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Enhancing emotion regulation with an in-situ socially assistive robot among LGBTQ+ youth with self-harm ideation: Protocol for a randomised controlled trial

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Complete List of Authors:	Williams, A. Jess; King's College London, Informatics; University of Nottingham, Institute of Mental Health Borschmann, Rohan; Murdoch Childrens Research Institute; University of Oxford Tench, Christopher; University of Nottingham, Division of Clinical Neuroscience Cleare, Seonaid; University of Glasgow Gross, James; Stanford University Hollis, Chris; University of Nottingham, Division of Psychiatry Chapman-Nisar, Amelia; University of Nottingham Naeche, Nkem; University of Nottingham Townsend, Ellen; University of Nottingham, School of Psychology Slovak, Petr; King's College London; University of Oxford
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Enhancing emotion regulation with an in-situ socially assistive robot among LGBTQ+ youth with self-harm ideation: Protocol for a randomised controlled trial

A. Jess Williams*, Rohan Borschmann, Christopher Tench, Seonaid Cleare, James J Gross, Chris Hollis, Amelia Chapman-Nisar, Nkem Naeche, Ellen Townsend, Petr Slovak

*Corresponding author: amy_jess.williams@kcl.ac.uk

Informatics,

Bush House

Strand Campus

King's College London

Abstract:

Introduction: Purrble, a socially assistive robot, was co-designed with children to support in-situ emotion regulation. Preliminary evidence has found that LGBTQ+ youth are receptive to Purrble and find it to be an acceptable intervention to assist with emotion dysregulation and their experiences of self-harm. The present study is designed to evaluate the impact of access to Purrble among LGBTQ+ youth who have self-harmful thoughts, when compared to waitlist controls.

Methods and analysis: The study is a single-blind, randomised control trial comparing access to the Purrble device with waitlist control. A total of 168 LGBTQ+ youth aged 16-25 years with current self-harmful ideation will be recruited, all based within the UK.

The primary outcome is emotion dysregulation (Difficulties with Emotion Regulation Scale-8) measured weekly across a 13-week period, including 3 pre-deployment timepoints. Secondary outcomes include self-harm (Self-Harm Questionnaire), anxiety (Generalised Anxiety Disorder-7), and depression (Patient Health Questionnaire-9). We will conduct analyses using linear mixed models to assess primary and secondary hypotheses.

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4 After the study has ended, a subset of participants will be invited to participate in semi-
5 structured interviews to explore engagement and appropriation of Purrble, considering the
6 young people's own views of Purrble as an intervention device.
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10 **Ethics and dissemination:** Ethical approval was received from King's College London
11 (RESCM-22/23-34570). Findings will be disseminated in peer review open-access journals
12 and at academic conferences.
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16 **Trial registration number:** Clinical trial gov: NCT06025942
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19 Strengths and limitations of this study

- 20
21 - This is the first randomised controlled trial to explore the impact of access of Purrble,
22 a socially assistive robot, compared to waitlist control on emotion regulation
23 difficulties within LGBTQ+ youth who have current experiences of self-harmful
24 ideation.
- 25
26 - Purrble was co-designed with youth to support emotion regulation in-situ.
- 27
28 - The study was co-designed with young people who have experience of mental health
29 difficulties (Sprouting Minds), including a detailed safeguarding procedure.
- 30
31 - Participants will not be blinded to participant group due to the nature of the
32 intervention.

33 Introduction

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36 Self-harm, defined as the intentional poisoning or injury of self, irrespective of intention [1], is
37 a key health concern among sexual orientation and/or gender identity minorities, LGBTQ+
38 populations [2]. Internationally, young LGBTQ+ people report higher prevalence of self-
39 harmful thoughts and behaviours, anxiety, depression, and substance misuse when
40 compared to their cisgender, heterosexual peers [3-8] It is well documented that those with a
41 history of self-harm are at greater risk of suicide [9], and recent evidence indicates that
42 LGBTQ+ youth are 3-6 times more likely attempt suicide than their cisgender, heterosexual
43 counterparts [10-11]. Despite the considerable risk of self-harm and associated adverse
44 outcomes [12-13], there is a lack of evidence-based interventions to support LGBTQ+ youth
45 struggling with self-harmful thoughts and behaviours.
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56 Youth who self-harm often do not seek professional help [14-15], and those that do find
57 services (e.g., Child and Adolescent Mental Health Services, Accident and Emergency or
58 social services) to be less helpful sources of support [16] or rarely re-attend services [17].
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4 Factors relating to this can include negative attitudes and behaviours/treatment from health
5 care staff (e.g., withdrawing pain-reducing medication for wound treatment [18]), concerns
6 about confidentiality [19], or perceived stigma surrounding self-harm [20-21]. Among
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8 LGBTQ+ people, help-seeking is even more complex, with one in seven avoiding services
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10 due to fears of discrimination on the basis of their sexual orientation or gender identity [22].
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12 Therefore, community-based interventions may be more appropriate to support LGBTQ+
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14 youth engaging in self-harm.
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18 As LGBTQ+ youth are frequent users of digital technologies [23-26], there is an opportunity
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20 for digital interventions to support those struggling with self-harm and other mental health
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22 difficulties. Evidence suggests that digital interventions support youth to bypass various
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24 barriers to help-seeking, such as lack of accessibility, anticipated stigma, inadequate
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26 resources, and the desire to be self-reliant [27], which are compounded by unique
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28 challenges facing LGBTQ+ youth (e.g. concerns about experiencing stigma or discrimination
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30 as a minority [28]).
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33 At present, the field concerning digital interventions among LGBTQ+ youth is small, yet
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35 those available are perceived as feasible, acceptable, and relatively effective [29]. However,
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37 most focus on physical health such as risk reduction or management of sexually transmitted
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39 illnesses (STIs; [29]), with few concerning mental wellbeing [30-33]. These mental health
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41 interventions are typically perceived positively by LGBTQ+ youth [30, 32-34], with mixed
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43 findings reported by the three considering the impact of the intervention on participants at
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45 this stage; 1) Rainbow SPARX [32]; 2) an online writing intervention [31]; and 3) QueerViBE
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47 [30]. In their pilot trial, Rainbow SPARX (a didactic PC game using Cognitive Behaviour
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49 Therapy principles) was associated with large reduction for depressive ($d=1.01$) and anxious
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51 ($d=0.95$) symptoms [32]. Whereas, QueerViBE (a series of brief, interactive videos designed
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53 for transgender and gender diverse youth) found a moderate decrease in psychological
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55 distress ($d=0.63$) when compared to the control group [30]. However, the expressive writing
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57 intervention demonstrated no difference in depressive symptoms in their randomised
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59 controlled trial [31]. Therefore, while limited, digital interventions are feasible, acceptable and
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potentially effective for improving mental health among LGBTQ+ youth. However, there are

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3 currently no evidence-based digital interventions targeting LGBTQ+ youth who struggle with
4 self-harm.
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9 Whilst self-harm among LGBTQ+ youth can be associated with multiple risks, complex
10 experiences, and unique stressors [35-37], a common issue is often emotional dysregulation
11 [38-41]. Emotion regulation (ER) is a well-known transdiagnostic risk factor [42-44], which
12 can be associated with higher risk of self-harm across ages, settings, and genders [45-46].
13 Typically, LGBTQ+ populations report greater difficulties with ER [40-41], which explains in
14 part the association between LGBTQ+ identity and self-harm [40-41]. Examining how ER
15 can be better supported in young LGBTQ+ people who self-harm through digital intervention
16 may be a helpful preventative strategy to aid LGBTQ+ youth broadly.
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25 To address this, a pilot study was conducted with LGBTQ+ youth who had recent
26 experiences of self-harmful thoughts and/or behaviours using an in-situ, emotion regulation
27 intervention tool, Purrble [47], designed to provide in-the-moment support see Intervention
28 section for further details. Purrble was originally developed for children in moments of
29 situated distress, but has been well-accepted across child and student populations delivering
30 notable benefits for emotion regulation [47-50]. Among a small sample of 21 LGBTQ+ young
31 people, Purrble was found to be a feasible and acceptable intervention with continued device
32 engagement across a 2-week deployment [47]. Notably, access to Purrble was also
33 associated with a reduction in anxiety symptoms and self-harmful thoughts. Qualitative data
34 indicated that this was linked to Purrble supporting ER practices (e.g., grounding, soothing)
35 to prevent young people acting on their self-harmful urges and, in some cases, preventing
36 them from considering self-harm at all [47]. Based on these findings, and Purrble's original
37 design to support in-situ, bottom-up ER [48-49], it appears that mental health outcomes such
38 as anxiety and self-harm [47, 50] are guided by the proximal change in emotion regulation.
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53 Although these early data are promising, there is a lack of robust quantitative data on the
54 impact of the intervention in a wider sample of LGBTQ+ young people who have self-
55 harmed. Evidence is therefore urgently needed to evaluate the efficacy of Purrble in a)
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delivering measurable changes in ER when compared to a control group, and b) the extent to which this impacts the frequency of self-harmful thoughts and/or anxiety symptoms.

Study objectives

Primary Objective: The primary objective of this study is to evaluate the impact of having access to the Purrble intervention, compared with a waitlist control, on emotion regulation difficulties (DERS8) among LGBTQ+ young people with self-harmful thoughts.

