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Clinical effectiveness and safety of adding a self-harm prevention app (BlueIce) to specialist mental health care for adolescents who repeatedly self-harm: A single blind randomised controlled trial (the BASH study)

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ABSTRACT

No randomised controlled trials have evaluated whether the addition of a smartphone app to usual child and adolescent mental health care (CAMHS) can reduce self-harm in adolescents (<18 years) with repeated self-harm. We enrolled 170 participants aged 12–17, receiving CAMHS treatment who had self-harmed ≥2 in the past 12 months. Participants were randomised via an independent web-based system (1:1, minimised for gender, age, self-harm frequency, and depression severity) to treatment as usual (TAU) or treatment as usual plus BlueIce (TAU+BI). BlueIce is a self-harm prevention app that includes techniques from CBT and DBT that was co-designed with adolescents who self-harm. The primary outcome was change from baseline to 12-weeks on the self-harm scale of the Risk Taking and Self-Harm Inventory for Adolescents (RTSHIA), analysed by intention to treat (ITT). Emergency department attendances or admissions for self-harm were assessed over 6-months via a review of clinical records. Both groups improved but there were no statistically significant between group differences at 12 weeks or 6 months on the self-harm scale of the RTSHIA. There were fewer emergency department attendances and admissions in those who received the app, a finding that approached statistical significance. BlueIce can be helpful in some important aspects by contributing to fewer emergency department admissions and attendances.

Trial registration: Trial registration number ISRCTN10541045.

1. Introduction

Self-harm i.e. intentional self-injury or self-poisoning, irrespective of motivation (NICE, 2022), is common during adolescence. The lifetime prevalence of self-harm in children (under the age of 12) and adolescents (aged 12–17) has been estimated to be between 16.9 % and 21.9 % (Geoffroy et al., 2020; Gillies et al., 2018). A number of factors have been shown to be related to self-harm including female sex, early teenage years (12–15 years) and depressive symptoms (Hawton et al., 2012). Of those who self-harm, half will engage in repeated events (Madge et al., 2008). Rates of self-harm have risen following COVID with adolescent presentations to health services and emergency departments increasing, particularly amongst adolescent girls (Steeg et al., 2022; Madigan et al., 2023).

Self-harm is an important risk factor for subsequent suicide in young people and is the second leading cause of death in young people aged 15–24 (Hawton et al., 2020; Mokdad et al., 2016). Reducing self-harm and suicide in adolescents are major public health concerns although the evidence for effective interventions for adolescents who self-harm is scarce (Bahji et al., 2021; Witt et al., 2021).

Few episodes of self-harm result in hospital presentations with most occurring outside of normal working hours, peaking in the hours around midnight (Geulayov et al., 2018; Evoy et al., 2023). This, alongside the limited availability of traditional mental health services, has stimulated

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interest in the use of digital technology to support patients (NHS England, 2019). Digital technologies are appealing to adolescents who are early adopters and enthusiastic users with nearly all (97 %) of those aged 12–17 in the UK owning their own mobile phone (Office of Communications, 2022). One digital technology, smartphone apps, are particularly popular, with an estimated 90 % of the population in developed countries using apps on a daily basis (Lecomte et al., 2020).

The availability of apps focusing on mental health have grown exponentially, although few have been developed specifically for adolescents under the age of 18 years (Grist et al., 2017; Melia et al., 2020). Systematic reviews have identified only two apps, specifically addressing self-harm, that have been developed for this age group (Cliffe et al., 2021; Grist et al., 2017; Melia et al., 2020). Both report findings from small scale, pilot feasibility studies but no randomised controlled trials have yet been undertaken (Di Simplicio et al., 2020; Stallard et al., 2018). In terms of participants, only one, BlueIce, has exclusively recruited adolescents with severe mental health problems receiving specialist mental health services (Stallard et al., 2018).

BlueIce is an app developed and co-designed with young people with a lived experience of self-harm, specifically focusing on the prevention and reduction of self-harm (Grist et al., 2018). Initial results from small, uncontrolled studies indicate that BlueIce is acceptable to young people, safe, perceived to be useful, and resulted in reductions in self-harm, and symptoms of anxiety and depression (Grist et al., 2018; Stallard et al., 2018). An adequately powered randomized controlled trial, Beating Adolescent Self-Harm (BASH), was initiated to assess the clinical and cost effectiveness, safety and acceptability of adding BlueIce to treatment as usual provided by specialist child and adolescent mental health services (CAMHS) (Greenhalgh et al., 2021).

The aim of this paper is to report on the clinical outcomes from the BASH trial and to test the hypotheses that the addition of BlueIce to usual care will result in less self-harm and fewer symptoms of depression, anxiety, insomnia, hopelessness and behavioural problems.

2. Methods

2.1. Design

BASH is a two-arm, single-blind, randomized controlled trial (RCT) comparing the addition of the BlueIce self-help app to treatment as usual (TAU + BI) with treatment as usual (TAU). Participants were recruited from specialist community child and adolescent mental health services (CAMHS) provided by Oxford Health NHS Foundation Trust in the UK across the geographical areas of Bath and North-East Somerset, Buckinghamshire, Oxfordshire, Swindon, and Wiltshire.

2.2. Participants

Eligible participants were identified by their mental health clinician. The research team provided regular presentations to clinical staff, attended clinical team meetings, provided study summaries, and progress briefings, to advertise the study. Contact details of interested participants were sent to the research team.

