The development and preliminary evaluation of Cognitive Behavioural Therapy (CBT) for Chronic Loneliness in Young People

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Abstract

Background: Approximately 10% of young people 'often' feel lonely, with loneliness being predictive of multiple physical and mental health problems. Research has found CBT to be effective for reducing loneliness in adults, but interventions for young people who report loneliness as their primary difficulty are lacking.
Method: CBT for Chronic Loneliness in Young People was developed as a modular intervention. This was evaluated in a single-case experimental design (SCED) with seven participants aged 11–18 years. The primary outcome was self-reported loneliness on the Three-Item Loneliness Scale. Secondary outcomes were self-reported loneliness on the UCLA-LS-3, and self- and parent-reported RCADS and SDQ impact scores. Feasibility and participant satisfaction were also assessed.
Results: At post-intervention, there was a 66.41% reduction in loneliness, with all seven participants reporting a significant reduction on the primary outcome measure ($p < .001$). There was also a reduction on the UCLA-LS-3 of a large effect ($d = 1.53$). Reductions of a large effect size were also found for parent-reported total RCADS ($d = 2.19$) and SDQ impact scores ($d = 2.15$) and self-reported total RCADS scores ($d = 1.81$), with a small reduction in self-reported SDQ impact scores ($d = 0.41$). Participants reported high levels of satisfaction, with the protocol being feasible and acceptable.
Conclusions: We conclude that CBT for Chronic Loneliness in Young People may be an effective intervention for reducing loneliness and co-occurring mental health difficulties in young people. The intervention should now be evaluated further through a randomised controlled trial (RCT).

Keywords: CBT; Child mental health; Loneliness

Introduction

Chronic loneliness is transdiagnostic and associated with multiple physical and mental health problems in young people (Bovin *et al.*, 1995; Ladd *et al.*, 1997; Loades *et al.*, 2020; Qualter *et al.*, 2010; Qualter *et al.*, 2013; Schinka *et al.*, 2012; Vanhalst *et al.*, 2012). In the United Kingdom, approximately 10% of 10- to 15-year-olds report that they 'often' feel lonely (Office for National Statistics, 2018). Chronic loneliness is a complex psycho-social issue and the population of young people at an elevated risk of loneliness is highly heterogenous; it includes those with chronic health

problems (Maes *et al.*, 2017), mental health difficulties (Loades *et al.*, 2020; Schinka *et al.*, 2012) and those on the autism spectrum (Bauminger *et al.*, 2003). Loneliness is also associated with broader social-cultural factors, such as experiences of discrimination, racism and the social isolation resulting from the COVID-19 pandemic (Priest *et al.*, 2014; Sabato *et al.*, 2021; Schinka *et al.*, 2012)

Psychological interventions can be effective in reducing loneliness across the lifespan (Hickin *et al.*, 2021). A recent meta-analysis of interventions for young people highlighted a range of approaches that may reduce loneliness as a secondary outcome in at-risk groups (Eccles and Qualter, 2021). However, they concluded that interventions specifically aimed at young people who report loneliness as their primary difficulty (rather than those at risk of loneliness) are lacking within the literature.

A meta-analytic review of adult loneliness interventions identified that the most efficacious approaches were those that targeted the underlying maladaptive social cognitions (Masi *et al.*, 2011), although a more recent review did not find cognitive behavioural therapy (CBT) to be statistically significantly superior to other approaches (Hickin *et al.*, 2021). A phase 3 randomised controlled trial (RCT) also found that a social identity intervention, Groups4Health (Haslam *et al.*, 2016), was non-inferior to CBT for depression for 15- to 25-year-olds with low mood and/or loneliness, with Groups4Health showing a slight advantage for loneliness scores at 12-month follow-up (Cruwys *et al.*, 2022). For the purposes of this study, it was considered that developing a CBT intervention for loneliness was warranted given that CBT for loneliness has a strong evidence base (Käll *et al.*, 2020b; Käll *et al.*, 2021; Masi *et al.*, 2011), and that a modular CBT intervention, derived from a modular theory of the maintenance of loneliness (Käll *et al.*, 2020a), would be well suited to the heterogenous presentations of young people with chronic loneliness as their primary difficulty. Furthermore, loneliness often occurs in the context of anxiety and depression for which CBT is the recommended treatment (National Institute for Health and Care Excellence, 2014; National Institute for Health and Care Excellence, 2019).

Käll *et al.* (2020a) have developed a modular cognitive behavioural analysis of chronic loneliness based upon a common elements approach. Interventions informed by this modular formulation have been shown to be efficacious in two internet-delivered RCTs for reducing loneliness in adulthood (Käll *et al.*, 2020b; Käll *et al.*, 2021). A modular approach may be particularly appropriate for adolescents, due to the high levels of heterogeneity in the presentations of young people presenting with chronic loneliness (Bauminger *et al.*, 2003; Loades *et al.*, 2020; Maes *et al.*, 2017; Schinka *et al.*, 2012) and as it is not yet known what interventions work for whom (Pearce *et al.*, 2021).

A criticism of previous loneliness interventions for young people has been the lack of controlled experimental research methodology (Eccles and Qualter, 2021). Single case experimental designs (SCEDs) are a methodology that provides a controlled experimental approach from which causal inferences can be drawn, whilst giving the detail and richness commonly associated with case studies (Kazdin, 2011). This study followed the Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (Skivington *et al.*, 2021) and a brief feasibility and piloting stage was completed prior to the SCED (Cawthorne, 2022).

