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Beating Adolescent Self harm (BASH). A randomised controlled trial comparing usual care versus usual care plus a smartphone self-harm prevention app (BlueIce) in young adolescents aged 12-17 who self-harm: study protocol.

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3 **Beating Adolescent Self harm (BASH). A randomised controlled trial**
4 **comparing usual care versus usual care plus a smartphone self-harm**
5 **prevention app (Bluelce) in young adolescents aged 12-17 who self-harm:**
6 **study protocol.**
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ABSTRACT

Introduction

A mobile app, BlueIce, was co-designed with young people with a history of self-harm with the aim of providing more accessible evidence-based support at times of distress. A preliminary evaluation found that BlueIce was acceptable, safe, and used by young people, and helped to reduce self-harm. The current study aims to determine the effectiveness and cost-effectiveness of adding BlueIce to usual specialist child and adolescent mental health service (CAMHS) interventions on self-harm and mental health.

Methods and analysis

Single blind, randomised controlled trial comparing usual CAMHS care with usual care plus BlueIce. 138 adolescents aged 12-17 with current or a history of self-harm will be recruited through the Oxford Health NHS Foundation Trust via their CAMHS clinician. Assessments of self-harm, mood, anxiety, hopelessness, general behaviour, sleep, impact on everyday life, health related quality of life and health care resource utilisation will be collected at baseline, 12 weeks and 6 months. Post-use interviews with young people will be undertaken at 12 weeks to determine the acceptability, safety and usability of BlueIce.

Ethics and dissemination

The project has been reviewed and approved by the South Central – Oxford B NHS Research Ethics Committee (19/SC/0212) and approved by the HRA and Health and Care Research Wales. The findings of this study will be disseminated through submission to high impact open access publications and through presentations at relevant academic and clinical conferences. Results will be made available to all participants after the completion of the study.

Trial registration: ISRCTN registry, registration number ISRCTN 10541045. Registered on 22/07/2019

Strengths and limitations of this study

- This is the first adequately powered randomised controlled trial of a digital self-help app for young people aged 12-17 years who self-harm.
- This study will add to the evidence-base and will document the effectiveness and cost-effectiveness of adding a self-help app to usual care.
- We have minimized the possibility of contamination between the trial arms as BlueIce is a prescribed app with a single-use download code.
- Researchers are blind to participants
- This study is investigating the effectiveness of BlueIce as a prescribed app (used alongside specialist mental health care) and we will not determine the efficacy of BlueIce as a standalone intervention.

Keywords

Bluelce, Self-Harm, Children, Adolescents, Mobile App. CAMHS, Mental Health, (m)Health

For peer review only

INTRODUCTION

Background

Self-harm is defined as the deliberate act of causing damage to one's body, for example through self-poisoning or self-cutting [1,2]. It is very prevalent, with around 17.2% of adolescents and 13.4% of young adults being estimated to self-harm [3]. Rates of self-harm are more likely to reduce in young adults compared with younger adolescents [4]. Most self-harm occurs in secret with comparatively few episodes resulting in hospital presentations [5-7]. While suicide is less prevalent amongst younger adolescents, it is the third most common cause of death in young people [8]. Self-harm has consistently been cited a risk factor for later suicide attempts [9].

Research has identified risk factors for self-harm, including: negative and stressful life events such as childhood maltreatment; self-harm or attempted suicide of a family member; drug and alcohol abuse; psychological factors such as feelings of hopelessness, perfectionist traits, emotional dysregulation, or diagnoses of psychological disorders; lower sociodemographic status; and being female [7,10-12]. Protective factors which may help reduce or prevent self-harm include better access to social support, higher levels of self-esteem and receiving support from parents, as well as being able to re-evaluate one's own thoughts and beliefs [4].

Evidence-based interventions for self-harm in children and adolescents are scarce. Few studies have evaluated cognitive behaviour therapy (CBT) or problem-solving approaches [13,14]. Family therapy does not appear effective [15]. There is some support for dialectical behaviour therapy (DBT) [16-19], and for mentalization-based treatment (MBT) [20]. However, a Cochrane review concluded that there is not much evidence on which to draw conclusions on the effects of interventions for adolescent self-harm and recommended that therapeutic assessment, metallization, dialectical behaviour and cognitive behaviour therapy warrant further evaluation [13]. With recent advance in technology the use of digital interventions to aid the delivery of mental health interventions has become more widespread. The NHS is encouraging the use of technology in order to improve access to, and the availability of, support and interventions, and to reduce demands on mental health services [21].

There are currently over 15,000 mobile (m)health apps available worldwide, with around 5,000 of these targeted at mental health [22]. Apps offer an accessible way of delivering and supporting mental health interventions for young people since over 80% of 12-15-year olds own a smartphone [23]. Alongside improving accessibility to support, mHealth apps are available 24/7, provide a means for symptom monitoring between face-to-face meetings, may be a preferable method of accessing support for some young people, and provide a route around barriers such as stigma. mHealth apps may also help to lessen the demand on healthcare resources [22,24,25]. However, the evidence base surrounding healthcare apps is severely lacking, with research unable to keep pace with the speed of their development [24]. Therefore, the safety, efficacy and acceptability of the majority of apps is unknown.

In response to the above, a self-help app, Bluelce, was co-developed with young people with a lived experience of self-harm [26]. It is designed to support self-management of distress and reduce self-harm behaviours. Bluelce has 24/7 accessibility and is a prescribed app to

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3 be used alongside face-to-face Child and Adolescent Mental Health Services (CAMHS) [27].
4 Bluelce is password protected and all data is stored locally on the phone [26]. It meets all
5 minimum standards required for NHS accredited apps [28].
6

7 Bluelce utilises evidence based approaches of CBT and DBT and includes 3 sections: 1)
8 mood diary; 2) mood lifting section; and 3) emergency contacts. Upon entering Bluelce,
9 young people rate their mood and, if this is rated as low, they are routed to the mood-lifting
10 section, which is also accessible from the main menu. The mood lifting section contains 8
11 personalised activities to enhance mood, including: a photo and music library, physical
12 activities, mood-changing activities, calming exercises, a thought diary, DBT skills (pros and
13 cons, self-soothe and ice-dive), and phone numbers of key contacts they can call or
14 message. If young people rate their mood as low following the use of the mood lifting
15 section, they are routed to the final section which provides emergency contact numbers they
16 can call for support [27].
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20 An initial open study to determine safety, acceptability and usability found that 73% (19/26)
21 of Bluelce users reported a reduction or cessation of self-harm at the 12-week follow-up [27].
22 No participants reported an increase in self-harm during the study. Post-use reductions in
23 symptoms of anxiety and depression were also reported with 88% (29/33) of users electing
24 to keep the app at the end of the study [27].
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28 **Study Objective**

29 The aims of this trial are to determine the effectiveness, cost- effectiveness and acceptability
30 of adding Bluelce to usual face-to-face specialist mental health care in the reduction of self-
31 harm in adolescents.
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METHODS

Trial design

This is a two arm, single blind, randomised controlled trial (RCT) comparing the addition of the BlueIce self-help app to usual face-to-face specialist mental health care (UC+BI) with usual specialist mental health care (UC).

Setting and participants

Participants will be recruited through CAMHS provided by Oxford Health NHS Foundation Trust, covering North-East Somerset, Bath, Swindon, Wiltshire, Buckinghamshire and Oxfordshire.

Young people will be eligible if they: (1) are receiving treatment from CAMHS at the time of referral; (2) have self-harmed at least twice in the last 12 months; and (3) are aged between 12 and 17 years.

Exclusion criteria are: (i) a diagnosis of psychosis; (ii) a significant learning disability which would interfere with the young person's ability to use the app; (iii) young people with active suicidal plans, or (iv) safeguarding concerns where the young person has suffered abuse within the last 6 months or is the subject of a safeguarding investigation.

