Research Article

EFFECTIVENESS OF DIALECTICAL BEHAVIOR THERAPY VERSUS COLLABORATIVE ASSESSMENT AND MANAGEMENT OF SUICIDALITY TREATMENT FOR REDUCTION OF SELF-HARM IN ADULTS WITH BORDERLINE PERSONALITY TRAITS AND DISORDER—A RANDOMIZED OBSERVER-BLINDED CLINICAL TRIAL

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Background: *Many psychological treatments have shown effect on reducing self-harm in adults with borderline personality disorder. There is a need of brief psychotherapeutical treatment alternative for suicide prevention in specialized outpatient clinics.* **Methods/Design:** *The DiaS trial was designed as a pragmatic single-center, two-armed, parallel-group observer-blinded, randomized clinical superiority trial. The participants had at least two criteria from the borderline personality disorder diagnosis and a recent suicide attempt (within a month). The participants were offered 16 weeks of dialectical behavior therapy (DBT) versus up to 16 weeks of collaborative assessment and management of suicidality (CAMS) treatment. The primary composite outcome was the number of participants with a new self-harm (nonsuicidal self-injury [NSSI] or suicide attempt) at week 28 from baseline. Other exploratory outcomes were: severity of borderline symptoms, depressive symptoms, hopelessness, suicide ideation, and self-esteem.* **Results:** *At 28 weeks, the number of participants with new self-harm in the DBT group was 21 of 57 (36.8%) versus 12 of 51 (23.5%) in the CAMS treatment (OR: 1.90; 95% CI: 0.80–4.40; P = .14). When assessing the effect of DBT versus CAMS treatment on the individual components of the primary outcome, we observed no significant differences in the number of NSSI (OR: 1.60; 95% CI: 0.70–3.90; P = .31) or number of attempted suicides (OR: 2.24; 95% CI: 0.80–7.50; P = .12).* **Conclusion:** *In adults with borderline*

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personality traits and disorder and a recent suicide attempt, DBT does not seem superior compared with CAMS for reduction of number of self-harm or suicide attempts. However, further randomized clinical trials may be needed. Depression and Anxiety 00:1–11, 2016.

Key words: *suicide prevention; self-harm; borderline personality disorder; dialectical behavior therapy; collaborative assessment and management of suicidality*

INTRODUCTION

A recent report from the World Health Organization (WHO) estimated that approximately 800,000 people die by suicide each year, and that there are approximately 20 suicides attempted for each suicide.[1] It is also estimated that the age-standardized suicide rate is 8.8 per 100,000 person years. In 2012, 625 people died by suicide in Denmark (population of 5.6 million inhabitants).[1] This is comparable to other Western countries.

Borderline personality disorder (BPD) affects 1–2% of the general population.[2] This debilitating disorder is associated with high rates of mental health service use.[3] Patients with BPD represent up to 10% of all psychiatric outpatients and 20% of all inpatients in psychiatric wards.[4,5] According to *the diagnostic and statistical manual of mental disorders (*DSM-IV), recurrent self-mutilation and suicidal behavior constitute one of the nine criteria of BPD.[6] Sixty to seventy percent patients with BPD will attempt suicide, and the lifetime risk of death by suicide is up to 10%.[7] Up to 75% of patients with BPD engage in self-harm.[5,8] Nonsuicidal self-injury (NSSI) is a strong predictor for suicide attempts.[5,9]

Until the 1990s, BPD was considered almost untreatable. In the recent Cochrane review from 2012, "Psychological therapies for people with borderline personality disorder,"[10] the authors found indications for a beneficial effect of different types of psychotherapy in the treatment of the core pathology of BPD. The authors also concluded that their findings support a substantial role for psychotherapy, but that there is a need for replicative studies of higher quality. In a recent review and meta-analysis investigating therapeutic interventions versus treatment as usual (TAU) for self-harm in adolescents, the authors also find a risk difference of −0.07 for any self-harm (95% CI: −0.01–0.13), $z = 2.31$; $P = .02$) in favor of treatment interventions compared to TAU. The treatment interventions with the largest effect sizes were: dialectical behavior therapy (DBT), mentalization-based treatment, and cognitive behavior therapy (CBT).[11] However, the effects were only observed for each modality in a single randomized clinical trial.

DBT is the most intensively studied psychotherapy for adult patients with BPD.[12] Studies have been performed in many clinical settings, also in populations other than patients with BPD and comorbidities. Other psychotherapeutic approaches, such as collaborative assessment CAMS treatment, have shown effect in reducing suicidal ideation and overall symptom distress, and increasing hope and reasons for living.[13,14] CAMS is a novel therapeutic suicide-specific framework. CAMS treatment is transdiagnostic and is not specifically developed to treat patients with borderline personality disorder. At this point of time, one randomized clinical trial that compares CAMS treatment with enhanced TAU (E-TAU)[14] has been published. At 12-month posttreatment, the CAMS treatment group showed a significantly better and sustained reduction in suicide ideation. The study had a low base rate of self-inflicted injury in both groups, which was only summarized in a descriptive table, but at all time-points CAMS had slightly fewer self-inflicted injuries than E-TAU.