Aims and objectives

The primary objective was to evaluate the efficacy of CBT for Chronic Loneliness in Young People using a SCED. The secondary objective was to investigate the feasibility and acceptability of the intervention and research protocol. It was hypothesised that there would be a significant decrease in self-reported loneliness between baseline and intervention and baseline and post-intervention on the Three-Item Loneliness Scale (Klein *et al.*, 2021). It was also hypothesised that there would be a reliable and clinically meaningful change (Jacobson and Truax, 1992) in total loneliness scores on the UCLA-LS-3, in impact scores on the SDQ and reliable change in total anxiety and

depression scores on the RCADS. It was also hypothesised that there would be a reduction in the proportion of young people presenting with 'clinically significant' ($\geq$70) and 'borderline clinical' ($\geq$65) total anxiety and depression scores on the RCADS (Chorpita *et al.*, 2000) at post-intervention.

Method

The study protocol has been published (Cawthorne *et al.*, 2022a) and registered with ClinicalTrails.gov (NCT05149963). The construction and reporting of the trial is in accordance with the Single-Case Reporting Guidelines in Behavioural Intervention (SCRIBE) (Tate *et al.*, 2016).

Study design

This study utilised a randomised multiple-baseline SCED (Kazdin, 2019). The design consisted of AB+ post-intervention, where A was the baseline phase, B was the intervention phase followed by a post-intervention phase. Participants completed a baseline research assessment before being randomised to one of four baseline lengths (12, 19, 26 or 33 days). The first four participants to consent were placed in Group 1 and the next set of participants in Group 2. All participants in each group started the baseline phase concurrently. Participants were repeatedly assessed for self-reported loneliness on the Three-item Loneliness Scale (Klein *et al.*, 2021), across each phase of the intervention. This repeated measurement and within-subject replication was used to test the effects of the intervention for individual participants and across the participant group. After completing the intervention phase each participant then completed a post-intervention research assessment.

Procedure

A CONSORT flow diagram is provided in Fig. 1. Participants were recruited via schools, social media and word of mouth. The setting for the entire study was remote via Zoom (www.zoom.us), with participants recruited from across the United Kingdom (UK). The full procedure is detailed in the study protocol (Cawthorne *et al.*, 2022a).

Participants

Seven participants were recruited; two were males, four were females and one identified with a non-binary gender identity. Six were recruited via social media advertisements and one from a school. The mean age was 14.85 years (range 13–17). Four of the participants presented as neurodiverse, one had a diagnosis of autism, two were currently undergoing autism assessments, and one had a diagnosis of sensory processing disorder. A further participant had treatment-resistant epilepsy, where she experienced regular seizures and presented with significant slow processing, and one of the participants had an eating disorder. Several of the participants presented with risk issues, including active self-harm and suicidal thoughts.

Full inclusion criteria are detailed in the study protocol (Cawthorne *et al.*, 2022a). All participants were aged between 11 and 18 and scored more than 42 on the UCLA Loneliness Scale (version 3) (Russell, 1996), which is more than one standard deviation above the mean in a large community adolescent sample (Shevlin *et al.*, 2015). All participants reported loneliness as their primary difficulty, reported that they had been experiencing loneliness for $\geq$3 months, were not currently attending another psychological therapy and had not begun anti-depressants in the last 8 weeks. No participants received other interventions during the trial period.
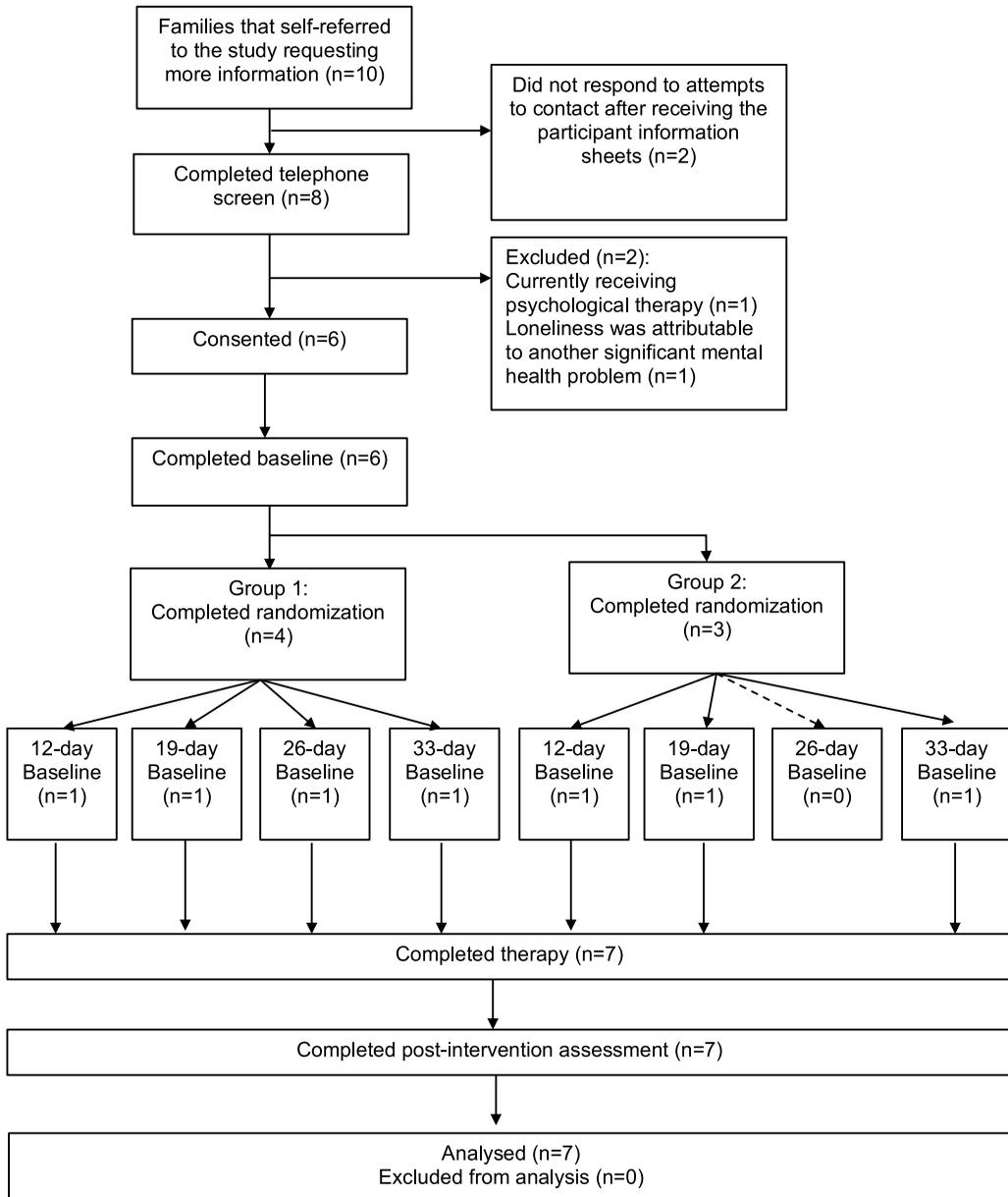
Figure 1. CONSORT diagram for the study design.

