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Original article

The relational approach to treating self-harm (RELATE): A feasibility randomised controlled trial of cognitive analytic therapy for adults who self-harm versus treatment at usual

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ABSTRACT

Background: There is currently a dearth of psychological support available to clients who self-harm in the NHS and there is a need to develop brief, targeted interventions to better fill this treatment gap. Cognitive analytic therapy (CAT) is a relational psychotherapy that holds promise for helping people who self-harm. A brief version of CAT has been developed and now requires evaluation.

Aims: To evaluate the feasibility of evaluating 8-session CAT to adult outpatients accessing community services who self-harm in a subsequent definitive trial.

Method: A feasibility randomised controlled trial evaluating 8-session CAT for self-harm in adult outpatients. Participants were randomly allocated (1:1) to brief CAT plus treatment as usual (TAU) or TAU alone. Rater-blind assessments occurred at baseline, 12-weeks and 18-weeks.

Results: Pre-specified study progression criteria concerning recruitment (n = 60 recruited over 12 months), retention (92 %), missing data on clinical outcomes (< 7 %) and engagement with therapy (90 % attended ≥ 4 sessions within a 10-week window) were all met. Urges to self-harm and psychological distress declined in the CAT arm and to a greater extent than the TAU arm (self-harm urges: 80 % CI:6.22 -1.68; psychological distress: 80 % CI:5.95, -2.22).

Conclusions: The results support the feasibility of evaluating brief CAT for self-harm and so progression to larger-scale definitive efficacy trial is warranted. CAT shows initial promise as a treatment for self-harm in adults but this now requires evaluation within a definitive trial.

Trial registration: The trial was pre-registered (21/10/22) on ISRCTN (ISRCTN code: ISRCTN75661422)

1. Introduction

People that self-harm can often struggle to access suitable interventions, falling down the gap between frontline psychological services that focus on common mental health difficulties (i.e., primary care services in the UK), and services for those with more complex and enduring difficulties (i.e., secondary care services in the UK; Dunn et al., 2024; Samaritans, 2020). This is concerning given both the rising prevalence of self-harm (McManus et al., 2019; Staring et al., 2024), and that self-harm is a robust predictor of future self-harm and death by suicide, as well as longer term psychosocial difficulties (Daukantaitė et al., 2020; Hawton et al., 2015; Kilroy-Findley, 2015; Ribeiro et al., 2016; Stanford et al., 2016). Psychotherapies recommended for adults who self-harm include cognitive behavioural therapy (CBT) and dialectical behaviour therapy (DBT; Chapman et al., 2024; National Institute for Health and Care Excellence, 2022b). Whilst there is evidence from recent trials supporting these approaches, the number of trials is still limited and treatment effects are small (Fox et al., 2020; Witt et al.,

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2021). DBT and CBT have an explicit 'here and now' behavioural focus (Chapman et al., 2024) but this focus may be less suitable for patients where self-harm is rooted developmental trauma and associated relational difficulties. Moreover, both DBT and CBT are intensive, expensive therapies, and given long waiting lists to access psychotherapy, brief interventions are needed (Saini et al., 2020). In the present trial we investigate the feasibility of offering brief 8-session cognitive analytic therapy (CAT; Ryle and Kerr, 2020) as a targeted intervention for self-harm within community psychology services.

CAT is a brief, structured, focussed, relational, transdiagnostic and integrative psychotherapy (Ryle and Kerr, 2020) and the 'past-present' focus of CAT acknowledges the important of interpersonal processes in the development of self-harm in developmental trauma and neglect. CAT has a growing evidence base (Hallam et al., 2020) and has low dropout rates compared to other therapies (Simmonds-Buckley et al., 2022). There have been no previous trials of CAT for self-harm. The RELATE (Relational Approach to Self-harm) trial is a key first step in evaluating CAT's potential with adults that self-harm within community psychological services. This trial builds on the established 8-session CAT model that is based on the same three-phase approach of reformulation, recognition and revision as the 16 and 24 session versions (Kellett et al., 2024; Wakefield et al., 2021).

RELATE is a randomised controlled trial (RCT) ascertaining the feasibility and acceptability of evaluating brief CAT for self-harm in adult outpatients compared to treatment as usual (TAU). The study was designed to answer a series of pre-defined feasibility uncertainties (see protocol for further detail; Taylor et al., 2024) and so indicate if a subsequent, efficacy-focused, definitive trial is feasible. Progression targets (see Method) were recruitment rates, retention, missing data and acceptability of CAT and the feasibility of collecting information required for an economic evaluation was also assessed. Adverse events were recorded (though caution is needed in ascertaining safety from feasibility trials; Leon et al., 2011). Treatment effects were estimated to inform parameters for a larger-scale trial (e.g. variance in outcome measures).

2. Method

2.1. Design

An assessor-blind feasibility RCT with 1:1 allocation to CAT plus TAU or TAU alone. Randomisation was independent of trial team, via an online service (sealedenvelope.com) using block randomisation (block sizes 4 and 6, sequentially selected at random), stratified by site (two NHS Trust). Randomisation results were communicated by the co-chief investigator (PT) to the therapists. Assessments took place at baseline, 12 weeks and 18-weeks post randomisation. The trial was pre-registered (ISRCTN code: ISRCTN75661422), the protocol published (Taylor et al., 2024) and ethical approval achieved (Greater Manchester West REC; ID: 318068). The trial was designed and implemented with the active involvement of a co-investigator with lived experience of self-harm and an advisory group of five people with lived experience of self-harm. The CONSORT 2010 statement extension for randomised pilot and feasibility trials (Eldridge et al., 2016) structures the reporting of this study. Self-harm behaviour, assessed with the Self-Injurious Thoughts and Behaviours Interview (SITBI; Nock et al., 2007), and urges to self-harm, assessed with the Alexian Brothers Urges to Self-Injure Scale (ABUSI; Washburn et al., 2010) were proposed as primary outcomes for a future trial but a further aim of this feasibility study was to determine their suitability (Taylor et al., 2024).

