−1.40	0.70	0.25	0.06 to 0.97	.044*	0.17	0.14	1.19	0.90 to 1.56	.255
Time 1 month	−1.19	0.57	0.30	0.10 to 0.93	.038*	−0.28	0.14	0.76	0.57 to 0.99	.044*
Time 3 months	−2.87	0.63	0.06	0.02 to 0.19	<.001***	−0.36	0.17	0.70	0.50 to 0.97	.031*
Time 6 months	−2.02	0.60	0.13	0.04 to 0.43	<.001***	−0.23	0.15	0.79	0.59 to 1.07	.109
Time 12 months	−2.96	0.63	0.05	0.02 to 0.18	<.001***	−0.34	0.16	0.71	0.52 to 0.97	.027*
CAMS × time 1 month	1.10	0.77	3.00	0.66 to 13.59	.159	−0.18	0.21	0.84	0.55 to 1.26	.378
CAMS × time 3 months	1.72	0.81	5.58	1.14 to 27.32	.035*	−0.17	0.24	0.84	0.53 to 1.35	.479
CAMS × time 6 months	0.29	0.81	1.34	0.27 to 6.54	.718	−0.27	0.24	0.76	0.48 to 1.22	.247
CAMS × time 12 months	1.36	0.81	3.90	0.80 to 19.06	.093	−0.52	0.26	0.59	0.36 to 0.99	.046*

* $p < .05$.
*** $p < .001$.

Table 6
Hypothesis 2a OLS regression for association between CAMS and OQ-45.

Variable	b	S.E.b	95 % CI	*p*
OQ45 total				
Intercept	83.69	3.17	77.48 to 89.90	<.001***
CAMS condition	2.95	4.49	−5.85 to 11.75	.511
Time 1 month	−7.89	3.29	−14.34 to −1.44	.016*
Time 3 months	−15.51	3.83	−23.02 to −8.00	<.001***
Time 6 months	−11.23	3.41	−17.91 to −4.55	<.001***
Time 12 months	−15.83	3.40	−22.49 to −9.17	<.001***
CAMS × 1 month	1.10	4.66	−8.03 to 10.23	.814
CAMS × 3 months	3.81	4.80	−5.60 to 13.22	.427
CAMS × 6 months	−2.89	4.90	−12.49 to 6.71	.555
CAMS × 12 months	−8.09	4.89	−17.67 to 1.49	.098
OQ IR subscale				
Intercept	18.13	0.79	16.58 to 19.68	<.001***
CAMS condition	1.93	1.12	−0.27 to 4.13	.085
Time 1 month	−0.96	0.86	−2.65 to 0.73	.264
Time 3 months	−3.29	0.89	−5.03 to −1.55	<.001***
Time 6 months	−2.64	0.89	−4.38 to −0.90	.003**
Time 12 months	−3.76	0.89	−5.50 to −2.02	<.001***
CAMS × 1 month	−0.33	1.22	−2.72 to 2.06	.790
CAMS × 3 months	0.27	1.26	−2.20 to 2.74	.832
CAMS × 6 months	−0.19	1.29	−2.72 to 2.34	.885
CAMS × 12 months	−1.59	1.28	−4.10 to 0.92	.215
OQ SR subscale				
Intercept	13.77	0.63	12.54 to 15.00	<.001***
CAMS condition	−0.28	0.89	−2.02 to 1.46	.751
Time 1 month	−1.47	0.76	−2.96 to 0.02	.052
Time 3 months	−2.02	0.78	−3.55 to −0.49	.010**
Time 6 months	−1.88	0.78	−3.41 to −0.35	.016*
Time 12 months	−2.62	0.78	−4.15 to −1.09	<.001***
CAMS × 1 month	0.88	1.07	−1.22 to 2.98	.414
CAMS × 3 months	0.57	1.11	−1.61 to 2.75	.605
CAMS × 6 months	0.46	1.13	−1.75 to 2.67	.683
CAMS × 12 months	−0.32	1.13	−2.53 to 1.89	.776
OQ SD subscale				
Intercept	51.78	2.10	47.66 to 55.90	<.001***
CAMS condition	1.83	2.97	−3.99 to 7.65	.537
Time 1 month	−5.48	2.09	−9.58 to −1.38	.009**
Time 3 months	−10.24	2.15	−14.45 to −6.03	<.001***
Time 6 months	−6.78	2.16	−11.01 to −2.55	.002**
Time 12 months	−9.49	2.16	−13.72 to −5.26	<.001***
CAMS × 1 month	0.96	2.94	−4.80 to 6.72	.744
CAMS × 3 months	2.92	3.04	−3.04 to 8.88	.337
CAMS × 6 months	−3.23	3.10	−9.31 to 2.85	.298
CAMS × 12 months	−6.20	3.10	−12.28 to −0.12	.045*