Inclusion criteria were accepted by, and/or receiving treatment from specialist CAMHS, repeated self-harmed ($\geq$2 in the past year) and, aged between 12 and 17 years (Greenhalgh et al., 2021). Self-harm was validated by the young person's CAMHS clinician and/or a review of the young person's clinical notes. Exclusion criteria were a diagnosis of psychosis, a significant learning disability which interfered with ability to use the app, immediate suicide risk (i.e. actively suicidal/planning suicide) or had suffered abuse or been subject to a safeguarding investigation within the past 6 months (Greenhalgh et al., 2021).

Young people under 16 provided informed assent with their parent or legal guardian providing informed consent. Both were required for inclusion. Those aged 16 years or older provided their own informed consent.

The trial was 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.

2.3. Procedures

Computer-generated randomization was undertaken by an independent researcher at Exeter Clinical Trials Unit who had no ongoing involvement with the rest of the trial. Participants were randomized in a 1:1 ratio to either TAU or TAU +BI, minimising for sex assigned at birth, age ($<$16 vs $\geq$16), self-harm frequency in last 4 weeks (0–2 or $\geq$3 times) and severity of depression (Mood and Feelings Questionnaire (MFQ) ($<$27 vs $\geq$27). Minimisation performs better than stratification in small, complex trials such as this with a number of prognostic factors.

Participants, or if under 16 their carers, were contacted by the principal investigator (PS) to confirm arm allocation. The principal investigator had no involvement in assessment and data collection. If allocated to BlueIce, the young person's telephone details and phone operating system were confirmed. They were provided with a single-use download code to install BlueIce, a link to an informational video providing an overview of the app, and a contact link (PS) in case of problems.

Data were collected from participants at baseline, post-intervention (12-weeks) and follow-up (6-months) by research assistants blind to treatment allocation. These were collected face-to-face pre-COVID but during the pandemic were collected via telephone or online meetings. Blindness was broken on 14 occasions during the 12-week assessment. To maintain blindness, the 6-month assessment was completed by a different research assistant.

Clinical staff were blind to treatment allocation. By the nature of the intervention participants were not blind to their allocation.

Those participants who completed the final assessment received a £20 shopping voucher.

2.4. Outcomes

The primary outcome was self-reported change on the self-harm scale of the Risk Taking and Self Harm Inventory (RTSHIA) from baseline to 12-weeks (Vrouva et al., 2010). The RTSHIA was developed and validated for use with the population who participated in this project: UK adolescents aged 12–18 years who had self-harmed and were receiving treatment from specialist child and adolescent mental health services. The self-harm inventory consists of 18 items assessing different forms of self-injury (e.g. hitting, burning, cutting), self-poisoning, relationship abuse, thoughts and acts of suicide, and injury severity. The self-harm scale includes items from established self-harm scales, the Deliberate Self-Harm Inventory (Gratz, 2001; Lundh et al., 2007) and Self-Harm Inventory (Sansone and Sansone, 2002), with additional items being generated and tested during scale development. Inter-item reliability (Cronbach's alpha 0.93) and test–retest reliability (Cronbach's alpha 0.87), were high with good correlation with standardised measures of depression and suicidality (Vrouva et al., 2010).

Secondary clinical outcomes were self-reported change from baseline to 12-weeks on the following standardised measures. Symptoms of depression were assessed by the Mood and Feelings Questionnaire (MFQ) (Costello and Angold, 1988). The MFQ is a 33-item self-report questionnaire which assesses depressive symptoms over a two-week period. Responses are rated on a 3-point scale, Not true (0), Sometimes true (1) and True (2). Total scores can range from 0 to 66 with a total score of 27 and above being associated with severe depression (Wood et al., 1995).

The revised Child Anxiety and Depression Scale (RCADS) is a 47-item self-report questionnaire assessing DSM-IV criteria for social phobia, separation anxiety, obsessive compulsive disorder, panic disorder, generalised anxiety disorder and low mood (Chorpita et al., 2000). Each item is rated on a 4-point Likert scale of frequency ranging from never

(0) to always (3). Items are then summed to produce sub-scale and total anxiety scores. There are age and gender related norms for identifying clinically significant scores (total score ≥64–80).

The Sleep Condition Indicator (SCI) is an eight item self-report measure, assessing sleep and impact on daytime functioning over the past month on a 5-point scale (Espie et al., 2014). Item scores are summed to produce a total score ranging from 0 to 32. The SCI is an internally consistent (α = 0.86) measure with a clinical cut-off <17 correctly identifying 89 % of those with probable DSM-5 insomnia disorder (Espie et al., 2014).

The Strengths and Difficulties Questionnaire (SDQ) is a widely used behavioural screening questionnaire consisting of 25 items assessing emotional symptoms, conduct problems, hyperactivity and/or inattention, peer relationship problems and prosocial behaviour (Goodman, 1997). Each item is rated as not true (0), somewhat true (1) or certainly true (2). A total difficulty score is calculated by summing scores from all subscales except the prosocial. Age and gender related norms are available to classify scores as close to average, slightly raised, high and very high. In addition, an impact supplement assesses the degree of distress created by the child's difficulties and the degree to which they interfere with home life, friendships, classroom learning and leisure activities. The five items are summed to produce a total 'impact on everyday life' score, which ranges from 0 to 10.

The Beck Hopelessness Scale (BHS) for children, was adapted from Beck's Hopelessness Scale, consists of 17 true– false items measuring hopelessness and negative expectations for the future (Beck et al., 1974; Kazdin et al., 1983). Items endorsed as 'true' are summed, with higher scores indicating greater hopelessness. The Hopelessness Scale for children has been widely used within adolescent samples and has consistently demonstrated strong psychometric properties (Kazdin et al., 1986).