2.2. Participants

Recruitment took place across two NHS Foundation Trusts (see protocol for further detail; Taylor et al., 2024) over 12-months. Potential participants were referred by services with the individuals' consent or individuals could self-refer in response to advertisements placed in Trust buildings and shared via Trust websites. An Associate Clinical Research Practitioner employed within one the Trusts also assisted with recruitment by screening caseloads for potential participants. Referrals were initially screened for eligibility on the telephone by a researcher. Participants were adult outpatients recruited from primary care NHS talking therapies services and other psychology services based in the community (e.g. NHS student mental health services), including secondary care services. To be eligible participants had to be: (a) aged $\geq$ 18 years, (b) have engaged in self-harm $\geq$ 3 times in the past year (confirmed via SITBI; Nock et al., 2007) and (c) be judged by their clinical team as safe to be seen for outpatient therapy. Exclusion criteria were: (a) the presence of a moderate-to-severe intellectual disability (i.e. IQ:<70) or organic cerebral disease/injury affecting receptive and expressive language comprehension, as judged by their clinical team, (b) being a psychiatric inpatient, (c) experiencing a current, active episode of mania or psychosis, as assessed via the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998), (d) inadequate English language ability preventing comprehension of study information, (e) receiving another 'high intensity' one-to-one psychological therapy at the point of randomisation (e.g. CBT, DBT; low intensity interventions such as support, psychoeducational or skills groups were not reasons for exclusion; participants in the TAU arm were free to access other therapies following randomisation), (f) judged to be an imminent risk to themselves, defined as the presence of active suicidal intent or planning to self-harm in the near future (e.g., next week). These individuals could take part in the trial once their level of risk had reduced. Escalations in risk once someone was in the trial was not necessarily a reason for exclusion.

2.3. Brief CAT for self-harm

Therapy began 2-weeks after randomisation. During this time the therapist contacted the participant by telephone and discussed expectations about CAT and provided written psychoeducation about CAT. Brief CAT was then eight 50–60 min weekly individual therapy sessions, with the intention of completing by the 12-week assessment. Sessions were conducted in person or remotely via video call according to patient preference as CAT can be delivered remotely (Catalyse, 2020). The brief 8-session version of the CAT model (Kellett et al., 2024) held the focus on self-harm and also the underlying patterns maintaining this behaviour. CAT defines 'target problems' (TPs) as the issues creating the need for intervention with 'target problem procedures' (TPPs) being the underlying patterns. One of TPs had to be self-harm, but other related and important TPs could be specified (e.g. self-hatred). Additional detail about the therapy approach is available in Supplement I and also in the protocol (Taylor et al., 2024). A follow-up session occurred 4-weeks after the end of CAT with the treating therapist, consistent with the brief CAT approach (19, 20).

There were five trial therapists at NHS band 8, all with appropriate core professional training (i.e., one CBT therapist, three clinical psychologists and a psychiatrist). Two therapists had completed post-qualification CAT training (one to CAT psychotherapist level), whilst three had at least one years' CAT post-qualification training or equivalent. All had fortnightly (60-minute) supervision from a CAT accredited psychotherapist and supervisor (SK). There was a session-by-session treatment protocol, and adherence to this was monitored in clinical supervision. Where participants consented, sessions were also audio-recorded for supervision and competency rating purposes. A subset (N = 20) of sessions were rated by a qualified CAT psychotherapist and supervisor, independent of the trial team, on the validated measure of CAT competency (CCAT; Bennett and Parry, 2004). To ensure spread across the phases of CAT session recordings were grouped by therapist and therapy phase before being randomly selected. The CCAT produces a score between 0–40, with scores of 20+ indicating competent CAT. The average CCAT score was 33.40 (SD = 8.26, range: 16–40) and all

Table 1
Feasibility progression criteria and outcomes.

Outcome	Criterion	Target	Achieved	Traffic light banding
Recruitment	Ability to randomise 60 participants in a 12-month recruitment window	Green ≥ 80 % Amber: 60 %–79 % Red: < 60 %	100 %	Green
Retention	Percentage of participants completing the 12-week assessment as potential primary outcome timepoint	Green ≥ 80 % Amber: 60 %–79 % Red: < 60 %	92 %	Green
Outcome suitability	Missing data on candidate primary outcomes (SITBI; ABUSI) at 12-week assessment.	Green ≤ 15 % Amber: 16 %–25 % Red: > 25 %	7 %	Green
Adherence	Percentage of participants receiving the minimum dose of therapy (≥4 sessions) within 10-week treatment window	Green ≥ 80 % Amber: 60 %–79 % Red: < 60 %	90 %	Green

ABUSI: Alexian Brothers Urges to Self-Injure Scale; SITBI: Self-Injurious Thoughts and Behaviours Interview-Short Form.

rated sessions scored >20 indicating competent CAT, bar a single session (CCAT score = 16).

2.4. Treatment as usual

TAU was the standard care offered to participants within the two NHS trusts. This was variable but included medication, structured psychological therapy (most commonly CBT and DBT), generic mental health support, clinical case management, coping skills groups, and crisis support. Service contact over the trial period was recorded at 18-weeks as part of the health economics data within the trial.

