

Beating Adolescent Self Harm (BASH)

Submission date 15/07/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Self-harm (intentional self-injury or poisoning) is common amongst young people aged 12-17 with up to one in six reporting self-harm at least once during the past year. Self-harm is linked to other mental health problems such as depression, anxiety and substance misuse and with an increased risk of suicide. Nearly all self-harm happens whilst the young person is on their own. However, most have access to a mobile phone at the time they harm themselves. Young people were consulted to develop an app that could provide them with help at times they were thinking of self-harming. Workshops were previously held with young people to design, develop and produce a smartphone app, BlueIce. The present study aims to test whether adding BlueIce to the usual care provided by specialist child and adolescent mental health services (CAMHS) for young people who self-harm reduces self-harm, improves how they feel and results in fewer emergency contacts.

Who can participate?

Young people aged 12-17 attending specialist CAMHS with a history of self-harm (i.e. 2 or more episodes of self-harm over the past 12 months).

What does the study involve?

The study will test whether adding BlueIce to the usual care provided by specialist child and adolescent mental health services (CAMHS) for young people who self-harm reduces self-harm, improves how they feel and results in fewer emergency contacts. Young people attending CAMHS will be allocated to usual care or usual care plus BlueIce. At the start of the study and after 12 and 26 weeks, self-harm, mood, feelings and any care received for self-harm (i.e. attending Emergency Departments) will be assessed.

What are the possible benefits and risks of participating?

We think that most young people taking part in this study will benefit from the research assessments which will monitor their progress. We do not expect any risks from participating in the study.

Where is the study run from?

Warneford Hospital, UK

When is the study starting and how long is it expected to run for?
January 2020 to December 2022

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
Prof. Paul Stallard
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Study website
<https://www.oxfordhealth.nhs.uk/blueice>

Contact information

Type(s)
Scientific

Contact name
Prof Paul Stallard

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42159

Study information

Scientific Title

A comparison of usual care versus usual care plus a smartphone self-harm prevention app (Blueice) in young adolescents aged 12-17 who self-harm: Beating Adolescent Self-Harm (BASH) - Version 1

Acronym

BASHv1

Study objectives

The addition of Blueice to usual care will result in less self-harm, improved psychological wellbeing and will be cost-effective

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/06/2019, South Central - Oxford B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; 020 7104 8049; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0212

Study design

Randomized; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Self-harm

Interventions

The study will test whether adding Blueice to the usual care provided by specialist child and adolescent mental health services (CAMHS) for young people who self-harm reduces self-harm, improves how they feel and results in fewer emergency contacts. Young people attending CAHMS will be allocated to usual care or usual care plus Blueice. At the start of the study and after 12 and 26 weeks, self-harm, mood, feelings and any care received for self-harm (i.e. attending Emergency Departments) will be assessed.

Our assessment of self-harm will consist of three parts: a brief interview, completion of the Risk-Taking and Self-harm Inventory and the provision of support and advice.

Part A: Interview. We will use items from the Avon Longitudinal Study of Parents and Children (ALSPAC) (<http://www.alspac.bris.ac.uk>). Young people will be asked "have you ever hurt yourself on purpose in any way (e.g. by taking an overdose of pills or by cutting yourself) over the past 3 months?" Those who answer yes will be asked further questions about frequency, method, reason for self-harming, whether they sought medical help and suicidal intent.

PART B: RTSHIA. Our primary outcome is self-reported self-harm assessed by the self-harm inventory of the RTSHIA. The RTSHIA was developed in the UK for use with adolescents (aged 11-19 years). It has been used as the primary outcome measure for a recent UK study evaluating a self-harm intervention for young people undertaken in the same setting (CAMHS teams) as we propose. The inventory assesses the presence and frequency of a range of intentional self-injury (e.g. cutting, burning, self-hitting, self-poisoning) over a defined period. We will quantify the frequency of self-harm and will ask additional questions to clarify whether they sought medical help and suicidal intent. The RTSHIA has good reliability and validity. We will use information from this to categorise changes in self-harm from baseline to 12 weeks and 6 months as reduced/stopped vs same/increased.

Part C: Support and Advice. At the end of the assessment young people will be given a list of contacts they can call if they are feeling worried about themselves.

Intervention Type

Behavioural

Primary outcome measure

Self-reported self-harm assessed by the self-harm inventory of the RTSHIA at baseline, 12 weeks and six months

Secondary outcome measures

Current secondary outcome measures as of 15/06/2023:

1. Anxiety, measured by the Revised Child Anxiety and Depressions Scale (RCADS) at baseline, post-intervention (12 weeks) and follow-up (6 months)
2. Depression, assessed by the Mood and Feelings Questionnaire (MFQ) at baseline, post-intervention (12 weeks) and follow-up (6 months)
3. Hopelessness, assessed by The Beck Hopelessness Scale at baseline, post-intervention (12 weeks) and follow-up (6 months)
4. General behaviour, assessed by the Strengths and Difficulties Questionnaire (SDQ) at baseline, post-intervention (12 weeks) and follow-up (6 months)
5. Insomnia assessed by the Sleep Condition Indicator (SCI) at baseline, post intervention (12 weeks) and 6 months.
- 6 Health-related quality of life (HRQoL), assessed by the Child Health Utility 9D (CHUD 9D) at baseline, post-intervention (12 weeks) and follow-up (6 months)

Previous secondary outcome measures:

1. Anxiety, measured by the Revised Child Anxiety and Depressions Scale (RCADS) at baseline, post-intervention (12 weeks) and follow-up (6 months)
2. Depression, assessed by the Mood and Feelings Questionnaire (MFQ) at baseline, post-intervention (12 weeks) and follow-up (6 months)
3. Hopelessness, assessed by The Beck Hopelessness Scale at baseline, post-intervention (12 weeks) and follow-up (6 months)
4. General behaviour, assessed by the Strengths and Difficulties Questionnaire (SDQ) at baseline, post-intervention (12 weeks) and follow-up (6 months)
5. Health-related quality of life (HRQoL), assessed by the Child Health Utility 9D (CHUD 9D) at baseline, post-intervention (12 weeks) and follow-up (6 months)

Overall study start date

01/06/2019

Completion date

23/12/2022

Eligibility

Key inclusion criteria

1. Aged 12-17 years
2. Attending specialist CAMHS
3. History of self-harm (i.e. 2 or more episodes of self-harm over the past 12 months)

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

Planned Sample Size: 170; UK Sample Size: 170

Total final enrolment

170

Key exclusion criteria

1. Suicidal
2. Diagnosed with psychosis
3. Current safeguarding concerns (i.e. the young person has suffered abuse within the last 6 months or is the subject of a safeguarding investigation),
4. Significant developmental disorder (e.g. autism) which interferes with their ability to use the app
5. Insufficient understanding of English in order to use BlueIce. At present, BlueIce is only available in English.

Date of first enrolment

01/01/2020

Date of final enrolment

07/07/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Warneford Hospital

Warneford Lane

Oxford

United Kingdom

OX3 7JX

Sponsor information

Organisation

Oxford Health NHS Foundation Trust

Sponsor details

Corporate Headquarters

4000 John Smith Drive

Oxford Business Park South

OXFORD

England

United Kingdom

OX3 7JX

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abc@email.com

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04c8bjx39>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2024

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	27/07/2021	19/05/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		10/06/2024	17/06/2024	Yes	No