Recruitment

Clinicians across Oxford Health NHS Foundation Trust will be invited to identify eligible young people who are open to CAMHS. Clinicians will discuss the study and provide interested young people, and if under 16 their parents/carers, with a project information sheet. If interested in participating, their details will be forwarded to the research team.

Consent

Researchers will meet with the young people, and if appropriate their parents/carers, to discuss the project. If the young person wants to take part, the researcher will obtain consent. If under 16 years old, the young person will be asked to provide assent while their parent or legal guardian will be asked for consent. Those aged 16 years or older will be able to provide their own signed consent. During the COVID pandemic the consent and assessment process will be undertaken remotely (i.e. online or via telephone) in order to maintain the safety of participants and the research team.

Randomisation

Computer generated randomisation will be independently undertaken by Exeter Clinical Trials Unit. Participants will be randomised in a 1:1 ratio to either usual specialist mental health care (UC) or usual specialist mental health care plus the BlueIce self-help app (UC+BI). Participants will be randomised using REDCap software minimising for gender, age

(over or under 16), self-harm frequency in last 4 weeks (0-2 or ≥ 3), and severity of depression (Mood and Feelings Questionnaire above or below 27, the cut off for severe depression). Following guidance from our participation group, those allocated to usual care will be provided with Bluelce at their final, six-month assessment.

Blinding

Due to the nature of the intervention it is not feasible to blind participants to allocation. The research team are aware of the need to maintain equipoise and to present the two interventions to referring clinicians and participants in a balanced way. Researchers will remain blind to treatment arm and, if this is inadvertently broken, subsequent assessments will be conducted by another member of the research team blind to participant status.

Interventions

Usual Care (UC): Young people will receive individual mental health interventions from specialist CAMHS clinicians. This will be either face-to-face, or, due to COVID, a remotely delivered telephone or video intervention. The nature, content and duration of this will be captured by the health care resource questionnaire.

Usual care plus Bluelce (UC+BI): In addition to usual care, young people will also receive access to the self-help Bluelce app. Bluelce is an application for android and apple smartphones. It contains a mood diary, personalised toolbox of mood lifting strategies that are available to the young person 24/7 and automatic routing to emergency contact numbers. (i). *Mood diary*: The young person is able to monitor their mood each day. For each mood rating the young person has the option of adding a note to record any particular reason why they might be feeling as they do. Their rating and notes are saved in a calendar which the young person and therapist can review to look for changes and patterns over time. (ii). *Mood lifting*: If the young person rates their mood as low, they will automatically be routed to the mood lifting section. Alternatively, if at any time the young person would like to access this section they can do so directly from the main menu. This section contains a menu of mood lifting activities personalised according to the interests of the young person. The activities are designed to counter the common reasons why young people self-harm (to punish themselves, emotional relief, feeling hopeless) and draws on common methods used in cognitive behaviour therapy (CBT) and dialectical behaviour therapy (DBT). The mood lifting section includes 8 activities: 1). Photo library: the young person can upload and save photographs, inspirational quotes and pictures that are associated with happy memories or which might make them feel good. These can be reviewed when low to help the young person remember the positive things in their life: 2). Music library: a music player is included where the young person can upload and store music they enjoy, and which has a positive effect on how they feel. This playlist can be readily accessed when the young person is low as a way of improving their mood: 3). Physical activities: the young person can identify physical activities they enjoy such as sporting activities (e.g. going for a run or riding a bike) or other aerobic activities such as walking the dog. The young person can access their personalised list when low and be reminded about what they can do to get active to improve their mood: 4). Mood changing activities: Bluelce includes a section of activities that make the young person feel good. These could be things like making a cake, watching an episode

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3 of a favourite TV series, reading a book, playing with a pet. These provide the young person
4 with a prompt list of activities they can use to change their mood when feeling down: 5).
5 Relaxation and mindfulness exercises: audio-recorded instructions for a 10-minute
6 mindfulness session, calming visualisation and a quick controlled breathing exercise (4-7-8
7 breathing) are included. These can be used to help the young person manage any
8 unpleasant emotions or distressing thoughts: 6). Identification of negative thoughts: this
9 section includes a thought diary where the young person can record any troubling thoughts
10 that are racing through their head. These can be directly typed into BlueIce where they are
11 saved and can be reviewed at a later date. This allows identification of any particular themes
12 that could be addressed during face-to-face work with their clinician: 7). Ride it out: this
13 section draws on ideas from DBT and helps the young person to tolerate their distress. This
14 includes instructions for an ice dive, a sensory toolbox and a “pros and cons” balance sheet
15 for self-harming: 8). Call a friend: the final section contains the phone numbers of 3-5 people
16 who the young person could contact if they were feeling low and in danger of self-harming.
17 These would be people who make them feel happy and those they could talk with about how
18 they are feeling. This section prompts the young person to reach out to others. (iii)
19 *Emergency contacts.* After accessing the mood lifter, the young person is asked to re-rate
20 their mood. If they are still low and feeling that they might harm themselves, they will be
21 routed through a series of questions to three emergency contact numbers. The young
22 person can select one of these options to automatically call/text emergency support.
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29 **Patient and public involvement**

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31 BlueIce was co-designed and produced with young people with a lived experience of self-
32 harm. They were involved in exploring the concept (would an app be helpful?), what an app
33 should look like (examples of apps liked and used), the design (font, colours, flow) and
34 content (evidence-based and ideas young people found helpful).
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37 In this study, two young people will be recruited to join our Study Steering Committee (SSC).
38 We plan participant workshops to develop study resources, to advise on recruitment and
39 retention issues, to discuss study findings, identify key messages, prepare understandable
40 research summaries in different formats and identify issues/implications for future research.
41 We intend to involve young people in events disseminating the findings of the study.
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45 **Assessment schedule**

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47 Data will be collected at: (i) baseline; (ii) post-intervention (12 weeks); and, (iii) follow-up (6
48 months after randomisation). Data will be collected by Research Assistants, blind to
49 treatment allocation. Participants will be given a £20 voucher after completing the final
50 assessment.
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52 *Baseline:* Standardised self-report measures of self-harm, depression, anxiety,
53 hopelessness, general behaviour, impact on everyday life, sleep and health-related quality of
54 life and resource use health care questionnaire. These will be complemented with case-note
55 review to detail resource use i.e. accident and emergency department attendances, out of
56 hours contacts, primary and secondary care attendances following incidents of self-harm in
57 the preceding 6 months.
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3 *Post-intervention (12 weeks):* Standardised self-report measures of self-harm, depression,
4 anxiety, hopelessness, general behaviour, impact on everyday life, sleep and health-related
5 quality of life and the resource use health care questionnaire will be repeated (baseline -12
6 weeks). Case note review will be repeated (baseline to 12 weeks) and the type and total
7 hours of direct and indirect CAMHS intervention provided from randomisation to 12 weeks
8 detailed. Those in UC + BI will complete a semi-structured interview detailing their use,
9 experience of, and satisfaction with BlueIce.
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12 *Follow-up (6 months after randomisation):* Standardised self-report measures of self-harm,
13 depression, anxiety, hopelessness, general behaviour, impact on everyday life, sleep and
14 health-related quality of life. Case note review will be repeated (12 weeks to 6 months) and
15 the type and total hours of direct and indirect CAMHS intervention provided from 12 weeks
16 to 6 months detailed.
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19 **Outcome measures**