* $p < .05$.
** $p < .01$.
*** $p < .001$.

Table 7
Hypothesis 2b OLS regression for association between CAMS and EQ5D index.

Variable	b	S.E.b	95 % CI	*p*
EQ5D index score				
Intercept	0.70	0.02	–	<.001***
CAMS condition	−0.02	0.03	−0.08 to 0.03	.378
Time 1 month	0.02	0.03	−0.03 to 0.08	.382
Time 3 months	0.05	0.03	−0.003 to 0.11	.068
Time 6 months	0.05	0.03	−0.01 to 0.10	.106
Time 12 months	0.08	0.03	0.02 to 0.14	.007**
CAMS × 1 month	0.03	0.04	−0.05 to 0.11	.492
CAMS × 3 months	0.01	0.04	−0.07 to 0.09	.836
CAMS × 6 months	0.05	0.04	−0.03 to 0.14	.190
CAMS × 12 months	0.05	0.04	−0.03 to 0.14	.192

** $p < .01$.
*** $p < .001$.

expected suicidal behavior and psychiatric hospitalizations and a comparable low proportion of participants withdrawn from treatment (0.01 CAMS vs. 0 TAU).

4. Discussion

CAMS was compared to TAU in a research clinic that mimicked our CMHC providing an NDA as after-care following a psychiatric admission due to suicide risk. While participants generally improved from baseline to 12 months, there were few differences between CAMS and TAU. Overall, there were no differences in suicidal behavior or suicidal ideation. In face of an imbalance in baseline suicidal ideation, TAU participants had a quicker remission of suicidal ideation by three months relative to higher baseline odds of suicidal ideation, and CAMS participants had a significant reduction in the severity of their suicidal ideation at 12 months relative to baseline. CAMS was not significantly more satisfactory to clients than TAU but it was significantly more acceptable and satisfactory to study therapists between-groups.

In contrast to our previous RCT's (Comtois et al., 2011; Jobes et al., 2017) and a recent meta-analysis (Swift et al., 2021), CAMS did not reduce the risk of suicidal ideation in the first three months. However, unlike our previous studies where ideation at the worst point of the past two weeks was assessed by interview and high suicidal ideation was an inclusion criterion and primary focus of the study, this study focused on suicide events and so to reduce participant burden administered the self-report BSS for "the past week including today" shortly before discharge. This may have resulted in lower baseline ideation and reduced the potential effect size. CAMS clinical trial data to date show that it is most effective treating those with serious *thoughts* of suicide (Swift et al., 2021), the largest population of those who struggle with suicide which can often be a neglected focus of treatment in and of itself (Jobes and Joiner, 2019).

There was no difference in psychological distress nor quality of life/overall functioning except a small difference in significantly improved symptom distress by CAMS from baseline to twelve months. Symptom distress was reduced in the pilot version of this study (Comtois et al., 2011) and in a Norwegian RCT (Ryberg et al., 2019), but not in a military study (Jobes et al., 2017). While there was no statistically significant difference in treatment satisfaction or dropout, contrary to our earlier findings (Comtois et al., 2011), therapist acceptability was significantly higher for CAMS than TAU clients. As previously seen, CAMS was quickly trained with high adherence to existing community therapists, supporting the feasibility of NDA use of CAMS.

This lack of replication of other CAMS RCT findings may be due to a more severely co-morbid sample—with an average of 1.8 additional areas of impairment beyond psychiatric illness and suicide risk (see Table 1). In this regard, there are data (Pistorello et al., 2020; Ryberg et al., 2020) that CAMS may be less effective with patients who struggle with substance abuse and chronic suicide risk (for whom Dialectical Behavior Therapy may be more effective—see Jobes and Chalker, 2019).

