

Research paper

Cognitive behavioral therapy for suicide prevention in youth admitted to hospital following an episode of self-harm: A pilot randomized controlled trial



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ABSTRACT

Background: Self-harm (SH) is among the strongest risk factors for eventual suicide death yet there are limited data on which interventions are most effective for treating SH in youth.

Methods: This single-blind, pilot randomized controlled trial examined brief cognitive behavioral therapy (BCBT) for suicide prevention vs. minimally-directive supportive psychotherapy in youth (aged 16–26) hospitalized following SH. Both therapies included 10 acute sessions over 15 weeks with three booster sessions occurring at three month intervals thereafter. The primary feasibility outcome was $\geq 70\%$ retention at study endpoint. Efficacy measures, including repeat SH, were secondary outcomes.

Results: Twenty-four subjects were enrolled (12 per group) with one BCBT subject and two controls dropping out prior to the first therapy session. Five (45%) of the remaining BCBT subjects and seven (70%) control subjects completed all 10 acute therapy sessions. All subjects who completed five sessions went on to complete 10. There were significantly fewer instances of repeat SH in BCBT subjects (7 of 62 weeks of acute follow-up; 11%) compared to control subjects (24 of 79 weeks; 30%) (OR 0.34, 95%CI:0.13–0.92). Three subjects, all in the control condition, made a total of five suicide attempts during the study.

Limitations: This study had a modest sample size and retention rate.

Conclusions: This study failed to achieve its primary feasibility retention goal for BCBT. However, it did demonstrate that initial adherence to follow-up predicted study completion. Despite small numbers, it also found a significant reduction in repeat SH in the BCBT group, a finding which requires replication.

1. Introduction

Suicide and self-harm (SH), including non-suicidal self-injury and suicide attempts, are a leading cause of disability adjusted life years worldwide (Haagsma et al., 2016) and suicide is the second most common cause of death amongst youth (henceforth defined as age ≤ 25)

(Government of Canada, 2018). Youth is a known high-risk time for suicidal thoughts/behavior, with prevalence of lifetime suicidal ideation at 10–30% and suicide attempts at 4–10% among adolescents (defined as age < 20) (Nock et al., 2013; Evans et al., 2005). Rates of SH are also increasing (Cullen et al., 2018; Knopf, 2017; Taylor et al., 2011), particularly in young women (McManus et al., 2019). Notably,

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self-injury where there was no suicidal intent, sometimes termed “non-suicidal self-injury” (NSSI) has been found to be one of the strongest predictors of future suicidal behavior (Andover et al., 2005; Guan et al., 2012; Hawton and Harriss, 2007; Mars et al., 2019). This may be because people who engage in self-injury even when there is no intent to die have, by definition, already shown themselves capable of harming themselves in response to psychological distress which is considered one of the necessary pre-requisites for suicide death (Mars et al., 2019; Van Orden et al., 2010). Furthermore, while the distinction between these two entities (NSSI and suicide attempts) may be important in acute management, differences in long-term risk are unclear (Kapur et al., 2013; Mars et al., 2019).

Rates of suicide in the year following a hospital presentation for SH in youth are 0.2–0.5%, a 50-fold increased risk compared to the general population (Hawton et al., 2015). Furthermore, the first month is a period of exceptionally high risk (Chung et al., 2019; Geulayov et al., 2019) with nearly half of all suicide deaths in the year following psychiatric hospitalization occur within the first month after discharge (Deisenhammer et al., 2007). Presentation to hospital after SH is therefore a marker of both a high risk patient and a high risk time.

It remains unclear which interventions for SH are most effective at modifying risk of future suicide or repeat SH (Calear et al., 2016; Cullen et al., 2018; Knopf, 2017; Robinson et al., 2016; Turner et al., 2014). A number of trials have tested different psychotherapies including cognitive behavioral therapy CBT, manual-assisted cognitive therapy (MACT), problem-solving therapy (PST), dialectical behavioural therapy (DBT), emotion regulation group therapy (ERGT), mentalization-based therapy (MBT), interpersonal therapy (IPT), voice-movement therapy (VMT), dynamic deconstructive psychotherapy (DDP), transference-focused psychotherapy (TFP), the Coping Long Term with Active Suicide Program (CLASP), and family therapy (De Silva et al., 2013; Turner et al., 2014; Yen et al., 2019). Note that some of these trials, for example those focusing on DBT, restrict subjects to those with specific diagnoses such as borderline personality disorder rather than anyone who presents with SH. Calear et al. (2016) conducted a systematic review examining a range of psychosocial interventions for youth suicide including those listed above delivered in a variety of settings (school based, community-based, healthcare setting). More than half of treatment program studies showed evidence of benefit with respect to suicide attempts and SH, although no particular treatment demonstrated superiority (Calear et al., 2016). Another systematic review found weak evidence that clinical interventions including CBT, DBT, family therapy, and brief contact interventions reduced repeat SH at follow-up in youth although the effect did not remain after low-quality studies were removed from the analysis (Robinson et al., 2018). Recently, King et al. (2019) found that the Youth-Nominated Support Team (YST) Intervention, a psychosocial treatment for suicidal adolescents in which they nominate specific “caring adults” to provide support following hospitalization, was associated with a reduction in suicides.

Systematic reviews of CBT specifically have produced some modest evidence of its efficacy for the treatment of suicide-related behaviors (Cox and Hetrick, 2017). One review found evidence that CBT reduced repeat SH in youth but noted that this finding came from only a single study (Robinson et al., 2011). Another found that CBT may be effective in treating suicidal behavior in adults but not in adolescents (Tarrrier et al., 2008). Four trials specifically examining CBT alone or in combination with other therapies in youth, showed significant reductions in SH over 6–18 months of follow-up compared to treatment as usual (Esposito-Smythers et al., 2011; Hazell et al., 2009; Slee et al., 2008; Wood et al., 2001). Youth with SH who were given an intervention that included cognitive behavioral and family components had a lower number of suicide attempts (Knopf, 2017). Finally, one pilot study of youth with a recent suicide attempt found improvement in measures of depression and suicidal ideation with both CBT and a supportive treatment condition but no difference between them

including in preventing repeat attempts (Donaldson et al., 2005).