Secondary Objectives: The secondary objectives are i) to investigate the impact of having access to Purrble on changes to LGBTQ+ young people's self-harmful thoughts over the trial period, in comparison to a waitlist control group; and ii) to investigate the impact of Purrble on changes in symptoms of anxiety (GAD-7), and symptoms of depression (PHQ-9) over the trial period, in comparison to waitlist controls. Finally, this will be the first opportunity to assess whether Purrble remains appealing and helpful to LGBTQ+ youth over an extended period.

Methods

Trial design

The study is a 2-arm randomised controlled trial comparing an intervention group (Purrble) with a waitlist control group. The trial period is across 13 weeks, built of 3 pre-deployment assessments and 10 deployment assessments, using weekly, self-reported, validated surveys (see table 1). The intervention period will commence once Purrble has been deployed to the intervention group, week 4 (T1). After the deployment period, the intervention participants will be able to keep their Purrble devices, and the waitlist control participants will be sent Purrble devices.

Table 1: Overview of assessment design for both participant groups

Surveys	Pre-deployment (week 1-3)	Deployment (week 4-13)	Follow-up (week 13+)
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	T(-2)	T(-1)	T(0)	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10
Register interest + screening	X												
Consent	x												
Main assessment	x	x		x	x	x	x		x	x	x	x	
Extended assessment			x					x					x
Qualitative interviews													x

Analyses will be conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT; [51]), with consideration given to the recommendation of psychological interventions [52]. Outcomes will be assessed 13 times across a 13-week period, including 3 baseline assessments and 10 weeks of deployment, with Purrble being delivered in time for week 4 (T1).

Intervention

The intervention takes the form of an interactive plush toy (figure 1), which was co-designed with children to support in-the-moment soothing [48-49]. The device is framed as an anxious creature, in need of care and attention when it feels distressed. This distress is indicated by a simulated heartbeat using embedded electronics to produce vibration patterns of i) frantic and anxious, to ii) slow, steady and relaxed. When held, the device emits a frantic heartbeat which can be slowed by stroking movements registered by embedded sensors. Once the device has been “soothed” for long enough, the heartbeat transitions into a purring vibration, indicating a relaxed state. This transition can be achieved in less than 60 seconds but is

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3 dependent on the device-human interaction. Further details on the logic model underlying
4 Purrble can be found in **supplementary materials 1**, or see previous research [49].
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29 *Figure 1: Purrble companion device*
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31 32 33 **Waitlist - Control**

34 The participants in the control group will be on a waitlist throughout the 13-week trial period.
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36 Once data have been collected at the final timepoint (week 13, T10), waitlist participants will
37 receive a Purrble to keep. Waitlist control group was selected following discussions with
38 Sprouting Minds members (see Patient and Public Involvement).
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44 **Participants**

45 **Eligibility Criteria**

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47 When potential participants register their interest for the study, they will be asked
48 demographic questions relating to the eligibility criteria, providing our information for our
49 inclusion criteria. These are: i) being between the ages of 16-25 years (inclusive); ii)
50 identifying as any part of the LGBTQ+ umbrella, iii) having current experiences of self-
51 harmful thoughts (e.g. in the last month), iv) being able to read, write, and speak English,
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60 and v) living in the UK for the duration of the study. Exclusion criteria are being outside of the

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3 age range, identifying as heterosexual cisgender, not experiencing current self-harmful
4 thoughts, being unable to understand English and living outside the UK.
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Recruitment, Randomisation, and Blinding

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11 LGBTQ+ youth will be recruited to the trial by several strategies. These include: i)
12 approaching secondary schools and colleges, ii) social media adverts, iii) advertising through
13 stakeholder charities and organisations (e.g., Bounce Black, Harmless, King's College
14 London newsletter), and iv) online platforms (e.g., MQ Participate). Those organisations
15 which involve gatekeepers (e.g., schools, colleges, charities, organisations) will be emailed
16 by one of the leading researchers offering an introductory meeting to discuss the outline of
17 study, explaining safeguarding protocols, and how to share this information with young
18 people. Young LGBTQ+ people will then be able to register their interest in the study,
19 anonymously from gatekeepers. At recruitment, participants will not be blinded to the fact
20 that Purrble was designed to support ER. The information sheet specifies that participants
21 will be asked about mood, self-harm, and ER over the course of the study.
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34 Once eligibility is confirmed and young LGBTQ+ people have provided written informed
35 consent, they will be 1:1 randomly assigned to either intervention or waitlist control group,
36 using a computerised algorithm. A stratification procedure will be applied to balance gender
37 identity (transgender and gender diverse youth vs. cisgender) across the two arms. The
38 researcher conducting randomisation will be blind to treatment group allocation. However,
39 the leading researcher and other team members who will be conducting safeguarding will be
40 aware of group allocation. Researchers collecting outcome measures will be blinded to
41 group allocation. Participants will be informed about their assigned condition. The
42 intervention group will receive Purrble devices before T1 data are collected, with waitlist
43 participants receiving their Purrble devices after the 3-month follow-up data collection.
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54 In the event of change of circumstance, such as a serious adverse event, participants are
55 asked to inform the research team. Specifically, for follow-up engagements a standard
56 operation protocol which asks that if a situation changes for a young person (e.g., they are
57 hospitalised) that the young person informs the research team. This will be directly asked
58 ("Has your situation changed at all which might impact how you'd like to engage with the
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3 study?" via email, with the understanding that the research team will have time to arrange
4 reasonable adjustments (e.g., if a young person still wants to take part but is within an in-
5 patient service).
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8 Power Analysis 9

10 Sample size was determined based on an a-priori power analysis to detect a difference
11 between the two arms when considering the primary outcome measure, the Difficulties with
12 Emotion Regulation Scale-8 (DERS8). On the basis of a pilot with LGBTQ+ youth [47] and
13 other Purrble studies [50, 53], we expect to see a medium effect size for this measure
14 (d=0.4). This would indicate fewer difficulties with ER among young people who had access
15 to Purrble.
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23 With the anticipated medium effect size, simulations were performed involving a range of
24 fixed and random effects. Simulations involved linearly increasing effect over the study
25 period, and sensitivity analysis was performed over a range of scenarios considering the
26 slope of effect change over time was either fixed or random. The simulation used a one
27 sided t-test ($\alpha=0.05$), and targeted a sample size giving at least 80% power. The statistic to
28 be compared between groups is the change in mean DERS8 score in the 2 weeks preceding
29 intervention (3 assessments in total), to the mean DERS8 assessed at weeks 8, 9, and 10.
30 The averaging over 3 assessments is intended to reduce the known variance in DERS8
31 when repeatedly assessed [54]. Other simulations considered only comparing the change in
32 DERS8 from baseline (week 0) to week 10, comparing the slope of the effect, assessed
33 using simple linear regression. All simulations suggested better than 60% power with 70
34 subjects per arm, with the mean change in DERS8 averaged over 3 assessments, and the
35 comparison of slopes, suggesting >80% power. The sample size of 140 is inflated by 20% to
36 account for dropout rate [55], rounding up the total sample to 168.
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51 Outcome Measures 52

53 An overview of all measures can be found in Table 2, and full details can be found in
54 **supplementary material 2**. Primary and mental health measures will be asked at all
55 timepoints, with the Purrble intervention group also receiving two additional engagement
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measures throughout deployment. An extended survey will replace the weekly survey at three time points, this will include three additional measures to be asked to all participants.

These additional measures were selected to explore the association between self-harm and emotion regulation (Process Model Emotion Regulation Questionnaire - PMERQ) [38-41], perceptions of hope (State Hope Scale - SHS) [13], and loneliness (3-item UCLA loneliness scale) [56], to further explore the qualitative findings represented in our pilot study (Williams et al., in prep). Our findings have previously indicated that Purrble was used to i) refocus or distract attention during moments of distress by addressing the physical manifestation of their discomfort (PMERQ), and ii) comfort in moments of loneliness and provide self-soothing mechanisms (UCLA, SHS) [47].

Considering participant burden, young people will be informed of the time to complete each weekly survey (15 minutes), the extended survey (22 minutes) and will be compensated for their time.

Table 2: Summary of the outcome measures

Outcome Measure	Questions (n)	Type of outcome	Frequency	Scoring	Details of assessment
<i>Primary measure</i>					
Difficulties in emotion regulation scale-8 DERS8; [54]	8	Primary outcome	All timepoints	8-40 (higher = more difficulties)	Difficulties associated with response to situations eliciting negative emotions.

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<i>Mental health measures</i>					
Self-Harm Questionnaire screening questions SHQ; [57]	3	Mental health	All timepoints	Analysed separately	Frequency and risk of self-harm thoughts, suicidal ideation, and behaviour.
Self-Harm Questionnaire additional items SHQ; [57]	22	Covariate	Once (baseline)	Analysed separately	4 dimensions of self-harm (NSSI, suicide attempts, suicide threats, suicide ideation).
Generalised Anxiety Disorder questionnaire GAD-7; [58]	7	Mental health	All timepoints	0-21 (higher = greater severity)	Presence and severity of generalized anxiety disorder
Patient Health Questionnaire PHQ-9; [59]	9	Mental health	All timepoints	0-27 (higher = greater severity)	Severity of depressive symptoms
<i>Proximal & mechanistic measures</i>					

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Process Model of Emotion Regulation Questionnaire PMERQ; [60]	9	Mechanistic	3 timepoints	2 subscales Average across each subscale, with higher scores indicating greater endorsement.	Attentional deployment subscales are selected; engagement and disengagement focus.
22 23 24 25 26 27 28 29 30	State Hope Scale SHS; [61]	6	Proximal	3 timepoints	6-48 (higher = greater state hopefulness)	Ongoing goal-directed thinking; agency and pathways.
31 32 33 34 35 36 37 38 39 40 41 42	The 3-item UCLA Loneliness scale for children [62]	3	Proximal	3 timepoints	3-12 (higher = more loneliness)	Subjective feelings of loneliness.
43 44 45 46	<i>Engagement measures</i>					
47 48 49 50 51 52 53 54 55 56 57 58 59 60	Bespoke Purrble questions [53]	7	Engagement	Deployment	Analysed separately	Purrble use and perceived usefulness.