2.5. Primary outcomes

Pre-specified feasibility and acceptability progression targets are listed in Table 1. A sample of 60 (i.e., 30 in each arm) was sought. This is considered adequate in a pilot trial to estimate key parameters (e.g. attrition rate, variance in outcome measures with sufficient precision) to inform a future trial (e.g. Lancaster et al., 2004). Adverse events (AEs) and serious adverse events (SAEs) were recorded (see Supplement II for definitions). The trial steering committee (TSC) reviewed all SAEs to determine relatedness to trial procedures (further details in protocol; Taylor et al., 2024). At the end of therapy participants in the CAT arm were asked to complete the Adverse Effects in Psychotherapy measure (AEP; Hutton et al., 2017; unpublished), to explore potential negative experiences.

2.6. Measures

Baseline Characteristics. Demographic and clinical information was gathered using a self-report form. The MINI (Sheehan et al., 1998) provided information on psychiatric difficulties. Only the depression, anxiety disorder, mania and psychosis subscales were completed to reduce burden. Participant postcode was used to generate an Indices of Multiple Deprivation (IMD; Department for Communities and Local Government, 2015) score to measure socioeconomic deprivation.

Clinical & Mechanistic Outcomes. A battery of psychometrically valid self-report measures was completed at all three assessment points. On all scales higher scores index greater difficulties/severity. Self-harm behaviour was assessed using the SITBI (Nock et al., 2007), with suicide attempts (SA) and non-suicidal self-injury (NSSI) separated out. Urges to self-harm were assessed using the ABUSI (Washburn et al., 2010), which assesses the severity of urges over the preceding week, with scores ranging from 0–30. A minimally clinically important difference (MCID) of between 4.3 and 2.6 can be estimated based on previous research (see Supplement III). The positive beliefs subscale of the Experiences of Self-Injury Questionnaire (ESIQ; Sandel et al., 2021) measures perceived dependence on self-harm (i.e., reliance, need or centrality of self-harm to one's life), with scores ranging from 08–40. The Personality Structure Questionnaire (PSQ; Pollock et al., 2001) measures identity disturbance and scores can range from 8–40. A clinical cut-off score of 26 has been suggested (Berrios et al., 2016). The Kessler Distress Scale (KDS; Kessler and Mroczek, 1994) assesses emotional distress over the past 30-days, and scores range from 10–50. Other mental health trials have adopted an MCID of 2.4 (Fletcher et al., 2021). Finally, interpersonal problems were assessed with the Inventory of Interpersonal Problems-32 (IIP; Barkham et al., 1996; Horowitz et al., 2000) where the total scale score ranges from 0–128.

Health Economics Measures. The EQ-5D-5L (Foundation., 2019) measured general health status at all assessment points to generate quality adjusted life years (QALYs). Respondents are asked to describe their health on that day in terms of mobility, self-care, engagement in activities, pain/discomfort and depression/anxiety. A global rating of health on a visual analogue scale (VAS) from 0 to 100 is also requested. A bespoke questionnaire, based on the Client Service Receipt Inventory (Beecham and Knapp, 2001), developed with people with lived experience of self-harm, was used at the 18-week assessment. This captured service utilization over the course of the study.

2.7. Procedure

Research assessments took place in person or online via video call, depending on practicality and preference. Eligible individuals were invited to an initial baseline assessment session with a researcher where informed consent was taken. Consent was taken either with a paper form when in-person, or verbal consent was audio-recorded if online. Following the baseline assessment, participants were then randomised within three working days. Participants completed follow-up assessments at 12- and 18-weeks post randomisation. The researchers conducting assessments were blind to group allocation. Where unblinding occurred a different researcher (who was still 'blind') completed subsequent assessments.

2.8. Statistical analysis

The statistical analysis plan was drafted prior to the statistician viewing the data (and was approved by TSC) and is available in Supplement IV. Analyses followed an intention-to-treat (ITT) approach. Descriptive statistics were calculated for recruitment, retention and attrition rates and a CONSORT flow diagram produced. Descriptive statistics and rates of missing data on clinical and mechanistic outcome measures were also generated. To gauge preliminary treatment effects, regression models (linear regression or negative-binomial in the case of NSSI) were fitted to estimate 80 % confidence intervals (Lee et al., 2014) for the adjusted, between-group difference at week 12 (see Table 4). Models controlled for age, sex and baseline outcome scores. Costs associated with the intervention (with downstream health and social care) were calculated for each participant (see Supplement V). QALYs were also calculated for each participant based on EQ-5D-5L scores (see Supplement V). EQ-5D-5L responses were converted to EQ-5D-3L utility

