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Single dose IV ketamine for adolescent suicidal ideation in the emergency department: a pilot randomized trial

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Abstract

Background Suicidal ideation (SI) is a common reason for emergency department (ED) visits by adolescents. While intravenous (IV) ketamine rapidly reduces SI in adults, its efficacy in adolescents remains unstudied. We assessed the feasibility of a trial of a single dose IV ketamine to reduce adolescent SI in the ED.

Methods This double-blind, randomized, placebo-controlled pilot trial was conducted from Jan-May 2024. Medically stable adolescents aged 12 to 17 years with moderate-to-severe SI were eligible. Participants were randomized to IV ketamine (0.5 mg/kg; max 50 mg) or IV normal saline (0.5 ml/kg; max 50 mL), infused over 40 min. They were monitored for 120 min and then received usual ED mental health care. The primary outcome was trial feasibility (enrolment and follow-up success). The primary clinical outcome was SI severity at 40 min post-infusion (T-40), measured using the Beck Scale for SI (SSI5), Montgomery-Asberg Depression Rating Scale item 10 (MADRS10) and Beck Depression Inventory item 9 (BDI9). Additional outcomes included hospital admission, adverse events, 30-day ED revisits and death.

Results Twenty participants were eligible and were enrolled. All participants completed the infusion and day-1 follow-up; 90% completed day-7 follow-up. No serious adverse events occurred. While SI severity did not differ significantly between groups at T-40 (SSI5: $p = 0.06$; MADRS10: $p = 0.19$; BDI9: $p = 0.18$), fewer participants randomized to ketamine were hospitalized at the initial visit (risk difference 40%, 95%CI: 7, 69%).

Conclusions Recruiting adolescents to an ED-based IV ketamine study for SI is feasible. A larger trial is needed to clarify potential clinical benefits.

Trial registration ClinicalTrials.gov ID NCT06366334 (Registered 20240412).

Keywords Ketamine, Suicidal ideation, Adolescents, Emergency department, Randomized controlled trial

Meetings: Study results were presented as a poster presentation at the 2025 Pediatric Academic Societies Meeting, April 2025, Honolulu, Hawaii.

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Background

Suicidal ideation (SI) is a common cause of morbidity in adolescents [1] and a frequent reason for emergency department (ED) visits [2]. Pediatric emergency departments across North America have experienced a marked rise in suicide-related visits in recent years [3].

The current ED management prioritizes safety assessments and discharge planning, but this approach does not address the severe acute distress experienced by youth in crisis. Antidepressants are rarely initiated in the ED, and their therapeutic onset is slow [4]. There is no acute ED intervention to rapidly alleviate distress experienced by youth in crisis.

Single-dose intravenous (IV) ketamine has been shown to rapidly reduce SI severity in adults [5]. Ketamine's distinct mechanism of action, which promotes neuroplasticity and synaptic growth, is hypothesized to drive its rapid anti-suicidal effects [6]. ED based trials of ketamine for the acute treatment of SI in adults suggest benefit from ketamine, though definitive efficacy remains to be proven and the durability of effect is thought to be limited [7, 8]. Although emerging evidence supports the use of multi-week ketamine protocols for adolescents with depression and suicidality, there are no published evaluations of rapid-acting interventions delivered in the ED [9, 10] If IV ketamine demonstrated efficacy as a rapid-acting intervention for adolescents in acute suicidal crisis, it would address a critical gap in emergency care. Our objective was to evaluate the feasibility of conducting a trial utilizing IV ketamine for SI in youth presenting to a pediatric ED.

Methods

We conducted a single-centre, double-blind, randomized, placebo-controlled pilot trial in a 1:1 allocation ratio from January to May 2024 in the Children's Hospital of Eastern Ontario (CHEO) ED, a tertiary care academic centre with an ED census of ~75,000 visits per year. The trial was registered at clinicaltrials.gov (ref: NCT06366334) on April 10, 2024.