Twente Engagement With eHealth Technologies Scale TWEETS; [63]	9	Engagement	Deployment	3 subscales Total score per subscale = greater engagement	Engagement with intervention device, considering behaviour, cognitive, and affective engagements.
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Post deployment Interviews

We will collect semi-structured interview data from LGBTQ+ young people from up to 40% of the intervention group (n=37), and approximately 20% of the control group (n=17). The interviews will be conducted following the deployment period. We will specifically aim to recruit young people who demonstrated the highest and lowest changes in the outcome data over the trial to explore and understand the potential moderators relating to the intervention and mental health across the trial period.

The semi-structured interview will explore the engagement and appropriation of the Purrble device, whether LGBTQ+ young people had felt that this had helped them with their ER, mental health more broadly, or self-harmful thoughts, and how Purrble may (or may not) be suitable for other audiences. We will compare these experiences between intervention and control participants, exploring other mechanisms used by LGBTQ+ youth who experience self-harm.

Hypotheses

Primary hypothesis

Across the trial, we hypothesise that access to the Purrble intervention (compared to the waitlist control) will lead to a direct decrease in self-reported difficulties with emotion

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3 regulation as measured by the primary outcome (DERS8), averaged between three pre-
4 deployment (weeks 1-3) and our final three deployment assessments (weeks 11-13).
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10 **Secondary hypothesis**

11 Intervention effects will be moderated by engagement with the device, measured by bespoke
12 questions and the TWEETS questionnaire. Secondary outcomes in the Purrble effectiveness
13 trial are: self-harmful thoughts, symptoms of anxiety, and symptoms of depression. These
14 three constructs were selected as secondary outcomes based on the high prevalence of
15 these experiences among LGBTQ+ youth [3-8] and their association with poor ER [38-41].
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21 The three secondary hypotheses are as listed when compared to waitlist controls:
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- 23 1. Engagement with the Purrble intervention will reduce the frequency of self-reported
24 self-harmful thoughts (SHQ).
- 25 2. Engagement with the Purrble intervention will reduce the severity of self-reported
26 anxiety symptoms (GAD-7).
- 27 3. Engagement with the Purrble intervention will reduce the severity of self-reported
28 depression symptoms (PHQ-9).
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34 **Additional analyses**

35 Additional hypotheses aim to understand the impact of Purrble on relevant proximal and
36 mechanistic outcomes. The following hypotheses will be investigated across the trial:
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- 40 1. Greater within-group changes will be seen among intervention group participants, with
41 increasing levels of endorsement for attentional deployment (PMERQ), than among
42 those participants of the control group.
- 43 2. There will be a greater increase in state hopefulness (SHS) in the Purrble intervention
44 group than the waitlist control.
- 45 3. Participants in the Purrble intervention group will report lower loneliness (UCLA) than
46 those in the waitlist control group.
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Statistical analyses

Testing the hypothesis that access to the Purrble intervention will lead to a reduction in emotion dysregulation, as measured by the composite primary outcome, will be done using a one-sided t-test.

As exploratory analyses linear mixed models will be fitted to gain insight into how emotion dysregulation is altered with access to the intervention. In particular, we will regress the weekly outcome score on an indicator for the Purrble condition, a linear time trend, and an interaction between the treatment indicator and time to examine differential trends in the two groups. We will adjust for baseline covariates and include participant-level random intercepts and slopes to account for persistent baseline differences between young people as well as person-specific time trends in the outcome. While the outcome is limited to DERS8 scores ranging from 8-40, we will model it as continuous data.

For secondary aims, we will use analogous linear mixed models to assess the impact of Purrble on relevant outcomes (cf., hypotheses above), adding baseline DERS8 as another covariate. We will not adjust for multiple comparisons, as these are exploratory aims meant to be hypothesis-generating. Similarly, we will also assess the impact of access to Purrble on changes in proximal outcomes, as well as explore whether these appear to moderate changes on primary and secondary outcomes.

Patient and Public Involvement

The study design was discussed with, and approved by, Sprouting Minds members (MRC Digital Youth Young Person Advisory group), with specific input considering the intervention arms and safeguarding procedures. These young people highlighted that “waitlist control” conditions mimic clinical experiences of waiting for services, therefore this was considered an acceptable and realistic control. Whereas safeguarding procedures needed to balance participant autonomy and ensuring safe research.

Ethics and dissemination

The study will be conducted according to local regulations and the Declaration of Helsinki of 1975, revised in 2008. The Ethical Committee at King's College London, UK approved the study (RESCM-22/23-34570). Written consent will be obtained from all participants prior to commencing their involvement in the study, with explicit understanding of the study and safeguarding procedures (see supplementary materials 3) being obtained during study briefing sessions. The trial is registered with ClinicalTrials.gov (NCT06025942).

We aim for our findings to be disseminated across academic fields (human-computer interactions, psychology, implementation sciences), alongside showcasing the findings to LGBTQ+ youth, community groups, and wider stakeholders. This will be achieved through presentations at national and international conferences, peer-reviewed journal publications, community outreach and PPI events. During dissemination, we will be liaising with youth populations to establish next steps for this research, considering additional co-design of materials to sit around/alongside Purrrble.

Discussion

Despite the high prevalence of self-harm among LGBTQ+ young people [10, 37], there is little/no evidence for interventions which support the reduction of self-harm through situated skill application of ER. This low-cost intervention has the potential to reduce difficulties associated with emotion regulation, and therefore offer an opportunity to improve youth's self-harm, as well as other associated mental health difficulties. If successful, the study will provide a proof-of-concept example of a bottom-up emotion regulation intervention, enabling young people to access ongoing support for their distress through an engaging digital resource.

Previous research with severely anxious students has indicated that Purrrble was associated with reductions of anxious symptoms, qualitatively explained by the adoption of ER strategies [50]. These findings were translated in our pilot study of Purrrble within the LGBTQ+ population [47]. Therefore, it is hypothesised that in this study, engagement with Purrrble will be associated with reduced anxiety and increased ER across the trial.

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3 Effective ER, such as utilising adaptive strategies (e.g., cognitive appraisal), can be seen as
4 a protective factor in self-harm and suicide research [64]. If Purrble can support reduction of
5 self-harmful thoughts in young LGBTQ+ people through enhanced ER, then this is
6
7 potentially a tangible, highly modular and scalable device which can be used to prevent the
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9 transition between motivational and volitional experiences [65].
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35 AJW, ET, PS conceived the study. AJW and PS designed the study, with statistical expertise
36 from CT and patient and public input from NN and ACN. AJW designed the study materials,
37 which were reviewed with feedback between NN, ACN, and SC. AJW obtained ethical
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Competing interests statement

PS has been involved in the development of what is now Purrble as part of his postdoctoral fellowship; and serves as a paid research adviser to the Committee for Children but has no financial stake in either CfC (Purrble brand owners) or Sproutel (company manufacturing Purrbles). Neither Committee for Children nor Sproutel had access to the data or had been part of the data collection in any way, nor did they approve or see the publication before it was submitted. There were no conflicting interests among the remaining research team.

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Purble: Intervention device

352x349mm (72 x 72 DPI)

Purrble logic model

Purrble operates on 3 levels:

1. Purrble directly provides in-the-moment soothing support in naturally occurring emotional moments when one would attempt to calm down. The physical and interactive design aims to tap into known regulatory factors using the extended Process Model of Emotion Regulation (Gross, 2015). This focuses on two separate stages of the ER process; i) the attentional deployment stage (Aldao et al., 2015; Sheppes & Gross, 2012; Sheppes et al., 2014; Farb et al., 2014) by shifting attention from the emotional situation towards interacting with the device, and ii) the response modulation stage (Beetz et al., 2012; Dore et al., 2017; Reeck et al., 2016; Coan et al., 2006; Crossman et al., 2018; Rabbit et al., 2015) by facilitating down-regulation through pleasant tactical interactions simulating the emotion regulatory effect of human-animal interactions.
2. Mechanisms of Purrble are designed to facilitate long-term engagement, by building on positive subjective experiences of in-the-moment soothing. As the device is framed as an anxious creature needing to be cared for, the key driver is that interactions are framed as helping regulate others' emotions (Dore et al., 2017; Cosley et al., 2010; Taylor, 2011), alongside facilitating a sense of relationship and responsibility for the well-being of the creature (Turkle, 2007; Hayashi & Kato, 2016; Donath, 2004; Lee et al., 2010).
3. Through repeated, soothing, and positive interactions with Purrble over time, it is anticipated that there will be a shift in ER practices and implicit beliefs about emotions (Ford & Gross, 2018), specifically the controllability of one's emotions (Schleider & Weisz, 2016).

Full Measurement Details

Primary Outcome Measure

The primary outcome measure in this study is the Difficulties with Emotion Regulation Scale-8 (DERS8) [54]. This will be given to participants as part of the main assessment at all time-points. The DERS8 contains 8 items which represent affect, thoughts, and actions in response to situations which elicit negative emotions. A single total score is calculated from all items, with higher scores indicating more difficulties with emotion.