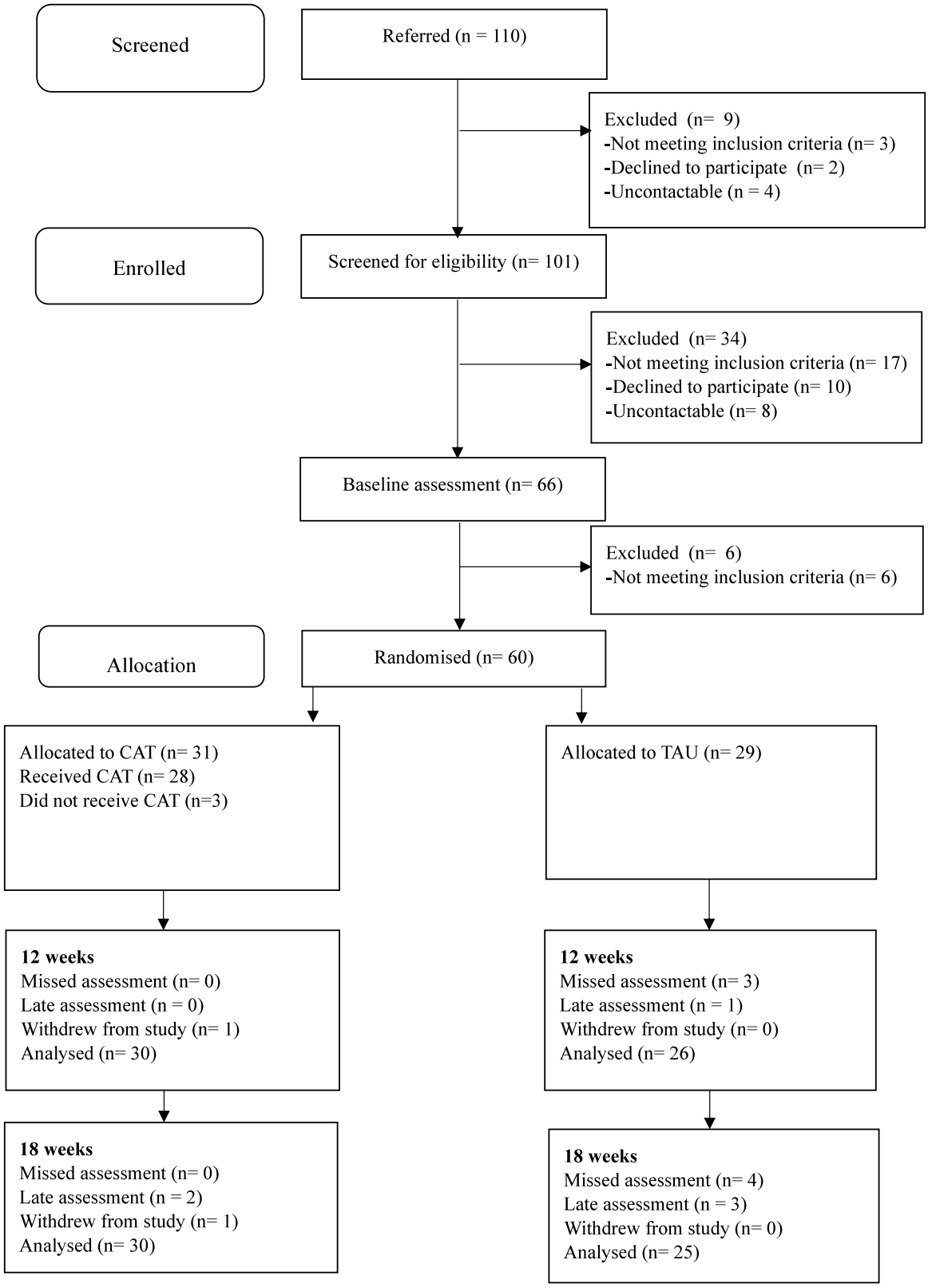

Fig. 1. CONSORT diagram.

values (Dolan, 1997) as required by the National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2022a)(see Supplements IV and V).

3. Results

3.1. Recruitment and retention

Recruitment rates (see Supplement VI) progressed steadily for both

Table 2
Participant baseline characteristics by treatment arm.