Safety was determined by adverse events (AE i.e. escalations in self-harm and/or Emergency Department attendance) and serious adverse events (SAE i.e. required hospital admission) over the 6 month duration of the trial. These were identified through young person or carer reports, clinician notifications and an audit of all clinical records.

2.5. Interventions

Treatment as Usual (TAU): Young people received mental health interventions from specialist mental health clinicians, either face-to-face or, remotely via telephone or Microsoft teams. Interventions focused on both their primary mental health problems and their self-harm. Interventions involved a combination of mental health and/or risk assessments; psychological therapy delivered individually or in groups, face to face or digitally, to young people and/or their carers; pharmacological interventions; multi-disciplinary team review and discussion; liaison with other services and professionals. Those assigned to TAU were provided with access to BlueIce after completing the 6-month assessment.

Treatment as Usual plus BlueIce (TAU+BI): In addition to usual care, young people received access to the self-help BlueIce app. BlueIce is a co-designed application for android and apple smartphones which contains a mood diary, personalised toolbox of mood lifting strategies and automatic routing to emergency contact numbers (Grist et al., 2018). The mood diary allows young people to monitor their mood and to record any particular reason why they might be feeling as they do. The mood lifter consists of eight sections which can be personalized according to the interests of the young person. The sections draw on common methods used in cognitive behaviour therapy (CBT) and dialectical behaviour therapy (DBT), promising interventions for the treatment of self-harm (Bahji et al., 2021; Witt et al., 2021). The mood lifter consists of a photo library of positive memories; a music library of uplifting music; a menu of physical activities to encourage activity; a menu of mood lifting activities that make the young person feel good; audio relaxation and mindfulness exercises; a diary to record and challenge troubling or unhelpful negative thoughts; exercises to help the young person ride out and tolerate their distress and a list of people to contact if feeling low and in danger of self-harming. Finally, details of emergency contacts where the young person can call/text emergency support were provided. The password protected app is installed on the young person's mobile phone and is available for use as often as they choose, 24/7. A more detailed overview of the app content is provided elsewhere (Grist et al., 2018) and can be viewed at https://www.oxfordhealth.nhs.uk/blueice/.

2.6. Statistical analysis

The statistician (GT) was blind to arm allocation until after the analyses were complete. The study was powered to detect a clinically important 2-point difference on the primary outcome (self-harm scale of the RTSHIA) between treatment groups. This equates to a reduction in self-harm frequency on one of the 18 items of self-harm from many times to once or, from more than once to never. To detect a 2-point difference on the self-harm scale of the RTSHIA, 69 participants per group were needed with a SD of 3.6, 90 % power and a 2-sided alpha set at 0.05. To allow for 20 % attrition a total cohort of 170 was required.

The primary analysis at 12 weeks was conducted on an intention-to-treat principle with all randomly assigned participants included in the analysis. The impact of missing data was assessed by (i) ascertaining amount (expected to be less than 10 %) and if large amounts were missing by (ii) comparing baseline covariates for missing and non-missing cases.

Descriptive statistics summarise baseline characteristics for each arm and patterns of missing follow-up data. Change on primary and secondary outcomes from baseline to 12-weeks and baseline to 6-months by intervention arm were explored. An analysis of variance (ANCOVA) of the primary outcome, total scores on the RTSHIA self-harm scale, was undertaken adjusting for baseline minimisation variables of age, sex assigned at birth, mood and self-harm frequency. Similar adjusted ANCOVA analyses for all secondary outcomes compared between group differences and include summary statistics and CIs. Sensitivity analyses were undertaken in which we adjusted for prognostic variables (age, sex assigned at birth, mood severity and self-harm frequency).

All randomly assigned participants were included in the safety analysis. Mental health adverse events (i.e. increases in self-harm and/or Emergency Department attendance) and serious adverse events (i.e. requiring hospital admission) were identified through clinician and participant/carer reports and a review of the clinical records of all participants. The analysis captured adverse events throughout the 6-month trial.

3. Results

Between 18 November 2019 and 7 July 2022, 244 potential participants were referred to the BASH study. Of these, 74 were not enrolled; 7 were not eligible, 47 declined to participate and it was not possible to contact 20. The remaining 170 were enrolled, assessed and randomized to TAU (n = 85) or TAU +BI (n = 85). At 12-weeks, the primary assessment point, 138 (81.2 %) participants were retained (70 TAU; 68 TAU+BI), with 129 (75.9 %) completing the final 6-month assessment (68 TAU; 61 TAU+BI). Of those who completed assessments, assessment completion was high with very few individual assessment items missing at 12-weeks and 6-months on the primary (<2 %) and secondary (<10 %) outcomes (eTable 1 in the Supplement).

The study CONSORT diagram is presented in Fig. 1.

Almost half (79, 46.5 %) of participants were referred from mental health practitioners or senior mental health practitioners (i.e. predominantly nurses). Child and adolescent psychiatrists (22, 12.9 %), clinical psychologists (13, 7.6 %) and family therapists (10, 5.9 %) were the next largest referrers. All core professional groups within specialist child mental health services referred participants to the trial.