This literature has numerous gaps. The use of “treatment as usual” rather than non-directive psychotherapies as comparators in most trials means that one cannot determine whether it is the therapeutic modality itself or merely the time spent in therapy that results in change (Calear et al., 2016; Hetrick et al., 2016). Furthermore, CBT protocols in these trials varied and it is thought that CBT interventions that target suicide-related behavior specifically might be more effective (Cox and Hetrick, 2017; Mewton and Andrews, 2016). This is supported by meta-analytic findings that CBT may only be effective when the main focus is imparting skills aimed specifically at preventing suicide rather than a standard CBT framework, for example, targeting depression (Tarrrier et al., 2008).

Time-limited versions of CBT specifically designed to target suicide prevention have been developed over the past decade (Bryan and Rudd, 2018; Wenzel et al., 2009). One particular approach, referred to as brief CBT for suicide prevention (BCBT; (Bryan and Rudd, 2018)) aims to strengthen emotion regulation and cognitive flexibility, two mechanisms believed to underlie recovery from high risk states (Bryan and Rozek, 2018). In a randomized clinical trial comparing BCBT to treatment as usual in a group of active duty soldiers, patients assigned to BCBT were 60% less likely to attempt suicide during the two-year follow-up (Rudd et al., 2015). Subsequent analyses that categorized patients into three groups based on the severity of suicidal symptoms further support the treatment's effectiveness across subgroups compared to treatment as usual (Bryan et al., 2018). To date, BCBT's effect on SH among youths remains unknown.

In light of the limited knowledge about effective treatments for the prevention of SH among youth and an absence of studies focusing on inpatients who are known to be at exceptionally high risk (Hawton et al., 2015), the aim of this pilot trial was to examine the feasibility, acceptability, and preliminary effectiveness of the BCBT protocol adapted for use with patients aged 16–26 years. The primary outcome was retention at 12 month endpoint and we hypothesized that $\geq 70\%$ of youth would remain in the study until endpoint. We further hypothesized that BCBT would be more effective than a supportive therapy control for preventing repeat SH.

2. Methods

2.1. Study design and participants

This study is a single-site, single-blind, pilot RCT of BCBT for suicide prevention versus an attentional control group (“minimally directive supportive psychotherapy”) for youth admitted to hospital following SH. The study was conducted at Sunnybrook Health Sciences Centre, a large university-affiliated academic hospital in Toronto, Canada. It was approved by the Sunnybrook Health Sciences Centre Research Ethics Board (ID# 083–2016) and written informed consent was obtained from all subjects. Details of the consent process and safety monitoring are provided in the supplementary file.

Subjects were recruited through the psychiatric inpatient unit and psychiatric consultation-liaison service (the latter assesses youth with SH on medical/surgical units). Inclusion criteria were: 1) youth (aged 16–26); 2) admitted to hospital following an episode of SH, defined as any intentional destructive action (e.g. cutting, burning, poisoning) regardless of whether the motivation was to die or to achieve some other goal and 3) ability to read and understand English. Note that originally, the trial intended to include youth defined more narrowly as aged 16–24. However, given slower than expected recruitment, the eligibility criteria were broadened to include subjects up to the age of 26. Subjects aged 15 at baseline who were due to turn 16 within 15 weeks/the planned length of acute treatment were also made eligible for inclusion. Also, the protocol allowed for SH to have occurred within 90 days prior to admission – an intentionally broad interval intended to capture as many youth inpatients with the risk factor as possible.

However, note that the majority of subjects actually included had engaged in SH within one day of admission, with the remainder having occurred within one week except for a single subject whose SH had occurred two weeks prior.

Given the potential trans-diagnostic impact of BCBT for reducing SH, there were no specific diagnostic requirements for inclusion in the study, only the presence of a hospital admission and recent SH. The only exclusion criterion was current or previous psychotic symptoms as these could impair subjects' ability to participate in BCBT. The study was planned to last for two years with the first year spent recruiting subjects and an additional year to allow all subjects to receive treatment and follow-up.

2.2. Intervention and control groups

Subjects who were admitted to hospital following SH were randomized to receive either BCBT or an enhanced usual care attentional control treatment consisting of minimally-directive supportive therapy. A random number generator was used to create the treatment allocation sequence such that by the end of recruitment there was a 1:1 ratio of subjects randomized to each condition. A member of the principal investigator's lab who was otherwise not involved in the study generated the list and created individual electronic files with allocation by subject number, protected by unique passwords that were only sent to the PI following each subject's inclusion in the intent-to-treat population.

Both treatment conditions consisted of 10 weekly 45 min sessions occurring over the first 15 weeks of enrollment with 3 booster sessions occurring at 6, 9 and 12-months after enrollment. Subjects engaged in sessions as inpatients while admitted and continued them as outpatients once discharged. Study treatments were added on to usual care provided by inpatient/outpatient psychiatric services. Usual care could include inpatient and/or outpatient psychiatric follow up, pharmacotherapy, and/or psychotherapy that had been ongoing for at least three months prior to study enrollment. Beginning a new psychotherapy was not allowed within the three months prior to study initiation or during the 10-treatment acute phase of the trial.

Both BCBT and the control condition were delivered by Masters level social workers (MSWs) with experience treating transitional age youth. MSWs who provided the BCBT intervention were required to have both formal training in standard CBT as well as experience delivering it to patients independently. They were further provided with the treatment manual, a brief treatment workshop, and supervision as needed from the principal investigator to troubleshoot any issues that arose with imparting the model (see below for fidelity monitoring).