Variable	CAT ($N = 31$)	TAU ($N = 29$)	Total sample ($N = 60$)
Age			
Mean (SD)	28.58 (10.25)	26.14 (8.15)	27.40 (9.30)
IMD rank[1]	3265 (1802, 14,035)	9632 (2592, 19,129).	6820 (2191, 16,296). Median is in bottom 30 % most deprived
Median rank (IQR)	Median is in bottom 10 % most deprived	Median is in bottom 30 % most deprived	
Gender			
Female	27 (87.10 %)	20 (68.97 %)	47 (78.33 %)
Male	2 (6.45 %)	6 (20.69 %)	8 (13.33 %)
Non-Binary	2 (6.45 %)	1 (3.45 %)	3 (5.00 %)
Trans-female	0	2 (6.90 %)	2 (3.33 %)
Sexuality			
Heterosexual	17 (54.84 %)	20 (68.97 %)	37 (61.67 %)
Gay/Lesbian	3 (9.68 %)	2 (6.90 %)	5 (8.33 %)
Bisexual	6 (19.35 %)	4 (13.79 %)	10 (16.67 %)
Pansexual	3 (9.68 %)	2 (6.90 %)	5 (8.33 %)
Other	1 (3.23 %)	1 (3.45 %)	2 (3.33 %)
Missing	1 (3.23 %)	0	1 (1.67 %)
Ethnicity			
White	26 (83.87 %)	24 (82.76 %)	50 (83.33 %)
Asian	2 (6.45 %)	2 (6.90 %)	4 (6.67 %)
Black	1 (3.23 %)	0	1 (1.67 %)
Chinese	0	1 (3.45 %)	1 (1.67 %)
Mixed	2 (6.45 %)	2 (6.90 %)	4 (6.67 %)
Relationship status			
Single	20 (64.52 %)	21 (72.41 %)	41 (68.33 %)
Married/partnered	7 (22.58 %)	8 (27.59 %)	15 (25.00 %)
Other (Open/ Widow/ Divorced)	4 (12.90 %)	0	4 (6.67 %)
Self-reported mental health diagnoses[2]	24 (77.42 %)	20 (68.97 %)	44 (73.33 %)
Depression	19 (61.29 %)	18 (62.07 %)	37 (61.67 %)
Anxiety	11 (35.48 %)	10 (34.48 %)	21 (35.00 %)
Agoraphobia	0	1 (3.45 %)	1 (1.67 %)
Anorexia	0	1 (3.45 %)	1 (1.67 %)
Bipolar disorder	0	1 (3.45 %)	1 (1.67 %)
Body dysmorphic disorder	1 (3.23 %) 04 (12.90 %)	1 (3.45 %)1 (3.45 %)2	2 (3.33 %)1 (1.67 %)6 (10.00 %)1
Eating disorder (not otherwise specified)	1 (3.23 %) 3 (9.68 %)	(6.90 %)0 5 (17.24 %)	(1.67 %) 8 (13.33 %)
Borderline Personality Disorder/EUPD	2 (6.45 %)	0	2 (3.33 %)
Panic disorder			
PTSD			
Schizophrenia			
Self-reported physical health diagnosis	13 (41.94 %)	10 (34.48 %)	23 (38.33 %)
Previous psychological therapy[2]	25 (80.65 %)	21 (72.41 %)	46 (76.67 %)
CBT	15 (46.67 %)	15 (53.33 %)	30 (50.00 %)
DBT group/coping skills	3 (10.00 %) 4 (13.22 %)	0 4 (13.22 %)	3 (5.00 %) 8 (13.33 %)
Counselling	2 (6.67 %)	0	2(3.33 %)
Interpersonal	1 (3.33 %)	0	1 (1.67 %)
EMDR	2 (6.67 %)	0	2 (3.33 %)
Family therapy	0	1 (3.33 %)	1 (1.67 %)
DBT	0	1 (3.33 %)	1 (1.67 %)
CAT	16 (53.33 %)	9 (30.00 %)	25 (41.67 %)
Unknown/other			
Current mental health medication	24 (77.42 %)	19 (65.52 %)	43 (71.67 %)
Past mental health medication	24 (77.42 %)	20 (68.97 %)	44 (73.33 %)
Current Psychopathology[2] **(MINI)**	16 (51.61 %) 9 (34.62 %)	20 (68.97 %) 9 (33.33 %)	36 (60.00 %) 18 (33.96 %)
Major Depression	18 (58.06 %)	17 (58.62 %)	35 (58.33 %)
Panic disorder[3]	16 (51.61 %)	15 (51.72 %)	31 (51.67 %)
Social Anxiety	14 (45.16 %)	17 (58.62 %)	31 (51.67 %)
Obsessive Compulsive Disorder			
Generalised Anxiety Disorder			
Suicidal ideation			
Lifetime	30 (96.77 %)	26 (89.66 %)	56 (93.33 %)
Days in past month – median (IQR)	4 (0, 18) 1 (0,3)	5 (1, 15) 0 (0. 3)	4.5 (1, 15) 1 (0, 3)
Days in past week – median (IQR)			
Suicide attempts			
Lifetime	20 (64.52 %)	19 (65.52 %)	39 (65.00 %)
Lifetime – median (IQR)	2 (0, 5) 0 (0, 1)	0 (0, 3) 0 (0, 1)	2 (0, 4.5) 0 (0, 1)
Past year – median (IQR)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Past month – median (IQR)			
Non-Suicidal Self-Injury			
Lifetime	31 (100 %)	29 (100 %)	60 (100 %)
Lifetime – median (IQR)	100 (50, 263) 15 (7, 52)	275 (40, 1000)	100 (50, 1000) 20 (7, 100)
Past year – median (IQR)	2 (0, 5)	50 (10, 200) 4 (1, 10)	2.5 (1, 5.5)
Past month – median (IQR)			

Note: Unless otherwise specified, values are N (%);[1] Rank is out of 32,844 neighbourhoods in England, with lower ranks are more deprived. [2] categories not mutually exclusive. [3] Due to coding error denominator is 26 (CAT) and 27 (TAU). CBT = cognitive behavioural therapy; DBT = dialectical behavioural therapy; EMDR = eye movement desensitisation and reprocessing.

sites and the recruitment target ($N = 60$) was met on time (see Table 1; average monthly rate = 5). Fig. 1 presents the CONSORT diagram. Eighty-three percent (95 % CI: 75–89) of screened referrals were eligible and 59 % (95 % CI: 50–68) were successfully randomised. The reasons for exclusion were presence of current mania or psychosis ($n = 15$), did not meet self-harm criteria ($n = 6$), already receiving therapy ($n = 3$), not under any services ($n = 1$) and outside of area ($n = 1$). Retention was high at 12- (92 %; 95 % CI: 82–96) and 18-weeks (83 %; 95 % CI: 72–91), meeting the progression criteria (see Table 1). If late assessments are still counted as valid then retention improved to 93 % and 92 % at weeks 12 and 18. There was better retention in the CAT arm than the TAU arm (90 % vs 76 % at 18 weeks, not counting late assessments). One participant requested to withdraw from the trial (CAT arm) due to being pregnant. There were four instances of unblinding and one partial unblinding, all in the CAT arm.

3.2. Participants

Baseline characteristics are presented in Table 2. The sample were predominantly female (78 %) and White (83 %), with ethnicity broadly aligning to the local population (https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/population-of-england-and-wales/latest/#by-ethnicity-5-groups). There was a high proportion of sexual minority participants (i.e., 37 % not heterosexual). There were high levels of psychopathology, with most participants meeting criteria for depression, social anxiety and obsessive-compulsive disorder (OCD) on the MINI. Most participants had received previous psychotherapies, mainly CBT.