For CMHC administrative reasons, we could not conduct this trial in our CMHC (i.e., clinicians see study clients as part of their existing caseload) as we did in the pilot trial. Instead, a research clinic modeled on our CMHC using extant policies and procedures was created in the same building. Because the study provided in-kind support to cover their CMHC responsibilities, study therapists were released to the study for 1–2 dedicated days during the week to see their study patients. Given the flow of participants through the study, CAMS and TAU clinicians ended up with more time to see clients during their study days in both conditions than they have in the CMHC or had in the pilot trial. Therefore, clients in both conditions of this trial received more care than in the pilot trial (11 and 13 average sessions in CAMS and TAU in this study vs. 8 and 5 in the pilot) (Comtois et al., 2011) with TAU clients receiving more time than CAMS in this trial vs. less than CAMS in the pilot and this could have reduced the effect size between conditions.

This study had other limitations including only one site and an imbalance in baseline suicidal ideation measured at hospital discharge. Recruiting challenges from area hospitals limited recruitment to two university-based hospitals and enrollment to 75 % of our planned target which reduced power even with the expansion of the suicide attempt

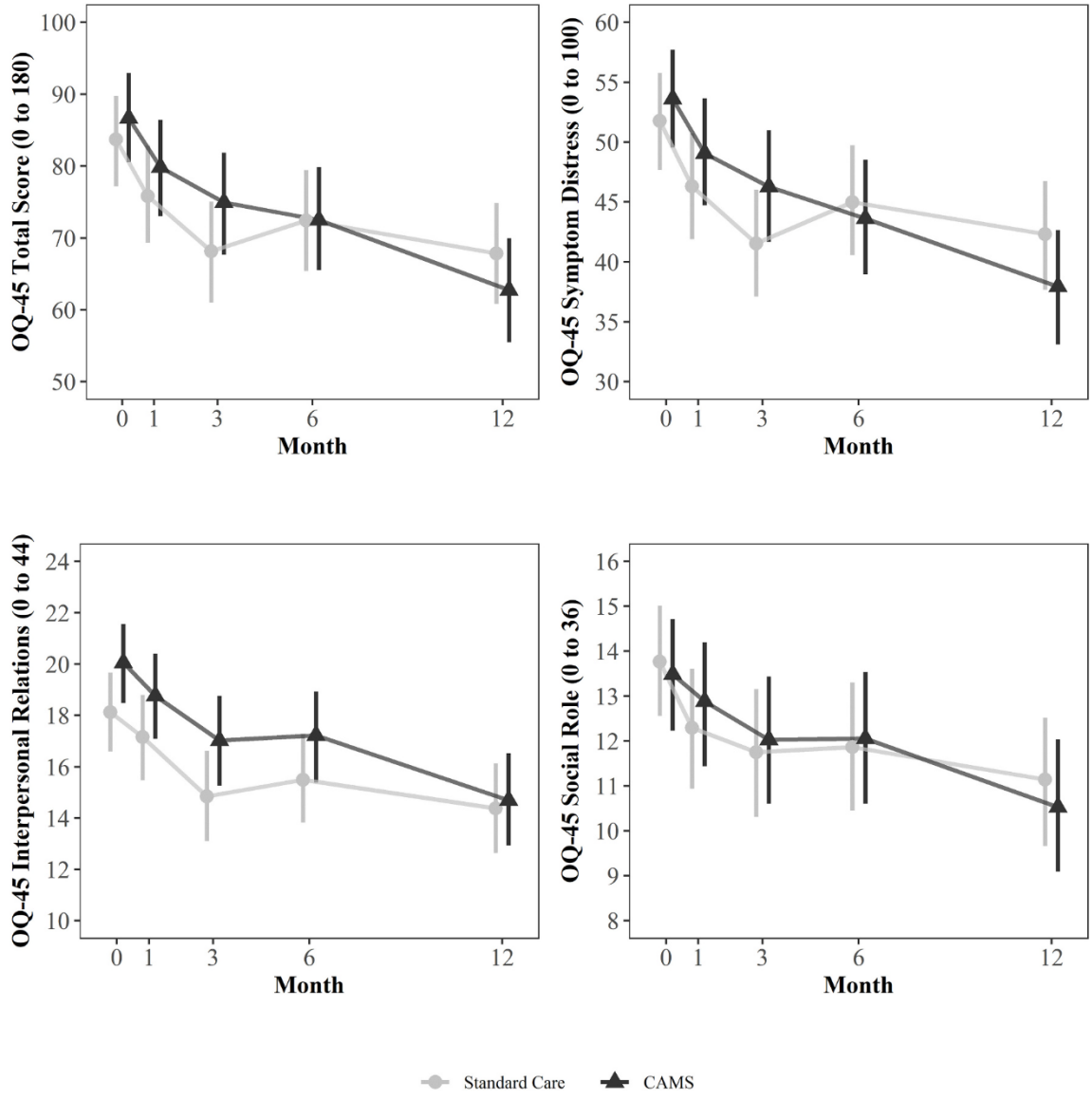

Fig. 3. OQ-45 plots.

inclusion criterion as described in the method section.

Future research is needed to understand if specific treatment strategies are associated with better suicide-related outcomes. Future research could further examine whether CAMS in less controlled systems than the research clinic would replicate our stronger pilot findings (Comtois et al., 2011). For example, a CAMS RCT in Norway with a heterogeneous set of participants with high levels of suicide ideation and overall morbidity treated by existing therapists in outpatient clinics, ambulatory outpatient teams, and inpatient wards found CAMS significantly lowered suicidal ideation and overall distress when compared to TAU (Ryberg et al., 2019). Alternatively, data from the present study might suggest that suicide-specific clinics like the one created for this trial may have overall benefits above and beyond the specific treatment model provided. This potential benefit was seen in a large Danish national observational study of regionally-based suicide-focused clinics across the country when compared to care in other settings (Erlangsen et al., 2015). A controlled study of suicide specific clinics for after-care following hospitalization should be further investigated.