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22 *Primary Outcome:* Our assessment of self-harm will consist of three parts: A). a brief
23 interview; B). completion of the Risk Taking and Self-Harm Inventory for Adolescents
24 (RTSHIA) [29] and C). the provision of support and advice.
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27 *Part A: Interview.* Young people will be asked “have you ever hurt yourself on purpose in any
28 way (e.g. by taking an overdose of pills or by cutting yourself) over the past 3 months?”
29 which was taken from the Avon Longitudinal Study of Parents and Children (ALSPAC)
30 (<http://www.alspac.bris.ac.uk>) [30]. Young people are asked to consider the last 6 months at
31 baseline, and the last 3 months at follow-ups. Those who answer yes will be asked further
32 questions about frequency, method, reason for self-harming, whether they sought medical
33 help and suicidal intent.
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37 *Part B: RTSHIA.* Our primary outcome is self-reported self-harm assessed by the self-harm
38 inventory of the RTSHIA. The RTSHIA was developed in the UK for use with adolescents
39 (aged 11-19 years) [20,29]. The self-harm inventory consists of 18 items and assesses the
40 presence and frequency of a range of intentional self-injuries (e.g. cutting, burning, self-
41 hitting, self-poisoning). The frequency of each item is rated on a 4-point scale (never, once,
42 more than once, many times) over a defined period. At baseline, the young person is asked
43 to consider the 6 months before their initial assessment. For the 12 week and 6-month
44 assessment the young person considers the 3-month period since their last assessment.
45 Each item is then scored (0,1,2,3) and totalled to provide a current self-harm score. The
46 RTSHIA has good reliability and validity [20,29]. We will analyse total scores and use this
47 information to categorise changes in self-harm from baseline to 12 weeks and 6 months as
48 reduced/stopped vs same/increased.
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52 *Part C: Support and Advice.* At the end of the assessment young people will be given a list
53 of contacts they can call if they are feeling worried about themselves. These include NHS
54 111, Childline and the Samaritans.
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57 *Secondary outcomes:* The Mood and Feelings Questionnaire (MFQ) [31], is a self-report
58 questionnaire for depression recommended by NICE consisting of 33 items rated as either
59 “true” (scores 2), “sometimes true” (scores 1) or not true (scores 0). The MFQ has high
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3 criterion validity and correlates well with other measures of depression [31]. A total score of
4 27 and above is associated with major depression, 20 with mild depression and 16 with no
5 mood disorder. The Hopelessness Scale for children, adapted from Beck's Hopelessness
6 Scale [32,33], consists of 17 true–false items measuring hopelessness and negative
7 expectations for the future. Items endorsed as "true" are summed, with higher scores
8 indicating greater hopelessness. The Hopelessness Scale for children has been widely used
9 within adolescent samples and has consistently demonstrated strong psychometric
10 properties [32,33]. The Revised Child Anxiety and Depression Scale (RCADS) [34] is a 47-
11 item questionnaire with items corresponding to DSM-IV criteria for anxiety in the areas of
12 social phobia, separation anxiety, obsessive compulsive disorder, panic disorder,
13 generalised anxiety disorder and for major depressive disorder. Each item is rated on a 4-
14 point Likert scale of frequency (never 0; sometimes 1; often 2; always 3) which are summed
15 to produce sub-scale and total anxiety scores. The Strengths and Difficulties Questionnaire
16 (SDQ) [35] is a widely used behavioural screening questionnaire consisting of 25 items
17 assessing emotional symptoms, conduct problems, hyperactivity and/or inattention, peer
18 relationship problems, and pro-social behaviour. Each item is rated as not true (0),
19 somewhat true (1) or certainly true (2). A total difficulties score is calculated by summing
20 scores from all subscales except the pro-social. In addition, an impact supplement assesses
21 the degree of distress created by the child's difficulties and the degree to which they interfere
22 with home life, friendships, classroom learning and leisure activities. The five items are
23 summed to produce a total 'impact on everyday life' score which ranges from 0-10. The
24 Sleep Condition Indicator (SCI) [36] is an eight item self-report measure assessing sleep and
25 impact on daytime functioning over the past month on a 5-point scale. Item scores are
26 summed to produce a total score ranging from 0-32. The SCI is an internally consistent
27 ($\alpha = .86$) measure with a clinical cut-off <17 correctly identifying 89% of those with probable
28 DSM-5 insomnia disorder [36].
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36 *Qualitative evaluation:* We will use the semi-structured interview developed in our initial
37 study [37] to assess participant's experience of BlueIce including use, ratings of satisfaction,
38 helpfulness, ease of use and whether they would recommend it to a friend. In addition, we
39 will assess the degree to which BlueIce was used and which parts of the app were used
40 most often. This will only be completed by UC+BI at 12 weeks.
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44 *Economic Analysis:* A cost-effectiveness analysis will be undertaken alongside the RCT to
45 estimate the incremental cost-effectiveness of usual care + BlueIce (UC+BI) compared to
46 usual care (UC) i.e. incremental cost per unit of health outcome (primary outcome) and
47 Quality Adjusted Life Years (QALYs) using the NHS and social care perspective. In order to
48 estimate QALYs we will use the Child Health Utility 9D (CHU-9D). This preference based
49 generic HRQoL measure is designed specifically for use in the economic evaluation of
50 health care interventions in young people [38]. The CHU-9D contains nine dimensions
51 (worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine and
52 activities), each with five levels of functioning rated for "today". The CHU-9D has been
53 validated for self-completion by young people (aged 7–17 years) [39] and with child and
54 adolescent mental health services [40]. Resource use and cost data will be collected from
55 the participants recruited in the RCT using a resource use questionnaire. Data on self-
56 reported resource use will be compared with the self-harm assessment data that are
57 recorded in clinical case notes (CareNotes). Clinical records will be reviewed for accident
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3 and emergency attendances, out of hours contacts, or primary and secondary care
4 attendances following self-harm over two periods (6 months to baseline; baseline to 6
5 months). We will also quantify the number of face-to-face appointments and total number of
6 hours of CAMHS input provided from baseline to 6 months. Incremental costs will be
7 combined with data on effectiveness/health outcomes. National unit costs will be obtained
8 from available sources including PSSRU (<https://www.pssru.ac.uk/>) and from the National
9 NHS cost collection (<https://www.england.nhs.uk/national-cost-collection/>). Analyses will
10 follow good practice for conducting economic evaluations in health technology assessment
11 [41] and findings will be reported using the CHEERS guidelines [42]. Results will include
12 disaggregated data, as well as synthesis of cost and outcome data, and will include
13 presentation of cost-effectiveness plane [43], cost-effectiveness acceptability curves [44],
14 and detailed consideration of the broader impacts of the results reported. Robustness will be
15 assessed through sensitivity analyses. Multiple imputation will be used to “fill-in” missing cost
16 and outcome data, making the assumption that the data are missing at random [45]. If the
17 young person is under 16, we will also ask their parent or guardian to complete both these
18 questionnaires.
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24 **Sample size**

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26 A 3-point difference on our primary outcome (RTSHIA) between treatment groups represents
27 a clinically important difference [29]. However, we propose to adopt a more conservative
28 approach and will power the study to detect a moderate effect representing a 2-point
29 difference. With a SD of 3.6, 90% power, alpha set at 0.05, we will require 69 participants
30 per group.
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32