Outcome measures

Loneliness

The Three-Item Loneliness Scale (Klein et al., 2021). This was the primary outcome measure of the study used to assess the child/young persons' self-reported loneliness throughout each of the three phases of the study. Answers are summed to a total score of 0–12, with higher scores indicating a higher level of loneliness. The Office for National Statistics (ONS) have validated a 3-reponse version of this measure with young people aged 10–15 years (Office for National Statistics, 2018). In qualitative testing of the measure, they identified that the words 'companionship' and 'isolation' were difficult for some young people to understand. These changes in wording were also used in

this study as the age range was similar to that used in the ONS validation. There is a fourth question, 'How often do you feel lonely?' that does not contribute to the overall score.

UCLA Loneliness Scale (UCLA-LS-3) (Russell, 1996). The measure was used as the secondary outcome to assess the child/young person's subjective experience of loneliness. Answers are summed to a total score of 20–80, with higher scores indicating a higher level of loneliness.

Psychological wellbeing
The Revised Child Anxiety and Depression Scale (RCADS) (Chorpita et al., 2000). The parent and self-report versions were used to assess the child's anxiety and depression. Raw scores are converted to T-scores. A T-score of 65 means the young person is scoring in the top 7% for unreferred young people and is classified as 'borderline clinical'. A T-score of 70 means that the young person is in the top 2% of unreferred young people and is described as the 'clinical' threshold. The Total Anxiety and Depression score was used as a secondary outcome measure.

The Strengths and Difficulties Questionnaires (SDQ) (Goodman, 2001). The self-report and parent-report versions were used to assess the child's psychological wellbeing. The SDQ has an 'impact scale', which assesses the impact that symptoms have on everyday life in a range of domains (home, school, leisure), and was used as a secondary outcome measure.

Parent/carer wellbeing
The Generalised Anxiety Disorder Assessment (GAD-7) (Spitzer et al., 2006). The measure was used to assess parent/carer self-reported anxiety. Scores of 5, 10 and 15 represent cut-off points for mild, moderate and severe anxiety, respectively.

The Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001). The measure was used to assess parent/carer self-reported depression. Scores of 5, 10, 15 and 20 represent cut-off points for mild, moderate, moderately severe and severe depression, respectively.

UCLA-LS-3 (Russell, 1996). This measure was also used to characterise the level of self-reported parent/carer loneliness.

Process measure
Goal-based outcomes (Law and Jacob, 2013). During their first session young people were asked to identify three intervention goals relating to their loneliness. They were asked to rate on a 1–10 scale where they are in terms of achieving this goal; with 1 being 'the furthest I could ever be from achieving this goal' and 10 being 'I have achieved this goal'. They then rated each goal as part of the routine outcome measures for each session. Goal-based outcomes have been shown to improve treatment retention, clinical outcomes and client progress (Delgadillo *et al.*, 2018; Tryon *et al.*, 2018).

Visual analogue scales (VAS) (Wewers and Lowe, 1990). For each session, young people were asked to rate their current mood, anxiety and loneliness on a 1–10 scale, where 10 is the worst. Visual analogue scales have been shown to have good validity and reliability (McCormack *et al.*, 1988).