Mental Health Measures

Self-harmful thoughts and behaviours will be assessed using the Self-Harm Questionnaire (SHQ) [57]. At baseline, those who indicate experiences of self-harm behaviour will be invited to complete the second section about historical self-harm behaviour. At all other timepoints, only the three screening questions will be presented; these query the frequency of self-harmful thoughts, suicidal ideation, and self-harmful behaviour. The items are scored individually from “no thoughts/behaviour” to “yes, five or more times”. The wording for these items will be adapted from “have you ever...” to “in the last week/month” (depending on assessment point).

Anxiety symptoms will be assessed using the Generalised Anxiety Disorder-7 (GAD-7) [58]. This is a seven-item instrument, used to identify or assess the severity of generalised anxiety disorder. Each item asks the individual to rate the severity of their symptoms over the time period. The total score is calculated by summing all items and ranges from 0-21. Higher scores indicate more severe levels of anxiety symptoms. The wording for these items will be adapted from “over the last two weeks” to “in the last week/month” (depending on assessment point).

Depressive symptoms will be assessed using the Patient Health Questionnaire-9 (PHQ9) [59]. Across nine items, this instrument measures the severity of depressive symptoms, the total score being calculated by summing all items with responses ranging from 0-27. Higher scores indicate greater depressive severity. Again, the wording for these items will be adapted from “over the last two weeks” to “in the last week/month” (depending on assessment point).

Proximal & Mechanistic Measures

All proximal and mechanistic measures will only be asked at three timepoints (T0, T5, T10), this is to reduce participant burden and encourage engagement, while also obtaining exploratory data to understand the impact of access to Purrble in greater detail. All additional measures total to 18 extra items, adding ~7 minutes to the assessment.

The Process Model of Emotion Regulation Questionnaire [60] is a 45-item measure which considers 10 ER strategies across the five stages of the Process Model of ER, and particularly how these strategies are used to decrease negative emotions. We will include 2 subscales focusing on attention deployment (focusing elsewhere (4 items) and cognitive distraction (5 items)). Each subscale is scored by taking the average of item-level responses.

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Hopefulness will be assessed using the State Hope Scale [61]. This is a six-item instrument concerning ongoing goal-directed thinking (agency and pathways). The total score (6-48) is calculated by summing responses, with higher scores relating to greater state hopefulness.

Loneliness is assessed using the 3-item UCLA loneliness scale for children [62] to consider participants' subjective loneliness. Items are summed to create a total score (3-12), whereby higher results indicate greater loneliness.

Engagement Measures

Engagement with Purrble will be assessed using two measures; a bespoke survey [53] and an adapted version of Twente Engagement with eHealth Technologies Scale (TWEETS) [63]. These will be deployed as part of the main assessment for participants allocated to the intervention group.

The bespoke survey [53] enquires about Purrble use and perceived usefulness over four items. These are analysed separately, with qualitative responses indicating contexts or situations where Purrble has been found helpful or unhelpful.

TWEETS [63] quantitatively measures intervention engagement across nine items. This is split into subsections considering behaviour, cognitive, and affective engagement. Total scores range from 0-36, with higher scores indicating greater engagement.

Safeguarding Procedures

The safeguarding procedures will be presented to potential participants in the information sheet before they consent to the study. These were codesigned and agreed with Sprouting Minds, based on previous studies conducted with young people with self-harmful experiences (Williams et al., 2021; Williams et al., 2022; Williams et al., in prep; Townsend et al., 2016). To support young people's safety during the study, the following measures will be instituted:

1. Before starting the study, all participants are required to attend an individual study briefing. At this point, they are taken through the study outline, invited to ask questions, and asked to create a safety plan (Brown & Stanley, 2012) with the support of a specially trained researcher. Safety planning is quick to complete, is tangible to participants and has been shown to be effective at reducing self-harmful thoughts and behaviours (Nuiji et al., 2021). Participants keep this safety plan containing their individualised strategies for their personal use beyond the life of the study. During the wellbeing check, participants are asked to reflect on their safety plan if they feel distressed at any other point during the study. This follows safety protocols used in other studies by the researcher (Williams et al., 2021; Williams et al., 2022, pilot studies).
2. During the briefing, participants will need to nominate a support contact (parent, friend over 18 years, GP, etc), with the understanding that if they do not respond to reactive safeguarding (which can be triggered for each of the main assessments), this person will be contacted to ensure that the participant is safe.
 - a. This nominated person will be contacted (via email) to inform them that the participant is taking part in a mental health study and that we will reach out if we are unable to contact the participant following indication that they are at increased risk.
3. All assessments will include signposting to additional supports (e.g., Young Minds, Samaritans, Papyrus) as well as encouraging participants to seek help from their GP if they are distressed.
4. All assessments will include a visual scale to rate mood pre- and post- completing the survey (1 - very distressed - 10 extremely happy). This is to examine whether the assessment process has an impact, positively or negatively, on the participant. Such assessments have been successfully used in prior self-harm research by the research team members as an indicator of assessment impact (Townsend et al., 2016; Williams et al., 2021).
5. Participants in need of support will be identified by checking their responses to the main battery of assessments, within 24 hours. If participants respond that they have had experiences of self-harmful or suicidal thoughts and self-harm behaviour, as well as showing a that the assessment has had a negative impact, they receive a wellbeing call the following day between 1pm-4pm. This allows enough time for the researcher to identify participant risk and inform the PI.
 - a. If the participant does not pick up the phone, they will be contacted via email, asking about their wellbeing, whether they wish to continue with the study, and to arrange a time convenient to complete a wellbeing check. During the wellbeing check, the researcher will be empathic to the difficulties of the participant. The participant will be asked whether they wish to continue the study and, if so, they will update their safety plan with the researcher. If participants do not wish to continue the study, they will be allowed to withdraw with no consequences. They will be invited to interview to discuss their

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3 thoughts, opinions and experiences of the study. This would also ask about why they
4 withdrew from the study.

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6 b. If a participant still does not respond to the email, the same procedure will be attempted
7 twice more. If there is still no contact from the participant by day 4, their support contact
8 (nominated during briefing) will be contacted.

9
10 Alongside this, all researchers who undertake briefing (including safety planning) and wellbeing calls will
11 be invited to take part in group supervision sessions once a week during data collection with leading
12 authors. This will be a confidential, safe space to discuss researchers' wellbeing and mental health, with
13 support for any difficulties which may surface.
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Enhancing emotion regulation with an in-situ socially assistive robot among LGBTQ+ youth with self-harm ideation: Protocol for a randomised controlled trial

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Manuscripts

Enhancing emotion regulation with an in-situ socially assistive robot among LGBTQ+ youth with self-harm ideation: Protocol for a randomised controlled trial

A. Jess Williams, Seonaid Cleare*, Rohan Borschmann, Christopher Tench, James J Gross, Chris Hollis, Amelia Chapman-Nisar, Nkem Naeche, Ellen Townsend, Petr Slovak, on behalf of Digital Youth

*Corresponding author: seonaid.cleare@glasgow.ac.uk

Informatics,
Bush House
Strand Campus
King's College London

Abstract:

Introduction: Purrble, a socially assistive robot, was co-designed with children to support in-situ emotion regulation. Preliminary evidence has found that LGBTQ+ youth are receptive to Purrble and find it to be an acceptable intervention to assist with emotion dysregulation and their experiences of self-harm. The present study is designed to evaluate the impact of access to Purrble among LGBTQ+ youth who have self-harmful thoughts, when compared to waitlist controls.

Methods and analysis: The study is a single-blind, randomised control trial comparing access to the Purrble robot with waitlist control. A total of 168 LGBTQ+ youth aged 16-25 years with current self-harmful ideation will be recruited, all based within the UK.

The primary outcome is emotion dysregulation (Difficulties with Emotion Regulation Scale-8) measured weekly across a 13-week period, including 3 pre-deployment timepoints.

Secondary outcomes include self-harm (Self-Harm Questionnaire), anxiety (Generalised Anxiety Disorder-7), and depression (Patient Health Questionnaire-9). We will conduct analyses using linear mixed models to assess primary and secondary hypotheses.

Intervention participants will have unlimited access to Purrble over the deployment period, which can be used as much or as little as they like. After all assessments, control participants will receive their Purrble, with all participants keeping the robot after the end of the study.

36 After the study has ended, a subset of participants will be invited to participate in semi-
37 structured interviews to explore engagement and appropriation of Purrble, considering the
38 young people's own views of Purrble as an intervention device.

39
40 **Ethics and dissemination:** Ethical approval was received from King's College London
41 (RESCM-22/23-34570). Findings will be disseminated in peer review open-access journals
42 and at academic conferences.

43
44 **Trial registration number:** Clinical trial gov: NCT06025942

45 Strengths and limitations of this study

- 46 - This is the first randomised controlled trial to explore the impact of access of Purrble,
47 a socially assistive robot, compared to waitlist control on emotion regulation
48 difficulties within LGBTQ+ youth who have current experiences of self-harmful
49 ideation.
- 50 - Purrble was co-designed with youth to support emotion regulation in-situ.
- 51 - The study was co-designed with young people who have experience of mental health
52 difficulties (Sprouting Minds), including a detailed safeguarding procedure.
- 53 - Participants will not be blinded to participant group due to the nature of the
54 intervention.