33 **Planned analysis**

34 *Statistical analysis*

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36 Our primary analysis will be at the end of the 12-week follow up of the last recruited
37 participant. A detailed Statistical Analysis Plan (SAP) will be developed by the trial
38 statistician in consultation with the project management group and agreed with the SSC
39 before database lock. We will follow the CONSORT extension for reporting randomised
40 controlled trials and will follow recommended guidelines for analysis of our data [46]. Our
41 primary analysis at 12-weeks will be analysed on an intention to treat principle. Although we
42 are not expecting a significant amount of missing data at 12 weeks, the impact of missing
43 data will be assessed by comparing baseline covariates for missing and non-missing cases.
44 In the event that there is evidence of bias being introduced into the analysis then further
45 consideration, including but not limited to multiple imputation, will be given regarding how to
46 address this.
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52 Descriptive statistics will summarise baseline characteristics for each arm and patterns of
53 missing follow-up data will be explored. We will also undertake a per protocol analysis of our
54 primary outcome, total scores on the RTSHIA. Regression analysis adjusting for baseline
55 minimisation variables of age, gender, mood and self-harm frequency will be undertaken.
56 We will conduct sensitivity analyses in which we adjust for prognostic variables for which
57 there is a baseline imbalance between intervention arms. Further sensitivity analyses will
58 use multiple imputation to deal with missing data.
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4 Similar regression analyses will be conducted for secondary outcomes (linear regression for
5 numerical outcomes and logistic regression for binary outcomes). All secondary outcome
6 measures will be compared between the groups and will include summary statistics and
7 confidence intervals for measures of effect size.
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10 Analysis of the 6-month data will be included in a repeated measures analysis to investigate
11 the maintenance of any effect seen at 12 weeks. Analysis of the 6-month follow-up data will
12 be undertaken using a repeated measures analysis of variance with both the 12 weeks and
13 6-month data being included and adjusted for the baseline. The analysis will also be
14 adjusted for the baseline minimisation variables: age, gender, mood and frequency of self-
15 harm as proposed for the primary analysis at 12 weeks.
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18 19 **Confidentiality**

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21 Each participant in the study will be assigned an ID code to keep data anonymous. All
22 information collected will be linked to the specific ID to maintain anonymity. Any confidential
23 data about the participants will be stored on a secure server in a password protected folder,
24 which is only accessible to the study researchers. Furthermore, upon publication no ID
25 codes or personal information will be available.
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29 All information provided will be confidential unless a researcher is concerned that the young
30 person or another is in immediate danger. If the researcher is concerned, they will contact
31 the study lead, who may contact the young person's lead clinician with the disclosed
32 information.
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35 **Adverse event reporting and harms**

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37 For the purposes of this trial, adverse events are defined as increases in extent of self-harm
38 or suicidal ideation regardless of whether they are casually related to the trial procedures.
39 Serious adverse events are those requiring hospital admission. All adverse and serious
40 adverse events will be reported to the project leader and will be reviewed by the Study
41 Steering Committee
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45 Referring clinicians will be requested to inform study researchers should a young person
46 experience an adverse event during their participation in the study. At both follow-up visits,
47 the young person (and parent if under 16) will be asked if any adverse events have occurred
48 and if they think the study is having any negative effects on their mental health and self-harm
49 frequency.
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52 53 **Ethics and dissemination**

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55 Favorable ethical opinion for the research was obtained from the South Central – Oxford B
56 NHS Research Ethics Committee (19/SC/0212) and was approved by the HRA and Health
57 and Care Research Wales, prior to the recruitment of participants commencing at any NHS
58 site. We will disseminate our findings to academics and researchers through high
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3 impact open access publications and through presentations at relevant academic and clinical
4 conferences. Results will be made available to all participants after the completion of the
5 study.
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8 **DISCUSSION** 9

10 There is little research evaluating the effectiveness and cost-effectiveness of interventions in
11 the treatment of self-harm in adolescents. The development of mHealth apps to support
12 mental health interventions for adolescents is novel and, whilst technology offers many
13 potential benefits, there is a lack of evidence regarding their efficacy, safety and acceptability
14 [24].
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18 A concern about the use of digital technologies to improve mental health relates to levels of
19 user engagement, uptake and adherence [47]. A process of co-design involving users and
20 research evidence is more likely to produce an intervention that is evidence-based,
21 engaging, acceptable and feasible to deliver [48]. BlueIce was developed and co-designed
22 with young people with a lived experience of self-harm where young people advised on all
23 aspects of app development including design, layout, flow, and content [27]. Workshops with
24 clinicians ensured that the mood-lifting techniques reflected both the recommended
25 interventions and clinical practice. The results from our initial open study are encouraging
26 [27]. Whilst they suggest that BlueIce is engaging and appealing to young people a more
27 robust analysis is required to substantiate these findings.
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31 Finally, this project will evaluate the use of BlueIce as a prescribed app, used in conjunction
32 with a specialist mental health intervention. Future research will be required to evaluate the
33 use of BlueIce as a standalone, freely accessed self-help app, or the mechanisms
34 underpinning any effects.
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TRIAL STATUS

Recruitment began in January 2020 and, pending COVID, will end around February 2022.

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AUTHOR'S CONTRIBUTION

PS, GT, AML and SR designed and obtained funding for the study. PS, IG and JT drafted the study protocol. All authors contributed to and approved the final version.

ETHICS APPROVAL

The project has been reviewed and approved by the South Central – Oxford B NHS Research Ethics Committee (19/SC/0212) and approved by the HRA and Health and Care Research Wales.

COMPETING INTERESTS

None.

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BMJ Open

Beating Adolescent Self harm (BASH). A randomised controlled trial comparing usual care versus usual care plus a smartphone self-harm prevention app (BlueIce) in young adolescents aged 12-17 who self-harm: study protocol.

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Mental health, Paediatrics, Health services research
Keywords:	MENTAL HEALTH, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Suicide & self-harm < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY

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3 **Beating Adolescent Self harm (BASH). A randomised controlled trial**
4 **comparing usual care versus usual care plus a smartphone self-harm**
5 **prevention app (Bluelce) in young adolescents aged 12-17 who self-harm:**
6 **study protocol.**
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ABSTRACT

Introduction

A mobile app, BlueIce, was co-designed with young people with a history of self-harm to provide them with more accessible and available evidence-based support at times of distress. A preliminary evaluation found that BlueIce was acceptable, safe, and used by young people, and helped to reduce self-harm. The present study is designed to assess the effectiveness and cost-effectiveness of adding BlueIce to usual child and adolescent mental health care (CAMHS).

Methods and analysis

This study is a single-blind, randomised controlled trial comparing usual CAMHS care with usual care plus BlueIce. A total of 138 adolescents aged 12-17 with current or a history of self-harm will be recruited through the Oxford Health NHS Foundation Trust via their CAMHS clinician. The primary outcome is self-harm at 12 weeks assessed using the Risk Taking and Self-Harm Inventory for Adolescents (RTSHIA). Secondary outcomes include mood, anxiety, hopelessness, general behaviour, sleep and impact on everyday life at 12 weeks and 6 months. Health related quality of life and health care resource utilisation data will be collected at baseline, 12 weeks, and 6 months. Post-use interviews at 12 weeks will determine the acceptability, safety, and usability of BlueIce.

Ethics and dissemination

The study was approved by the NHS South Central – Oxford B NHS Research Ethics Committee (19/SC/0212) and by the HRA and Health and Care Research Wales. Findings will be disseminated in peer review open-access journals and at academic conferences.

Trial Registration number

ISRCTN10541045.

Strengths and limitations of this study

- This is the first randomised controlled trial to explore the effects of adding a self-help app (BlueIce) to usual care on the self-harm of adolescents receiving specialist mental health care.
- The study includes a detailed economic analysis to determine the cost-effectiveness of BlueIce
- The BlueIce app was co-designed with young people with a lived experience of self-harm.
- Participants will not be blinded to participant group as this is prohibited by the nature of the intervention.