2.3. Brief CBT for suicide prevention

In contrast to traditional CBT for depression that treats suicidal behavior as a symptom which is expected to improve with improvement of the underlying condition, BCBT treats SH as a maladaptive form of coping that is the primary target of treatment. It is a validated, manualized treatment that is active, goal-oriented, and follows a sequence of steps within and across sessions (Bryan and Rudd, 2018). In the first two sessions of BCBT, the therapist conducts a narrative assessment of the index suicidal episode or attempt, develops a core case-conceptualization of the "suicidal mode" (i.e. the steps that led to the SH event), and collaboratively develops a crisis response plan, also known as a safety plan. BCBT then proceeds in three sequential phases. In the first phase, patients learn strategies designed to foster emotion regulation (e.g., relaxation skills, mindfulness skills, reasons for living); in the second phase, patients learn strategies designed to foster cognitive flexibility (e.g. cognitive reappraisal skills, activity planning); and in the third phase, patients review and consolidate material learned and complete a relapse prevention task multiple times. In the relapse prevention task, the patient is first asked to recall in detail the environmental, interpersonal, and intrapsychic factors that led to the original

instance of SH prompting this treatment course, and then is asked to visualize how he or she might have used skills learned in BCBT to avert or otherwise prevent that instance of SH. Once patients master this task, they are asked to apply these same steps to an anticipated or imagined future crisis, again using visualization. Subsequent booster sessions to consolidate learning are conducted at 6, 9 and 12-months. Note that minor alterations were made to the treatment manual by the primary investigator in consultation with coinvestigators. These were: creation of a session outline for each session highlighting points that must be covered by the therapist including check-in/homework review, review of prior learning, new skills imparted, and new homework; removal of the manual's risk assessment protocol (as the study had its own protocol); a new Crisis Response Plan template which included local resources; adjustment of the means restriction counselling section to remove aspects deemed inapplicable to youth in Toronto (e.g. firearm safety practices); inclusion of a section covering thought records and a tip-sheet for correcting thinking errors; additional brief psychoeducation about the role of emotions in mental health. Sessions were recorded and fidelity to the model assessed by independent raters according to a checklist (see supplementary file) based on the expectations that BCBT would include a) discussion of the session agenda at its outset, b) a review of homework, c) a review of symptoms including suicidal ideation and behavior since the last meeting, d) skills training, e) assignment of new homework, and f) discussion and review of a safety plan. Sessions were also assessed for the number of directive statements made by the therapist (i.e. suggesting a course of action, or skill to employ as opposed to statements of general support). The minimally-directive supportive therapy control was expected to include none of these elements. At least two sessions were randomly selected for fidelity testing per subject (unless a subject dropped out prior to completing two sessions). In two instances, sessions in the BCBT group were ended prematurely at the request of a subject and these were excluded from fidelity testing given that the therapist did not have time to complete all of the required elements. Fidelity was 92% with an average of 11.5 directive statements in the BCBT arm and 99% with an average of 1.5 directive statements in the minimally-directive supportive therapy arm.

2.4. Visits and measures

Subjects all had a baseline visit with the principal investigator and research coordinator. Diagnostic information was obtained by the research coordinator from the case history and confirmed using The Mini-International Neuropsychiatric Interview (MINI). A research visit, including separate meetings with an investigator and a blinded research coordinator who obtained study measures, occurred following every subsequent treatment visit (i.e. up to 13 visits for those who attended all 10 acute sessions and three boosters). The purpose of the meeting with the investigator was a brief safety assessment, an opportunity to answer any questions about the study that had arisen, and a brief review of symptoms which was used to inform a clinical impression of severity/improvement (see scales below). Neither the investigator nor the research coordinator provided therapeutic support during these meetings. The blinded research coordinator did not discuss any of the information gleaned during the research visit with unblinded members of the research team except in the rare case of an acute safety concern when the principal investigator was informed and asked to assess the subject. Subjects were given \$5 per session as a modest reimbursement for travel and their time.

The primary feasibility outcome was retention to 12-months/the final visit across all subjects (we defined $\geq 70\%$ retention as the pre-specified threshold for feasibility). Secondary outcome measures included repeated SH (i.e. any episode of self-injury regardless of intent occurring between research visits) as well as suicide attempts (i.e. any episode of self-injury with at least some intent to die between research visits) derived from the Columbia Suicide Severity Rating Scale (C-

SSRS), the Scale for Suicidal Ideation (SSI), the Montgomery-Asberg Depression Rating Scale (MADRS), the Beck Depression Inventory (BDI), the Columbia Impairment Scale (CIS), and the Clinical Global Impression Severity (CGI-S) and Improvement (CGI-I) scales. Psychometric properties of these scales are provided in the supplementary file. There was also an initial plan to assess subject satisfaction after acute treatment with a 9-item Likert questionnaire created for the study, however only two subjects (<10%) returned the questionnaire and therefore the data quality was deemed too low for publication.

Additional data collected included age and sex as well as concomitant pharmacotherapy and psychotherapy, where applicable.

2.5. Statistical analysis

Twelve subjects have been shown to be the minimum number required to ensure that the margin of error in the confidence interval is sufficiently small to be informative (van Belle, 2002). Therefore, this study included 24 subjects (12 per group). This study used an intent-to-treat approach including all 24 subjects randomized into the trial each of whom had at least a baseline visit. This study used Generalized Estimating Equations (GEE) modeling which accounts for repeated measures and missing participant data. An autoregressive correlation was selected and the model tested for the main effects of group with time as a within-subject variable. Survival analyses with Cox regression and Kaplan Meier survival curves were used to compare the probability of dropouts and repeat self-harm between the two groups.