Feasibility and experience measure
Experience of Services Questionnaire (ESQ) (Brown et al., 2014). During the post-intervention assessment, the participants were asked to complete the child and parent-report versions of the ESQ regarding their experience of the intervention. The ESQ asks young people and their parents/carers a series of questions to which they can answer 'Certainly true', 'Partly true', 'Not true' and

'Don't know', with each of the questions being positively phrased, e.g. 'I felt like the people who saw me listened to me'.

All participating families were also asked how COVID-19 or other events had impacted the child's loneliness during the intervention period. Finally, any adverse events that occurred during the trial period were recorded, reported and discussed within supervision.

Intervention

The intervention was developed using a modular approach based upon Käll *et al.*'s (2020b) modular cognitive behavioural formulation. The manual consists of 10 treatment modules (see Table S1 in Supplementary material). It incorporates translated elements of Käll *et al.*'s (2021) internet-based intervention for adults with chronic loneliness, and is informed by the Modular Approach to Therapy for Children with Anxiety, Depression, Trauma or Conduct problems (MATCH-ADTC) (Chorpita and Weisz, 2009), Groups4Health (Haslam *et al.*, 2016), PEERS social skills training (Laugeson *et al.*, 2012), CBT for Social Anxiety Disorder for adolescence (Leigh and Clark, 2018) and the literature implicating social camouflaging in mental health difficulties for those on the autism spectrum (Cook *et al.*, 2021). These different sources of information were synthesised into a 200-page treatment manual (Cawthorne *et al.*, 2022b).

All participants completed Module 1 (Assessment), Module 2 (Formulation and Psychoeducation) and Module 10 (Relapse Prevention). Other intervention modules were chosen in collaboration with the participants based upon their personalised formulation and treatment goals and the three pillars of evidence-based practice (Sackett, 1997), incorporating the participants' values, the clinical expertise of the research team and the relevant research. The number of sessions delivered for each module was determined by treatment priorities and individual progress up to (on average) 12 therapy sessions. Each therapy session lasted approximately 50 minutes and was delivered one-to-one by the primary author (T.C.) who was a Trainee Clinical Psychologist. He received weekly supervision from R.S., A.K. and/or S.B. throughout the research and intervention process to ensure fidelity to the agreed protocol. The format of each session consisted of (1) reviewing the routine outcome measures, (2) reviewing the homework, (3) collaboratively developing the agenda, (4) teaching a skill/conducting a behavioural experiment within the session and then (5) collaboratively agreeing a homework task to practise prior to the next appointment.

A personalised intervention was chosen due to the heterogenous presentations of young people presenting with chronic loneliness (Bauminger *et al.*, 2003; Loades *et al.*, 2020; Maes *et al.*, 2017; Schinka *et al.*, 2012). Each participant's personalised intervention plan is shown in Fig. S1 in Supplementary material. If there was deterioration in wellbeing, or risk issues were identified, local statutory or healthcare services were contacted as appropriate. Participants were able to withdraw from the trial at any time.

Data analysis plan

The full data analysis plan is detailed in the study protocol (Cawthorne *et al.*, 2022a). The primary outcome measure of the SCED, self-reported scores on the Three-Item Loneliness Scale (Klein *et al.*, 2021), was analysed using visual inspection (Krasny-Pacini and Evans, 2018; Lane and Gast, 2014). This was supplemented by Tau-U (Parker *et al.*, 2011), which is a statistical test specifically designed for single case research and has been used in previous SCEDs of psychological interventions (Veale *et al.*, 2015; Willson *et al.*, 2016). Tau-U was used to analyse the overlap between the baseline and intervention and the baseline and post-intervention phase. Any unwanted trends or variability in baseline scores were controlled for in all analyses. The trial was consistent with reporting guidelines and trial standards (Smith, 2012; Tate *et al.*, 2016), with a

sufficient number of observations per phase for adequately powered statical analysis (Parker *et al.*, 2011; Shadish *et al.*, 2014).

It was assessed how many of the participants displayed (a) reliable and (b) clinically meaningful change (Jacobson and Truax, 1992) in total loneliness scores on the UCLA-LS-3 (Russell, 1996) and parent- and self-reported impact scores on the SDQ (Goodman, 2001). It was also examined how many participants displayed reliable change and how many reported 'clinically significant' and 'borderline clinical' scores at baseline and post-intervention for Total Anxiety and Depression Scores on the RCADS (Chorpita *et al.*, 2000). The Leeds Reliable Change Indicator (Morley and Dowzer, 2014) was used for calculating reliable and clinically meaningful change.

For all secondary outcome measures, the pre–post intervention effect size was calculated and reported using raw scores. Effect sizes were Cohen's *d* (Cohen, 1988) and were calculated using the Leeds Reliable Change Indicator (Morley and Dowzer, 2014). The effect sizes were classified based on Cohen (1988) and categorised in the following way: small ($d = 0.2$), medium ($d = 0.5$) and large ($d = 0.8$). The goal-based outcomes (Law and Jacob, 2013) and VAS scores (Wewers and Lowe, 1990) are also visually presented and the means and standard deviations of scores at baseline and post-intervention were reported.