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3 **Trial registration:** ISRCTN registry, registration number ISRCTN 10541045. Registered on
4 22/07/2019
5

6 **Keywords**

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9 Blueice, Self-Harm, Children, Adolescents, Mobile App. CAMHS, Mental Health, (m)Health
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13 **BACKGROUND**

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17 Self-harm is defined as the deliberate act of causing damage to one's body, for example
18 through self-poisoning or self-cutting [1,2]. It is very prevalent, with around 17.2% of
19 adolescents and 13.4% of young adults being estimated to self-harm [3]. Rates of self-harm
20 are more likely to reduce in young adults compared with younger adolescents [4]. Most self-
21 harm occurs in secret with comparatively few episodes resulting in hospital presentations [5-
22 7]. The most common reasons for self-harm include tension relief, escape from intolerable
23 psychological pain, self-punishment and to show others how bad they are feeling (7). While
24 suicide is less prevalent amongst younger adolescents, it is the third most common cause of
25 death in young people [8]. Self-harm has consistently been cited a risk factor for later suicide
26 attempts [9]. Studies have demonstrated that adolescent non-suicidal self-harm is a strong
27 predictor of future suicide attempts in young adults [10]. Findings such as these highlight the
28 importance of intervening with those who are self-harming in preventing future suicides [11]
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33 Research has identified risk factors for self-harm, including: negative and stressful life events
34 such as childhood maltreatment; self-harm or attempted suicide of a family member; drug
35 and alcohol abuse; psychological factors such as feelings of hopelessness, perfectionist
36 traits, emotional dysregulation, or diagnoses of psychological disorders; lower
37 sociodemographic status; and being female [7,12-14]. Protective factors which may help
38 reduce or prevent self-harm include better access to social support, higher levels of self-
39 esteem and receiving support from parents, as well as being able to re-evaluate one's own
40 thoughts and beliefs [4].
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44 Evidence-based interventions for self-harm in children and adolescents are scarce. Few
45 studies have evaluated cognitive behaviour therapy (CBT) or problem-solving [15,16]. Family
46 therapy does not appear effective [17]. There is some support for dialectical behaviour
47 therapy (DBT) [18-21], and for mentalization-based treatment (MBT) [22]. However, a
48 Cochrane review concluded that there is not much evidence on which to draw conclusions
49 on the effects of interventions for adolescent self-harm and recommended that therapeutic
50 assessment, metallization, dialectical behaviour, and cognitive behaviour therapy warrant
51 further evaluation [15]. Recent reviews have identified new studies evaluating DBT with
52 adolescents and suggest that DBT does now meet criteria for a well-established treatment
53 for self-harm [23]. With recent advances in technology the use of digital interventions to aid
54 the delivery of mental health interventions has become more widespread. The NHS is
55 encouraging the use of technology to improve access to, and the availability of, support and
56 interventions, and to reduce demands on mental health services [24].
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3 There are currently over 15,000 mobile (m)health apps available worldwide, with around
4 5,000 of these targeted at mental health [25]. Apps offer an accessible way of delivering and
5 supporting mental health interventions for young people since over 80% of 12-15-year-olds
6 own a smartphone [26]. Alongside improving accessibility to support, mHealth apps are
7 available 24/7, provide a means for symptom monitoring between face-to-face meetings,
8 may be a preferable method of accessing support for some young people, and provide a
9 route around barriers such as stigma. mHealth apps may also help to lessen the demand on
10 healthcare resources [25,27,28]. However, the evidence base surrounding healthcare apps
11 is severely lacking, with research unable to keep pace with the speed of their development
12 [27]. Therefore, the safety, efficacy, and acceptability of most apps is unknown.
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16 In terms of self-harm and suicide prevention, mhealth appears very acceptable and
17 appealing to young people and offers a way of providing immediate support at times of crisis.
18 However, hardly any suicide or self-harm prevention apps have been developed with a
19 recent systematic review identifying only four [29]. Similarly, systematic reviews evaluating
20 the efficacy of technology and mhealth interventions in preventing suicide or self-harm in
21 adolescents [30] and university students [31] have raised similar concerns. In addition, the
22 availability of self-harm prevention apps is extremely limited with few being available for
23 clinical use [31]. Whilst these reviews all highlight the potential of self-help apps, further
24 research is required to determine their efficacy in self-harm and suicide prevention with
25 clinical populations.
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30 In response to the above, a self-help app, BlueIce, was co-developed with young people with
31 a lived experience of self-harm [32]. It is designed to support self-management of distress
32 and reduce self-harm behaviours. BlueIce has 24/7 accessibility and is a prescribed app to
33 be used alongside face-to-face Child and Adolescent Mental Health Services (CAMHS) [33].
34 BlueIce is password protected and all data is stored locally on the phone [32]. It meets all
35 minimum standards required for NHS accredited apps [34].
36
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38 An initial open study to determine safety, acceptability and usability found that 73% (19/26)
39 of BlueIce users reported a reduction or cessation of self-harm at the 12-week follow-up [27].
40 No participants reported an increase in self-harm during the study. Post-use reductions in
41 symptoms of anxiety and depression were also reported with 88% (29/33) of users electing
42 to keep the app at the end of the study [33].
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45 The aims of this trial are to determine the effectiveness, cost- effectiveness and acceptability
46 of adding BlueIce to usual face-to-face specialist mental health care in the reduction of self-
47 harm in adolescents.
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METHODS

Trial design

This is a two arm, single blind, randomised controlled trial (RCT) comparing the addition of the BlueIce self-help app to usual face-to-face specialist mental health care (UC+BI) with usual specialist mental health care (UC).

Setting and participants

Participants will be recruited through CAMHS provided by Oxford Health NHS Foundation Trust, covering Bath and North-East Somerset, Swindon, Wiltshire, Buckinghamshire, and Oxfordshire.

Young people will be eligible if they: (1) are receiving treatment from CAMHS at the time of referral; (2) have self-harmed at least twice in the last 12 months; and (3) are aged between 12 and 17 years.

Exclusion criteria are: (i) a diagnosis of psychosis; (ii) a significant learning disability which would interfere with the young person's ability to use the app; (iii) young people with active suicidal plans, or (iv) safeguarding concerns where the young person has suffered abuse within the last 6 months or is the subject of a safeguarding investigation.

Recruitment

Clinicians across Oxford Health NHS Foundation Trust will be invited to identify eligible young people who are open to CAMHS. Clinicians will discuss the study and provide interested young people, and if under 16 their parents/carers, with a project information sheet. If interested in participating, their details will be forwarded to the research team.

Consent

Researchers will meet with the young people, and if appropriate their parents/carers, to discuss the project. If the young person wants to take part, the researcher will then obtain consent. If under 16 years old, the young person will be asked to provide assent while their parent or legal guardian will be asked for consent. Those aged 16 years or older will be able to provide their own signed consent. During the COVID pandemic the consent and assessment process will be undertaken remotely (i.e., online or via telephone) to maintain the safety of participants and the research team.

Randomisation

Computer generated randomisation will be independently undertaken by Exeter Clinical Trials Unit. Participants will be randomised in a 1:1 ratio to either usual specialist mental health care (UC) or usual specialist mental health care plus the BlueIce self-help app (UC+BI). Participants will be randomised using REDCap software minimising for gender, age

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3 (over or under 16), self-harm frequency in last 4 weeks (0-2 or ≥ 3), and severity of
4 depression (Mood and Feelings Questionnaire above or below 27, the cut off for severe
5 depression). Because of the nature of the intervention, participants will not be blind to their
6 allocation. However, researchers involved in data collection will remain blind to allocation.
7 Participant allocation will be undertaken by a member of the project team who is not involved
8 in undertaking patient assessments.
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11 12 **Interventions**

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15 Usual Care (UC): Young people will receive individual mental health interventions from
16 specialist CAMHS clinicians. This will be either face-to-face, or, due to COVID, a remotely
17 delivered telephone or video intervention. The nature, content, and duration of this will be
18 captured by the health care resource questionnaire.
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21 Usual care plus Bluelce (UC+BI): In addition to usual care, young people will also receive
22 access to the self-help Bluelce app.
23

24
25 Bluelce is an application for android and apple smartphones. It contains a mood diary,
26 personalised toolbox of mood lifting strategies that are available to the young person 24/7
27 and automatic routing to emergency contact numbers.
28