The DiaS trial was initiated due to the need for new alternatives for short-term treatment in specialized clinics for suicidal prevention. Since 2009, the Excellence Center of Suicide Prevention in Copenhagen has offered a standard treatment based on CAMS principles and the patients received sessions of psychotherapy within the CAMS framework. The majority of the patients at the center were challenged by emotion dysregulation, and it was estimated that 19% had a diagnosis of BPD.[15] The trial was planned as a pragmatic trial, where the results could evaluate the effects of DBT versus CAMS treatment for BPD patients in a real-life specialized outpatient clinic; in this way, the generalizability of the results would be greater. Before commencing the trial, the standard treatment was optimized, and the therapists followed a course of formal training. Adherence rating and supervision were added. The aim of this randomized clinical trial was to compare the effectiveness of DBT with CAMS treatment in reducing self-harm in adults with borderline personality traits and disorder.

METHODS

TRIAL DESIGN

The DiaS trial[16] was designed as a pragmatic, single-center, two-armed, parallel-group, observer-blinded, randomized clinical superiority trial, offering two brief psychotherapeutic interventions: DBT and collaborative assessment and management of suicidality (CAMS) treatment for patients with borderline personality traits and a recent suicide attempt. The participants were randomized to either 16 weeks of DBT or CAMS treatment (optimized standard treatment). The CAMS treatment duration varied according to the established methods of treatment, but lasted a maximum of 16 weeks. The design and rationale of the DiaS trial are described in more detail in the published

design paper.[16] The length of treatment should be brief (16 weeks instead of the standard DBT course of 52 weeks) due to the assumption that the recruited participants would have a less severe symptomatology, which again was based on the inclusion criteria related to the BPD diagnosis. The DBT treatment was offered at the Center of Excellence in Suicide Prevention, Psychiatric Center Copenhagen; and the CAMS treatment was offered at the Center of Excellence in Suicide Prevention at Psychiatric Center Copenhagen and Psychiatric Center Amager. The treatments were offered by the Danish public health-care system, and the participants did not pay for treatment. If the participants underwent all the follow-up interviews, they received a gift card (approximately 90$). The protocol was approved by the Regional Ethics Committee in the Capital Region of Denmark and the Danish Data Protection Agency (registered under RHP-2011–2012). The trial was registered under ClinicalTrials.gov NCT01512602.

We, thus, chose to include patients fulfilling two or more criteria related to BPD diagnosis. DBT was chosen to be one of the interventions in the trial, because of the focus on treating emotion regulation in self-harming patients with BPD, and also because emotion regulation is one of the core problems for many suicidal patients.

PARTICIPANT INCLUSION AND EXCLUSION CRITERIA

To be included, the participants had to meet the following criteria: (1) 18–65 years of age; (2) two or more criteria from the BPD diagnosis according to DSM-IV[7]; (3) a recent suicide attempt (until November 2013, defined as within a month from the inclusion interview; from November 2013, this criterion was changed to a suicide attempt within the previous 5 years, due to recruitment difficulties); and (4) signed informed consent. The exclusion criteria were: (1) severe depression (i.e., >23 points on Hamilton Depression Rating Scale [HDRS] 17 items); (2) bipolar disorder; (3) psychosis in the schizophrenia spectrum; (4) anorexia nervosa; (5) alcohol or drug dependence; (6) mental retardation; (7) insufficient ability to speak and understand Danish; or (8) lack of informed consent.

Once enrolled, the participants were assessed for DSM-IV diagnosis using the Mini International Interview (MINI),[17] the module for BPD in Structured Clinical Interview for DSM-IV Axis II disorder (SCID-II),[18] and HDRS-17[19] for depressive symptoms. All psychotropic medication was registered at baseline and at follow-up interviews. There was no restriction on ancillary psychotropic medication or medication protocol in the trial.

OUTCOME ASSESSMENT

The screening and assessments were done by a team of five independent investigators, four medical doctors, and one psychologist (K.T.A., C.W., H.K.J., K.K., and L.R.), all with psychiatric and research experience. In advance, three doctors and one psychologist (K.T.A., C.W., L.R., and K.K.) were trained in both MINI and SCID-II. They did not know about the allocation of participants when making the assessments. Follow-up interviews were performed at 17, 28, and 52 weeks after randomization.

PRIMARY OUTCOME

The primary composite outcome was self-harm[20] after randomization until week 28 (yes/no). The primary composite outcome self-harm can be divided into NSSI and suicide attempts (with or without intent to die). Self-harm refers to any act of self-poisoning or self-injury carried out by a person, irrespective of their motivation. This commonly involves self-poisoning with medication or self-injury by cutting.[20] NSSI refers to acts that damage body tissue (e.g., cutting, burning) without suicidal intent.[21] In the DiaS trial, we used the suicide attempt definition used by WHO (1986):

> *Attempted suicide is an act with nonfatal outcome, in which an individual deliberately initiates a nonhabitual behavior that, without intervention from others, will cause self-harm, or deliberately ingests a substance in excess of prescribed or generally recognized therapeutic dose, and which is aimed at realizing changes which the subject desired via the actual or expected physical consequences.*

The Suicide Attempt and Self-Injury Interview (SASII)[22] was used to collect data regarding self-harm at baseline. At the follow-up interviews, we used a questionnaire with questions regarding self-harm (number of acts, intent to die, and method used) after entering the trial and from the time period between follow-up interviews. The number and methods of self-harm acts including intent to die were registered.