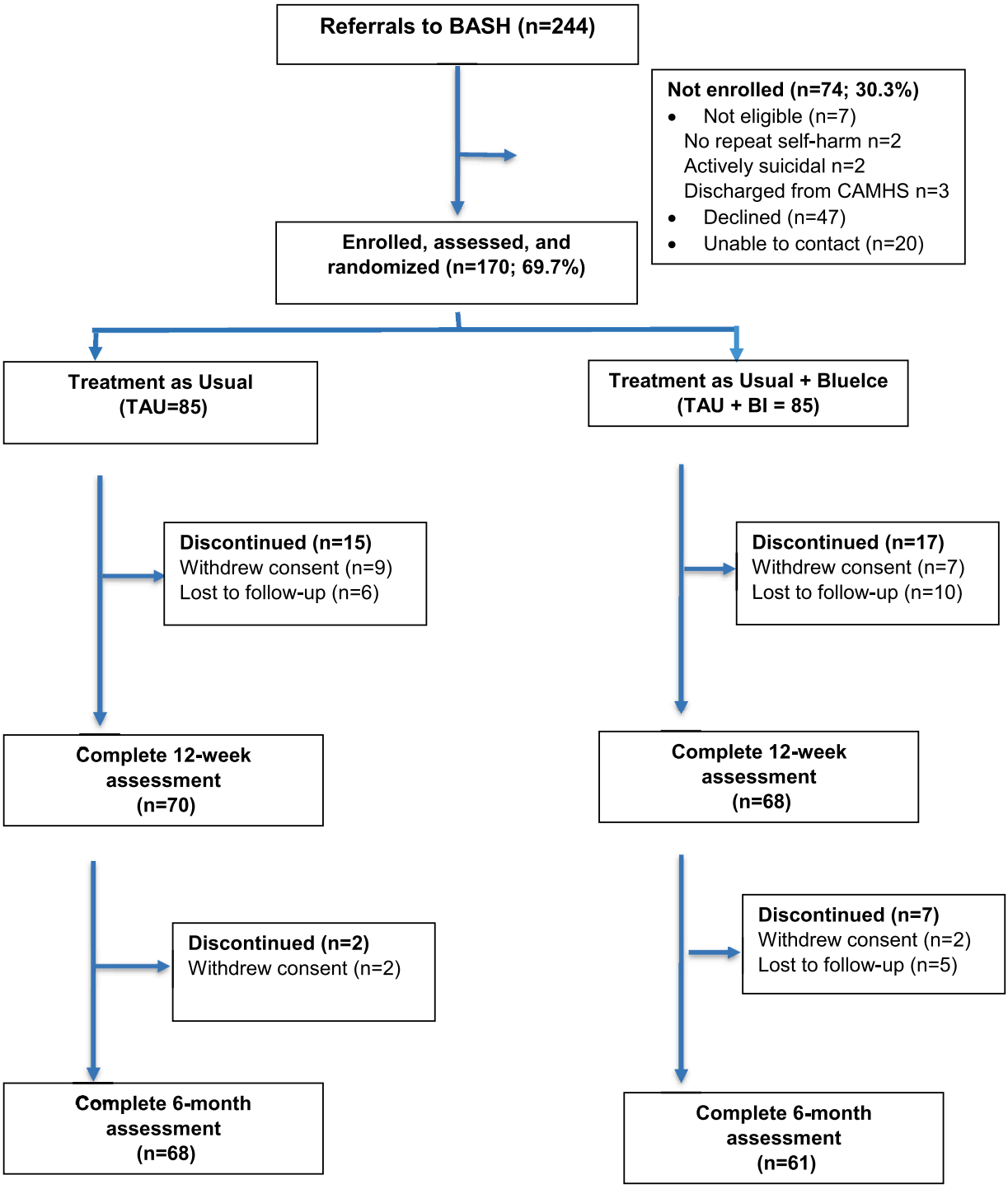

Fig. 1. BASH consort diagram.

The mean age of participants was 15.6 (SD 1.4; range 12.2 to 17.8) years (Table 1). Participants were predominantly female at birth, 154 (91 %), and of British white ethnicity, 151 (89 %). The primary mental health diagnoses recorded in clinical records were mood disorders (n = 49, 29 %), anxiety disorders (n = 35, 21 %) or mixed mood/anxiety disorders (n = 55, 32 %), with 57 (34 %) also presenting with diagnosed or suspected (i.e. referred for further assessment) neurodevelopmental disorders. Mental health medication had been prescribed to 66 (38.8 %) participants in the 6 months prior to study enrolment.

At baseline, 158 (93 %) scored ≥27 on the MFQ, the cut-off for identifying severe depression. Two-thirds, (111, 66 %) achieved t-scores of ≥70 on the RCADS indicating clinical levels of anxiety. On the SCI, 139 (82 %) scored <17 suggesting probable insomnia with 121 (71 %) scoring ≥ 20 (top 5 % of population) on the SDQ, indicating significant behavioural or emotional problems.

Recent self-harm was common, with 154 (91 %) reporting self-harm in the past <30 days with 111 (65 %) self-harming >10 times in the past 6 months. Table 2 one third, (56, 33.1 %) reported that their intention was to die during their last episode of self-harm with 152 (89 %) feeling that life was not worth living and 155 (91 %) wishing they were dead and away from it all.

In terms of treatment as usual, there were no statistically significant

Table 1
Demographics by trial arm.