5. Conclusions

In conclusion, this negative study did not replicate earlier findings of improvements in suicidal ideation, psychological distress, or client satisfaction. This study does replicate previous findings that CAMS is a feasible and acceptable treatment that is easily trained to community mental health clinicians who preferred it significantly more that TAU providers. This study also demonstrated that a clinic providing aftercare for acutely suicidal individuals discharged from inpatient psychiatry is feasible and acceptable and should be considered in future research.

CRediT authorship contribution statement

KAC, KH, AK, and DJ were responsible for conceptualization and design of the study. KAC, KH, SC, JC, TH, and DJ acquired data, while KAC, CD, AK, and KH analyzed data. KAC, KEH, CD, SC, AK, JC, and DJ interpreted data, and KAC, KEH, CD, SC, JC, TH, and DJ drafted the manuscript. All authors reviewed and approved the final version of the manuscript to be submitted.

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Conflict of Interest

Katherine Anne Comtois, Karin Hendricks, Chris DeCou, Samantha Chalker, Amanda Kerbrat, and Tierney Huppert declare that they have no conflict of interests. Potential conflicts of interest for David Jobes include research funding from the National Institute of Mental Health (NIMH), book royalties from American Psychological Association (APA) Press and Guilford Press, and as the founder and co-owner of CAMS-care, LLC (a professional and consultation company). Jennifer Crumlish reports personal fees from CAMS-care LLC, outside the submitted work. For this study, all recruitment, consent, enrollment, baseline, and follow-up data were collected at the University of Washington (UW) by Dr. Comtois' team. The Collaborative Assessment and Management of Suicidality (CAMS) study treatment was trained and monitored by Dr. Jobes and his team at Catholic University of America (CUA) with no direct contact with the participants and no role in the consent process nor outcome data collection, except as it specifically related to the CAMS Suicide Status Form and the CAMS Rating Scale (for adherence and fidelity purposes with both arms of the trial). Outcome data were analyzed at UW independently from Dr. Jobes and the CUA team who only reviewed results of analyses in summary (they neither handled raw data nor performed any statistical analyses).

Data availability

Research data are currently not shared.

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