EXPLORATORY OUTCOMES

To investigate the symptomatology of the patients further, we chose several exploratory outcomes not based on power calculations. These were: NSSI; suicide attempt; BPD severity measured by Zanarini Rating Scale (ZAN-BPD)[23]; depressive symptoms measured by the interview-based HDRS-17[19]; and the self-report questionnaire, Beck Depression Inventory, 21 items (BDI-II).[24] Suicide ideation, hopelessness, and self-esteem were measured by: Beck Suicide Ideation Scale,[25] Beck Hopelessness Scale (BHS),[26] and Rosenberg Self-Esteem Scale (RSE).[27]

TREATMENT AND THERAPISTS

DBT. DBT is a manual-based treatment based on principles of CBT, dialectics, and Zen Buddhism.[12] DBT consists of four components: (1) individual therapy, (2) skills training in groups, (3) access to telephone coaching with therapists, and (4) supervision and consultations for the team of therapists.[12] The treatment is organized around a treatment hierarchy, which consists of (1) eliminating life-threatening behavior, including DSH and suicide attempts; (2) eliminating treatment-interfering behaviors; and (3) ameliorating behaviors leading to decreased quality of life, such as drug dependence. Patients are taught four modules of primary skills in groups: (1) mindfulness, (2) emotional regulation, (3) distress tolerance, and (4) interpersonal effectiveness. The individual therapy focuses on the skills taught in the groups.

In the DiaS trial, DBT was offered as a 16-week treatment course, which consisted of one individual session (1 hr) and one group session (2 hrs) weekly. The treatment was manualized, and the material handed out to the participants was based on the format in Rathus and Miller's manual, *DBT for adolescents* (DBT-A)[28] and were adjusted to an adult target group. The decision of applying DBT-A in this trial, was primarily done to accommodate the time frame of treatment delivery. Rathus and Miller's work is based on Marsha Linehans four primary skills (mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance). The manual consisted of a short introduction to DBT and chapters describing the theory of the skills and associated exercises. The manual also included a modified chapter of dialectical dilemmas "walking a middle path" with a focus on strategies of change and acceptance, self-validation/validation of others, and behaviorism (ways to increase and decrease/stop behaviors). The adjustments and modifications were done by two experienced DBT therapists. The course did not include multifamily group.

The individual sessions started within the first week after randomization, and participants could wait a maximum of 4 weeks before receiving group sessions. The skill training was conducted in two groups and was divided into four skill modules. New participants could enter group training between the skill modules, but had to wait if a module already had started. The participants had the opportunity for telephone

contact and coaching by one of the DBT therapists, who were on-call in rotation all week from 8 a.m. to 10 p.m. The therapists were trained by Professor Alan Fruzzetti, University of Reno, at a 10-day intensive DBT course, which was spread over 6 months. The therapists had 2 hrs of supervision and group consultation twice a month with a senior DBT trainer. All individual sessions were videotaped for supervision and adherence rating. The team of therapists consisted of two clinical psychologists, one psychiatric nurse, and one occupational therapist with 11, 25, 25, and 6 years clinical psychiatric experience, respectively, and 2, 18, 7, and 6 years of experience working with psychotherapy, respectively.

We found no publicly available adherence instrument; therefore, we used a DBT session feedback form developed by Professor Alan Fruzzetti (not published). The DBT session feedback form consists of six categories with 58 questions in total. The categories are: session structure, acceptance strategies, change strategies, dialectical strategies, in-session behavior management, and mindfulness. The items are rated on a 5-point scale from very effective to very ineffective (1 = very effective, 2 = effective, 3 = mixed, 4 = ineffective, 5 = very ineffective, and 6 = not delivered). Adherence rating was done by an external rater experienced in DBT, and the results of the ratings (in average) were as follows: (1) session structures = 3.5 (range: 2.8–4.3), acceptance strategies = 2.4 (range: 2.0–2.8), change strategies = 3.7 (range: 3.5–4.0), dialectical strategies = 3.8 (range: 3.6–4.1), in-session behavior = 2.9 (range 2.2–3.4), and mindfulness = 2.0 (range: 1.4–2.3). Due to technical challenges, only 5% of the videotaped sessions could be used in the adherence rating. It remains unknown whether these sessions are representative for the rest of the sessions given.

CAMS Treatment. CAMS treatment is formerly known as CAMS-informed supportive psychotherapy.[29,30] The duration of treatment could vary depending on the suicidality of the participant, but lasted a maximum of 16 weeks. CAMS treatment is an overall process of clinical assessment, treatment planning, and management of outpatient suicidal risk.[30] CAMS could be seen as a framework and philosophy that is flexible enough to be integrated with different modes of psychotherapy such as CBT, psychodynamic psychotherapy, systemic therapy, etc. The main idea of CAMS is to engage and cooperate with the participant in the assessment and management of his/her suicidality. This involves that the therapist express understanding for the suicidal thoughts and behaviors without condoning them. The approach is thought to strengthen and emphasize the therapeutic alliance.

A main element of the CAMS approach is the core multipurpose tool "Suicide Status Form" (SSF).[31] The SSF consists of Likert-scaled and open-ended questions concerning six suicide-related markers: psychological pain, stress, agitation, hopelessness, self-hate, and overall risk of suicide. It also addresses a self-compared-to-others orientation to suicide, reasons for living versus reasons for dying, wish to live compared to wish to die, and a "one-thing" response.

In addition, various "drivers" of suicidality are identified and investigated. The CAMS therapeutic worksheet (Jobes, unpublished) discerns direct drivers (thoughts, feelings, behaviors, and interpersonal themes that lead to suicidal thoughts and acts) from indirect drivers (other factors that contribute but do not directly lead to suicidal ideation or feelings).