Variable	Category	TAU + BI (n = 85)		TAU (n = 85)	
		Mean (SD)	Min, Max	Mean (SD)	Min, Max
Baseline age	Years	15.56(1.40)	12.16,17.83	15.70(1.32)	13.08,17.83
		Number	**%**	**Number**	**%**
Birth Gender	Female	78	91.8	76	89.4
	Male	7	8.2	9	10.6
Identifies with sex assigned at birth	No	10	11.8	8	9.4
	Yes	75	88.2	77	90.6
Referrer	Senior mental health Practitioner	33	38.8	35	41.2
	Mental health Practitioner	5	5.9	6	7.1
	CBT therapist	4	4.7	5	5.9
	Clinical Psychologist	5	5.9	8	9.4
	Consultant Psychiatrist	9	10.6	13	15.3
	Educational Wellbeing Practitioner	5	5.9	1	1.2
	Child Psychotherapist	4	4.7	2	2.4
	Professional in training	5	5.9	2	2.4
	Family Therapist	6	7.1	4	4.7
	Other (SW, OT, support worker, AP)	4			
	4.7	6	7.0		
	Child Wellbeing Practitioner	5	5.9	3	3.5
Ethnicity	British White	75	88.2	76	89.4
	Mixed White Asian	2	2.4	1	1.2
	Mixed White Caribbean	1	1.2	1	1.2
	Mixed White African	0	0.0	1	1.2
	Mixed unspecified	4	4.7	2	2.4
	Declined to say	3	3.5	4	4.7
Primary mental health problem	Mood disorders	22	25.9	27	31.8
	Anxiety disorders	19	22.4	16	18.8
	Mixed mood/anxiety	31	36.5	24	28.2
	Eating disorders	5	5.9	10	11.8
	Stress reactions	4	4.7	6	7.1
	Other	4	4.7	2	2.4
Prescribed mental health medication (in past 6 months)	Yes No	33 52	38.8 61.2	33 52	38.8 61.2
Underlying Neurodevelopmental disorder (ND)	No	54	63.5	59	69.4
	ASD	14	16.5	9	10.6
	ADHD	3	3.5	6	7.1
	ASD + ADHD	7	8.2	3	3.5
	Tourette's syndrome	0	0.0	4	4.7
	Other	1	1.2	0	0.0
	Waiting ND assessment	6	7.1	4	4.7

ASD=Autistic Spectrum Disorder; ADHD=Attention Deficit Hyperactivity Disorder.

between group differences in mental health contacts or mental health medication during the 6 months of the trial. Participants in TAU+BI had a mean of 8.53 (sd=8.60) mental health contacts compared with 9.00 in TAU (SD=9.71) [t_{168}=−0.335, p = 0.738; 95 %CI −3.25 to 2.31]. Similarly, 40 participants in TAU+BI were prescribed mental health medication compared with 45 in TAU (X^2=0.588, df=1, p.443).

A comparison of baseline scores between those who completed the 12-week assessment and those who did not by treatment arm are presented in the supplement (eTable 2). There were no statistically significant differences on any measure or sub-scale. Unadjusted mean scores on the primary and secondary scales and sub-scales at 12-weeks and 6-months are reported (eTables 3 & 4 in the Supplement). At 12-weeks after randomisation, the mean change in RTSHIA self-harm scale was statistically significant for TAU+BI (-7.14, 95 % CI: -10.28 to -4.01) and TAU (−5.53, 95 % CI: −8.33 to −2.73) (Table 3). The change difference between the groups was not statistically significant (1.61; 95 %CI −1.20 to 4.43, p = 0.26). Improvements continued at 6-months with a mean change on the RTSHIA self-harm scale for TAU+BI of −8.54 (95 %CI −12.12 to −4.95) versus −8.34 (95 %CI −11.52 to 5.16) for TAU but no statistically significant between group difference (0.20; 95 %CI −2.98 to 3.37, p = 0.90). Sensitivity analysis (eTable 5 in the Supplement) exploring baseline randomisation variables identified age as statistically significant at 12-weeks (p = 0.025) with those ≥16 in TAU+BI showing a lower RTSHIA self-harm score (11.04, SE=2.06; 95 %CI 7.00 to 15.08) than those in TAU (15.46, SE=1.62; 95 %CI 12.28 to 18.64). At 6-months, males in TAU showed statistically greater reductions (p = 0.029) on the RTSHIA self-harm scale (8.01, SE=2.47; 95 %CI 3.17 to 12.85) than those in TAU+BI (18.88, SE=3.68; 95 %CI 11.67 to 26.09) although numbers are small (TAU+BI=5, TAU=8) making interpretation difficult

For the secondary outcomes, there were statistically significant improvements at 12-weeks and 6-months on all measures of mental health. Although there was a trend for larger changes in TAU+BI there were no statistically significant between group differences at 12-weeks (Table 3). At 6-months, the mean change difference favoured TAU+BI in lower social anxiety (1.62; 95 %CI 0.22 to 3.01, p = 0.023) and total anxiety scores (4.43; 95 %CI 0.16 to 8.70, p = 0.042).

A total of 72 mental health adverse events (AE) involving escalations in self-harm and/or Emergency Department attendance were reported by 43 (25.3 %) participants (eTable 6 in the Supplement). Of these, 23 events involving 16 (9.4 %) participants were severe adverse events (SAE) requiring hospital admission. There were less AEs (19 events, 15 participants) and SAEs (6 events, 5 participants) in TAU+BI than TAU (AEs: 30 events, 21 participants: SAEs 17 events, 11 participants), a difference that was approaching statistical significance (t_{168} =−1.90; 95 %CI −0.53 to 0.01, p = 0.06, point estimate −0.259).

The cost of providing BlueIce for 6 months was £32.26 per participant (eTable 7 in the Supplement).