Participants

Adolescents aged 12 to 17.99 years were eligible if they presented to the ED with a mental health complaint, answered 'yes' to item 5 of the Ask Suicide-Screening Questionnaire (ASQ: 'Are you having thoughts of killing yourself right now?'), had moderate-to-severe SI (Beck Scale for Suicide Ideation-first 5 items [SSI5], score ≥ 3), and were medically stable. Adolescents were excluded if acutely intoxicated, pregnant or breastfeeding; required chemical of physical restraint; had an intellectual disability, a non-psychiatric neurologic disorder, active psychosis, or contraindications to ketamine; were under an involuntary psychiatric hold; or were previously enrolled.

Interventions and blinding

Participants were randomized to receive IV ketamine (0.5 mg/kg; max 50 mg) or IV normal saline (0.5 ml/kg; max 50 mL), infused over 40 min. The pharmacy prepared sequentially numbered, identical appearing packets according to a computer-generated randomization list provided by the study statistician. Ketamine and normal saline were prepared as clear, colorless solutions in identical volumes. Research nurses allocated participants by selecting the "next-in-line" study packet. Caregivers, participants, health care providers, research staff (including outcome assessors), and investigators remained blind to group allocation.

Measures

Suicidal ideation (SI) severity was assessed using three instruments: the first five items of the Beck Scale for Suicide Ideation (SSI5; range 0–10) [12], the suicide-specific item (item 10) from the Montgomery–Åsberg Depression Rating Scale (MADRS10; range 0–6) [13], and suicide-specific item (item 9) from the Beck Depression Inventory (BDI9; range 0–3) [14]. These single items were selected because they directly assess suicidal thoughts within their respective validated depression scales and have been used in prior ketamine studies to capture rapid changes in suicidality.

There is currently no gold standard measure for detecting rapid SI changes in adolescents in acute care settings. While all three measures have demonstrated responsiveness to rapid change in adult ketamine trials, their performance in adolescents receiving ketamine in the emergency department is unknown. Each tool has distinct strengths and limitations: the SSI5 offers multi-item depth but may pose comprehension challenges for youth in acute crisis; the MADRS10 and BDI9 are single-item measures that are pragmatic and efficient but may not capture the multidimensional nature of suicidal ideation. Given this uncertainty regarding responsiveness, feasibility, and appropriateness in our population, we administered all three measures in this pilot study to inform selection of the most suitable primary outcome for a future definitive trial.

Depressive symptoms were assessed using the Children's Depression Rating Scale–Revised (CDRS-R; range 17–113, with scores > 60 indicating severe depression) [15]. Dissociation was measured using the simplified Clinician-Administered Dissociative States Scale (CADSS-6; total score > 6 or ≥ 4 on a single item) [16, 17].

Procedures and outcomes

Potential participants were screened by research nurses. Written informed consent was obtained from participants and their legal guardians. At baseline, participant demographics, depressive symptoms (CDRS-R), and SI

severity (SSI5, MADRS10, BDI9), were assessed. SI severity (SSI5, MADRS10, BDI9) was re-assessed at 40, 80, and 120 min after the infusion started (time 0) and on days 1 and 7 following enrolment. Follow up SI assessments were conducted by telephone by a research nurse. Dissociation (CADSS-6) was measured at baseline, and 20 and 40 min after the start of the infusion.

After the 120-minute monitoring period, adolescents received routine ED mental health care. Final disposition decisions were made by the hospital's mental health team and were not influenced by study personnel or procedures.

The primary outcome was study feasibility, measured by enrolment success and completion of the infusion/follow-up. The primary clinical outcome was SI severity at 40 min after the infusion started, assessed using each of the three SI instruments (SSI5, MADRS10, BDI9). Additional outcomes were SI severity at all subsequent times, hospital admission and length of stay, ED revisits within 30 days, subsequent hospitalizations, and death within 30 days. Adverse events were monitored. The study protocol has been published [11].

Sample size and statistical analysis

To provide sufficient information on the feasibility outcomes and estimates of the distribution of SI severity measures, we enrolled 20 adolescents. The trial was not powered to detect clinical efficacy of ketamine therapy.