A treatment plan was collaboratively formulated that emphasized a "crisis response plan" to establish outpatient stability. The CAMS treatment emphasized problem-focused interventions that target and treat the identified suicidal drivers and ultimately eliminate suicidal coping.[31] The treatment consisted of individual therapy sessions of approximately 1 hr once a week in the therapist's office. Each session started with the patient and therapist sitting side-by-side and completing the SSF tracking form. The duration of the CAMS treatment differed depending on the patient's suicidality. The therapist concluded CAMS treatment after three successive sessions at which the patient was assessed to be nonsuicidal according to the SSF criteria.[29]

The CAMS therapists consisted of three clinical psychologists, two nurses, and one social worker. They had a varying amount of clinical and therapeutic experience. Psychiatric clinical experience was: 1, 2, 3, 6, 17, and 27 years, respectively, and experience with working with psychotherapy was: 3, 8, and 17 years. Three therapists had no former experience with psychotherapy. All therapists attended a 2-day course on CAMS treatment held by David Jobes twice. They had 1.5 hrs of weekly supervision by an experienced psychiatrist with thorough knowledge and experience in CAMS treatment. Each therapy session was videotaped and all therapists were rated for adherence according to the CAMS rating scale (CRS; Jobes, unpublished) by external raters experienced in CAMS treatment. The CRS is an observer rating scale and consists of three parts and 14 items in total. Part 1 covers the treatment philosophy (collaboration and suicide focus); part 2, the clinical/session framework (assess for risk, treatment planning, and intervention); and part 3, the overall rating. The items were rated on a 6-point scale from 0 = poor to 6 = excellent. All the therapists were rated to adhere (3 or above in all items) to the CAMS principles.

RANDOMIZATION AND BLINDING

The randomization of the patients was performed by the Copenhagen Trial Unit (CTU). The randomization was conducted by means of a computer-generated random sequence using alternating block sizes,[6,8,10] and was unknown to the investigator. Randomization was stratified by sex and number of self-harm (NSSI and suicide attempts) events (one or multiple) in order to avoid overrepresentation of patients with multiple self-harm in one treatment group. After randomization, the specific treatment was initiated. After the participant was included by the assessor, the therapists called a secretary at the CTU, and after giving information of civil registration number and case number, the secretary performed the randomization. The participants and the therapists were not blinded. The assessors were blinded. The assessors and therapists were located at separate geographic locations. In addition, the participants were carefully instructed not to reveal the group to which they had been randomized to the assessors. This were stressed a number of times, before the participant underwent the follow-up interview. If a participant was unmasked, the remaining outcome assessments were to be performed by a second blinded assessor. There were no cases of unmasking.

ETHICAL CONSIDERATIONS

The participants were informed about the trial both verbally and by through written information before signing the consent. It was stressed that participation in the trial was voluntary. Participation and the written consent could be withdrawn at any time during the trial, and this could be done with no consequence for future treatment. The trial protocol was approved by the regional ethics committee in the Capital Region of Denmark under file number H-1-2011-042. The Danish Data Protection Agency approved the management of data in the trial under the file number 2007-58-0015. Finally, the trial is registered under ClinicalTrial.gov as NCT01512602.

STATISTICAL ANALYSES

SAMPLE SIZE CALCULATION

We expected that the number of participants with a new event of deliberate self-harm would be 50% in the CAMS group[12] compared to 25% in the DBT group.[32] With a power of 90% and a type-1 error probability associated with this test of 0.05, we planned to randomize

154 participants, with about 77 participants in each intervention group.

All analyses were carried out using the Statistical Package for the Social Sciences (SPSS version 20.0). We handled missing data using logistic regression with multiple imputations[33] as described below.

The two group baseline characteristics were compared using Student's *t*-test for independent samples or chi-square test for binary variables. All analyses were based on the Intention-to-treat analysis (ITT), and included all randomized participants regardless of adherence to treatment. Then, we calculated the odds ratio to compare the effect between the intervention groups. Binary outcomes were analyzed using logistic regression and continuous outcomes were analyzed using linear regression with sex and previous self-harm (baseline variables) as covariates. More than 5% of data in the primary outcome were missing; therefore, multiple imputations were used and considered as the primary result. For multiple imputations, we used a linear regression model with 100 imputations and 20 iterations. The pooled estimates from the imputations were used for our analysis. Odds ratio was calculated afterward. We used two-tailed tests for statistical significance with alpha set at $P < .05$.

RESULTS

PARTICIPANT INCLUSION

Between January 2012 and January 2014, 197 screen-positive patients were recruited from the Excellence Center for Suicide Prevention. Of the 197 patients, 129 were clinically assessed in the trial, and 108 were included (Fig. 1).

BASELINE CHARACTERISTICS

One hundred and twenty-nine patients were referred to the trial and screened by the trial assessors; 108 were found eligible for the trial. Fifty-seven participants were allocated to the DBT group, and 51 were allocated to the CAMS treatment group. There were no significant differences between the treatment groups in sociodemographics, number of criteria in DSM-IV for BPD, severity of BPD traits, depressive symptoms, or suicide ideation. We found no differences between the groups at baseline in the suicidal variables, such as BPD symptoms or history of self-harm. In total, 96% of the complete sample fulfilled the original criteria of having a suicide attempt within a month of inclusion in the trial, again with no difference between the treatment groups. The sociodemographic variables and clinical characteristics are summarized in Tables 1 and 2.