4. Discussion

Improvements on measures of self-harm, depression, anxiety, sleep, general behaviour and emotional problems, were observed in both arms at 12-weeks and maintained at 6-months. Whilst we found no additional

Table 2
Baseline symptomatology by trial arm.

Variable	Category	TAU + BI (n = 85)		TAU (n = 85)	
		Number	%	Number	%
Have you ever hurt yourself on purpose in any way over the past 6 months?	Yes	85	100	84	98.8
How many times have you self-harmed in the last 6 months?	>10	55	64.7	56	67.1
When was the last time you hurt yourself on purpose?	<30 days	79	92.9	75	89.3
During the recent episode was your intention to die?	Yes	26	30.6	30	35.7
Over the last 6 months have you felt that life was not worth living?	Yes	75	88.2	77	91.7
Over the past 6 months have you found yourself wishing you were dead and away from it all?	Yes	77	90.6	78	92.9
Self-Harm		**Mean (SD)**	**Min, Max**	**Mean (SD)**	**Min, Max**
RTSHIA	Total score	20.65 (8.86)	3, 45	23.18 (8.95)	4, 46
Mood					
MFQ	Total score	45.99 (10.52)	17, 65	45.12 (12.20)	12, 64
Anxiety					
RCADS	Social Anxiety	19.89 (5.33)	6, 27	19.39 (6.34)	3, 27
	Panic	13.64 (5.68)	2, 26	13.87 (5.89)	1, 26
	Depression	19.89 (5.44)	7, 30	19.52 (5.39)	8, 30
	Separation Anxiety	8.56 (3.33)	1, 17	8.54 (4.21)	0, 18
	Generalised Anxiety	10.85 (3.18)	4, 18	10.89 (4.03)	2, 18
	OCD	8.86 (4.37)	1, 18	8.20 (4.45)	0, 18
	Total Anxiety	61.80 (16.20)	25, 96	60.89 (20.32)	7, 103
	Total RCADS	81.69 (18.93)	40,125	80.41 (23.90)	19, 131
Sleep					
SCI	Total score	11.8 (7.55)	0, 32	10.24 (7.38)	0, 32
General behaviour					
SDQ	Emotional scale	7.61 (1.61)	2, 10	7.26 (1.87)	2, 10
	Conduct scale	2.99 (2.01)	0, 8	3.70 (2.39)	0, 9
	Hyperactivity scale	6.96 (2.07)	1, 10	7.17 (1.95)	2, 10
	Peer scale	3.77 (2.16)	0, 8	4.57 (2.18)	0, 10
	Pro-social scale	7.32 (2.03)	1, 10	6.79 (2.38)	2, 10
	Total SDQ	21.33 (4.80)	6, 33	22.70 (5.42)	9, 33
	Total SDQ Impact	3.75 (2.17)	0, 9	4.44 (2.76)	0, 10
Hopelessness					
BHS	Total Hopelessness	9.47 (4.62)	1, 17	10.02 (4.65)	0, 17
	Hopefulness	4.41 (2.28)	0, 8	4.69 (2.16)	0, 8
	Negative Expects	5.06 (2.73)	0, 9	5.33 (2.92)	0, 9

RTSHIA=Risk Taking and Self Harm Inventory; MFQ=Mood and Feelings Questionnaire; RCADS=Revised Child Anxiety and Depression Scale; SCI=Sleep Condition Indicator; SDQ=Strengths and Difficulties Questionnaire; BHS=Beck Hopelessness Scale.

benefit of BlueIce we also found no evidence of any detrimental effects. Indeed, there were fewer mental health adverse and serious adverse events requiring hospital attendance or admission in those who received the app, a finding that was approaching statistical difference. Whilst only a small proportion of self-harm episodes result in presentations to hospital (Geulayov et al., 2018) this data may suggest that BlueIce provided adolescents with immediate access to coping techniques at times of distress thereby reducing the likelihood of emergency department attendance or admission.

Reducing hospital admission is an important objective since longer psychiatric admissions have been found to be linked to increases in multiple self-harm (Ougrin et al., 2021). Alternatives to psychiatric admission, such as intensive community care services, may offer a viable alternative for some subgroups of young people with serious mental illness (Ougrin et al., 2018). Our results suggest that hospital attendance and admission for some young people with repeated self-harm may be reduced through the addition of digital self-help. Further evaluation is required to substantiate the short and medium term effects of BlueIce on hospital attendance and admission and who in particular may benefit from digital self-help.

Whilst there were statistically important improvements on our primary measure of self-harm, the RTSHISA self-harm scale, in both groups at 12-weeks and 6-months, there were no statistically significant between group differences. The failure to find differences in clinical settings in self-harm and suicidal behaviour between targeted self-care interventions and usual care has been noted (Cottrell et al., 2018; Gaynor et al., 2023; Green et al., 2011). Possible explanations include the high rates of natural recovery associated with adolescent self-harm and suicidal behaviour (Green et al., 2011). However, within our sample, self-harm was well established prior to study enrolment with two-thirds self-harming more than 10 times over the past 6 months. Alternatively, the improvements we report might reflect the quality of treatment as usual provided for this complex group of adolescents (Green et al., 2011; Cottrell et al., 2018). In our study clinical staff were blind to treatment allocation and as such there were no requirements for clinical staff to review app use, identify helpful strategies or to resolve any problems or barriers to use. Whether the benefits of adding BlueIce to treatment as usual could be further enhanced by integrating it more fully into therapeutic work needs to be assessed.

