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Brief Education Supported Treatment for adolescent borderline personality disorder

Submission date	Recruitment status	[_] Prospectively registered
28/01/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/02/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Current plain English summary as of 09/01/2020:
Background and study aims
This study investigates a brief intervention that aims to equip education professionals with the knowledge and skills to support pupils with symptoms of borderline personality disorder (BPD) who have self-harmed. Staff from participating schools and colleges will take part in a training workshop in preparation for co-delivering a series of 3 – 6 sessions to individual pupils from their institution together with a mental health professional. The intervention is designed to reduce BPD symptoms by decreasing the emotional instability at the heart of the disorder, both by: (a) delivering the key elements of evidence-based interventions for adolescent BPD at an early stage, before symptoms become entrenched, and (b) reducing the confusion and anxiety that often surrounds young people with BPD who have self-harmed by equipping education professionals with the knowledge and skills to support pupils with BPD.

Who can participate?
Young people aged 13-18 at participating schools/colleges with symptoms of BPD who have self-harmed

What does the study involve?
In the first stage of the study, the findings of existing research are used to refine the intervention and pilot it within schools and colleges. In the second stage, to test whether it is possible to evaluate the effects of the intervention in a fair and unbiased way in a future trial, participants are allocated at random to either receive the study intervention or standard care. All participants are offered an assessment of their mental health with a study research assistant on entry to the study and 12 and 24 weeks later. The results of the study are shared with participating schools and colleges and used to inform the design of a future study evaluating whether the intervention leads to improved outcomes for young people.

What are the possible benefits and risks of participating?
Eligible participants will have the opportunity to try out a new treatment designed to help them understand and cope with some of the things they have been finding difficult. However, because the BEST intervention is new, it is not known for sure that it will be helpful. The results of the study will be used to to improve the support available to other young people in the future. To

thank participants for their time and effort, they will be given a £10 shopping voucher for each assessment they participate in. Some people can find talking about personal things difficult or upsetting. If a participant becomes upset whilst taking part in the research, a member of the team will stay with them until they feel better and make sure they know where to go for further support if they need it later.

Where is the study run from?
1. City College Norwich (UK)
2. East Coast College (UK)
3. Dereham Neatherd High School (UK)
4. Acle Academy (UK)
5. Catch 22 Include (UK)
6. East Norfolk Sixth Form (UK)
7. Hellesdon High School (UK)
8. Jane Austen College (UK)
9. Ormiston Victory Academy (UK)
10. Taverham High School (UK)
11. Thorpe St Andrew School (UK)

When is the study starting and how long is it expected to run for?
November 2018 to March 2021

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

Who is the main contact?
Dr Brioney Gee
Brioney.gee@nsft.nhs.uk

Previous plain English summary:
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Contact information

Type(s)
Scientific

Contact name
Dr Brioney Gee

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http://orcid.org/0000-0003-0781-7753

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80 St Stephens Road
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United Kingdom
NR1 3RE
+44 (0)1603 974701
Brioney.gee@nsft.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40236

Study information

Scientific Title
Brief Education Supported Treatment (BEST) for adolescent borderline personality disorder: a feasibility study of delivery of specialised early intervention for borderline personality disorder through collaboration with education providers, incorporating a feasibility randomised controlled trial

Acronym
BEST for adolescent BPD

Study objectives
The study hypothesis is that it will be feasible to implement the modified BEST intervention and evaluate its effectiveness and cost-effectiveness in a randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - South Yorkshire Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, Tel: +44 (0)207 1048091, Email: nrescommittee.yorkandhumber-southyorks@nhs.net, 07/11/2018, ref: 18/YH/0416

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

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
Borderline personality disorder (BPD) and self-harm

Interventions
This study investigates a brief intervention that aims to equip education professionals with the knowledge and skills to support pupils with symptoms of borderline personality disorder (BPD) who self-harm. Staff from participating schools and colleges will take part in a training workshop in preparation for co-delivering a series of 3 – 6 sessions to individual pupils from their institution together with a mental health professional. The intervention is designed to reduce BPD symptoms by decreasing the emotional instability at the heart of the disorder, both by: (a) delivering the key elements of evidence-based interventions for adolescent BPD at an early stage, before symptoms become entrenched, and (b) reducing the confusion and anxiety that often surrounds young people with BPD who self-harm by equipping education professionals with the knowledge and skills to support pupils with BPD symptoms.