TREATMENT ATTENDANCE AND RETENTION

The participants in the DBT group attended an average of 8.91 (SD 5.3) individual sessions, 7.4 (SD 5.4) skill training group sessions, and 2.0 (SD 3.7) telephone sessions within a treatment duration of maximum 19 weeks (16 + 3). The participants started in a skill training group at the start of the first module; therefore, some had to wait up to 4 weeks before being enrolled. Corresponding figures for attendance in the CAMS group are an average of 10.3 (SD 5.3) individual sessions and 1.8 (SD 2.6) telephone contacts within the 16-week treatment period (potentially 19 weeks including waiting time for entering a skill training group). CAMS treatment did not include group therapy sessions. Participants were considered dropouts in the DBT group when they had missed three consecutive individual sessions (a policy of treatment termination of the Excellence Center for Suicide Prevention). Five participants never attended treatment in the DBT group. In total, 23 (40%) participants completed the DBT treatment. The treatment retention rate was 40%. According to the CAMS resolution, a dropout was defined as any case participating in less than four sessions. The treatment attrition rate was 9.8% and included the two participants who never attended the CAMS treatment.

PRIMARY OUTCOME: SELF-HARM

None of the participants died during the trial period. When comparing DBT with CAMS treatment at week 28, we observed no significant difference in the primary composite outcome of self-harm during follow-up. The number of participants with new self-harm in the DBT group was 21 of 57 (36.8%) versus 12 of 51 (23.5%) in the CAMS group (OR: 1.90; 95% CI: 0.80–4.40; $P = .14$). When assessing the effect of DBT versus CAMS treatment on the individual components in the primary composite outcome (attempted suicide and NSSI), we did not observe any significant difference between the two outcomes. The results were as follows: (1) attempted suicide in the DBT group was 12 of 57 (19.3%) and in the CAMS group five of 51 (9.8%; OR: 2.45; 95% CI: 0.8–7.5; $P = .12$), and (2) NSSI: DBT-group 16 of 57 (28.1%) and in the CAMS group 10 of 51 (19.6%; OR: 1.60; 95% CI: 0.7–3.9; $P = .31$; Fig. 2).

EXPLORATORY OUTCOMES

When comparing DBT versus CAMS treatment on other exploratory outcomes, such as HDRS-17, BDI, ZAN-BPD RSE, and BHS, we found no significant differences (Table 3). This was also the result when comparing the DBT group with the CAMS treatment group with regard to BPD symptoms, suicide ideation, hopelessness, and self-esteem (Table 3). When using repeated measurement with log likelihood based mixed model with unstructured covariance comparing the two treatments at week 17, 28, and 52, we found no significant difference at any of the above-mentioned variables.

The use of psychotropic medication in the treatment groups was registered at baseline and at the follow-up interview at week 28. There were no statistically significant differences between groups in psychotropic medication use (Table 4).

When comparing the baseline profile of the nonattendees and the attendees at the follow-up interview at week