3.3. Therapy acceptability

Twenty-two (71 %) participants randomised to CAT attended all 8 sessions (95 % CI: 53–84) with a median of 8 sessions attended (IQR = 7–8). The median changed to 7 (IQR = 4–8) when based on sessions conducted within the planned 10-week window. Ninety-seven percent

($n = 30$) of participants in the CAT arm attended at least one session. The progression target was met, as 90 % ($n = 28$) attended ≥ 4 sessions within the planned 10-week window. In practice it was often challenging to fit all 8-sessions into the 10-week window, and 14 participants completed final sessions outside of this window (e.g. due to factors including holidays and illness of clients and therapists). The average number of sessions out of window was 1.03 (SD = 1.38; median = 0, IQR = 0–2). One participant was hospitalised due to a decline in their mental health and CAT was temporarily paused. Four participants chose to discontinue therapy early. Two did so because they were told other therapies had become available to them. One (noted above) became pregnant and withdrew from the trial altogether. One person did not attend any sessions and said they did not feel able to commit to the therapy at this time. Twenty-three participants (75 %) attended the follow-up session.

3.4. Clinical and mechanistic outcomes

Descriptive statistics for clinical and mechanistic outcomes are reported in Table 3, including missing data. Rates of missing data across the ABUSI and SITBI at 12-weeks were < 1 % if those not attending the session at all were not counted and 7 % if non-attenders are counted. Therefore, this progression criterion was met (see Table 1). There were improvements in self-harm urges, dependence on self-harm, distress, interpersonal problems and identity disturbance in the CAT arm over time, with change being less apparent in the TAU arm (see Table 4). Table 4 reports 80 % confidence intervals for treatment effects controlling for age, sex and baseline outcome scores. Mean imputation was used to generate total scale scores where < 20 % of items were missing, but otherwise missing data was handled via case wise deletion. All outcomes improved to a greater extent in the CAT arm. Suicide attempts were not analysed as an outcome given their rarity. For NSSI, an extreme outlier (one person in TAU with > 500 reported NSSI instances at 12-weeks) was excluded, but this made minimal difference to the CI (< 0.10). The low base rate of NSSI means caution is needed in interpreting these effects. The PPI advisory group supported the ABUSI and K10 as primary outcomes for a future trial. Based on our data, previous research, and the guidance of our PPI advisory group, a minimally clinically important difference (MCID) of N3.5 is suggested for the ABUSI and 3 for the K10 (see Supplementary File III). These values fall

Table 3
Descriptive statistics for trial outcomes.

Variable	CAT Group				TAU Group			
	Baseline (All)	Baseline (if still in study at week 12)	Week 12	Week 18	Baseline (All)	Baseline (if still in study at week 12)	Week 12	Week 18
ABUSI Total								
N	31 16	30 16	30	30	29 15	26 16	26	24
Mean (SD)	.3 (6.50)0	.4 (6.56)0	10.5	11.3 (7.8)	.7 (9.52)0	.2 (9.43)0	14.0	13.8 (8.5)
Range	–26	–26	(6.97)0	0	–30	–30	(8.57)0	0
			–25	–26			–30	–30
ESIQ Total								
N	31	30	30	30	29	25	25	24
Mean (SD)	22.5	22.5 (8.15)	19.4	19.4 (7.1)	23.8	24.1 (7.54)	22.4	21.5 (7.5)
Range	(8.02)	9–39	(7.11)	8–36	(7.24)	12–36	(7.25)	9–39
	9–39		8–36		12–36		9–35	
K10 Total								
N	31	30	30	30	29	25	25	24
Mean (SD)	34.5	34.5 (7.06)	31.1	30 (6.5)	34.4	33.8 (7.99)	33.8	32.6 (9.3)
Range	(6.94)	13–47	(5.39)	12–40	(7.67)	13–49	(7.51)	15–50
	13–47		19–40		13–49		15–50	
IIP-32 Total								
N	31	30	30	30	29	25	25	24
Mean (SD)	58.8	57.7 (16.3)	52.7	49.6	63.2	62.2 (18.9)	60.9	58.4
Range	(17.1)	22–82	(16.4)	(17.4)	(18.4)	22–97	(17.4)	(18.1)
	22–92		14–85	2–86	22–97		24–88	22–98
PSQ Total								
N	31	30	30	30	29	25	25	24
Mean (SD)	32.0	31.9 (4.45)	30.6	29.5 (5.2)	32.0	32.1 (4.51)	31.7	30 (5.6)
Range	(4.39)	22–39	(4.14)	19–40	(4.68)	23–40	(5.70)	20–39
	22–39		20–40		23–40		21–40	
Suicide Attempts								
(in the past month)	31	30	30	30	29	26	26	25
N	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Median (IQR)	0–4	0–4	0–5	0–0	0–1	0–1	0–0	0–2
Range								
Suicide Attempts	-	-		-	-	-		
(since last assessment)			30	30			26	25
N			0 (0, 0)	0 (0, 0)			0 (0, 0)	0 (0, 0)
Median (IQR)			0–25	0–0			0–1	0–2
Range								
Non-Suicidal Self-Injury (past month)								
N	31	30	30	30	29	26	26	25
Median (IQR)	2 (0, 5)	2 (0, 5)	1 (0, 2)	1 (0, 3)	4 (1, 10)	4 (1, 14)	1 (0, 5)	1 (0, 2)
Range	0–18	0–18	0–12	0–30	0–560	0–560	0–50	0–15
Non-Suicidal Self-Injury (since last	-	-			-	-		
assessment)			30	30			26	24
N			2 (0, 6)	1.5 (0, 3)			2 (0, 10)	0.5 (0,
Median (IQR)			0–36	0–30			0–150	4.5)
Range								0–30

Week 18 data refers only to participants with available data at baseline and week 18.

