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Beating Adolescent Self Harm (BASH)

Submission date	Recruitment status	[X] Prospectively registered
15/07/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/08/2025	Mental and Behavioural Disorders	

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 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.

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
paul.stallard@oxfordhealth.nhs.uk

Study website
https://www.oxfordhealth.nhs.uk/blueice

Contact information

Type(s)
Scientific

Contact name
Prof Paul Stallard

ORCID ID
https://orcid.org/0000-0001-8046-0784

Contact details
Oxford Health NHS Foundation Trust
Work Address CAMHS
Temple House
Keynsham
United Kingdom
BS31 1HA
01865903889
paul.stallard@oxfordhealth.nhs.uk

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
-
abc@email.com

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04c8bjx39

Funder(s)

Funder type
Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1217-20004

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
Protocol article		23/11/2021	01/08/2025	Yes	No