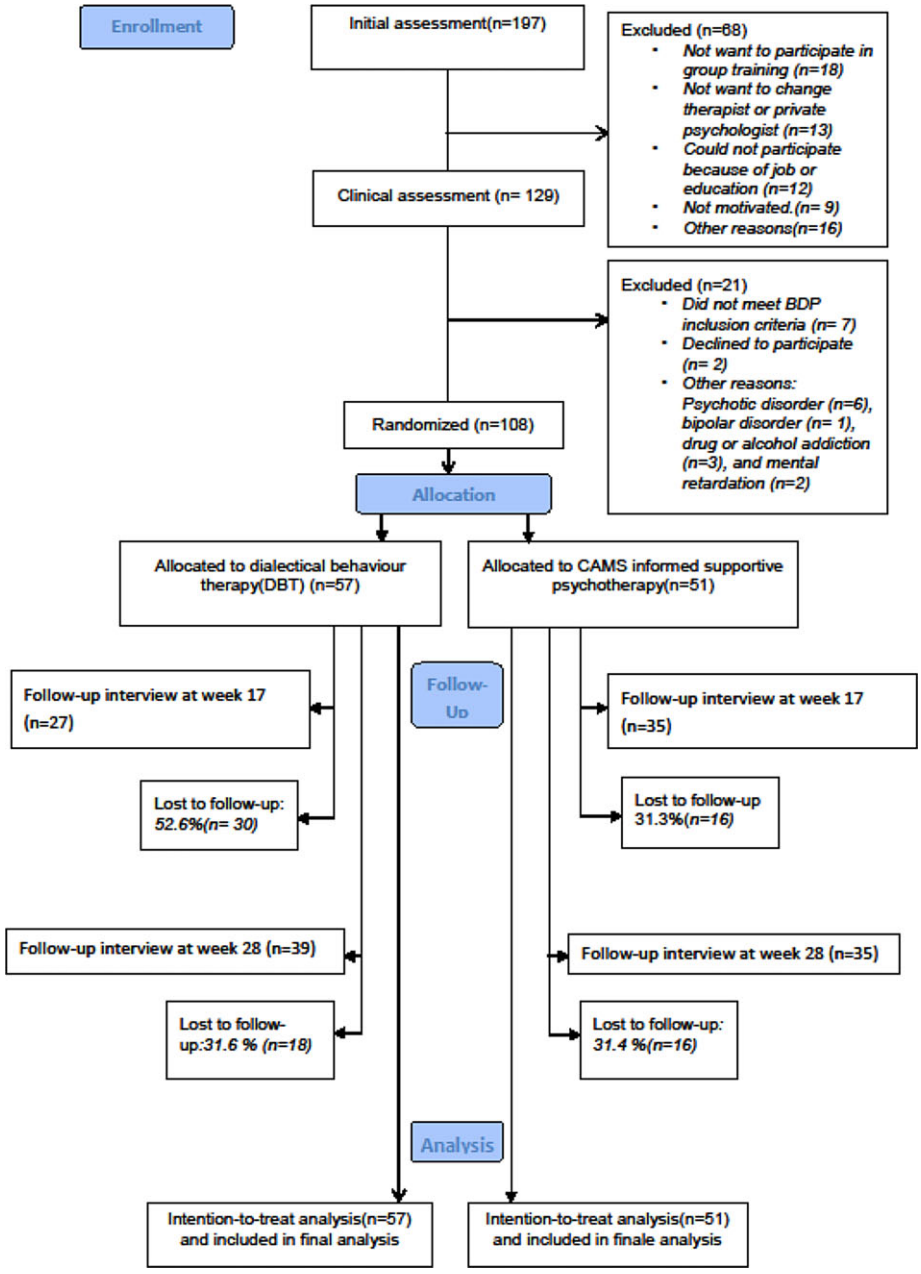

Figure 1. Flow diagram over the DiaS trial.

28, we found no significant differences between groups with regard to BPD symptoms, BPD severity, history of self-harm, and depressive symptoms measured at baseline. The number of nonattenders in the DBT group was 18 (31.6%) and in the CAMS group 16 (31.4%).

DISCUSSION

To our knowledge, this is the first randomized clinical trial to compare the two treatments, DBT versus CAMS, for patients with borderline personality traits and disorder and a recent suicide attempt. The trial demonstrated that there were no significant differences between groups in the effectiveness of the two treatments. Contrary to our expectations, a short course in DBT did not seem superior to CAMS treatment in the reduction of self-harm.

STRENGTHS AND LIMITATIONS

The randomization process was conducted though a central allocation by a computer-generated sequence unknown to the investigators.[34–37] We stratified for sex and the number of self-harm events; our treatment groups seem well randomized, and we considered

TABLE 1. Sociodemographic and clinical characteristics for participants at baseline

Variable	DBT ($n = 57$)	CAMS ($n = 51$)	Total sample ($N = 108$)
Age, mean (years; SD)	32.4 (13.2)	30.8 (12.1)	31.69 (12.7)
Female *n* (%)	41 (71.9%)	39 (76.5%)	80 (74.1%)
Education level			
High school graduate level (12 years; %)	25 (43.9%)	20 (39.2%)	45 (41.7%)
Employment (%)			
Employed or studying (%)	29 (50.9%)	32 (62.7%)	61 (56.0%)
Sick leave (%)	14 (24.6%)	15 (29.4%)	29 (26.9%)
BPD symptoms			
BPD diagnosis[a]	28 (47.5%)	31 (52%)	59 (54.6%)
BPD severity, ZAN for BPD (SD)	10.0 (6.5)	9.5 (5.4)	9.7 (6.0%)
Suicidality			
History of recurrent suicide attempt (%)	39 (68.4%)	34 (66.7%)	73 (67.6%)
History of recurrent deliberate self-harm (%)	33 (57.9%)	30 (58.8%)	63 (58.3%)
Becks Suicide Ideation Scale (SD)	22.5 (36%)	25.2 (36%)	24.3 (36.0%)
Current DSM-IV diagnoses[b]			
Major Depressive Disorder (%)	43.0 (75.4%)	37 (72.5%)	80 (74.1%)
Generalized Anxiety Disorder (%)	27.0 (49.1%)	20 (40.8%)	47 (45.2%)
Panic Disorder (%)	9.0 (15.8%)	4 (7.8%)	13 (12.0%)
Depression			
HDRS-17 (SD)	14.5 (6.5)	13.6 (6.0)	14.0 (6.3)
BDI-II (SD)	25.3 (12.7)	26.8 (11.2)	26.01 (12.0)
Other			
Becks Hopelessness Scale (SD)	29.6 (2.2)	29.9 (2.1)	29.7 (3.3)
RSE (SD)	12.5 (7.1)	12.4 (5.4)	12.46 (6.3)

[a]Assessed by SCID-II (22).
[b]Assessed by using MINI (21).

TABLE 2. Criteria of BPD diagnosis fulfilled at baseline in trial population ($N = 108$)

BPD-criteria[a]	2	3	4	5	6	7	8	9
Participants (*n*)	14	13	22	15	11	17	13	3
%	13.0	12.0	20.4	13.9	10.2	15.7	12.0	2.8

[a]According to DSM-IV (6).

stratification in our analyses.[38,39] The outcome assessors were blinded to the treatment allocation of the patients, and we observed no breaking of the intervention code.[34,36,37] We performed an ITT analysis, and the missing data were handled by using logistic regression with multiple imputations.[40] We were able to exclude

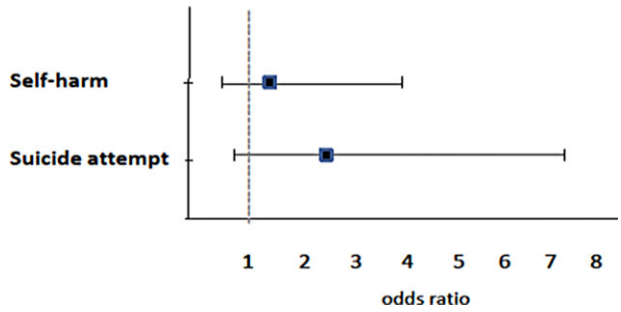

Figure 2. Odds ratio with 95% confidence intervals of NSSI and suicide attempts, favoring CAMS treatment.

with a reasonable likelihood that DBT should be substantially superior to CAMS treatment, at least in the form implemented in the present trial.