Table 4
80 % Confidence intervals for treatment effect estimates for outcomes.

Continuous clinical Outcomes	N	Mean change from baseline to week 12; CAT arm (95 % CI)	Mean change from baseline to week 12; TAU arm (95 % CI)	Treatment effect at week 12; *B* (80 % CI)[a]
Self-harm urges (ABUSI)	56	−5.93 (−8.74, −3.13)	−2.23 (−5.15, 0.69)	−3.95 (−6.22, −1.68)
Distress (K10)	55	−3.37 (−5.60, −1.13)	0.00 (−2.91, 2.91)	−4.08 (−5.95, −2.33)
Perceived dependence on self-harm (ESIQ)	55	−3.10 (−5.27, −0.93)	−1.72 (−3.85, 0.41)	−2.78 (−4.42, −1.14)
Interpersonal problems (IIP-32)	55	−5.00 (−10.07, 0.07)	−1.32 (−5.99, 3.35)	−4.58 (−8.52, −0.64)
Identity disturbance (PSQ)	55	−1.30 (−2.69, 0.09)	−0.40 (−2.37, 1.57)	−1.31 (−2.67, 0.05)
Binary clinical Outcome	**N**	**Median change from baseline to week 12; CAT arm (95 % CI)**	**Median change from baseline to week 12; TAU arm (95 % CI)**	**Treatment effect at week 12; IRR 80 % C.I.**
Past month NSSI (STIBI)	55	−1.5 (−2, 0)	−2 (−6, 0)	0.75 (0.44, 1.26)

[a] Negative effects favour CAT arm; *B* = linear regression non-standardised coefficients; *IRR* = Incidence Risk Ratio; ABUSI (Alexian Brothers Urges to Self-Injure Scale); ESIQ (Experiences of Self-Injury Questionnaire); Inventory of Interpersonal Problems-32 (IIP); The Kessler distress scale (KDS); The Personality Structure Questionnaire (PSQ); Self-Injurious Thoughts and Behaviours Interview (SITBI).

within the treatment effect 80 % CI in the present study.

3.5. Adverse events

Fourteen SAEs were reported (13 acts of self-harm, one escalation in suicidal ideation), all of which were judged by the TSC as being unrelated to the trial. There were hospitalisations in two of these cases. Whilst there were slightly more SAEs in the CAT arm (nine versus five events; five versus three participants), three of these events were identified by the therapists. Therefore, added therapist oversight may have partly accounted for the identification of additional SAEs. There were 93 AEs recorded (58 in CAT arm), 90 relating to self-harm (i.e., this often concerned a period of self-harm rather than an individual event), and 3 related to increases in suicidal thoughts. AEs related to 29 people in the CAT arm versus 23 in TAU. Again, many AEs in the CAT arm were identified by the therapists (13 in CAT arm).

3.6. Adverse events questionnaire

The AEQ was only administered to participants in the CAT arm (n = 21 providing data). Average scores per item and occurrences of items scoring over 3 (indicating they occurred more than "a little") are listed in Supplement VII. Average scores were $\leq$ 1.05 (1 = "very little") for all negative experiences. Whilst scores $\geq$ 3 were noted, these were only endorsed by two or three participants at most on each item. For two participants, taking part increased self-harm ideation, though one also provided additional written comments contextualising this further ("*It's natural I think to feel more anxious or urges to harm when you're bringing up said images in the harsh light of day. It's a necessary struggle and the best decision I have made.*"). One person also stated that taking part had increased suicidal thoughts but noted that taking part had also helped them "quite a lot". Overall, fourteen participants stated that CAT had helped them "quite a lot" or "very much", and five indicated that they felt they had improved to the point they did not require any more help.

3.7. Health economics

Resource use data were complete for 83 % (25/29) participants in TAU and 97 % (30/31) participants in CAT at week-18. The mean CAT intervention costs per service user was estimated to be £472.26 (80 % CI: 436.13, 508.38; see Supplement V). Participants in the CAT arm tended to have more contacts with health or social care services during the 18-week trial period. CAT participants had higher engagement with a broader range of mental health services (e.g., psychiatrists, psychologists, mental health nurses, crisis teams, and support workers) compared with the TAU group. TAU participants showed higher usage of therapists/counsellors. EQ-5D-5L across all five domains and VAS data were collected from all participants at baseline. At 12-weeks, the response rate for CAT was to 97 % (30/31) and TAU was 86 % (25/29), and this remained the same at 18-weeks (including late assessments). No difference in reported health status was observed between groups at baseline. Both arms show increase in the mean EQ-5D-3L index value at 12-weeks compared with baseline. At week-18, the EQ-5D-3L index value decreased again in the TAU arm returning closer to baseline levels, whereas values remained stable for CAT (see Supplement V).

4. Discussion

The RELATE trial aimed to ascertain the feasibility of evaluating brief CAT for self-harm in adults. All trial progression criteria were met, supporting the feasibility of undertaking a larger scale definitive trial of 8-session CAT for self-harm. The results highlight the potential promise of brief CAT as a focused intervention for self-harm that could contribute to the psychological service offer in the UK and elsewhere. In CAT, the 24-session version would normally be offered for patients that self-harm, and so brief CAT represents a significant shortening of treatment time and without losing the three-phase theoretical foundations of the approach or changing the clinical competencies.