55 Introduction

56 Self-harm, defined as the intentional poisoning or injury of self, irrespective of intention [1],
57 is a key health concern among sexual orientation and/or gender identity minorities, LGBTQ+
58 populations [2]. Internationally, young LGBTQ+ people report higher prevalence of self-
59 harmful thoughts and behaviours, anxiety, depression, and substance misuse when
60 compared to their cisgender, heterosexual peers [3-8]. It is well documented that those with
61 a history of self-harm are at greater risk of suicide [9], and recent evidence indicates that
62 LGBTQ+ youth are 3-6 times more likely attempt suicide than their cisgender, heterosexual
63 counterparts [10-11]. Despite the considerable risk of self-harm and associated adverse
64 outcomes [12-13], there is a lack of evidence-based interventions to support LGBTQ+ youth
65 struggling with self-harmful thoughts and behaviours.

66
67 Youth who self-harm often do not seek professional help [14-15], and those that do find
68 services (e.g., Child and Adolescent Mental Health Services, Accident and Emergency or
69 social services) to be less helpful sources of support [16] or rarely re-attend services [17].
70 Factors relating to this can include negative attitudes and behaviours/treatment from health
71 care staff (e.g., withdrawing pain-reducing medication for wound treatment [18]), concerns
72 about confidentiality [19], or perceived stigma surrounding self-harm [20-21]. Among
73 LGBTQ+ people, help-seeking is even more complex, with one in seven avoiding services due
74 to fears of discrimination on the basis of their sexual orientation or gender identity [22].

75 Therefore, community-based interventions may be more appropriate to support LGBTQ+
76 youth engaging in self-harm.

77
78 As LGBTQ+ youth are frequent users of digital technologies [23-26], there is an opportunity
79 for digital interventions to support those struggling with self-harm and other mental health
80 difficulties. Evidence suggests that digital interventions support youth to bypass various
81 barriers to help-seeking, such as lack of accessibility, anticipated stigma, inadequate
82 resources, and the desire to be self-reliant [27], which are compounded by unique challenges
83 facing LGBTQ+ youth (e.g., concerns about experiencing stigma or discrimination as a
84 minority [28]).

85
86 At present, the field concerning digital interventions among LGBTQ+ youth is small, yet
87 those available are perceived as feasible, acceptable, and relatively effective [29]. However,
88 most focus on physical health such as risk reduction or management of sexually transmitted
89 illnesses (STIs; [29]), with few concerning mental wellbeing [30-33]. These mental health
90 interventions are typically perceived positively by LGBTQ+ youth [30, 32-34], with mixed
91 findings reported by the three studies which considered the impact of the intervention on
92 participants; 1) Rainbow SPARX [32]; 2) an online writing intervention [31]; and 3) QueerViBE
93 [30]. In their pilot trial, Rainbow SPARX (a didactic PC game using Cognitive Behaviour
94 Therapy principles) was associated with large reduction for depressive ($d=1.01$) and anxious
95 ($d=0.95$) symptoms [32]. QueerViBE (a series of brief, interactive videos designed for
96 transgender and gender diverse youth) found a moderate decrease in psychological distress
97 ($d=0.63$) when compared to the control group [30]. However, the expressive writing
98 intervention demonstrated no difference in depressive symptoms in their randomised
99 controlled trial [31]. Therefore, while limited, digital interventions are feasible, acceptable,
100 and potentially effective for improving mental health among LGBTQ+ youth. However, there
101 are currently no evidence-based digital interventions targeting LGBTQ+ youth who struggle
102 with self-harm.

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104 Whilst self-harm among LGBTQ+ youth can be associated with multiple risks, complex
105 experiences, and unique stressors [35-37], a common issue is often emotional dysregulation
106 [38-41]. Experiencing difficulties with emotion regulation (ER) is a well-known transdiagnostic
107 risk factor [42-44], which can be associated with higher risk of self-harm across ages,
108 settings, and genders [45-46]. Typically, LGBTQ+ populations report greater difficulties with
109 ER [40-41], which explains in part the association between LGBTQ+ identity and self-harm
110 [40-41]. Examining how ER can be better supported in young LGBTQ+ people who self-harm
111 through digital intervention may be a helpful preventative strategy to aid LGBTQ+ youth
112 broadly.

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114 To address this, a pilot study was conducted with LGBTQ+ youth who had recent experiences
115 of self-harmful thoughts and/or behaviours using an in-situ, emotion regulation intervention

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3 116 device, Purrble [47], designed to provide in-the-moment support, see Intervention section
4 117 for further details. Purrble was originally developed for children in moments of situated
5 118 distress, but it has since been well-accepted across child and student populations delivering
6 119 notable benefits for emotion regulation [47-50]. Among a small sample of 21 LGBTQ+ young
7 120 people, Purrble was found to be a feasible and acceptable intervention with continued device
8 121 engagement across a 2-week deployment [47]. Notably, access to Purrble was also
9 122 associated with a reduction in anxiety symptoms and self-harmful thoughts. Qualitative data
10 123 indicated that this was linked to Purrble supporting ER practices (e.g., grounding, soothing)
11 124 to prevent young people acting on their self-harmful urges and, in some cases, preventing
12 125 them from considering self-harm at all [47]. This is the only study to date, which has explored
13 126 the impact of a socially assistive robot among LGBTQ+ youth, who are at-risk of self-harm
14 127 [47]. Based on these findings, and Purrble's original design to support in-situ, bottom-up ER
15 128 [48-49], it appears that mental health outcomes such as anxiety and self-harm [47, 50] are
16 129 guided by the proximal change in emotion regulation.
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24 131 Socially assistive robots (SARs) have previously been used to support children in education
25 132 [51], family [49] or health settings [52-53], as well as adults with health conditions such as
26 133 dementia or physical illnesses [54-55]. These studies have shown promising results in the
27 134 context of motivation, skill development and enhancement, as well as supporting mental
28 135 health outcomes, e.g., reducing loneliness and stress [49-55]. Similarly, students and at-risk
29 136 young people have described Purrble robots as a mechanism for comfort and distress relief
30 137 [47, 50]. However, an ethical challenge raised in SARs literature is the use of these device as a
31 138 replacement for humans, which could incur negative impacts considering social isolation
32 139 [56]. Therefore, research utilising SARs should be mindful of this, considering this influence in
33 140 process analysis, and have additional procedures to prevent overreliance on these devices.
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40 142 Although, early data relating to Purrble robots is promising [47], there is a lack of robust
41 143 quantitative data on the impact of the Purrble robot in a wider sample of LGBTQ+ young
42 144 people who have self-harmed. Evidence is therefore urgently needed to evaluate the efficacy
43 145 of Purrble in a) delivering measurable changes in ER when compared to a control group, and
44 146 b) the extent to which this impacts the frequency of self-harmful thoughts and/or anxiety
45 147 symptoms.
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49 148 Study objectives

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51 149 **Primary Objective:** The primary objective of this study is to evaluate the impact of having
52 150 access to the Purrble robot, compared with a waitlist control, on emotion regulation
53 151 difficulties (DERS8) among LGBTQ+ young people with self-harmful thoughts.
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56 152
57 153 **Secondary Objectives:** The secondary objectives are i) to investigate the impact of having
58 154 access to Purrble on changes to LGBTQ+ young people's self-harmful thoughts over the trial
59 155 period, in comparison to a waitlist control group; and ii) to investigate the impact of Purrble
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156 on changes in symptoms of anxiety (GAD-7), and symptoms of depression (PHQ-9) over the
 157 trial period, in comparison to waitlist controls. Finally, this will be the first opportunity to
 158 assess whether Purrble remains appealing and helpful to LGBTQ+ youth over an extended
 159 period.

160 Methods

161 Trial design

162 The study is a 2-arm randomised controlled trial comparing an intervention group (Purrble
 163 robot) with a waitlist control group. The trial period is across 13 weeks, built of 3 pre-
 164 deployment assessments and 10 deployment assessments, using weekly, self-reported,
 165 validated surveys hosted by Qualtrics (see table 1). The intervention period will commence
 166 once Purrble has been deployed to the intervention group, week 4 (T1).

167

168 **Table 1: Overview of assessment design for both participant groups**

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Surveys	Pre-deployment (week 1-3)			Deployment (week 4-13)			Follow-up (week 13+)
	T(- 2)	T(- 1)	T(0)	T1- T4	T5	T6- T9	T10
Register interest + screening	X						
Consent	x						
Main assessment	x	x		x		x	
Extended assessment			x		x		x
Qualitative interviews							x

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172 Analyses will be conducted and reported in accordance with the Consolidated Standards of
 173 Reporting Trials (CONSORT; [57-58]), with consideration given to the recommendation of
 174 psychological interventions [52]. Outcomes will be assessed 13 times across a 13-week
 175 period, including 3 baseline assessments and 10 weeks of deployment, with Purrble being
 176 delivered in time for week 4 (T1).

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177 Intervention

178 The intervention takes the form of an interactive plush toy-robot (figure 1), which was co-
179 designed with children to support in-the-moment soothing [48-49]. Purrble is framed as an
180 anxious creature, in need of care and attention when it feels distressed. This distress is
181 indicated by a simulated heartbeat using embedded electronics to produce vibration
182 patterns of i) frantic and anxious, to ii) slow, steady, and relaxed. When held, the device emits
183 a frantic heartbeat which can be slowed by stroking movements registered by embedded
184 sensors. Once the device has been "soothed" for long enough, the heartbeat transitions into
185 a purring vibration, indicating a relaxed state. This transition can be achieved in less than 60
186 seconds but is dependent on the device-human interaction. Further details on the logic
187 model underlying Purrble can be found in [supplementary materials 1](#), or see previous
188 research [49].