There are some critical limitations in the DiaS trial that may explain our neutral findings. First, the trial was underpowered. We recruited 108 participants of the 154 that would have been optimal according to our sample size calculation; accordingly, the risk of type-II errors is high. Second, at week 28, we observed only half of the outcomes we had projected in the CAMS group, which also reduces the power of our trial. Third, with DBT showing a beneficial effect over control in reducing parasuicidality with a standardized mean difference of −0.54, 95% CI: −0.92–0.16; $I^2 = 0\%$,[10,32,41,42] we realize that we exaggerated grossly the potential therapeutic effect of DBT by hypothesizing that DBT could be double as effective as CAMS treatment.[16] This aspect further decreased the sample size of our trial and added to our neutral outcome. Fourth, the delivery of DBT could potentially be inferior compared to

TABLE 3. The results of the DiaS trial, based on multiple imputations, comparisons of week 28

	DBT ($n = 57$)	CAMS ($n = 51$)	Chi-square, odds ratio, and P values
Self-harm (week 28)[a]	21 (36.8%)	12 (23.5%)	Chi-square: 0.22; OR: 1.90 (95% CI: 0.8–4.4); $P = .14$
Suicide attempt[a]	12 (19.3%)	5 (9.8%)	Chi-square: 0.12; OR: 2.45 (95% CI: 0.8–7.5); $P = .12$
NSSI[a,b]	16 (28.1%)	10 (19.6%)	Chi-square: 0.37; OR: 1.60 (95% CI: 0.7–3.9); $P = .31$
HDRS-17[b]	11.6 (SE 3.2)	11.00 (SE 2.1)	$P = .87$
BDI-II[b]	10.8 (SE 1.8)	10.7 (SE 1.8)	$P = .98$
ZAN for BPD[b]	7.6 (SE 2.4)	7.4 (SE 1.3)	$P = .97$
Beck Suicide Ideation[b]	5.6 (SE 1.3)	4.1 (SE 1.2)	$P = .39$
BHS[b]	19.6 (SE 1.1)	17.5 (SE 1.1)	$P = .19$
RSE[b]	21.8 (SE 0.4)	22.6 (SE 0.4)	$P = .18$

Observed participants: DBT = 38 of 57 (66.7%), CAMS = 35 of 51 (68.6%) for the primary outcomes. Missing values = 35 of 108 (32.4%).
[a]Imputations are based on sex, NSSI, suicide attempt, and allocation at baseline.
[b]Imputations are based on baseline value and allocation.

previous conducted DBT trials. The reason is that we had to launch the trial and treatment of participants before the intensive DBT training course was finished, so the therapists were not sufficiently adherence-rated before starting. Two of the four therapists did not have any previous experience with DBT. With regard to the DBT therapist rating or adherence rating, videotaping of the sessions were not done consistently. As a result, only 5% of the individual sessions were taped and therefore very few dyads were rated per therapist. The results from using the "DBT therapist rating and feedback form" developed by Alan Fruzzetti and Micheal Worall (unpublished work) showed that some of the treatment categories were delivered ineffectively, especially change and dialectical strategies. This could obviously have influenced the quality of the DBT treatment offered. It also remains unknown whether these 5% videotaped sessions are representative for the rest of the sessions given. It would, therefore, be relevant to replicate the trial under more ideal circumstances without these flaws. Fifth, the primary outcome was based on self-reporting of self-harm and could therefore be subject to responder bias, as the participants were not blinded.[34–37]

In regard to the CAMS treatment group, we cannot disregard a potential risk of pollution of the therapists. All therapists in the trial were offered training in both DBT and CAMS treatments.

The choice of altering the TAU to an optimized TAU can also explain the failure to detect differences in outcomes. The design of the DiaS trial started in 2010 and finished in 2011. In the process of designing the trial, it was decided to optimize the TAU offered in the Excellence Center for Suicide Prevention, which was a supportive psychotherapy based on the CAMS principles. The therapists required a more consistent TAU, and the result was the CAMS treatment including a short

TABLE 4. Use of psychotropic medication (baseline and week 28)

	DBT		CAMS		Total	
	Baseline $n = 57$	Week 28 $n = 39$	Baseline $n = 48$	Week 28 $n = 35$	Baseline $n = 108$	Week 28 $n = 75$
Antidepressant, *n* (%)	25 (43.9)	16 (28.1)	16 (33.3)	15 (31.3)	41 (38.0)	31 (28.7)
Antipsychotic, *n* (%)	5 (8.8)	5 (8.8)	5 (10.4)	6 (12.5)	10 (9.3)	11 (10.2)
Mood stabilizer, *n* (%)	1 (1.8)	2 (3.5)	4 (8.3)	6 (12.1)	5 (4.6)	8 (7.4)

TABLE 5. Exploratory outcome, based on multiple imputations, comparison at week 0 and 28

	DBT		CAMS		
Week	0	28[a]	0	28[a]	P value
Suicidal ideation (SD)	22.5 (36)	5.6 (1.3)	25.2 (36)	4.1 (1.2)	$P = .39$
Depression (SD)	14.5 (6.5)	11.6 (3.2)	13.6 (6.0)	11.00 (2.1)	$P = .06$
Hopelessness (BHS; SD)	29.6 (2.2)	30.9 (0.34)	29.9 (2.1)	29.5 (0.42)	$P = .01$
Self-esteem (RSE SD)	12.5 (7.1)	19.6 (1.1)	12.4 (5.4)	17.5 (1.1)	$P = .19$