A strength of our primary outcome measure of self-harm was that it was developed and evaluated with a similar population to those participating in this study: a clinical sample of young people attending mental health services in the UK who were self-harming. However, a limitation of the RTSHIA self-harm scale is the emphasis upon self-harming behaviours rather than cognitions with only 2 of the 18 items assessing self-harming thoughts or suicidal ideation. Given the importance of self-harm and suicidal thoughts as precursors to self-harming acts (Hawton et al., 2020; Kidger et al., 2012) a more detailed assessment of self-injurious and suicidal cognitions may have been helpful.

4.1. Strengths

This is the first randomized controlled trial evaluating a self-harm

Table 3
Primary and secondary outcome scores and response to treatment.

Assessment	TAU+ BI: mean change from baseline (95 % CI)	TAU: mean change from baseline (95 % CI)	Mean change difference (95 %CI)	P value
Self-harm RTSHIA				
12 weeks	-7.14 (-10.28, -4.01)	-5.53 (-8.33, -2.73)	1.61 (-1.20, 4.43)	0.258
6 months	-8.54 (-12.12, -4.95)	-8.34 (-11.52, 5.16)	0.20 (-2.98, 3.37)	0.903
Mood MFQ				
12 weeks	-9.90 (-14.34, -5.47)	-6.13 (-10.09, -2.17)	3.77 (-0.18, 7.72)	0.061
6 months	-10.78 (-15.99, -5.58)	-9.26 (-13.83, -4.70)	1.52 (-3.01, 6.05)	0.508
Anxiety RCADS				
Social anxiety 12 weeks	-2.40 (-4.10, -0.70)	-1.20 (-2.73, 0.33)	1.20 (-0.33, 2.73)	0.123
Social anxiety 6 months	-4.15 (-5.72, -2.58)	-2.54 (-3.94, -1.14)	1.62 (0.22, 3.01)	0.023 *
Panic 12 weeks	-1.21 (-2.68, 0.26)	-0.62 (-1.94, 0.70)	0.59 (-0.72, 1.91)	0.375
Panic 6 months	-2.81 (-4.40, -1.23)	-2.32 (-3.72, -0.91)	0.50 (-0.90, 1.90)	0.481
Depression 12 weeks	-3.17 (-5.05, -1.28)	-1.87 (-3.56, -0.19)	1.29 (-0.39, 2.98)	0.132
Depression 6 months	-3.57 (-5.55, -1.58)	-3.34 (-5.10, -1.59)	0.22 (-1.53, 1.97)	0.802
Separation anxiety 12 weeks	-1.68 (-2.81, -0.55)	-1.71 (-2.72, -0.70)	-0.025 (-1.04, 0.99)	0.960
Separation anxiety 6 months	-2.21 (-3.33, -1.10)	-1.77 (-2.75, -0.78)	0.44 (-0.54, 1.42)	0.374
Generalised anxiety 12 weeks	-2.12 (-3.18, -1.06)	-1.19 (-2.13, -0.24)	0.93 (-0.01, 1.86)	0.053
Generalised anxiety 6 months	-2.98 (-4.20, -1.76)	-2.18 (-3.26, -1.11)	0.80 (-0.27, 1.87)	0.142
OCD 12 weeks	-1.89 (-3.17, -0.61)	-1.25 (-2.38, -0.11)	0.65 (-0.49, 1.79)	0.264
OCD 6 months	-2.60 (-3.85, -1.36)	-1.56 (-2.65, -0.47)	1.04 (-0.05, 2.14)	0.062
Total anxiety 12 weeks	-9.47 (-14.53, -4.40)	-6.06 (-10.59, -1.53)	3.41 (-1.14, 7.96)	0.140
Total anxiety 6 months	-15.03 (-19.87, -10.20)	-10.60 (-14.88, -6.33)	4.43 (0.16, 8.70)	0.042 *
Total RCADS 12 weeks	-12.73 (-19.10, -6.36)	-7.93 (-13.62, -2.24)	4.80 (-0.92, 10.52)	0.099
Total RCADS 6 months	-18.55 (-24.87, -12.24)	-13.95 (-19.54, -8.36)	4.61 (-0.97, 10.18)	0.105
Sleep SCI				
Sleep 12 weeks	0.86 (-1.24, 2.96)	1.07 (-0.82, 2.97)	0.21 (-1.67, 2.10)	0.823
Sleep 6 months	2.19 (-0.56, 4.94)	2.78 (0.35, 5.20)	0.59 (-1.78, 2.95)	0.624
General Behaviour SDQ				
Emotional 12 weeks	-0.88 (-1.53, -0.22)	-0.76 (-1.33, -0.19)	0.12 (-0.46, 0.70)	0.685
Emotional 6 months	-1.09 (-1.90, -0.28)	-0.74 (-1.44, -0.05)	0.35 (-0.34, 1.03)	0.318
Conduct 12 weeks	-0.06 (-0.71, 0.59)	-0.28 (-0.88, 0.33)	-0.22 (-0.78, 0.35)	0.451
Conduct 6 months	0.25 (-0.39, 0.90)	0.06 (-0.54, 0.66)	-0.19 (-0.74, 0.36)	0.487
Hyperactivity 12 weeks	0.06 (-0.60, 0.71)	-0.21 (-0.80, 0.38)	-0.27 (-0.84, 0.31)	0.364
Hyperactivity 6 months	-0.20 (-1.00, 0.61)	-0.18 (-0.89, 0.53)	0.01 (-0.66, 0.69)	0.969
Peer 12 weeks	0.29 (-0.27, 0.85)	0.04 (-0.48, 0.55)	-0.26 (-0.76, 0.24)	0.307
Peer 6 months	-0.10 (-0.78, 0.58)	-0.22 (-0.84, 0.40)	-0.12 (-0.70, 0.47)	0.694
Pro-social 12 weeks	0.05 (-0.61, 0.71)	0.14 (-0.46, 0.74)	0.09 (-0.50, 0.69)	0.757
Pro-social 6 months	0.38 (-0.35, 1.11)	0.73 (0.08, 1.39)	0.35 (-0.18, 0.98)	0.274
Total SDQ 12 weeks	-0.92 (-2.60, 0.77)	-1.39 (-2.95, 0.17)	-0.47 (-1.88, 0.94)	0.509
Total SDQ 6 months	-1.70 (-3.61, 0.22)	-1.42 (-3.19, 0.35)	0.28 (-1.28, 1.83)	0.727
SDQ Impact 12 weeks	-0.91 (-1.73, -0.10)	-0.77 (-1.50, -0.03)	0.15 (-0.60, 0.89)	0.697
SDQ Impact 6 months	-1.20 (-2.08, -0.32)	-0.67 (-1.47, 0.14)	0.53 (-0.22, 1.29)	0.165
Hopelessness BHS				
Total Hopelessness 12 weeks	-0.35 (-1.26, 0.55)	-0.80 (-1.61, 0.02)	-0.45 (-1.26, 0.37)	0.280
Total Hopelessness 6 months	-0.47 (-1.58, 0.65)	-1.13 (-2.12, -0.15)	-0.66 (-1.63, 0.30)	0.174
Hopefulness 12 weeks	-0.32 (-1.03, 0.40)	-0.42 (-1.06, 0.23)	-0.10 (-0.74, 0.54)	0.752
Hopefulness 6 months	-0.41 (-1.26, 0.45)	-0.84 (-1.59, -0.08)	-0.43 (-1.17, 0.30)	0.245
Negative expects 12 weeks	-0.35 (-1.26, 0.55)	-0.80 (-1.61, 0.02)	-0.45 (-1.26, 0.37)	0.280
Negative expects 6 months	-0.47 (-1.58, 0.65)	-1.13 (-2.12, -0.15)	-0.66 (-1.63, -0.30)	0.174