29 (i). *Mood diary*: Upon entering Bluelce, young people rate their mood. For each mood rating
30 the young person has the option of adding a note to record any particular reason why they
31 might be feeling as they do. Their rating and notes are saved in a calendar which the young
32 person and therapist can review to look for changes and patterns over time. (ii). *Mood lifting*:
33 If the young person rates their mood as low, they will automatically be routed to the mood
34 lifting section. Alternatively, if at any time the young person would like to access this section
35 they can do so directly from the main menu. This section contains a menu of mood lifting
36 and distress tolerance activities, personalised according to the interests of the young person.
37 The activities are designed to counter the common reasons why young people self-harm (to
38 punish themselves, emotional relief, feeling hopeless) and draws on common methods used
39 in cognitive behaviour therapy (CBT) and dialectical behaviour therapy (DBT). The mood
40 lifting section includes 8 activities: 1). Photo library: the young person can upload and save
41 photographs, inspirational quotes and pictures that are associated with happy memories or
42 which might make them feel good. These can be reviewed when low to help the young
43 person remember the positive things in their life: 2). Music library: a music player is included
44 where the young person can upload and store music they enjoy, and which has a positive
45 effect on how they feel. This playlist can be readily accessed when the young person is low
46 as a way of improving their mood: 3). Physical activities: the young person can identify
47 physical activities they enjoy such as sporting activities (e.g., going for a run or riding a bike)
48 or other aerobic activities such as walking the dog. The young person can access their
49 personalised list when low and be reminded about what they can do to get active to improve
50 their mood: 4). Mood changing activities: Bluelce includes a section of activities that make
51 the young person feel good. These could be things like making a cake, watching an episode
52 of a favorite TV series, reading a book, playing with a pet. These provide the young person
53 with a prompt list of activities they can use to change their mood when feeling down: 5).
54 Relaxation and mindfulness exercises: audio-recorded instructions for a 10-minute
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mindfulness session, calming visualisation and a quick controlled breathing exercise (4-7-8 breathing) are included. These can be used to help the young person manage any unpleasant emotions or distressing thoughts: 6). Identification of negative thoughts: this section includes a thought diary where the young person can record any troubling thoughts that are racing through their head. These can be directly typed into BlueIce where they are saved and can be reviewed at a later date. This allows identification of any themes that could be addressed during face-to-face work with their clinician: 7). Ride it out: this section draws on ideas from DBT and helps the young person to tolerate their distress. This includes instructions for an ice dive, a sensory toolbox and a “pros and cons” balance sheet for self-harming: 8). Call a friend: the final section contains the phone numbers of 3-5 people who the young person could contact if they were feeling low and in danger of self-harming. These would be people who make them feel happy and those they could talk with about how they are feeling. This section prompts the young person to reach out to others. (iii) *Emergency contacts*. After accessing the mood lifter, the young person is asked to re-rate their mood. If they are still low and feeling that they might harm themselves, they will be routed through a series of questions to three emergency contact numbers. The young person can select one of these options to automatically call/text emergency support.

Patient and public involvement

BlueIce was co-designed and produced with young people with a lived experience of self-harm. They were involved in exploring the concept (would an app be helpful?), what an app should look like (examples of apps liked and used), the design (font, colours, flow) and content (evidence based and ideas young people found helpful).

In this study, two young people will be recruited to join our Study Steering Committee (SSC). We plan participant workshops to develop study resources, to advise on recruitment and retention issues, to discuss study findings, identify key messages, prepare understandable research summaries in different formats, and identify issues/implications for future research. We intend to involve young people in events disseminating the findings of the study.

Assessment schedule

Data will be collected at: (i) baseline; (ii) post-intervention (12 weeks); and, (iii) follow-up (6 months after randomisation). Data will be collected by Research Assistants, blind to treatment allocation. Participants will be given a £20 voucher after completing the final assessment.

Baseline: Standardised self-report measures of self-harm, depression, anxiety, hopelessness, general behaviour, impact on everyday life, sleep and health-related quality of life and resource use health care questionnaire. These will be complemented with case-note review: to detail resource use i.e., accident and emergency department attendances, out of hours contacts, primary and secondary care attendances following incidents of self-harm in the preceding 6 months.

Post-intervention (12 weeks): Standardised self-report measures of self-harm, depression, anxiety, hopelessness, general behaviour, impact on everyday life, sleep and health-related

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3 quality of life and the resource use health care questionnaire will be repeated (baseline -12
4 weeks). Those in UC + BI will complete a semi-structured interview detailing their use,
5 experience of, and satisfaction with Bluelce.
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8 *Follow-up (6 months after randomisation):* Standardised self-report measures of self-harm,
9 depression, anxiety, hopelessness, general behaviour, impact on everyday life, sleep and
10 health-related quality of life. Case note review will be repeated (12 weeks to 6 months) and
11 the type and total hours of direct and indirect CAMHS intervention provided from
12 randomisation to 6 months detailed.
13