Baseline subject characteristics between groups were compared using one-way Analysis of Variance (ANOVA) and two-sided chi-square tests (or Fisher's exact tests for the case of low expected counts), for continuous and categorical variables respectively. All analyses were performed using IBM SPSS Statistics 24 (SPSS Inc, Chicago, IL). Given the exploratory nature of this pilot study, no statistical correction was made for multiple comparisons.

3. Results

3.1. Study participants

Sixty three patients were identified as eligible for the trial and deemed suitable to be approached by their most responsible physician. Of these, a total of 24 subjects were enrolled in the trial (12 randomized into each group) during an 18 month recruitment period (September 2016-February 2018) (see Fig. 1). Baseline demographic and clinical characteristics of subjects are shown in Table 1. There was no difference in mean age, sex, baseline SSI, MADRS, CGI-S or BDI scores between groups. Psychiatric diagnoses by group are shown in Table 2. Of the 24 subjects, 18 had been admitted following a suicide attempt (i.e. SH with stated suicidal intent).

3.2. Primary feasibility outcome

Of the 24 subjects enrolled, 21 had at least one post-baseline visit (one subject in the BCBT arm and two subjects in the control group dropped out following randomization). BCBT did not meet the pre-specified threshold of feasibility for acute treatment with five of 11 subjects (45%) completing all 10 sessions. Seven of 10 subjects (70%) completed 10 sessions in the control group. Hazard ratio for dropout in the BCBT group was not statistically significant (HR 1.52, 95%CI: 0.48–4.81). Neither arm achieved feasibility over the full 12-month study period (BCBT: one subject, 9%; control: four subjects, 40%).

3.3. Secondary outcomes

3.3.1. Repeat SH and suicide attempts

During the acute phase of treatment BCBT had significantly fewer instances of repeat SH with SH occurring in 7 of 62 weeks of follow-up

(11%) in the BCBT group compared to 24 of 79 weeks (30%) in controls (OR 0.34, 95%CI:0.13–0.92). Time to repeat SH is shown in Fig. 2 with a numerically lower proportion of BCBT subjects engaging in the behavior at any time during acute treatment compared to controls (33% vs. 58%; HR 0.56, 95%CI: 0.16–1.91). There were no suicide attempts during the acute phase in either group. During the booster phase, three of the seven control subjects had a total of five suicide attempts over 48 months of follow-up. There were no suicide attempts during the 12 months of follow-up for the two BCBT subjects who attended booster sessions.

3.4. Suicide and depression scores

Change in SSI and MADRS scores over time are shown in Figs. 3 and 4, respectively. Both groups showed reductions in suicide and depression scores over time, however between-group differences were not significant at any time point (week 10 MADRS: $B = -1.56$, $SE(B) = 2.95$, $p = 0.60$, SSI: $B = -1.61$, $SE(B) = 2.41$, $p = 0.51$). At week 10, BDI scores were reduced by 8.5 from baseline in the BCBT group and by 5.6 in the control group, however this difference was not significantly different ($B = -4.67$, $SE(B) = 3.96$, $p = 0.24$). Likewise, at week 10, CGI-S scores had reduced by 2.2 in the BCBT group and 1.3 in the control group although the between-group difference was not significant ($B = -0.73$, $SE(B) = 0.30$, $p = 0.81$). At week 10, CGI-I scores had improved by 0.5 in the BCBT group and were unchanged in the control group compared to week 1, a difference that was likewise not significant ($B = 0.28$, $SE(B) = 0.23$, $p = 0.21$).

3.5. Standard treatment

The number of patients receiving specific pharmacological treatments was often but not always similar between groups (see supplementary Table 1): Regarding other psychotherapy, one BCBT subject received ongoing supportive counselling during the booster-phase of treatment. In the control group, one subject engaged in a one-month DBT program and another received weekly family therapy after completion of acute-phase treatment.

4. Discussion

This pilot RCT tested the feasibility and preliminary effectiveness of BCBT for youth recently admitted to hospital following SH compared to an attentional control group. It did not achieve the a priori feasibility outcome. However, while the study was not planned to be adequately powered for efficacy outcomes, it is of considerable interest that the frequency of repeat SH during acute treatment was statistically significantly lower in the BCBT group. It is also of interest that all of the repeat suicide attempts occurred in the control group although large discrepancies in the duration of follow up do limit the ability to interpret that comparison. These findings should be considered preliminary and in need of replication. The number of subjects who ultimately attended all acute and booster sessions was five, including only one in the active treatment arm, and fewer than 70% of those enrolled completed the acute sessions in both groups. The unexpected finding that 70% of control subjects completed acute treatment with only 45% of BCBT subjects doing so must be interpreted with caution given the small sample size but could be interpreted several ways. It might suggest that the work of BCBT was more challenging and less acceptable than the control condition which did not impart any specific learning. However, the preliminary effectiveness data pointing to less repeat SH in the BCBT arm might also suggest another explanation. Given the BCBT focus on skills acquisition, it may be that fewer active treatment subjects followed up as they thought they had acquired the necessary skills and did not need more “therapy”. This notion is supported by evidence that targeted treatments as brief as three sessions may reduce the risk of repeat suicide attempts (Gysin-Maillart et al., 2016). This conjecture