[insert figure 1 around here]

Figure 1: Purrble – socially assistive robot

194 Waitlist – Control

195 The participants in the control group will be on a waitlist throughout the 13-week trial
196 period. Once data have been collected at the final timepoint (week 13, T10), waitlist
197 participants will receive a Purrble to keep. Waitlist control group was selected following
198 discussions with Sprouting Minds members (see Patient and Public Involvement).

199 Participants

200 Eligibility Criteria

201 When potential participants register their interest for the study, they will be asked
202 demographic questions relating to the eligibility criteria, providing our information for our
203 inclusion criteria. These are: i) being between the ages of 16-25 years (inclusive); ii)
204 identifying as any part of the LGBTQ+ umbrella, iii) having current experiences of self-
205 harmful thoughts (e.g., in the last month), iv) being able to read, write, and speak English,
206 and v) living in the UK for the duration of the study. Exclusion criteria are being outside of
207 the age range, identifying as heterosexual cisgender, not experiencing current self-harmful
208 thoughts, being unable to understand English and living outside the UK.

210 Recruitment, Randomisation, and Blinding

211 LGBTQ+ youth will be recruited to the trial by several strategies. These include: i)
212 approaching secondary schools and colleges, ii) social media adverts, iii) advertising through
213 stakeholder charities and organisations (e.g., Bounce Black, Harmless, King's College London

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3 214 newsletter), and iv) online platforms (e.g., MQ Participate). Those organisations which involve
4 215 gatekeepers (e.g., schools, colleges, charities, organisations) will be emailed by one of the
5 216 leading researchers offering an introductory meeting to discuss the outline of study,
6 217 explaining safeguarding protocols, and how to share this information with young people.
7 218 Young LGBTQ+ people will then be able to register their interest in the study, anonymously
8 219 from gatekeepers. At recruitment, participants will not be blinded to the fact that Purrble was
9 220 designed to support ER. The information sheet specifies that participants will be asked about
10 221 mood, self-harm, and ER over the course of the study.
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16 223 Once eligibility is confirmed and young LGBTQ+ people have provided written informed
17 224 consent (supplementary material 2), they will be 1:1 randomly assigned to either intervention
18 225 or waitlist control group, using a computerised algorithm. A stratification procedure will be
19 226 applied to balance gender identity (transgender and gender diverse youth vs. cisgender)
20 227 across the two arms. The researcher conducting randomisation will be blind to treatment
21 228 group allocation. However, the leading researcher and other team members who will be
22 229 conducting safeguarding will be aware of group allocation. Researchers collecting outcome
23 230 measures will be blinded to group allocation. Participants will be informed about their
24 231 assigned condition. The intervention group will receive the Purrble before T1 data are
25 232 collected, with waitlist participants receiving their Purrble devices after the 3-month follow-
26 233 up data collection. Participants may withdraw at any time, once they have received their
27 234 Purrble device it is theirs to keep.
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34 236 In the event of change of circumstance, such as a serious adverse event, participants are
35 237 asked to inform the research team. Specifically, for follow-up engagements a standard
36 238 operation protocol which asks that if a situation changes for a young person (e.g., they are
37 239 hospitalised) that the young person informs the research team. This will be directly asked
38 240 ("Has your situation changed at all which might impact how you'd like to engage with the
39 241 study?") via email, with the understanding that the research team will have time to arrange
40 242 reasonable adjustments (e.g., if a young person still wants to take part but is within an in-
41 243 patient service).
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46 244 Power Analysis

47 245 Sample size was determined based on an a-priori power analysis to detect a difference
48 246 between the two arms when considering the primary outcome measure, the Difficulties with
49 247 Emotion Regulation Scale-8 (DERS8). On the basis of a pilot with LGBTQ+ youth [47] and
50 248 other Purrble studies [50, 59], we expect to see a medium effect size for this measure ($d=0.4$).
51 249 This would indicate fewer difficulties with ER among young people who had access to
52 250 Purrble.
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57 252 With the anticipated medium effect size, simulations were performed involving a range of
58 253 fixed and random effects. Simulations involved linearly increasing effect over the study
59 254 period, and sensitivity analysis was performed over a range of scenarios considering the

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3 255 slope of effect change over time was either fixed or random. The simulation used a one sided
4 256 t-test ($\alpha=0.05$), and targeted a sample size giving at least 80% power. The statistic to be
5 257 compared between groups is the change in mean DERS8 score in the 2 weeks preceding
6 258 intervention (3 assessments in total), to the mean DERS8 assessed at weeks 8, 9, and 10. The
7 259 averaging over 3 assessments is intended to reduce the known variance in DERS8 when
8 260 repeatedly assessed [60]. Other simulations considered only comparing the change in DERS8
9 261 from baseline (week 0) to week 10, comparing the slope of the effect, assessed using simple
10 262 linear regression. All simulations suggested better than 60% power with 70 subjects per arm,
11 263 with the mean change in DERS8 averaged over 3 assessments, and the comparison of slopes,
12 264 suggesting >80% power. The sample size of 140 is inflated by 20% to account for dropout
13 265 rate [61], rounding up the total sample to 168.
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21 267 Outcome Measures

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23 268 An overview of all measures can be found in Table 2, and full details can be found in
24 269 [supplementary material 3](#). Primary and mental health measures will be asked at all
25 270 timepoints, with the Purrble intervention group also receiving two additional engagement
26 271 measures throughout deployment. An extended survey will replace the weekly survey at
27 272 three time points, this will include three additional measures to be asked to all participants.
28 273 All surveys will be distributed via Qualtrics using individualised links for each participant.
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33 275 These additional measures were selected to explore the association between self-harm and
34 276 emotion regulation (Process Model Emotion Regulation Questionnaire - PMERQ) [38-41],
35 277 perceptions of hope (State Hope Scale - SHS) [13], and loneliness (3-item UCLA Loneliness
36 278 scale) [62], to further explore the qualitative findings represented in our pilot study [47]. Our
37 279 findings have previously indicated that Purrble was used to i) refocus or distract attention
38 280 during moments of distress by addressing the physical manifestation of their discomfort
39 281 (PMERQ), and ii) comfort in moments of loneliness and provide self-soothing mechanisms
40 282 (UCLA, SHS) [47].
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46 284 Considering participant burden, young people will be informed of the time to complete each
47 285 weekly survey (15 minutes), the extended survey (22 minutes) and will be compensated for
48 286 their time.
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289 **Table 2: Summary of the outcome measures**

Outcome Measure	Questions (n)	Type of outcome	Frequency	Scoring	Details of assessment
Primary measure					
Difficulties in emotion regulation scale-8 DERS8; [60]	8	Primary outcome	All timepoints	8-40 (higher = more difficulties)	Difficulties associated with response to situations eliciting negative emotions.
Mental health measures					
Self-Harm Questionnaire screening questions SHQ; [63]	3	Mental health	All timepoints	Analysed separately	Frequency and risk of self-harm thoughts, suicidal ideation, and behaviour.
Self-Harm Questionnaire additional items SHQ; [63]	22	Covariate	Once (baseline)	Analysed separately	4 dimensions of self-harm (NSSI, suicide attempts, suicide threats, suicide ideation).
Generalised Anxiety Disorder questionnaire GAD-7; [64]	7	Mental health	All timepoints	0-21 (higher = greater severity)	Presence and severity of generalized anxiety disorder
Patient Health Questionnaire PHQ-9; [65]	9	Mental health	All timepoints	0-27 (higher = greater severity)	Severity of depressive symptoms
Proximal & mechanistic measures					
Process Model of Emotion Regulation Questionnaire PMERQ; [66]	9	Mechanistic	3 timepoints	2 subscales Average across each subscale, higher = greater endorsement.	Attentional deployment subscales; focus on engagement and disengagement.
State Hope Scale SHS; [67]	6	Proximal	3 timepoints	6-48 (higher = greater state hopefulness)	Goal-directed thinking; agency and pathways.
UCLA Loneliness scale for children; [68]	3	Proximal	3 timepoints	3-12 (higher = more loneliness)	Subjective feelings of loneliness.

Engagement measures					
Bespoke Purrble questions; [59]	7	Engagement	Deployment	Analysed separately	Purrble use and perceived usefulness.
Twente Engagement With eHealth Technologies Scale TWEETS; [69]	9	Engagement	Deployment	3 subscales Total score per subscale = greater engagement	Engagement with intervention device; behavioural, cognitive, and affective engagements.

290

291 Post deployment Interviews

292 We will collect semi-structured interview data from LGBTQ+ young people from up to 40%
 293 of the intervention group (n=37), and approximately 20% of the control group (n=17). The
 294 interviews will be conducted following the deployment period. We will specifically aim to
 295 recruit young people who demonstrated the highest and lowest changes in the outcome
 296 data over the trial to explore and understand the potential moderators relating to the
 297 intervention and mental health across the trial period.

298

299 The semi-structured interview will explore the engagement and appropriation of the Purrble
 300 device, whether LGBTQ+ young people had felt that this had helped them with their ER,
 301 mental health more broadly, or self-harmful thoughts, and how Purrble may (or may not) be
 302 suitable for other audiences. We will compare these experiences between intervention and
 303 control participants, exploring other mechanisms used by LGBTQ+ youth who experience
 304 self-harm.

305 Hypotheses

306 **Primary hypothesis**

307 Across the trial, we hypothesise that access to the Purrble intervention (compared to the
 308 waitlist control) will lead to a direct decrease in self-reported difficulties with emotion
 309 regulation as measured by the primary outcome (DERS8), averaged between three pre-
 310 deployment (weeks 1-3) and our final three deployment assessments (weeks 11-13).