Baseline participant characteristics, primary feasibility outcomes, and safety data were reported using descriptive statistics. Measures of central tendency and variance for each SI assessment tool were calculated. Analysis of covariance was used to report between-group differences in SI severity at 40 min, adjusting for baseline SI severity, sex, age, and CDRS-R scores. Between-group differences in SI severity at 80-minutes, 120-minutes, 1-day, and 7-days post-intervention was analyzed using analysis of covariance without adjustment for multiple comparisons in this exploratory analysis. Cohen's d was calculated using the adjusted mean difference divided by the pooled standard deviation. Additional analyses examined differences in the proportions hospitalized and their length of stay. The proportions with a return ED visit for mental health, subsequent hospitalization, or death within 30 days were also compared between groups. All statistical hypothesis tests were two-sided; p-values less than 0.05 were considered statistically significant. Efficacy analyses were based on the intention-to-treat principle. All analyses were conducted using R statistical software [18].

Results

Of 129 potentially eligible adolescents visiting the ED during research nurse hours, 73 were screened by a research nurse; 20 were eligible and all consented to participate. All randomized patients were included in the analysis. All participants completed the infusion and day-1 follow-up. Eighteen (90%) completed day-7 follow-up. The two lost to follow-up were in the placebo group (Fig. 1).

A minority of participants had an ED mental health visit in the previous month or a prior mental health hospitalization, while half were on antidepressants. Baseline mean (SD) depression scores measured by CDRS-R were 85.8 (8.3) and 69.7 (9.9) for the ketamine and placebo groups, respectively. Baseline SI severity measured by SSI5 was similar between groups, but different when measured by MADRS-10 and BDI9 (Table 1).

Adjusting for baseline SI of the corresponding measure, depression, age and sex, ketamine was associated with a greater reduction in SSI5 scores, compared with placebo at 40 min (adjusted mean difference – 2.5, 95%CI: -5.2, 0.1; $p = 0.06$). At 120 min, the difference was similar but statistically significant (-2.9, 95%CI: -5.8, 0.00; $p = 0.049$) (Table 2). These SSI5 differences corresponded to large standardized effect sizes (Cohen's d = -0.9 and – 1.2 respectively, favouring ketamine). At these timepoints (40- and 120-minutes), differences for MADRS10 and BDI9 were not statistically significant. At day-7, the adjusted mean difference in MADRS10 scores favoured placebo (2.2, 95%CI: 0.1, 4.3; $p = 0.04$). No statistically significant between-group differences were observed at 80-minutes or day-1 for any SI measure, or at day-7 for SSI5 or BDI9. Standardized effect sizes for all comparisons are presented in Table 2. The unadjusted mean SI severity scores for each measure and time period are presented in Table 3, along with standardized effect sizes.

Four (40%) participants in the placebo group were hospitalized at the enrollment visit versus none in the ketamine group (risk difference [RD] 40%, 95%CI: 7, 69%). Their median length of stay was 2.5 days (IQR 1.5, 4.5). The number returning to the ED within 30 days was 7/10 (70%) for the ketamine group and 1/10 (10%) for placebo (RD 60%, 95%CI: 18, 84%); of these, two ketamine group participants were hospitalized at a repeat ED visit. No deaths occurred in the study period.

One participant in the ketamine group vomited in the ED. Some participants reported dissociation before the infusion began (3/10 ketamine, 1/10 placebo; RD 20%, 95%CI: -17, 53%). During the infusion, dissociation was reported by 9/10 (90%) and 4/10 (40%) in the ketamine and placebo groups, respectively (RD 50%, 95%CI: 9, 77%).