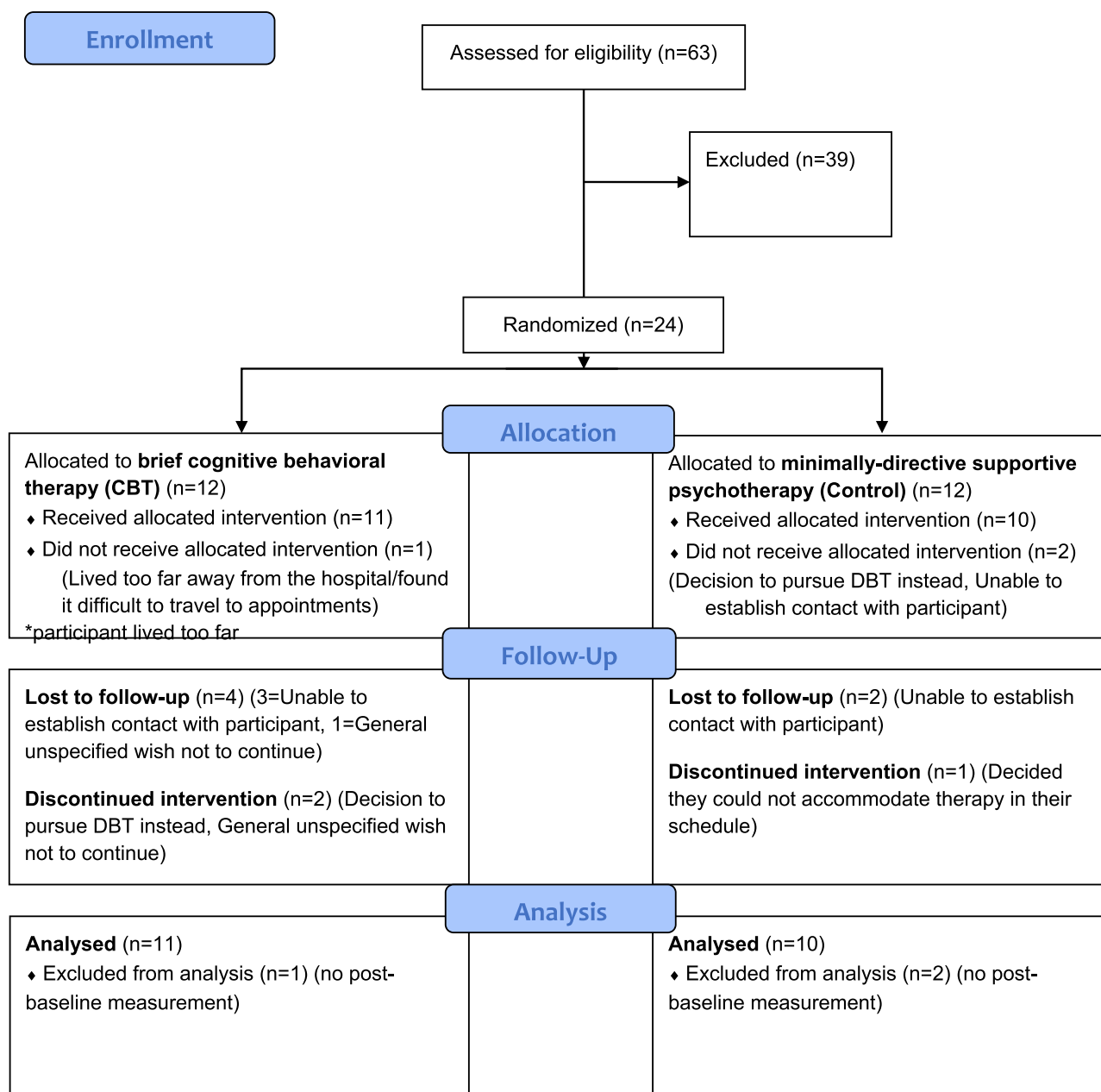


Fig. 1. Flow diagram for inclusion and exclusion of subjects in the acute phase of the trial (i.e. for the primary analysis).

*Note: During the booster phase a further 4 BCBT subjects dropped out (1 = General unspecified wish not to continue, 3 = Unable to establish contact with participants) and 3 Control subjects dropped out (2 = Unable to establish contact with participant, 1 = “Busy”) dropped out. Two subjects in the BCBT group attended the first booster session and only one attended the second and third. Seven, five and four subjects attended the first, second, and third boosters, respectively, in the control arm. **BCBT: Brief Cognitive Behavioral Therapy for Suicide Prevention; DBT: Dialectical Behavioral Therapy.

would need to be confirmed by future research.

Although the number of dropouts was high, it is noteworthy that all of the acute phase dropouts occurred within the first four weeks in the BCBT group and within the first five weeks in the control condition. This may suggest, for example, that a one-month trial of BCBT could be offered to all youth following SH. Youth could then be divided into the group who may wish to attend further sessions and dropouts who could be provided with more active engagement from providers and/or other interventions such as family therapy.

It is well known that a major obstacle to treating people, particularly youth, who engage in SH is lack of engagement with therapy; roughly 25–50% of youth will not attend follow-up sessions after being discharged from hospital post-SH (Granboulan et al., 2001; Taylor and Stansfeld, 1984). However, the retention rate in this study was

nevertheless substantially lower than the first study of CBT for suicide prevention in youth (Stanley et al., 2009). This lower retention rate may be explained by the present study's focus on recently hospitalized subjects who were likely more acutely ill. Greater engagement from parents may have mitigated some of the specific reasons for dropouts including being too busy, living too far away, and difficulties contacting subjects. The Family Intervention for Suicide Prevention (FISP) is an example of a single session intervention in youth acute care visits that has improved retention to outpatient treatment (Hughes and Asarnow, 2013). Something similar could be considered as an add-on to BCBT in youth. Likewise, there is a growing literature on brief contacts such as text-based messages and phone calls for reducing self-harm/suicide which may be useful as interventions (Milner et al., 2015) but might also help to further strengthen youth engagement and retention

Table 1

Baseline demographic and clinical characteristics of youth ($n = 24$) admitted to hospital following self-harm randomized to Brief Cognitive Behavioural Therapy (BCBT) or a minimally-directive supportive therapy control.