311

312 **Secondary hypothesis**

313 Intervention effects will be moderated by engagement with the device, measured by
 314 bespoke questions and the TWEETS questionnaire. Secondary outcomes in the Purrble
 315 effectiveness trial are: self-harmful thoughts, symptoms of anxiety, and symptoms of

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3 316 depression. These three constructs were selected as secondary outcomes based on the high
4 317 prevalence of these experiences among LGBTQ+ youth [3-8] and their association with poor
5 318 ER [38-41]. The three secondary hypotheses are as listed when compared to waitlist controls:
6
7 319 1. Engagement with the Purrble intervention will reduce the frequency of self-reported
8 self-harmful thoughts (SHQ).
9 320
10 321 2. Engagement with the Purrble intervention will reduce the severity of self-reported
11 anxiety symptoms (GAD-7).
12 322
13 323 3. Engagement with the Purrble intervention will reduce the severity of self-reported
14 depression symptoms (PHQ-9).
15 324

17 325 **Additional analyses**

18
19 326 Additional hypotheses aim to understand the impact of Purrble on relevant proximal and
20 327 mechanistic outcomes. The following hypotheses will be investigated across the trial:
21
22 328 1. Greater within-group changes will be seen among intervention group participants, with
23 329 increasing levels of endorsement for attentional deployment (PMERQ), than among those
24 330 participants of the control group.
25
26 331 2. There will be a greater increase in state hopefulness (SHS) in the Purrble intervention
27 332 group than the waitlist control.
28
29 333 3. Participants in the Purrble intervention group will report lower loneliness (UCLA) than
30 334 those in the waitlist control group.
31
32 335

34 336 **Statistical analyses**

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36 337 Testing the hypothesis that access to the Purrble intervention will lead to a reduction in
37 338 emotion dysregulation, as measured by the composite primary outcome, will be done using
38 a one-sided t-test.
39 339

40 340
41 341 As exploratory analyses linear mixed models will be fitted to gain insight into how emotion
42 342 dysregulation is altered with access to the intervention. In particular, we will regress the
43 343 weekly outcome score on an indicator for the Purrble condition, a linear time trend, and an
44 interaction between the treatment indicator and time to examine differential trends in the
45 344 two groups. We will adjust for baseline covariates and include participant-level random
46 345 intercepts and slopes to account for persistent baseline differences between young people
47 346 as well as person-specific time trends in the outcome. While the outcome is limited to DERS8
48 347 scores ranging from 8-40, we will model it as continuous data.
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54 350 For secondary aims, we will use analogous linear mixed models to assess the impact of
55 351 Purrble on relevant outcomes (cf., hypotheses above), adding baseline DERS8 as another
56 352 covariate. We will not adjust for multiple comparisons, as these are exploratory aims meant
57 353 to be hypothesis-generating. Similarly, we will also assess the impact of access to Purrble on
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3 354 changes in proximal outcomes, as well as explore whether these appear to moderate
4 355 changes on primary and secondary outcomes.

8 356 Patient and Public Involvement

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10 357 The study design was discussed with, and approved by, Sprouting Minds members (MRC
11 358 Digital Youth Young Person Advisory group), with specific input considering the intervention
12 359 arms and safeguarding procedures. These young people highlighted that "waitlist control"
13 360 conditions mimic clinical experiences of waiting for services, therefore this was considered an
14 361 acceptable and realistic control. Whereas safeguarding procedures needed to balance
15 362 participant autonomy and ensuring safe research.

19 363 Ethics and dissemination

20 364 This manuscript has been written with insights from the Spirit 2013 checklist (supplementary
21 365 material 4). The study will be conducted according to local regulations and the Declaration of
22 366 Helsinki of 1975, revised in 2008. The Ethical Committee at King's College London, UK
23 367 approved the study (RESCM-22/23-34570). Written consent will be obtained from all
24 368 participants prior to commencing their involvement in the study, with explicit understanding
25 369 of the study and safeguarding procedures (see supplementary materials 5) being obtained
26 370 during study briefing sessions. The trial is registered with ClinicalTrials.gov (NCT06025942).

27 371
28 372 We aim for our findings (and any modifications to this protocol) to be disseminated across
29 373 academic fields (human-computer interactions, psychology, implementation sciences),
30 374 alongside showcasing the findings to LGBTQ+ youth, community groups, and wider
31 375 stakeholders. This will be achieved through presentations at national and international
32 376 conferences, peer-reviewed journal publications, community outreach and PPI events. During
33 377 dissemination, we will be liaising with youth populations to establish next steps for this
34 378 research, considering additional co-design of materials to sit around/alongside Purrble.

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390 Author contributions

391 AJW, ET, PS conceived the study. AJW and PS designed the study, with statistical expertise
392 from CT and patient and public input from NN and ACN. AJW designed the study materials,
393 which were reviewed with feedback between NN, ACN, and SC. AJW obtained ethical
394 approval. JG, ET, PS and AJW contributed to measure selection. AJW drafted the first version
395 of the protocol manuscript for publication, with input from all authors (AJW, RB, SC, ET, NN,
396 ACN, CH, PS). RB and AJW revised the submitted protocol manuscript together.

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401 data collection, management, analysis, interpretation or dissemination. This is now included.

402 Competing interests statement

403 PS has been involved in the development of what is now Purrble as part of his postdoctoral
404 fellowship; and serves as a paid research adviser to the Committee for Children but has no
405 financial stake in either CfC (Purrble brand owners) or Sproutel (company manufacturing
406 Purrbles). Neither Committee for Children nor Sproutel had access to the data or had been
407 part of the data collection in any way, nor did they approve or see the publication before it
408 was submitted. There were no conflicting interests among the remaining research team.

410 Data availability statement

411 Data will be available upon reasonable request once the trial is complete. To date there is no
412 data that has been collected or analysed for this study. The data will be held at King's
413 College London, following the data management agreement of Digital Youth.

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Figure 1: Purrble – socially assistive robot

Peer review only

Supplementary material 1

Purrble logic model

Purrble operates on 3 levels:

1. Purrble directly provides in-the-moment soothing support in naturally occurring emotional moments when one would attempt to calm down. The physical and interactive design aims to tap into known regulatory factors using the extended Process Model of Emotion Regulation (Gross, 2015). This focuses on two separate stages of the ER process; i) the attentional deployment stage (Aldao et al., 2015; Sheppes & Gross, 2012; Sheppes et al., 2014; Farb et al., 2014) by shifting attention from the emotional situation towards interacting with the device, and ii) the response modulation stage (Beetz et al., 2012; Dore et al., 2017; Reeck et al., 2016; Coan et al., 2006; Crossman et al., 2018; Rabbit et al., 2015) by facilitating down-regulation through pleasant tactical interactions simulating the emotion regulatory effect of human-animal interactions.
2. Mechanisms of Purrble are designed to facilitate long-term engagement, by building on positive subjective experiences of in-the-moment soothing. As the device is framed as an anxious creature needing to be cared for, the key driver is that interactions are framed as helping regulate others' emotions (Dore et al., 2017; Cosley et al., 2010; Taylor, 2011), alongside facilitating a sense of relationship and responsibility for the well-being of the creature (Turkle, 2007; Hayashi & Kato, 2016; Donath, 2004; Lee et al., 2010).
3. Through repeated, soothing, and positive interactions with Purrble over time, it is anticipated that there will be a shift in ER practices and implicit beliefs about emotions (Ford & Gross, 2018), specifically the controllability of one's emotions (Schleider & Weisz, 2016).

Supplementary material 2

CONSENT FORM FOR PARTICIPANTS IN RESEARCH PROJECTS

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research

Title of project: An exploratory investigation of the acceptability and feasibility of using an in-situ socially assistive robot with at-risk young people.	
Ethical review reference number: 34570	Version number: 3-23
Please read and confirm your consent to taking part in this project by initialing all boxes, and signing (by typing your name) below:	Tick or initial
1. I confirm that I have read and understood the information sheet dated 3-23 for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	
2. I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason, up to 2 weeks following my completion of the study.	
3. I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled under the terms of UK data protection law, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.	
4. I understand that my anonymised information may be subject to review by responsible individuals from the College for monitoring and audit purposes.	
5. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs.	
6. I agree that the researcher/research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would not be identifiable in any report).	
7. I confirm that I am between 16-25 years old, who currently lives in the UK and identifies as any part of the LGBTQ+ umbrella.	
8. I understand that I need to provide the name and email address for my support contact (who will only be contacted to i) inform them that you are taking part in a mental health study, and ii) in the event that you can not be reached for a wellbeing check after 3 daily contact attempts via phone/email).	
9. I understand I will be randomised into either an intervention or control group, which impacts when I receive Purrble but irrespective I will be paid for all surveys completed across the 13 week period.	
10. I consent to completing three baseline surveys at the start of the study (weeks 1-3).	

11. I consent to be contacted via SMS to complete a weekly survey for 13 weeks (including the three baseline surveys).	
12. I consent to be invited to take part in an online interview to discuss my experience of the study.	
13. I consent to my interview being audio recorded, and shared with a third-party transcriber who will have signed a confidentiality agreement.	
14. I consent to be invited to take part in a co-designed workshop following the study.	
15. I confirm that I am happy to share my contact information as part of the study (name, email, phone number, home address)	
16. I understand that if I take part in the study, I will receive a Purrble through Royal Mail to my home address.	
17. I agree to take part in this project.	