Feasibility and satisfaction measures

The proportion of our minimum recruitment target of six participants achieved was reported. The proportion of participants retained, defined as completing both the baseline and intervention assessments, was also reported; with an 80% retention rate indicating feasibility, based on previous studies (Walters *et al.*, 2017). Acceptability was indicated by 80% positive responses on the Experience of Services Questionnaire (Brown *et al.*, 2014).

Results

Participant baseline characteristics are reported in Table 1 and baseline scores on the secondary outcomes in Table S2 in the Supplementary material. High levels of difficulties were observed, although there was heterogeneity across the participant group.

Primary outcome measures

Visual analysis

Self-reported loneliness on the Three-Item Loneliness Scale (Klein *et al.*, 2021) across the baseline, intervention and post-intervention phase is displayed in Fig. 2. All seven participants showed some variability during the baseline period. For participants 2–6 this variability does not appear directional, with the baseline phase providing a stable control for comparison with the subsequent intervention and post-intervention phases. For participants 1 and 7 there is evidence of an upwards trend in loneliness scores during the baseline period. This may suggest that they are experiencing deterioration and the baseline phase may not provide a stable comparison for visual analysis.

When examining the change in symptom severity across phases, for participants 1, 2, 4, 5, 6 and 7 there is clear evidence of a downwards trend in symptom severity during the intervention phase. When comparing participants across the multiple-baseline design, the downwards trend occurs after the introduction of the intervention, although there is variability in the immediacy of the response. The degree of the slope of the curve indicates that the change in trend was strongest for participants 2, 6 and 7, although the change in trend is still strong for participants 1, 4 and 5. For participant 3 there is some evidence of a very slight downwards slope across the intervention phase, but the overall gradient of the slope indicates a weak change in trend.

Table 1. Baseline demographics of the SCED participants

|	Age	Gender	Ethnicity	Education status	Parent/carer age	Parent gender	Parent employment status	Parent education level	Household composition	Household income	Parent UCLA-LS-3	Parent GAD-7	Parent PHQ-9	Child diagnoses
P1	15	Male	White British	Full-time mainstream school/college	42	Female (mother)	Full-time employment (30+ hours)	NVQ	Mother, sister, stepfather	£15,001–£20,000	46	14 (moderate)	8 (mild)	Autism
P2	13	Female	White British	Full-time mainstream school/college	45	Female (mother)	Part-time employment (<30 hours)	PGCE	Mother, father, brother	£35,001–£40,000	48	9 (mild)	10 (moderate)	Under assessment for autism
P3	17	Female	White British	Full-time mainstream school/college	51	Female (mother)	Full-time employment (30+ hours)	PhD	Mother, father, two brothers, two sisters	£50,001–£75,000	40	6 (mild)	7 (mild)	Treatment-resistant epilepsy
P4	16	Female	White British	Full-time mainstream school/college	49	Female (mother)	Part-time employment (<30 hours)	MSc	Mother, father, brother, sister	£100,001 plus	54	1 (minimal)	2 (minimal)	None
P5	15	Non-binary	White British/Irish	Full-time mainstream school/college	43	Female (mother)	Full-time employment (30+ hours)	Undergraduate degree	Mother, stepfather	£75,001–£100,000	48	12 (moderate)	7 (mild)	Under assessment for autism
P6	14	Male	White British	Full-time mainstream school/college	49	Female (mother)	Full-time employment (30+ hours)	Degree equivalent	Mother, father	£50,001–£75,000	27	15 (severe)	16 (moderately severe)	Sensory processing disorder
P7	14	Female	White British	Full-time mainstream school/college	44	Female (mother)	Part-time employment (<30 hours)	Diploma	Mother, father, sister	£50,001–£75,000	33	5 (mild)	11 (moderate)	None
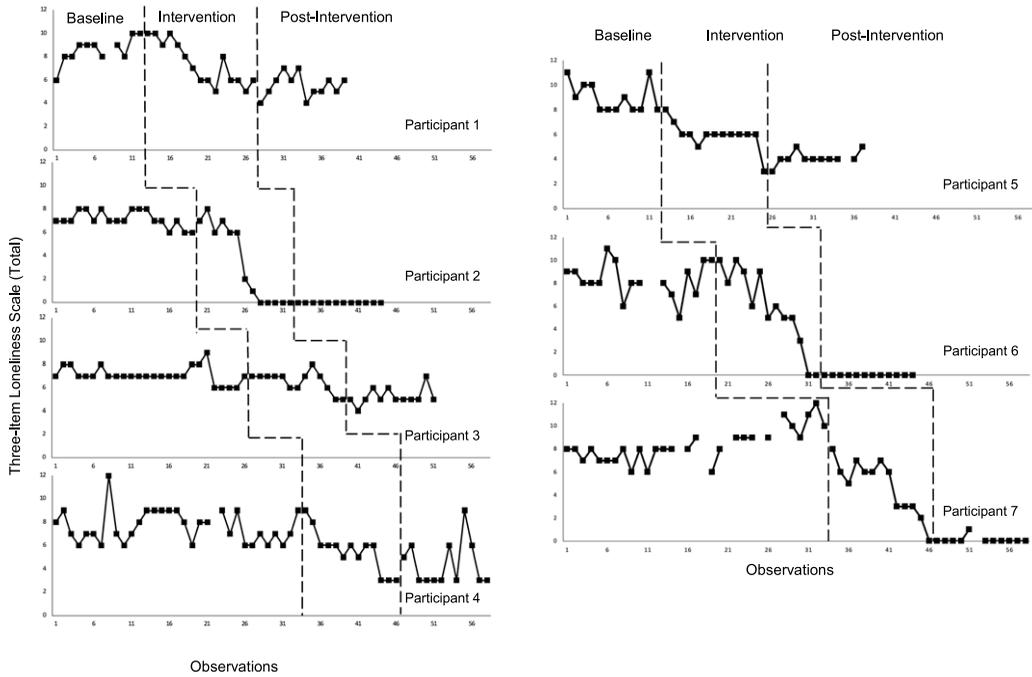
Figure 2. The total scores on the Three-Item Loneliness Scale across the baseline, intervention and post-intervention phases.