Discussion

This is the first ED-based trial investigating ketamine for rapid treatment of SI in adolescents. We demonstrate that enrolment and implementation of an ED-based IV ketamine study is feasible. All eligible patients consented

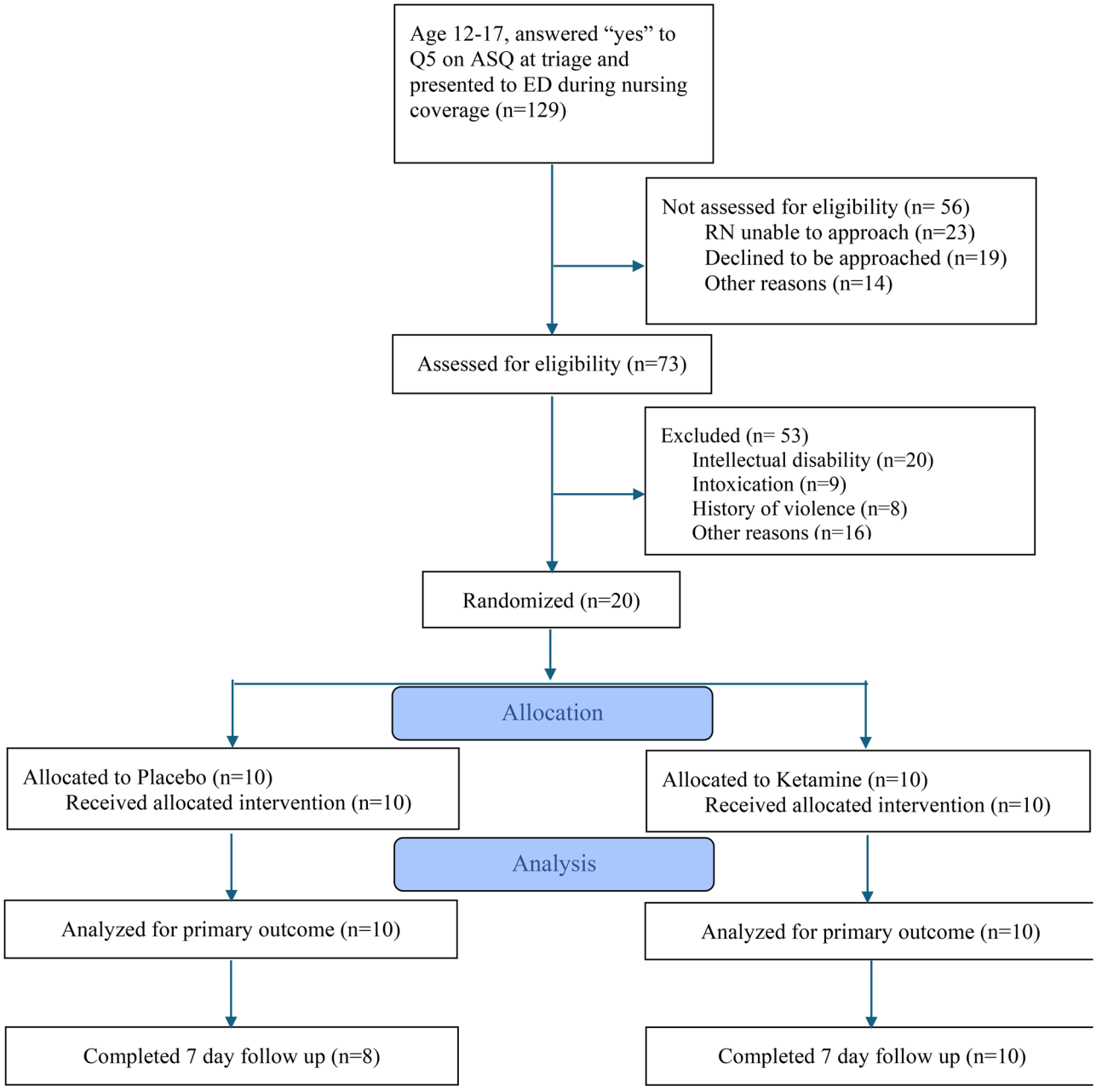

Fig. 1 CONSORT flow diagram

and were enrolled, study procedures were conducted without any deviations and 90% of participants completed day-7 follow up. Recruitment was completed in four months, further highlighting the feasibility of conducting interventional studies in this population in the ED setting.