Name:

Email address:

Your phone number:

Home address:

Name of Participant

Date

Signature

Name of Researcher

Date

Signature

If you have any questions or require further information, please contact

Researcher: A. Jess Williams

Email: amy_jess.williams@kcl.ac.uk

PI: Petr Slovak

Email: petr.slovak@kcl.ac.uk

Supplementary material 3

Full Measurement Details

Primary Outcome Measure

The primary outcome measure in this study is the Difficulties with Emotion Regulation Scale-8 (DERS8) [60]. This will be given to participants as part of the main assessment at all time-points. The DERS8 contains 8 items which represent affect, thoughts, and actions in response to situations which elicit negative emotions. A single total score is calculated from all items, with higher scores indicating more difficulties with emotion.

Mental Health Measures

Self-harmful thoughts and behaviours will be assessed using the Self-Harm Questionnaire (SHQ) [63]. At baseline, those who indicate experiences of self-harm behaviour will be invited to complete the second section about historical self-harm behaviour. At all other timepoints, only the three screening questions will be presented; these query the frequency of self-harmful thoughts, suicidal ideation, and self-harmful behaviour. The items are scored individually from “no thoughts/behaviour” to “yes, five or more times”. The wording for these items will be adapted from “have you ever...” to “in the last week/month” (depending on assessment point).

Anxiety symptoms will be assessed using the Generalised Anxiety Disorder-7 (GAD-7) [64]. This is a seven-item instrument, used to identify or assess the severity of generalised anxiety disorder. Each item asks the individual to rate the severity of their symptoms over the time period. The total score is calculated by summing all items and ranges from 0-21. Higher scores indicate more severe levels of anxiety symptoms. The wording for these items will be adapted from “over the last two weeks” to “in the last week/month” (depending on assessment point).

Depressive symptoms will be assessed using the Patient Health Questionnaire-9 (PHQ9) [65]. Across nine items, this instrument measures the severity of depressive symptoms, the total score being calculated by summing all items with responses ranging from 0-27. Higher scores indicate greater depressive severity. Again, the wording for these items will be adapted from “over the last two weeks” to “in the last week/month” (depending on assessment point).

Proximal & Mechanistic Measures

All proximal and mechanistic measures will only be asked at three timepoints (T0, T5, T10), this is to reduce participant burden and encourage engagement, while also obtaining exploratory data to understand the impact of access to Purrble in greater detail. All additional measures total to 18 extra items, adding ~7 minutes to the assessment.

The Process Model of Emotion Regulation Questionnaire [66] is a 45-item measure which considers 10 ER strategies across the five stages of the Process Model of ER, and particularly how these strategies are used to decrease negative emotions. We will include 2 subscales

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3 focusing on attention deployment (focusing elsewhere (4 items) and cognitive distraction (5
4 items)). Each subscale is scored by taking the average of item-level responses.
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7 Hopefulness will be assessed using the State Hope Scale [67]. This is a six-item instrument
8 concerning ongoing goal-directed thinking (agency and pathways). The total score (6-48) is
9 calculated by summing responses, with higher scores relating to greater state hopefulness.
10

11 Loneliness is assessed using the 3-item UCLA loneliness scale for children [68] to consider
12 participants' subjective loneliness. Items are summed to create a total score (3-12), whereby
13 higher results indicate greater loneliness.
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16 ***Engagement Measures***

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18 Engagement with Purrble will be assessed using two measures; a bespoke survey [59] and an
19 adapted version of Twente Engagement with eHealth Technologies Scale (TWEETS) [69].
20 These will be deployed as part of the main assessment for participants allocated to the
21 intervention group.
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24 The bespoke survey [59] enquires about Purrble use and perceived usefulness over four
25 items. These are analysed separately, with qualitative responses indicating contexts or
26 situations where Purrble has been found helpful or unhelpful.
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29 TWEETS [69] quantitatively measures intervention engagement across nine items. This is split
30 into subsections considering behaviour, cognitive, and affective engagement. Total scores
31 range from 0-36, with higher scores indicating greater engagement.
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Supplementary material 4



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page and line No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 1-4
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2 44
	2b	All items from the World Health Organization Trial Registration Data Set	n.a.
Protocol version	3	Date and version identifier	n.a.
Funding	4	Sources and types of financial, material, and other support	Page 13 399-401
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 5-13
			Page 13 391-396
	5b	Name and contact information for the trial sponsor	Page 13 400-401
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 13 401-402

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5d Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) n.a.

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 2-4 55-149
	6b	Explanation for choice of comparators	Page 6 195-199
			Page 12 360-362
Objectives	7	Specific objectives or hypotheses	Page 4 150-161
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 4-5 163-178

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 6-7 204-222
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6 201-209
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 5-6 179-199
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 7 234-235

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4		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 8 285-287
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8		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n.a.
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11	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 8-10 268-292 SupMat3
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20	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 6-7 211-244
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24	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 7-8 245-267
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30	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6-7 211-222
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Methods: Assignment of interventions (for controlled trials)

Allocation:

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37	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 7 224-228
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45	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 7 224-228
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50	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 7 224-231
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1 2 3 4 5 6 7	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 7 224-231
8 9 10 11		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n.a.

Methods: Data collection, management, and analysis

12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 4-5 163-178 Page 7-10 245-292 SupMat3
29 30 31 32 33 34 35 36 37 38 39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n.a.
40 41 42 43 44 45 46 47 48 49	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Digital Youth management agreement
50 51 52 53 54 55 56 57 58 59 60	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 11-12 307-357
		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 11-12 327-336 352-357
		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n.a.

Methods: Monitoring

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4	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
5			Page 13
6			400-403
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11		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
12			n.a.
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16	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
17			Page 7
18			237-244
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20			SupMat5
21	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
22			n.a.
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26	Ethics and dissemination		
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28	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
29			Page 12-13
30			367-369
31	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
32			Page 13
33			375-381
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37	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
38			Page 7
39			224-225
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41			Page 12-13
42			369-372
43			
44		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
45			n.a.
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48	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
49			SupMat2
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52	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
53			Page 13-14
54			404-410
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4	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 14 412-415
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8	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
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12	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13 375-381
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19		31b	Authorship eligibility guidelines and any intended use of professional writers	n.a.
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22		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n.a.
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26	Appendices			
27	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	SupMat2
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30	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n.a.
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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

Supplementary material 5

Safeguarding Procedures

The safeguarding procedures will be presented to potential participants in the information sheet before they consent to the study. These were codesigned and agreed with Sprouting Minds, based on previous studies conducted with young people with self-harmful experiences [1-3]. To support young people's safety during the study, the following measures will be instituted:

1. Before starting the study, all participants are required to attend an individual study briefing. At this point, they are taken through the study outline, invited to ask questions, and asked to create a safety plan [4] with the support of a specially trained researcher. Safety planning is quick to complete, is tangible to participants and has been shown to be effective at reducing self-harmful thoughts and behaviours [5]. Participants keep this safety plan containing their individualised strategies for their personal use beyond the life of the study. During the wellbeing check, participants are asked to reflect on their safety plan if they feel distressed at any other point during the study. This follows safety protocols used in other studies by the researcher [1-3].
2. During the briefing, participants will need to nominate a support contact (parent, friend over 18 years, GP, etc), with the understanding that if they do not respond to reactive safeguarding (which can be triggered for each of the main assessments), this person will be contacted to ensure that the participant is safe.
 - a. This nominated person will be contacted (via email) to inform them that the participant is taking part in a mental health study and that we will reach out if we are unable to contact the participant following indication that they are at increased risk.
3. All assessments will include signposting to additional supports (e.g., Young Minds, Samaritans, Papyrus) as well as encouraging participants to seek help from their GP if they are distressed.
4. All assessments will include a visual scale to rate mood pre- and post- completing the survey (1 - very distressed - 10 extremely happy). This is to examine whether the assessment process has an impact, positively or negatively, on the participant. Such assessments have been successfully used in prior self-harm research by the research team members as an indicator of assessment impact [36].
5. Participants in need of support will be identified by checking their responses to the main battery of assessments, within 24 hours. If participants respond that they have had experiences of self-harmful or suicidal thoughts and self-harm behaviour, as well as showing a that the assessment has had a negative impact, they receive a wellbeing call the following day between 1pm-4pm. This allows enough time for the researcher to identify participant risk and inform the PI.
 - a. If the participant does not pick up the phone, they will be contacted via email, asking about their wellbeing, whether they wish to continue with the study, and to arrange a time convenient to complete a wellbeing check. During the wellbeing check, the researcher will be empathic to the difficulties of the participant. The participant will be asked whether they wish to continue the study and, if so, they

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3 will update their safety plan with the researcher. If participants do not wish to
4 continue the study, they will be allowed to withdraw with no consequences. They
5 will be invited to interview to discuss their thoughts, opinions and experiences of
6 the study. This would also ask about why they withdrew from the study.
7

- 8 b. If a participant still does not respond to the email, the same procedure will be
9 attempted twice more. If there is still no contact from the participant by day 4,
10 their support contact (nominated during briefing) will be contacted.
11

12 Alongside this, all researchers who undertake briefing (including safety planning) and wellbeing
13 calls will be invited to take part in group supervision sessions once a week during data collection
14 with leading authors. This will be a confidential, safe space to discuss researchers' wellbeing
15 and mental health, with support for any difficulties which may surface.
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20 21 **References**

- 22 1. Williams AJ, Arcelus J, Townsend E, Michail M. Feasibility and acceptability of
23 experience sampling among LGBTQ+ young people with self-harmful thoughts and
24 behaviours. *Frontiers in psychiatry*. 2022 Aug 17;13:916164.
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31 Investigating the feasibility, acceptability and appropriation of a socially assistive robot
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