For participants 2, 5, 6 and 7, there is clear evidence of stability in the symptom reduction observed during the intervention phase, with there being no significant variability during the post-intervention period. Similarly, for participant 3, although only a weak change in trend was identified, this appears to be sustained at post-intervention with there being little between-observation variability. For participants 1 and 4, there is evidence of variability in scores across the post-intervention period, with this coinciding with their school exams. However, despite this variability, when examining scores across the three phases, evidence of a downward trend is still found for both participants.

Tau-U

There was a significant baseline trend for participant 1 ($p = .023$, 90% CI: 0.13, 0.89) and participant 7 ($p < .001$, 90% CI: 0.33, 0.77) and these were corrected for in all Tau-U analysis following the recommendations of Parker *et al.* (2011). All other participants showed no evidence of a significant baseline trend.

The results of the Tau-U analysis are presented in Table 2. When comparing baseline and intervention, six of the seven participants showed a significant reduction ($p < .05$) in baseline scores. The weighted average across all the cases was also significant for baseline ($M = 7.83$, $SD = 1.36$) *vs* intervention ($M = 5.66$, $SD = 2.53$), $p < .001$, 95% CI [−88, −0.56]. For baseline ($M = 7.83$, $SD = 1.36$) *vs* post-intervention ($M = 2.63$, $SD = 2.70$), all seven of the participants showed a reduction in loneliness scores at the $p < .001$ level. The weighted average across the cases was also significant, $p < .001$, CI [−1.0, −0.91].

The mean scores for the additional fourth question of the Three-Item Loneliness Scale (Office for National Statistics, 2018), 'How often do you feel lonely?', also showed a linear reduction across the group between baseline ($M = 4.12$, $SD = 0.46$), intervention ($M = 3.21$, $SD = 1.03$) and post-intervention ($M = 2.19$, $SD = 1.03$).

Table 2. The results of the Tau-U analysis for baseline *vs* intervention and baseline *vs* post-intervention

Participant	Mean (SD)			Baseline *vs* intervention				Baseline *vs* post-intervention			
	Baseline	Intervention	Post	Tau	SD Tau	*p*-value	90% CI	Tau	SD Tau	*p*-value	90% CI
P1	8.55 (1.13)	7.40 (1.84)	5.50 (1)	−0.52	0.23	0.03	[−0.91, −0.14]	−1.15	0.25	<0.001	[−1, −0.80]
P2	7.00 (0.72)	3.31 (3.33)	0.00 (0)	−0.70	0.21	<0.001	[−1, −0.36]	−1	0.22	<0.001	[−1, −0.64]
P3	7.12 (0.71)	6.54 (0.88)	5.25 (0.75)	−0.33	0.20	0.09	[−0.66, −0.01]	−0.90	0.20	<0.001	[−1, −0.56]
P4	7.63 (1.41)	5.54 (1.81)	4.42 (1.98)	−0.66	0.19	<0.001	[−0.98, −0.35]	−0.80	0.20	<0.001	[−1, −0.47]
P5	9 (1.21)	5.92 (1.12)	4.50 (0.71)	−0.96	0.24	<0.001	[−1, −0.57]	−1	0.25	<.001	[−1, −0.60]
P6	8.29 (1.53)	5.85 (3.39)	0.00 (0)	−0.43	0.22	0.05	[−0.78, −0.07]	−1	0.20	<0.001	[−1, −0.64]
P7	8.36 (1.50)	4.77 (2.35)	0.09 (0.30)	−1.46	0.20	<0.001	[−1, −1]	−1.68	0.20	<0.001	[−1, −1]
Weighted average				−0.72		<0.001	95% CI [−88, −0.56]	−1.07		<0.001	95% CI [−1, −0.91]

Secondary outcome measures

The participants' baseline and post-intervention scores on each of the secondary outcome measures are displayed in Table 3. For the UCLA-LS-3 the pre–post effect size between baseline ($M = 58.86$, $SD = 7.31$) and post-intervention ($M = 47.71$, $SD = 12.20$) was $d = 1.53$ (large effect). Four of the seven participants met the criteria for clinically significant change, with a post-intervention score of <51. Three participants met the criteria for clinically reliable improvement with a score reduction of >11 points. None of the participants showed clinically reliable deterioration.