14 15 **Outcome measures**

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17 *Primary Outcome:* Our assessment of self-harm will consist of three parts: A). a brief
18 interview; B). completion of the Risk Taking and Self-Harm Inventory for Adolescents
19 (RTSHIA) [35] and C). the provision of support and advice.
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21
22 *Part A: Interview.* Young people will be asked “have you ever hurt yourself on purpose in any
23 way (e.g., by taking an overdose of pills or by cutting yourself) over the past 3 months?”
24 which was taken from the Avon Longitudinal Study of Parents and Children (ALSPAC)
25 (<http://www.alspac.bris.ac.uk>) [36]. Young people are asked to consider the last 6 months at
26 baseline, and the last 3 months at follow-ups. Those who answer yes will be asked further
27 questions about frequency, method, reason for self-harming, whether they sought medical
28 help and suicidal intent.
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32 *Part B: RTSHIA.* Our primary outcome is self-reported self-harm assessed by the self-harm
33 inventory of the RTSHIA. The RTSHIA was developed in the UK for use with adolescents
34 (aged 11-19 years) [35]. The self-harm inventory consists of 18 items and assesses the
35 presence and frequency of a range of intentional self-injuries (e.g., cutting, burning, self-
36 hitting, self-poisoning). The frequency of each item is rated on a 4-point scale (never, once,
37 more than once, many times) over a defined period. At baseline, the young person is asked
38 to consider the 6 months before their initial assessment. For the 12 week and 6-month
39 assessment the young person considers the 3-month period since their last assessment.
40 Each item is then scored (0,1,2,3) and totalled to provide a current self-harm score. The
41 RTSHIA has good reliability and validity [22,35]. We will analyse total scores and use this
42 information to categorise changes in self-harm from baseline to 12 weeks and 6 months as
43 reduced/stopped vs same/increased.
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48 *Part C: Support and Advice.* At the end of the assessment young people will be given a list
49 of contacts they can call if they are feeling worried about themselves. These include NHS
50 111, Childline and the Samaritans.
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52
53 *Secondary outcomes:* The Mood and Feelings Questionnaire (MFQ) [37], is a self-report
54 questionnaire for depression recommended by NICE consisting of 33 items rated as either
55 “true” (scores 2), “sometimes true” (scores 1) or not true (scores 0). The MFQ has high
56 criterion validity and correlates well with other measures of depression [37]. A total score of
57 27 and above is associated with major depression, 20 with mild depression and 16 with no
58 mood disorder. The Hopelessness Scale for children, adapted from Beck’s Hopelessness
59 Scale [38,39], consists of 17 true–false items measuring hopelessness and negative
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3 expectations for the future. Items endorsed as "true" are summed, with higher scores
4 indicating greater hopelessness. The Hopelessness Scale for children has been widely used
5 within adolescent samples and has consistently demonstrated strong psychometric
6 properties [38,39]. The Revised Child Anxiety and Depression Scale (RCADS) [40] is a 47-
7 item questionnaire with items corresponding to DSM-IV criteria for anxiety in the areas of
8 social phobia, separation anxiety, obsessive compulsive disorder, panic disorder,
9 generalised anxiety disorder and for major depressive disorder. Each item is rated on a 4-
10 point Likert scale of frequency (never 0; sometimes 1; often 2; always 3) which are summed
11 to produce sub-scale and total anxiety scores. The Strengths and Difficulties Questionnaire
12 (SDQ) [41] is a widely used behavioural screening questionnaire consisting of 25 items
13 assessing emotional symptoms, conduct problems, hyperactivity and/or inattention, peer
14 relationship problems, and pro-social behaviour. Each item is rated as not true (0),
15 somewhat true (1) or certainly true (2). A total difficulties score is calculated by summing
16 scores from all subscales except the pro-social. In addition, an impact supplement assesses
17 the degree of distress created by the child's difficulties and the degree to which they interfere
18 with home life, friendships, classroom learning and leisure activities. The five items are
19 summed to produce a total 'impact on everyday life' score which ranges from 0-10. The
20 Sleep Condition Indicator (SCI) [42] is an eight item self-report measure assessing sleep and
21 impact on daytime functioning over the past month on a 5-point scale. Item scores are
22 summed to produce a total score ranging from 0-32. The SCI is an internally consistent
23 ($\alpha = .86$) measure with a clinical cut-off <17 correctly identifying 89% of those with probable
24 DSM-5 insomnia disorder [42].
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31 *Qualitative evaluation:* We will use the semi-structured interview developed in our initial
32 study [43] to assess participant's experience of BlueIce including use, ratings of satisfaction,
33 helpfulness, ease of use and whether they would recommend it to a friend. In addition, we
34 will assess the degree to which BlueIce was used and which parts of the app were used
35 most often. This will only be completed by UC+BI at 12 weeks.
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39 *Economic Analysis:* A cost-effectiveness analysis will be undertaken alongside the RCT to
40 estimate the incremental cost-effectiveness of usual care + Blue Ice (UC+BI) compared to
41 usual care (UC) i.e., incremental cost per unit of health outcome (primary outcome) and
42 Quality Adjusted Life Years (QALYs) using the NHS and social care perspective. In order to
43 estimate QALYs we will use the Child Health Utility 9D (CHU-9D). This preference-based
44 generic HRQoL measure is designed specifically for use in the economic evaluation of
45 health care interventions in young people [44]. The CHU-9D contains nine dimensions
46 (worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine and
47 activities), each with five levels of functioning rated for "today". The CHU-9D has been
48 validated for self-completion by young people (aged 7–17 years) [45] and with child and
49 adolescent mental health services [46]. Resource use and cost data will be collected from
50 the participants recruited in the RCT using a resource use questionnaire. Data on self-
51 reported resource use will be compared with the self-harm assessment data that are
52 recorded in clinical case notes (CareNotes). Clinical records will be reviewed for accident
53 and emergency attendances, out of hours contacts, or primary and secondary care
54 attendances following self-harm over two periods (6 months to baseline; baseline to 6
55 months). We will also quantify the number of face-to-face appointments and total number of
56 hours of CAMHS input provided from baseline to 6 months. Incremental costs will be
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3 combined with data on effectiveness/health outcomes. National unit costs will be obtained
4 from available sources including PSSRU (<https://www.pssru.ac.uk/>) and from the National
5 NHS cost collection (<https://www.england.nhs.uk/national-cost-collection/>). Analyses will
6 follow good practice for conducting economic evaluations in health technology assessment
7 [47] and findings will be reported using the CHEERS guidelines [48]. Results will include
8 disaggregated data, as well as synthesis of cost and outcome data, and will include
9 presentation of cost-effectiveness plane [49], cost-effectiveness acceptability curves [50],
10 and detailed consideration of the broader impacts of the results reported. Robustness will be
11 assessed through sensitivity analyses. Multiple imputation will be used to “fill-in” missing cost
12 and outcome data, making the assumption that the data are missing at random [51]. If the
13 young person is under 16, we will also ask their parent or guardian to complete both these
14 questionnaires.
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19 **Sample size**

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21 A 3-point difference on our primary outcome (RTSHIA) between treatment groups represents
22 a clinically important difference [35]. However, we propose to adopt a more conservative
23 approach and will power the study to detect a moderate effect representing a 2-point
24 difference. With a SD of 3.6, 90% power, alpha set at 0.05, we will require 69 participants
25 per group.
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29 **Planned analysis**

30 *Statistical analysis*

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32 Our primary analysis will be at the end of the 12 weeks follow up of the last recruited
33 participant. A Statistical Analysis Plan (SAP) will be developed by the trial statistician in
34 consultation with the project management group, and agreed with the SSC before database
35 lock. We will follow the CONSORT extension for reporting randomised controlled trials and
36 will follow recommended guidelines for analysis of our data [52]. Our primary analysis at 12-
37 weeks will be analysed on an intention to treat principle. Although we are not expecting a
38 significant amount of missing data at 12 weeks, the impact of missing data will be assessed
39 by comparing baseline covariates for missing and non-missing cases. In the event that there
40 is evidence of bias being introduced into the analysis then further consideration, including
41 but not limited to multiple imputation, will be given regarding how to address this.
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46 Descriptive statistics will summarise baseline characteristics for each arm and patterns of
47 missing follow-up data will be explored. We will also undertake a per protocol analysis of our
48 primary outcome, total scores on the RTSHIA. Regression analysis adjusting for baseline
49 minimisation variables of age, gender, mood and self-harm frequency will be undertaken.
50 We will conduct sensitivity analyses in which we adjust for prognostic variables for which
51 there is a baseline imbalance between intervention arms. Further sensitivity analyses will
52 use multiple imputation to deal with missing data.
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56 Similar regression analyses will be conducted for secondary outcomes (linear regression for
57 numerical outcomes and logistic regression for binary outcomes). All secondary outcome
58 measures will be compared between the groups and will include summary statistics and
59 confidence intervals for measures of effect size.
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4 Analysis of the 6-month data will be included in a repeated measures analysis to investigate
5 the maintenance of any effect seen at 12 weeks. Analysis of the 6-month follow-up data will
6 be undertaken using a repeated measures analysis of variance with both the 12 weeks and
7 6-month data being included and adjusted for the baseline. The analysis will also be
8 adjusted for the baseline minimisation variables: age, gender, mood and frequency of self-
9 harm as proposed for the primary analysis at 12 weeks.
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12 13 **Trial Management**

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15 An independent Study Steering Group (SSG) will be established to monitor progress,
16 advise the investigators in general scientific and management issues and ensure that there
17 are no major deviations from the study protocol. The SSG will include an independent chair,
18 and at least 2 other independent members with research experience with young people with
19 mental health problems and/or self-harm. The SSG will also include two young people from
20 the Oxford Health participation group. The SSG will meet at least once per year. The lead
21 applicant will inform the SSG Chair who may call additional meetings when there are matters
22 arising from the conduct or management of the trial that might require their advice
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26 A Data Monitoring Committee (DMC) was not convened as there were no planned interim
27 analysis. Adverse events were reviewed by the SSG.
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29

30 **Adverse event reporting and harms**

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32 For the purposes of this trial, adverse events are defined as increases in extent of self-harm
33 or suicidal ideation regardless of whether they are casually related to the trial procedures.
34 Serious adverse events are those requiring hospital admission. All adverse and serious
35 adverse events will be reported to the project leader and will be reviewed by the Study
36 Steering Committee
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40 Referring clinicians will be requested to inform study researchers should a young person
41 experience an adverse event during their participation in the study. At both follow-up visits,
42 the young person (and parent if under 16) will be asked if any adverse events have occurred
43 and if they think the study is having any negative effects on their mental health and self-harm
44 frequency.
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48 **Ethics and dissemination**

49 Favorable ethical opinion for the research was obtained from the South Central – Oxford B
50 NHS Research Ethics Committee (19/SC/0212) and was approved by the HRA and Health
51 and Care Research Wales, prior to the recruitment of participants commencing at any NHS
52 site. We will disseminate our findings to academics and researchers through high
53 impact open access publications and through presentations at relevant academic and clinical
54 conferences. Results will be made available to all participants after the completion of the
55 study.
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DISCUSSION

There is little research evaluating the effectiveness and cost-effectiveness of interventions in the treatment of self-harm in adolescents. Intervening with those who self-harm is important since self-harm during adolescence is a significant risk factor for future suicide attempts and completed episodes (10,11). The development of mHealth apps to support mental health interventions for adolescents offers a novel and accessible way of providing support at times of crisis. However, whilst technology offers many potential benefits, few apps to prevent self-harm have been developed and there is a lack of evidence regarding their efficacy, safety, and acceptability [25].