	Treatment Group	
	BCBT ($n = 12$)	Control ($n = 12$)
Mean Age	18.0 \pm 2.7	18.0 \pm 3.2
Female Sex (%)	10 (83%)	7 (58%)
Preexisting, longstanding psychotherapy (%)		
CBT	1 (8%)	1 (8%)
Family Therapy	1 (8%)	1 (8%)
Other counselling	1 (8.3%)	0 (0%)
Pre-existing Medication		
SSRI antidepressant	8 (67%)	7 (58%)
Other newer antidepressant	6 (50%)	3 (25%)
Anticonvulsant	3 (25%)	3 (25%)
Benzodiazepine	3 (25%)	1 (8%)
Trazodone	2 (17%)	2 (17%)
Antipsychotic	1 (8%)	2 (17%)
Lithium	1 (8%)	1 (8%)
Methadone	0 (0%)	1 (8%)
SSI (mean \pm SD)	15.00 \pm 9.63	15.08 \pm 7.01
MADRS (mean \pm SD)	29.50 \pm 11.43	29.17 \pm 8.43
CGI-S	5.42 \pm 0.67	5.08 \pm 0.79
BDI	29.42 \pm 13.85	33.25 \pm 10.24

SD (standard deviation); SSRI (selective serotonin reuptake inhibitor); SSI (Scale for Suicidal Ideation); MADRS (Montgomery–Åsberg Depression Rating Scale); Clinical Global Impression Severity Scale (CGI-S); BDI (Beck Depression Inventory).

*Chi-squared Fischer's Exact Test.

Table 2

Diagnostic characteristics * of youth ($n = 24$) admitted to hospital following self-harm randomized to Brief Cognitive Behavioural Therapy (BCBT) or a minimally-directive supportive therapy control.

	BCBT ($n = 12$)	Control ($n = 12$)
Diagnosis		
Depressive Disorders		
Major Depressive Disorder	10	11
Dysthymic Disorder	1	0
Anxiety Disorders		
Generalized anxiety disorder	10	9
Agoraphobia	10	8
Social phobia, current	5	5
Panic disorder, lifetime	5	4
Other Disorders		
Bipolar II Disorder	5	5
Alcohol Use Disorder	3	3
Other Substance Use Disorder	2	4
Obsessive-compulsive disorder	3	4
Posttraumatic stress disorder	3	5
Borderline personality disorder	5	2
Bulimia Nervosa	1	2
Adjustment Disorder	0	1
Learning Disability	0	1

* Diagnostic information was obtained from the case history and confirmed using The Mini-International Neuropsychiatric Interview (MINI).

in future studies. In general, these findings suggest that delivery models for youth with SH might need great emphasis on family support, increased efforts at patient engagement and optimal timing and location of treatment delivered (e.g. therapy delivered at a youth's school during regular hours) to achieve greater retention.

It is notable that although suicidal ideation and depression scores did diminish in both the intervention and control groups over time, both were still prominent in the overall sample at acute treatment endpoint. This suggests that the cognitive antecedents of SH were present throughout acute treatment, albeit diminished over time in

both groups. People who engage in SH experience emotion dysregulation and depression (Andover et al., 2012; Gratz and Roemer, 2008). The most common motivations for SH can include relief of unpleasant emotions and also a wish to be dead (Jacobson and Gould, 2007; Madge et al., 2008). However, identifying motives can often be challenging and SH, regardless of motive, is among the most important risk factors for eventual suicide death (Andover et al., 2005; Guan et al., 2012; Hawton and Harriss, 2007). This is why the present study focused on SH regardless of motive and intent. Deficits in problem solving have also been implicated as a major driver of repeat SH (McAuliffe et al., 2002), and CBT directly targets these deficits by understanding the triggering factors, thoughts, emotions and behaviors that precede SH and teaching alternative coping strategies (Stanley et al., 2009).

Trials of CBT following SH often measure and report improvements in suicidal ideation but do not measure repeat SH (Alavi et al., 2013). The main strength of the present trial was its focus on a key behavioural outcome, SH, in a high-risk group. The fact that repeat SH was significantly lower in the BCBT group provides some pilot evidence that it may have imparted those necessary skills and achieved its most important intended result. That is, it prevented repeat SH even in those experiencing suicidal thoughts and/or low mood supporting the notion that its mechanism of action lies outside of any effect on underlying psychiatric illness.

A further question worth considering is the potential mechanism of improvement in CBT for suicide prevention. In contrast to standard CBT, the BCBT intervention applied here incorporates elements from other therapies such as DBT specifically targeting processes related to emotion regulation, problem solving, distress tolerance, and negative thinking. The degree to which specific aspects such as chain analysis, safety planning, psychoeducation and efforts to addressing feelings of hopelessness/promote reasons for living may modify risk is unclear and worthy of further study. Likewise, whether specific potential strengths of the minimally-directive supportive therapy intervention such as maximizing therapeutic alliance, active listening and validation were of benefit and could be used to inform and strengthen future CBT interventions ought to be investigated.

This study does have several limitations. The most important is the small sample size inherent to a pilot trial. Although the two groups appeared well matched according to baseline measures, the small number of subjects creates a greater possibility that chance factors may have influenced results and did not allow for well-powered tests of efficacy measures. Furthermore, this was an add-on study that did not account for differences in standard treatment such as pharmacotherapy or length of hospital stay. Larger studies might be able to identify whether other factors, such as differences in concurrent medication treatment, might be associated with different outcomes. Recruitment for the study was somewhat more challenging than expected, an important consideration for future trials, and this necessitated expanding slightly the age range for inclusion which could have impacted results. Youth were not involved in the development of BCBT or the trial protocol. There is increasing awareness of the importance of including those with lived experience into research design (Shippee et al., 2015). By doing so, future trials of BCBT and similar interventions could potentially improve retention as well as user experience and possibly outcomes. This study also examined youth at a single site in a large Canadian city. The degree to which results might generalize to other locations or populations is unclear. Finally, SH remains a proxy measure for suicide deaths which did not occur in this study. Although we would expect a treatment that diminishes SH to prevent suicide deaths, this study is not designed to confirm that supposition.