Notably, every eligible adolescents and their families consented to participate. This universal consent rate is uncommon in ED-based trials and likely speaks to the high level of distress experienced by youth presenting with SI, as well as the desire of families for interventions that might provide immediate relief. The adolescent and family willingness to engage in a novel intervention underscores the absence of effective rapid-acting treatment options in the ED and highlights the importance of pursuing research in this area.

Table 1 Participant characteristics and baseline scores

	Overall *N* = 20	Ketamine *N* = 10	Placebo *N* = 10
Demographics			
Age (years); Mean (SD)	15.5 (1.7)	15.6 (1.8)	15.5 (1.8)
Female sex assigned at birth	18 (90%)	8 (80%)	10 (100%)
Gender			
Girl/Woman	15 (75%)	7 (70%)	8 (80%)
Boy/Man	3 (15%)	2 (20%)	1 (10%)
Other	2 (10%)	1 (10%)	1 (10%)
Sexual orientation			
Heterosexual	7 (35%)	4 (40%)	3 (30%)
Homosexual	2 (10%)	0 (0%)	2 (20%)
Bisexual	7 (35%)	3 (30%)	4 (40%)
Other	4 (20%)	3 (30%)	1 (10%)
Mental Health History			
ED mental health visits in past 30 days			
0	12 (60%)	5 (50%)	7 (70%)
1	6 (30%)	4 (40%)	2 (20%)
2	2 (10%)	1 (10%)	1 (10%)
Lifetime previous suicide attempts			
0	4 (20%)	2 (20%)	2 (20%)
1	4 (20%)	2 (20%)	2 (20%)
2	3 (15%)	1 (10%)	2 (20%)
3+	9 (45.0%)	5 (50%)	4 (40%)
Previous hospitalizations for SI/attempt			
0	13 (65%)	7 (70%)	6 (60%)
1	3 (15%)	1 (10%)	2 (20%)
2+	4 (20%)	2 (20%)	2 (20%)
Current medication			
None	12 (60%)	7 (70%)	5 (50%)
Atypical antipsychotic	4 (20%)	1 (10%)	3 (30%)
Benzodiazepine	3 (15%)	1 (10%)	2 (20%)
Antidepressants and/or psychostimulants	10 (50%)	2 (20%)	8 (80%)
Weeks on psychotropic medication			
0	13 (65%)	8 (80%)	5 (50%)
4+	6 (30%)	2 (20%)	4(50%)
Unknown	1 (10%)	0 (0%)	1 (10%)
Baseline scores Mean (SD)			
Depression (CDRS-R; max score 113)	77.8 (12.1)	85.8 (8.3)	69.7 (9.9)
Dissociation (CADSS; max score 24)	3.7 (4.8)	4.9 (5.5)	2.4 (3.9)
N (%)	4 (20%)	3 (30%)	1 (10%)
Beck SSI5 (max score 10)	7.7 (1.6)	7.9 (1.1)	7.4 (2.0)
MADRS10 (max score 6)	4.5 (1.3)	4.9 (0.9)	4.0 (1.6)
BDI9 (max score 3)	2.4 (0.8)	2.7 (0.5)	2.1 (0.9)

Although the trial was not powered to detect clinical efficacy, our findings provide preliminary signals that ketamine may influence important outcomes. No statistically significant difference in SI was observed at 40 min, but all point estimates up to and including day 1 favoured ketamine. Moderate to large effect sizes were observed for SSI5 at 40 and 120 min, suggesting a possible early reduction in suicidal ideation following ketamine administration. However, effect size estimates in small pilot trials are inherently unstable and may overestimate true effects. These findings should therefore be interpreted cautiously and viewed as hypothesis-generating.

For planning a future definitive trial, assuming a moderate standardized effect size ($d = 0.5$), a two-arm randomized trial with 80% power and $\alpha = 0.05$ would require approximately 64 participants per group. Given potential attrition and site variability, a multi-centre trial enrolling 150–180 participants would be reasonable.