Recruitment targets were met. Recruitment was paused at two points due to limited therapist capacity. Modelling of therapist capacity for a future trial will therefore require further consideration. LGBTQ+ participants formed a large proportion, consistent with research highlight the elevated self-harm risk in this population (Dunlop et al., 2020; Taylor et al., 2018). Rates of retention were excellent, with engagement an acknowledged service challenge in this population (Murphy et al., 2010). There were higher rates of missed assessments in the TAU arm (though still above 80 % at 12- weeks), possibly due to reduced motivation connected to being allocated to TAU, highlighting a potential issue for a definitive trial. Both the ABUSI and SITBI had low rates of missing data at 12-weeks, supporting their suitability as outcome measures.

Session attendance rates were impressive with over 80 % of participants receiving $\geq$ 4 sessions within the 10-week period, consistent with meta-analytic findings that CAT is associated with low dropout rates (Simmonds-Buckley et al., 2022). Of the four participants who discontinued therapy, none cited issues with CAT, although one participant left the trial early due to being offered a longer-term intervention elsewhere. Fitting all eight CAT sessions into a 10-week period was challenging, due to a combination of client (e.g. difficult interpersonal relationships, physical illness, difficulties travelling, etc.) and therapist factors (annual leave, illness). In a future definitive trial, a longer therapy window is needed.

All SAEs were independently judged unrelated to the therapy or trial procedures. SAEs mostly concerned self-harm, which would be an expected event in this population. Whilst many psychotherapy trials only include AE monitoring, this study also asked CAT participants about adverse therapeutic experiences. These data did highlight that for a minority of participants, CAT could be a challenging experience, contributing to extant distress or thoughts about self-harm. However, a number of those participants who highlighted such experiences also noted that CAT had been helpful and that short-term negative

experiences were understandable, tolerable and expected. Importantly, there was no indication that CAT led to increases in self-harm behaviour. Rates of NSSI declined in both arms during the trial (see Table 4). The TAU group did not complete the AEP measure and this has been done in other trials (Hutton et al., 2023) and would be a component of a definitive trial. Nonetheless, the potential that CAT can be a challenging therapy for some is an important finding, and so the monitoring of ongoing tolerability by CAT therapists is helpful.

Given the small sample size, treatment effect estimates for clinical and mechanistic outcomes should be treated with due caution. All outcomes favoured CAT. The large rate of zero responses for self-harm behaviour (especially suicide attempts, but also for NSSI) mean a large sample will be required if this is a primary outcome measure in a future definitive trial. It has been argued that recovery from self-harm needs to be considered more holistically than just being defined the absence of self-harm related thoughts or behaviours (Bradley et al., 2024). Psychological distress, measured with the K10 here, may therefore represent another suitable primary clinical outcome. The suggested MCID for the K10 and ABUSI fell within the 80 % CI for the treatment effect.

The tools employed to collect health and social care resource use performed well, with very little missing data. Caution is required in interpreting costs given the small sample, lack of assessment of baseline costs and brief follow-up period. There was some increase in downstream resource use in the CAT arm. It is not clear whether this is a real difference attributable to the intervention or a function of variations in baseline resource use. In a definitive study, we would also collect these data at baseline to allow for adjustment of downstream resource usage by baseline resource usage. The tools used to collect health status data performed well, with very little missing data. However, the mapping algorithm used to convert EQ-5D-5L to EQ-5D-3L has limitations because of the necessity to exclude data from people who do not identify as male or female. Including health status data from non-binary people increased possible QALY gain by a factor of ten in this small sample. A possible solution is to treat participants who categorise themselves as nonbinary for gender as missing and using multiple imputation to impute the missing index values.

Limitations should be noted. Clinical and mechanistic outcomes were based on self-report data, so reviewing hospital or general practice records as an additional source of information concerning episodes of self-harm would have been useful. However, such sources are still limited, given most self-harm does not result in hospital or GP attendance (Geulayov et al., 2018). The sample whilst diverse in some ways (e.g. LGBTQ+ status) was predominantly female and lacked ethnic diversity, with most participants being White, although proportions do match national data.

To conclude, these results support the feasibility of evaluating brief 8-session CAT for self-harm in adults and so progression onto a larger definitive trial (and this should adopt a longer treatment window). Severity of self-harm urges and psychological distress both represent potential primary outcomes. Self-harm behaviour may also be a suitable primary outcome but would require a large sample. If found to be efficacious, brief CAT for self-harm would make a valuable addition to services by providing a relational psychotherapy where self-harm is a treatment priority and more intensive therapies (e.g. DBT) are not indicated, suitable, acceptable, or available.

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Ethical statement

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Transparency declaration

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data availability

An anonymised version of the final trial dataset will be made available to other researchers following publication of the study, upon reasonable request. Copies of analytic code and study materials are available on reasonable request.

CRediT authorship contribution statement

Peter James Taylor: Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Isabel Adeyemi:** Writing – review & editing, Project administration, Methodology, Investigation. **Katie Marlow:** Writing – review & editing, Project administration, Investigation, Data curation. **Sarah Cottam:** Writing – review & editing, Project administration, Investigation. **Zerena Airnes:** Writing – review & editing, Project administration, Investigation. **Victoria Howells:** Writing – review & editing, Project administration, Investigation. **Barnaby D. Dunn:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Rachel A. Elliott:** Writing – original draft, Methodology, Formal analysis. **Mark Hann:** Writing – review & editing, Writing – original draft, Methodology, Funding acquisition, Formal analysis. **Cameron Latham:** Supervision, Methodology, Funding acquisition, Conceptualization. **Fanyi Su:** Writing – original draft, Methodology, Formal analysis. **Catherine Robinson:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization. **Clive Turpin:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Conceptualization. **Stephen Kellett:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

There are no conflicts of interest to declare

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2025.116859.

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