Preventing suicide in youth, adults and in hospitals is increasingly a focus both at the clinical and public health levels in Canada and beyond. In 2014, for example, Toronto Public Health issued 12 recommendations for suicide prevention including the need to focus on youth and for healthcare organizations to mandate evidenced-based training for providers who work with high-risk patients (Toronto Public

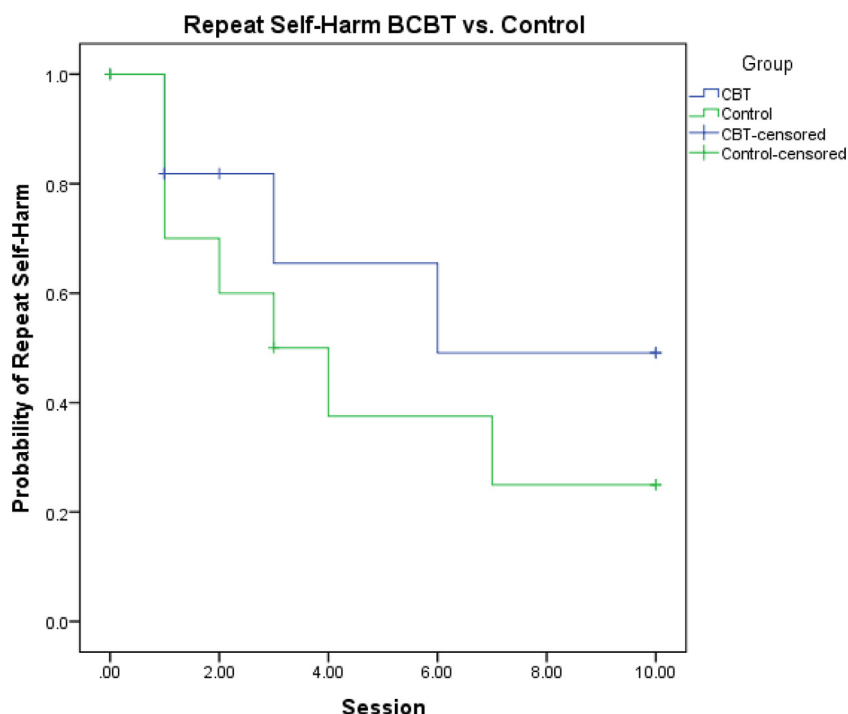


Fig. 2. Time to repeat self-harm (SH) in youth ($n = 24$) admitted to hospital following self-harm randomized to Brief Cognitive Behavioural Therapy (BCBT) or a minimally-directive supportive therapy control.

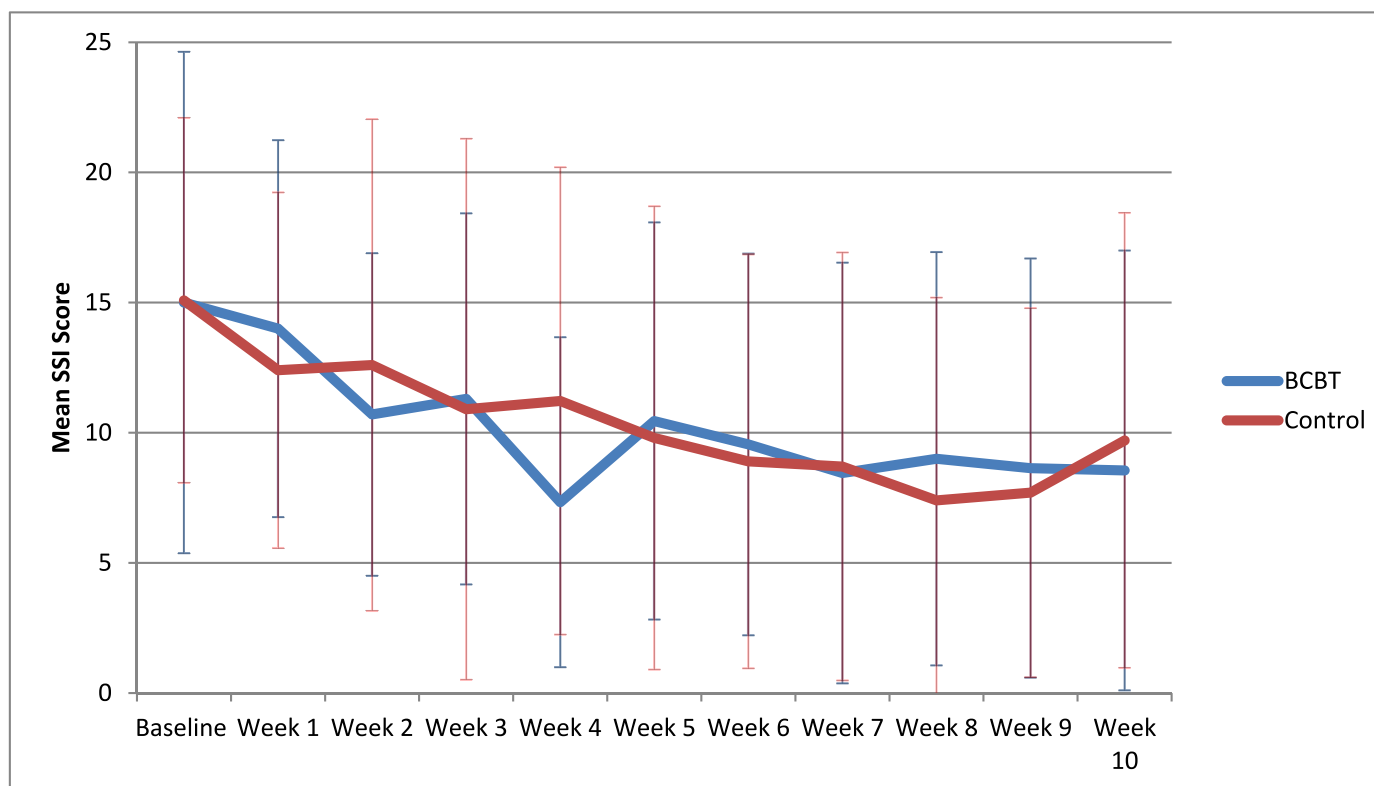


Fig. 3. Scale for Suicide Ideation (SSI) scores from baseline to the end of acute treatment (week 10) in youth ($n = 24$) admitted to hospital following self-harm randomized to Brief Cognitive Behavioural Therapy (BCBT) or a minimally-directive supportive therapy control.