No participants in the ketamine group required admission at the index visit, compared with 40% in the placebo group, suggesting a possible role for ketamine in reducing the immediate need for inpatient care. These findings are exploratory and should only be interpreted as hypothesis-generating.

The tools we used to assess SI capture different facets of suicidality, which may explain discrepancies in baseline scores and changes over time across measures. The psychometric validity of individual items, particularly in acute care settings, is less well established [19]. Adolescents in crisis may struggle to interpret or respond to the questions in these tools or hesitate to disclose suicidal thoughts, limiting the sensitivity of these tools to rapid symptom change [20, 21].

Although all participants met criteria for moderate-to-severe SI, for some, SI may have reflected transient situational distress rather than chronic, treatment-resistant depression. This distinction is relevant, as ketamine's proposed mechanisms (e.g., enhanced glutamatergic signaling and synaptic plasticity) are theorized to target biologically rooted mood disorders. Future studies should consider stratifying participants based on clinical and biological risk factors to better identify adolescents most likely to benefit from ketamine therapy.

While no participants in the ketamine group were hospitalized at the index visit, they returned to the ED more frequently within 30-days compared to those in the placebo group. This may reflect higher baseline depressive symptom severity, as indicated by their CDRS-R scores, or could indicate that ketamine therapy

Table 2 Adjusted mean difference in suicidal ideation (SI) across groups

SI severity measure	Adjusted mean score*		Adjusted mean difference* (Ketamine-Placebo)	95% CI	*P* value	Cohen's d†
	Ketamine	Placebo				
40 min						
Beck SSI5	6.3	8.8	-2.5	-5.2, 0.1	0.06	-0.9
MADRS10	3.7	5.4	-1.7	-4.3, 0.9	0.19	-0.9
BDI9	1.7	2.7	-1.0	-2.5, 0.5	0.18	-0.9
80 min						
Beck SSI5	6.0	7.7	-1.7	-4.3, 0.8	0.17	-0.8
MADRS10	3.5	4.9	-1.4	-3.5, 0.6	0.16	-1.0
BDI9	1.5	2.1	-0.6	-1.8, 0.5	0.24	-0.8
120 min						
Beck SSI5	5.0	7.9	**-2.9**	**-5.8**, **0.0**	**0.049**	**-1.2**
MADRS10	3.5	4.9	-1.4	-3.9, 1.1	0.25	-0.8
BDI9	1.5	2.5	-1.0	-2.2, 0.1	0.07	-1.2
Day 1						
Beck SSI5	5.2	6.6	-1.4	-4.7, 2.0	0.40	-0.6
MADRS10	3.4	3.7	-0.3	-2.2, 1.5	0.69	-0.3
BDI9	1.5	1.9	-0.4	-1.7, 0.9	0.52	-0.5
Day 7						
Beck SSI5	4.9	3.8	1.1	-2.7, 4.9	0.54	0.5
MADRS10	3.7	1.5	**2.2**	**0.1**, **4.3**	**0.04**	**1.5**
BDI9	1.2	1.1	0.1	-0.9, 1.0	0.91	0.1

* Adjusted for baseline SI severity score, sex, age, and baseline depression score

† Cohen's d calculated as adjusted mean difference divided by pooled standard deviation. Negative values indicate lower SI scores in the ketamine group (favoring ketamine)

Abbreviations: SI, suicidal ideation; Beck SSI5, Beck Scale for Suicidal Ideation - First 5 Questions; MADRS10, Montgomery-Asberg Depression Rating Scale – Question 10; BDI9, Beck Depression Inventory – Question 9

Note: unadjusted mean SI severity scores can be found in Table 3

influenced subsequent help-seeking behaviours. Any future trial would need to monitor outcomes such as ED revisits and subsequent admissions following the enrolment visit.