For the child-report RCADS Total scores the pre–post effect size between baseline ($M = 71.86$, $SD = 16.75$) and post-intervention ($M = 41.57$, $SD = 19.87$) was $d = 1.81$ (large effect). Three of the participants showed reliable change, meeting the age and gender-specific RCI scores (Chorpita *et al.*, 2005). A fourth participant reported a reduction of 26 points, which was approaching the required RCI value of 27.51. None of the participants showed evidence of clinically reliable deterioration. At baseline, three participants scored above the clinical threshold (≥ 70), with one participant scoring as borderline clinical (≥ 65). At post-intervention two participants scored in the clinical range, with the remaining five participants all scoring in the non-clinical range (<65).

For the parent-report RCADS Total scores the pre–post effect size between baseline ($M = 55.71$, $SD = 8.16$) and post-intervention ($M = 37.86$, $SD = 15.51$) was $d = 2.19$ (large effect). Three of the participants met the age and gender-specific RCI values for clinically reliable improvement and none showed clinically reliable deterioration (Chorpita *et al.*, 2005). At baseline, five participants scored above the clinical threshold (≥ 70), with two participants scoring as borderline clinical (≥ 65). At post-intervention, one participant scored in the clinical range, three in the borderline range and three in the non-clinical range (<65).

For SDQ self-report impact scores the pre–post effect size between baseline ($M = 3.00$, $SD = 1.73$) and post-intervention ($M = 2.29$, $SD = 2.56$) was $d = 0.41$ (small effect). It was identified that four participants met the criteria for clinically significant improvement scoring <2.4. One of the four participants scored 0 at both baseline and post-intervention. Four of the participants met the gender-specific RCI values for clinically reliable improvement of $RCI = 0.97$ for males and $RCI = 0.85$ for females, two stayed the same and one showed clinically reliable deterioration.

For SDQ impact parent report scores the pre–post effect size between baseline ($M = 4.43$, $SD = 1.13$) and post-intervention ($M = 2.00$, $SD = 1.83$) was $d = 2.15$ (large effect). Four of the participants met the criteria for clinically significant change (<2.08). Five of the participants met the gender-specific RCI values for reliable change of $RCI = 1.40$ for males and $RCI = 1.18$ for females, one stayed the same, with one showing reliable deterioration.

Session-by-session measurement

Across the participant group there was a general downwards trend in VAS loneliness, anxiety and mood scores across the intervention period (see Fig. S2 in the Supplementary material). For VAS loneliness the pre–post effect size between baseline ($M = 6.29$, $SD = 1.60$) and post-intervention ($M = 3.14$, $SD = 1.77$) was $d = 1.97$ (large effect). For VAS anxiety scores the pre–post effect size between baseline ($M = 5.00$, $SD = 2.94$) and post-intervention ($M = 2.57$, $SD = 1.13$) was $d = 0.83$ (large effect). For VAS mood scores the pre–post effect size between baseline ($M = 5.29$, $SD = 1.80$) and post-intervention ($M = 2.57$, $SD = 1.40$) was $d = 1.51$ (large effect). A clear upwards trend was also identified for GBO scores (see Fig. S3 in Supplementary material). The pre–post effect size between baseline ($M = 4.14$, $SD = 1.84$) and post-intervention ($M = 8.19$, $SD = 1.99$) was $d = 2.20$ (large effect).

Table 3. The baseline and post-intervention scores for the secondary outcome measures

		Participant 1		Participant 2		Participant 3		Participant 4		Participant 5		Participant 6		Participant 7	
		Baseline	Post	Baseline	Post	Baseline	Post	Baseline	Post	Baseline	Post	Baseline	Post	Baseline	Post
Self-report	UCLA-LS-3	55	63	61	36	65	61	57	55	66	33	45	39	63	47
	SDQ-Impact	3	4	3	0	5	7	0	0	5	3	3	1	2	1
	RCADS Total (raw)	77	68	66	25	61	63	66	24	81	56	50	24	102	31
	RCADS Total T-score	76	70	61	40	60	60	69	56	79	70	58	43	>80	46
Parent-report	SDQ-Impact	5	0	6	3	3	5	5	0	3	3	5	1	4	2
	RCADS Total (raw)	49	34	60	42	61	63	66	24	60	44	43	15	51	43
	RCADS Total T-score	70	58	73	66	66	70	71	44	76	65	65	46	70	65

Feasibility and satisfaction

Our minimum recruitment target of six participants was exceeded. All seven participants were retained throughout the study period, completing both the baseline and post-intervention assessments. Overall, the participants completed 260/277 (93.9%) of the observations and all seven participants attended 100% of their intervention appointments. On the ESQ, 99.2% of the responses were positive, with the one negative response being from a young person who said the sessions were not at convenient times.

Discussion

This randomised multiple-baseline SCED provides preliminary evidence that CBT for Chronic Loneliness in Young People is efficacious. On the primary outcome measure all seven participants showed a significant reduction in loneliness scores between baseline and post-intervention at the $p < .001$ level, with a 66.41% reduction in loneliness scores being evident. A 'large' pre–post effect size of $d = 1.53$ was also found on the secondary outcome measure of loneliness. This indicates that this intervention may provide an effective treatment for young people who report chronic loneliness as their primary problem.

Several existing evidence-based interventions for anxiety and depression have been shown to be ineffective for reducing co-occurring loneliness (Conoley and Garber, 1985; Masia-Warner *et al.*, 2005; Stice *et al.*, 2010). In contrast, in this study large reductions in both parent ($d = 2.19$) and self-reported ($d = 1.81$) anxiety and depression scores were found. This supports the hypothesis that interventions aimed at reducing loneliness may be an important active ingredient in treatments for anxiety and depression in young people (Pearce *et al.*, 2021). It also indicates that CBT for Chronic Loneliness in Young People may have significant implications for children and adolescents presenting with co-occurring loneliness and mental health difficulties.