Health, 2014). This study provides preliminary evidence that BCBT may reduce repeat SH in youth recently admitted to hospital following an episode of SH. The fact that this was the case despite it not meeting pre-specified feasibility criteria suggests that they may have been overly stringent and that brief treatment may yield substantial benefit. If

replicated, these findings would have important clinical implications for preventing suicide in youth, in particular indicating that trained practitioners delivering targeted interventions like BCBT ought to be available to high risk youth. Further study of BCBT with greater efforts to optimize accessibility and retention is warranted.

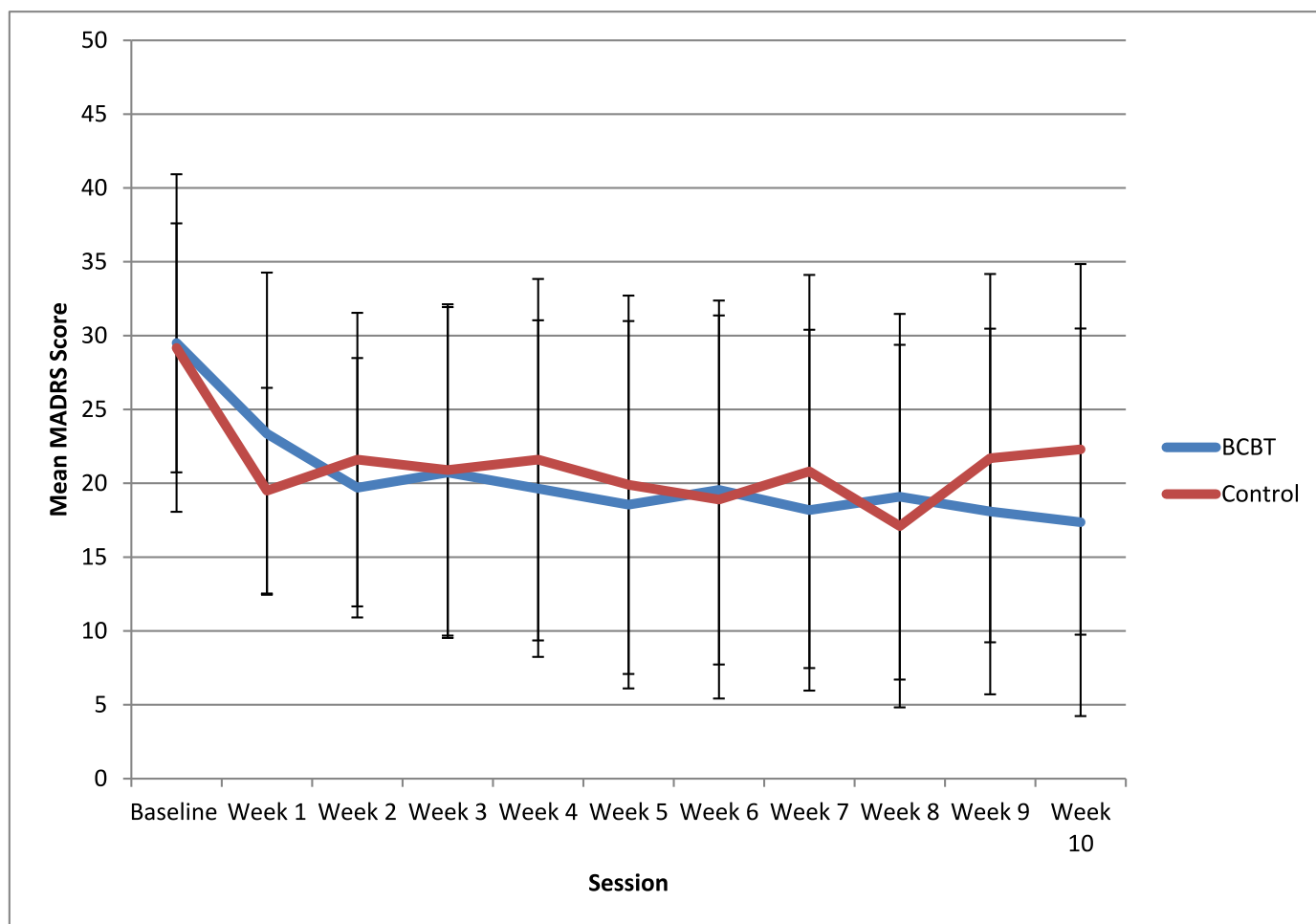


Fig. 4. Montgomery-Åsberg Depression Rating Scale (MADRS) scores from baseline to the end of acute treatment (week 10) in youth ($n = 24$) admitted to hospital following self-harm randomized to Brief Cognitive Behavioural Therapy (BCBT) or a minimally-directive supportive therapy control.

Author contributions

Conception and study design: MS, RM, AS, JE, BIG, AHG, SS, AK and HT

Data collection: MS, MW, RM, and RZ

Data Analysis: MS, MW, and RZS

Data interpretation: All authors

Prepared first article draft: MS

Critical revision for important intellectual content/final approval: All authors

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Declaration of Competing Interest

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.jad.2020.01.178](https://doi.org/10.1016/j.jad.2020.01.178).

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