RTSHIA=Risk Taking and Self Harm Inventory; MFQ=Mood and Feelings Questionnaire; RCADS=Revised Child Anxiety and Depression Scale; SCI=Sleep Condition Indicator; SDQ=Strengths and Difficulties Questionnaire; BHS=Beck Hopelessness Scale.

prevention app for adolescents aged 12–17 years. Despite the restrictions of COVID, the predetermined cohort was successfully recruited, with good retention at 12 weeks (81.2 %) and 6 months (75.9 %). The study involved a real world sample of young people with severe mental health symptomatology and comorbidity, repeated and chronic self-harm and significant suicidal ideation being treated within routine mental health clinics in the UK.

4.2. Limitations

We do not have any independent verification of whether BlueIce was used or if so, how often. BlueIce does not upload or save data to any central site and as such the potential recall and response bias from retrospective self-reports needs to be acknowledged. Secondly, although participants were recruited from five geographical locations in the UK these were served by one mental health trust. We are unable to determine how "treatment as usual" provided by this Trust compares with other services. Whilst services should be providing NICE recommended treatments we are unable to confirm whether this is the case. Thirdly, participants were predominantly white British females, and we cannot assume the generalisability of these results until replicated with a more diverse population. Fourthly, we relied on adolescent self-report measures of self-harm and mental health. Although, we were able to objectively verify adverse mental health events requiring hospital attendance or admission through a review of clinical records we did not collect data on other possible adverse events such as increases in self-harming thoughts or stress. Fifthly, although clinical diagnoses were extracted from clinical notes we did not undertake any structured diagnostic interviews to confirm them. Finally, our follow-up was limited to 6-months post-randomisation. Repeated self-harm is associated with an increased risk of suicidal thoughts and plans and as such a

longer term evaluation of whether these short-term improvements persist would be indicated.

5. Conclusion

Our results suggest that the BlueIce self-harm prevention app for adolescents who repeatedly self-harm is a safe addition to usual care.

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Role of the funder

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Data sharing

The study investigators own and have complete control of the research data which can be accessed at any time. For statistical analysis, the data will be stored on a computer system maintained by the University of Exeter, UK. Deidentified participant data and a data dictionary will be made publicly available after publication upon reasonable request to the chief investigator according to NIHR policy. The study protocol has been published and the statistical analysis plan is provided in the appendix (pp2–10).

Additional contributions

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CRediT authorship contribution statement

Paul Stallard: Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Conceptualization. **Kathryn Whittle:** Writing – review & editing, Validation, Project administration. **Emma Moore:** Writing – review & editing, Validation, Project administration. **Antonieta Medina-Lara:** Writing – review & editing, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Nia Morrish:** Writing – review & editing, Formal analysis. **Bethany Cliffe:** Writing – review & editing, Project administration. **Shelley Rhodes:** Writing – review & editing, Methodology, Funding acquisition. **Gordon Taylor:** Writing – review & editing, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

BlueIce is the intellectual property of PS., the creator of the app. He has no financial benefits from the app The remaining authors have no competing or potential conflicts of interest to declare.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2024.116017.

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