The baseline RCADS and SDQ scores of the participants included in this study were broadly similar to those identified in young people seeking support from community CAMHS services (Gibbons *et al.*, 2021). Six of the seven participants also presented with co–morbid conditions, including factors typically associated with a poorer treatment response such as autism, co–morbid depression and social anxiety (O'Neil and Kendall, 2012; Wang *et al.*, 2021; Wergeland *et al.*, 2016). The mothers whose children showed the strongest treatment response also reported the highest anxiety and depression scores, contrary to what is often found in treatment outcome studies (De Haan *et al.*, 2013; Kunas *et al.*, 2021). Therefore, this indicates that this intervention may have particular applications to groups of young people who frequently respond poorly to existing interventions.

All the young people and their parents/carers reported that COVID-19 had a significant impact on the young person's loneliness and broader mental wellbeing over the last two years. Three parents and one young person felt that COVID-19 was still impacting their loneliness during the period of the research study. This indicates that the intervention may also provide an effective treatment to combat loneliness in any future circumstances that requite social distancing as experienced during the COVID-19 pandemic.

The intervention also appears to be feasible and acceptable. The recruitment target of six participants was exceeded, with all seven participants retained throughout the study. Both young people and their parents were also very positive about the intervention and its delivery. The ESQ (Brown *et al.*, 2014) ratings were consistent with, or above, existing interventions used in child and adolescent mental health services (Brown *et al.*, 2014; Graham *et al.*, 2012), suggesting that the intervention has utility for use within real-world clinical practice.

Limitations and areas for future research

Several limitations were identified. Firstly, participants included in this study were diverse in terms of neurodiversity, household income, geographical location within the UK, gender, LGBTQ+ identity and family composition. However, all the participants were White British, so it is not possible to consider how the intervention can be adapted or applied across different cultures. Another limitation was that the intervention was delivered by a single therapist, so it is not possible to distinguish to what extent the efficacy of the intervention was related to therapist-specific effects. However, a recent review identified that therapist effects within controlled designs average 8.2% (Johns *et al.*, 2019), suggesting the impact of this on the results is likely to be minimal.

A third limitation is that the three-item scale used as the primary outcome measure of this study was derived from the UCLA-LS-3, which was the secondary outcome measure of loneliness. The three-item scale was also an adapted version that has not been quantitively validated, although the use of non-validated measures in SCEDs is common practice when alongside validated generalisation measures (Kazdin, 2019).

Fourthly, whilst this study reported a well-controlled SCED allowing for causal inferences to be drawn regarding the primary outcome measure (Kazdin, 2011), causality cannot be inferred for the secondary outcome measures as they were only collected once at baseline and at post-intervention. Now that preliminary evidence of efficacy has been identified, the intervention should be tested in an adequately powered RCT and compared with existing interventions shown to be efficacious for reducing loneliness in young people (e.g. Groups4Health; Cruwys *et al.*, 2022). A large-scale RCT would also be beneficial for investigating the role of the specific intervention modules as interacting treatment mechanisms. As although each participant's intervention was based upon the same formulation model, it was delivered based upon the principle of flexibility within fidelity (Kendall *et al.*, 2008) and the small number of participants included in this present study meant that there was a relatively small overlap in each participant's personalised intervention plan (Fig. S1 in Supplementary material). However, we would consider the ability to personalise the intervention a strength of the approach.

Finally, the participant with the poorest response had a co–morbid chronic health condition, despite evidence that CBT interventions can be efficacious for this group of young people (Moore *et al.*, 2019). When considering the proposed mechanisms of action for effective loneliness interventions (Pearce *et al.*, 2021), we hypothesise that social strategies, including finding shared understanding with peers, may be an important mechanism for this client group. This study took place within the context of COVID-19 when opportunities to engage with peer support groups were limited. Future research should therefore investigate whether incorporating peer support results in improved outcomes for young people with chronic health problems.

Summary

The results of this study provide preliminary evidence of efficacy for CBT for Chronic Loneliness in Young People. Reductions in both self and parent-reported anxiety, depression and impact scores were also found at post-intervention. The participants included in this study presented with complex difficulties, including several characteristics typically associated with a poorer treatment response, including autism, co–morbid depression and high levels of anxiety (O'Neil and Kendall, 2012; Wang *et al.*, 2021; Wergeland *et al.*, 2016). This indicates that the intervention may have significant applications for real-world clinical practice. The intervention and research protocol were also both acceptable and feasible and the intervention should now be evaluated within an adequately powered RCT. Future research could also consider diverse applications of the intervention, including internet-based individual and group treatments.

Data availability statement. The data that support the findings of this study are available on request from the corresponding author, T.C. The data are not publicly available in order to maintain confidentiality due to the small number of participants. All participants consented to publication.

Competing interests. The authors declare none.

Ethical standard. The authors have abided by the Ethical Principles of Psychologists and Code of Conduct as set out by the BABCP and BPS. The study received ethical approval from Royal Holloway, University of London on 22 March 2021 (ethical approval number: 2489). All participants provided informed consent.

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