Conclusion

We found enrolling adolescents with SI in a trial of IV ketamine is feasible, acceptable to adolescents and their families and that the intervention was well tolerated. This study highlights both the urgent need for rapid-acting interventions and the potential for ketamine to fill that gap. Early moderate-to-large standardized effect sizes favoring ketamine were observed at 40 and 120 min, although these estimates are imprecise given the small pilot sample. Larger, adequately powered trials are needed to evaluate clinical efficacy, including reduction in hospital admission, and identify the adolescents most likely to benefit from ketamine.

Table 3 Unadjusted mean SI severity scores

Characteristic Mean (SD)	Overall *N* = 20	Ketamine *N* = 10	Placebo *N* = 10	mean difference (Ketamine-Placebo)	Cohen's d
SSI5 Scores					
Baseline	7.7 (1.6)	7.9 (1.1)	7.4 (2.0)	0.5	-
40 min	6.6 (2.9)	6.7 (2.9)	6.5 (3.0)	0.2	0.1
80 min	6.6 (2.2)	6.9 (1.8)	6.3 (2.7)	0.6	0.3
120 min	6.6 (2.3)	6.4 (2.1)	6.8 (2.7)	-0.4	-0.2
Day 1	5.3 (2.4)	5.5 (2.2)	5.0 (2.6)	0.5	0.2
Day 7	4.3 (2.2)	4.8 (2.5)	3.8 (1.7)	1.05	0.5
Missing	2	0	2	2	
MADRS10 scores					
Baseline	4.5 (1.3)	4.9 (0.9)	4.0 (1.6)	0.9	-
40 min	4.0 (1.8)	3.8 (2.2)	4.2 (1.4)	-0.4	-0.2
80 min	4.0 (1.5)	3.9 (1.4)	4.1 (1.5)	-0.2	-0.1
120 min	3.9 (1.7)	3.7 (1.6)	4.0 (1.9)	-0.3	-0.2
Day 1	3.4 (1.3)	3.5 (1.2)	3.2 (1.4)	0.3	0.2
Day 7	2.6 (1.6)	3.4 (1.6)	1.6 (1.1)	1.8	1.2
Missing	2	0	2	2	
BDI9 Scores					
Baseline	2.4 (0.8)	2.7 (0.5)	2.1 (0.9)	0.6	-
40 min	2.1 (1.1)	1.9 (1.1)	2.2 (1.1)	-0.3	-0.3
80 min	1.9 (0.8)	1.7 (0.7)	2.0 (0.9)	-0.3	-0.4
120 min	1.8 (0.8)	1.6 (0.8)	2.0 (0.8)	-0.4	-0.5
Day 1	1.6 (0.9)	1.7 (1.1)	1.5 (0.8)	0.2	0.2
Day 7	1.2 (0.6)	1.1 (0.6)	1.3 (0.7)	0.05	-0.2
Missing	2	0	2	2	

Abbreviations

SSI5	Beck Scale for Suicide Ideation-first 5 items
MADRS10	The suicide-specific item (item 10) from the Montgomery–Åsberg Depression Rating Scale
BDI9	Suicide-specific item (item 9) from the Beck Depression Inventory
CADSS-6	Simplified Clinician-Administered Dissociative States Scale
CDRS-R	Children's Depression Rating Scale–Revised
RD	Risk difference

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Author contributions
MB, AP, and developed the study concept and designed the trial. MB, ACP, MS, CG, NB obtained funding, interpreted the data, critically reviewed and revised the manuscript. MS and MB drafted the initial manuscript. NB designed the trial, conducted the data analysis and critically reviewed and revised the manuscript. TC coordinated and supervised data collection and critically reviewed and revised the manuscript for important intellectual content. SK conducted the data analysis and critically reviewed and revised the manuscript. MB takes responsibility for the paper as a whole.

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Data availability
The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study received approval from the CHEO Research Ethics Board (protocol number 23/02E). The CHEO Research Ethics Board follows the principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2022), which is the national standard in Canada. The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained by participants or their legal guardian, and assent was obtained when appropriate.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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