[a]Observed cased at week 28: DBT group: BSS: 37 of 57, HDRS-17: 27 of 57, BHS: 31 of 57, RSE: 35 of 57; CAMS: BSS: 37 of 51, HDRS-17: 26 of 51, BHS: 26 of 51, RSE: 32 of 51.
BHS, Beck Hopelessness Scale; BSS, Beck Suicide Ideation Scale; HDRS-17, Hamilton Depression Rating Scale 17; RSE, Rosenberg Self-Esteem Scale.

training course, adherence rating, and supervision by an expert. When comparing an experimental treatment with a control group receiving an "active" treatment, the differences in effectiveness between the groups could become undetectable. Also, the fact that CAMS is a framework but where the therapist can choose the intervention/orientation he/she prefers, makes it difficult to actually measure the CAMS effect, and not the effect of the intervention given within the CAMS framework. In the DiaS trial, we were not able to register with the different interventions used in the CAMS sessions, due to difficulties of the therapists defining their psychotherapeutical orientation/intervention in the sessions. CAMS treatment has showed superiority in a trial in comparison with TAU.[43] Another study also showed no differences in efficacies when comparing DBT with general psychiatric management (GPM).[44] GPM could also be considered an active control group. The GPM is endorsed by the American Psychiatric Association (APA).

The results of exploratory outcomes show an improvement from baseline to follow-up interview (week 28; Table 5). The question is, how much of this improvement is caused by the treatments or by the natural course of the illnesses in general.[45] Both treatments commenced soon after the patient with a recent suicide attempt was referred to the trial; thus, many participants were in an emotional crisis. If the trial had a control group that did not receive any treatment at all (unexposed control group), we might have been able to answer this question. This was not initiated due to ethical considerations related to treating such a vulnerable population. The exploratory outcomes were based on questionnaires, which turned out to be too difficult for the participants to understand and fill in.

We had to alter the inclusion criterion with regard to the "time frame" for a recent suicide attempt, from "within one month" before entering the trial to "within five years." As mentioned above, 96.3% of the whole population met the old criterion of the suicide should have happened within 1 month before inclusion in the trial.

The treatment retention rate of 40% in the DBT group was considerably lower than other trials, especially compared to a retention rate of 75% for Linehan et al.,[46] 57% for Clarkin and Levy,[47] and 62% for McMain et al.[44] The retention rates of the two treatment groups were not comparable, due to the different definitions of dropout. The dropout rule in the DBT group was strict compared to other DBT trials, but it follows the overall policies of treatment termination in the Excellence Center for Suicide Prevention. In other DBT trials for adults three dropped sessions are accepted, and Rathus and Miller usually accept four dropped sessions in a course. Therefore, the strict dropout rule in the DiaS trial could have giving the DBT treatment difficult conditions in regard to retention. The retention rate could also be influenced by the practical challenges, since participants allocated to the DBT treatment group had to attend the outpatient clinic twice weekly. More than half of the participants (56%) were employed or studying. In comparison, the CAMS treatment group had a low treatment attrition rate (9.8%), maybe because the treatment was only once weekly, or because the therapists were better at retaining the participants in therapy. The retention rate in the two groups combined with the fact that CAMS treatment was the existing treatment in the Excellence Center for Suicide Prevention and DBT the new intervention, could also have influenced the results.

The DiaS trial was considered a pilot trial for larger multicenter trials. Before planning these larger pragmatic trials, it is essential to ensure the quality standard of the delivered DBT, as well as the availability of the global DBT rating scale and raters. Also, a different time frame could be considered for the inclusion criterion regarding the suicide attempt before entering the trial, so phases of emotional crisis could be avoided. Instead of a time frame of "within a month after a recent suicide attempt," as was chosen for the DiaS trial, we propose several months, so participants would be less affected by a recent emotional crisis. We suggest this should be taken into account when offering complex treatment approaches such as DBT and CAMS.

The duration of the DBT may have been too short. When planning the trial, the expectation was that participants would have less chronicity and severity of BPD symptoms, due to the inclusion criterion (two or more BPD criteria); and we reasoned this would correlate with the duration of treatment offered. It turned out, however, that half of our participants had a full diagnosis of BPD; therefore, it would have been obvious to plan a longer treatment duration to correlate with the severity of symptoms.

The DiaS trial was planned as a pragmatic trial and with all the strengths and limitations. Therefore, we could not control everything, which would have been possible under ideal research circumstances.

After collecting the follow-up results after 52 weeks, we performed an analysis (repeated measurement in a log-likelihood based mixed model with an unstructured covariance), and again we did not find any significant differences between group at any time point.

CONCLUSION

In this study, we compared DBT versus CAMS treatment in patients with BPD, and we found no statistically significant differences between the groups in relation to reducing self-harm. A number of factors can potentially explain why DBT did not seem superior to CAMS treatment. Therefore, there is a need to replicate this randomized clinical trial and ensure that it is conducted under more ideal circumstances. Short-term treatments for self-harm are needed in specialized outpatient clinics.

Authors' Contributions

K.A. was responsible for the study conception, drafting the protocol and the manuscript. M.N. was

responsible for study conception, drafting the protocol and the manuscript, and critical revision of the work. J.K. was responsible for conducting the analyses, drafting the protocol and manuscript, and critical revision of the work. L.R., C.W., and K.K. participated in collecting data, drafting the manuscript, and critical revision of the work. C.G. participated in drafting the protocol and manuscript and critical revision of the drafts. H.J. participated in collecting data, writing the manuscript, and critical revision of the work. All the authors have approved the final manuscript.

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