Strengths and limitations

This is the first adequately powered randomised controlled trial of a digital self-help app co-designed with, and used by, young people aged 12-17 years in receipt of specialist mental health services. This study will add to the evidence-base and will document the effectiveness and cost-effectiveness of adding a self-help app to usual care. If benefits are identified, BlueIce app can be widely made available to young people attending specialist CAMHS to provide help at times of distress.

As it is not feasible to blind participants to allocation, the research team are aware of the need to maintain equipoise and to present the two interventions to referring clinicians and participants in a balanced way. Researchers will remain blind to treatment arm and, if this is inadvertently broken, subsequent assessments will be conducted by another member of the research team. Similarly, following guidance from our participation group, those allocated to usual care will be provided with BlueIce at their final, six-month assessment.

We have minimised the possibility of contamination between the trial arms. BlueIce is a prescribed app and is not freely available to download and use. Those allocated to UC+BI will be sent a single use download code. Once activated, BlueIce will automatically be installed on the participant's smartphone and the access code will no longer work. Participants are therefore unable to share/pass the app/access code to others.

Finally, this project will evaluate the use of BlueIce as a prescribed app, used in conjunction with a specialist mental health intervention. Future research will be required to evaluate the use of BlueIce as a standalone, freely accessed self-help app, or the mechanisms underpinning any effects.

TRIAL STATUS

Recruitment began in January 2020 and, pending COVID, will end around June 2022.

TRIAL SPONSOR

Oxford Health NHS Foundation Trust. The sponsor will have no role in interpreting data, writing reports or decisions to publish findings.

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AUTHOR'S CONTRIBUTION

PS, GT, AML and SR designed and obtained funding for the study. PS, IG and JT drafted the study protocol. All authors contributed to and approved the final version.

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ETHICS APPROVAL

The project has been reviewed and approved by the South Central – Oxford B NHS Research Ethics Committee (19/SC/0212) and approved by the HRA and Health and Care Research Wales.

COMPETING INTERESTS

Bluece is the intellectual property of Paul Stallard, the creator of the app. He has no financial benefits from the app. The other authors have declared no interests.

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

Section/item	Item No	Description
Administrative information		
Title	1	Beating Adolescent Self harm (BASH). A randomised controlled trial comparing usual care versus usual care plus a smartphone self-harm prevention app (BlueIce) in young adolescents aged 12-17 who self-harm: study protocol (Paper page 1)
Trial registration	2a	ISRCTN registry, registration number ISRCTN 10541045. Registered on 22/07/2019 (Paper page 2)
	2b	All items from the World Health Organization Trial Registration Data Set (N/A)
Protocol version	3	Attached protocol, dated 18.01.2019, version 1.
Funding	4	This study was funded by the National Institute for Health Research, Research for Patient Benefit programme (PB-PG-1217-20004). (Paper page 13)
Roles and responsibilities	5a	PS, GT, AML and SR designed and obtained funding for the study. PS, IG and JT drafted the study protocol. All authors contributed to and approved the final version (Paper page 13)
	5b	Oxford Health NHS Foundation Trust (Paper page 13I)
	5c	The sponsor/funder will have no role in interpreting data, writing reports or decisions to publish findings (Paper page 13).
	5d	Trial management defined (Paper page 11)
Introduction		
Background and rationale	6a	Paper page 3-4
	6b	This is a two arm, single blind, randomised controlled trial (RCT) comparing the addition of the BlueIce self-help app to usual face-to-face specialist mental health care (UC+BI) with usual specialist mental health care (UC). (Paper page 5)

1			
2	Objectives	7	The aims of this trial are to determine the effectiveness, cost-
3			effectiveness and acceptability of adding BlueIce to usual face-to-face
4			specialist mental health care in the reduction of self-harm in
5			adolescents. (Paper page 4)
6			
7	Trial design	8	Paper page 5 trial design
8			
9			

Methods: Participants, interventions, and outcomes

15	Study setting	9	Paper page 5 setting and participants
16			
17	Eligibility criteria	10	Paper page 5 under setting and participants
18			
19	Interventions	11a	Paper pages 6-7 under interventions
20			
21		11b	N/a
22			
23		11c	N/a
24			
25		11d	Paper page 6 usual care.
26			
27	Outcomes	12	Outcomes defined paper pages 8-9.
28			
29	Participant	13	Assessment timeline defined paper pages 7-8.
30	timeline		
31			
32	Sample size	14	Sample size defined paper page 9.
33			
34	Recruitment	15	N/a
35			

Methods: Assignment of interventions (for controlled trials)

Allocation:

40	Sequence	16a	Randomisation defined paper page 5-6
41	generation		
42			
43	Allocation	16b	Concealment described paper page 6
44	concealment		
45	mechanism		
46			
47	Implementation	16c	Participant allocation described paper page 6
48			
49	Blinding	17a	Blinding described paper page 6
50	(masking)		
51			
52		17b	N/a
53			
54			

Methods: Data collection, management, and analysis

57	Data collection	18a	Outcome assessments and assessment schedule defined paper
58	methods		pages 7-9
59			
60			

1			
2		18b	N/a
3			
4	Data	19	Data management procedures are described in the attached protocol
5	management		page 14.
6			
7	Statistical	20a	Described in statistical analysis paper page 10
8	methods		
9			
10		20b	Described in statistical analysis paper page 10
11			
12		20c	Described in statistical analysis paper page 10
13			
14	Methods: Monitoring		
15			
16	Data monitoring	21a	No interim analysis was planned and as such a DMC was not
17			considered necessary. Data monitoring and review of adverse events
18			was undertaken by the SSG. Trial management section paper page
19			11
20			
21		21b	N/a. No interim analysis was planned.
22			
23			
24	Harms	22	Reporting of serious adverse events defined in attached protocol page
25			13.
26			
27	Auditing	23	N/a
28			
29			
30	Ethics and dissemination		
31			
32	Research ethics	24	Ethical approval stated paper page 11
33	approval		
34			
35	Protocol	25	Protocol will be updated with version number and date as appropriate
36	amendments		
37			
38	Consent or assent	26a	Summarised paper page 5
39			
40		26b	N/a
41			
42	Confidentiality	27	Management of personal information described in the attached
43			protocol page 14.
44			
45	Declaration of	28	Competing interest statement declared paper page 13.
46	interests		
47			
48	Access to data	29	Summarised in attached protocol page 14
49			
50			
51	Ancillary and	30	N/a
52	post-trial care		
53			
54	Dissemination	31a	Dissemination plans described in paper page 11.
55	policy		
56			
57		31b	Not specified
58			
59		31c	None made
60			

Appendices

Informed consent materials	32	Consent forms uploaded
Biological specimens	33	N/a

*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](#)" license.

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