In the first stage of the study, the trialists will use the findings of existing research to refine the intervention and pilot it within schools and colleges. In the second stage, to test whether it will be possible to evaluate the effects of the intervention in a fair and unbiased way in a future trial, participants will be allocated at random to either receive the study intervention or standard care. Participants will be randomised in a 1:1 allocation ratio using pre-set lists of permuted blocks with randomly distributed block size. Randomisation will be stratified by school/college. The allocation sequence will be generated and managed remotely via a web-based system and will not be accessible by the research team, school/college staff or study participants.

Young people aged 13-18 years with symptoms of BPD including self-harm will be invited to take part and, if they consent, will be screened to ensure the study is suitable for them. All participants will be offered an assessment of their mental health with a study research assistant on entry to the study and 12 and 24 weeks later. The results of the study will be shared with participating schools and colleges and will be used to inform the design of a future study evaluating whether the intervention leads to improved outcomes for young people.

Intervention Type
Behavioural

Primary outcome measure
As this is a feasibility trial, the primary output will be the design of the subsequent definitive trial. A number of feasibility outcomes will be assessed to facilitate this output, including:
1. Recruitment rate: the ability to recruit participants to time and target
2. Retention rate: the ability to retain participants in the trial post randomisation, measured at 12 week and 24 week follow up
3. The ability of staff to deliver the intervention as intended, and the acceptability of the intervention from the perspective of staff and young people. Video/audio recordings of treatment sessions will be made and rated against the intervention adherence checklist. In-depth interviews will be conducted with a subsample of participants after the conclusion of their intervention to assess acceptability from the perspective of young people taking part and staff involved in intervention delivery will be invited to take part in focus groups at the end of each phase of the study.

4. The degree of contamination of the control arm, i.e. the extent to which participants randomised to the control arm receive elements of the trial intervention. Contamination will be assessed via staff logs of contact with control arm participants, observations within schools and colleges, in-depth interviews with a subsample of control arm participants, and staff focus groups
5. The acceptability and suitability of the proposed outcome measures. The rate of completion of each outcome measure at baseline, 12 and 24 weeks will be calculated. Qualitative information about acceptability of the measures will be gathered via in-depth interviews with participants. In addition, the usefulness of the EQ-5D-5L in adolescents with BPD symptoms will be explored by comparing EQ-5D-5L scores with other study outcome measures.

Secondary outcome measures
The proposed primary outcome measure for the definitive trial is severity of borderline personality features measured using the Borderline Personality Features Scale for Children (BPFS-C). In this feasibility trial, the BPFS-C will be administered at baseline, 12 and 24 weeks. In addition, the following data will be collected at baseline, 12 and 24 weeks:
1. Self-reported self-harm measured using the Risk Taking and Self Harm Inventory for Adolescents
2. Self-reported emotional dysregulation measured using the Difficulties in Emotion Regulation Scale
3. Perceived social support measured Childhood and Adolescent Social Support Scale
4. Time spent engaged in structured activity measured using the Time Use Survey
5. Health status measured using the EQ-5D-5L
6. Use of health and social care services measured using a modified version of the Client Service Receipt Inventory
7. School/college attendance and exclusions assessed using data on attendance and fixed-term and permanent exclusions collected by the participants school or college

Overall study start date
01/11/2018

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Aged 13-18 years (school years 9-13)
2. Enrolled at a participating school/college
3. Score above 34 on the Borderline Personality Features Scale for Children
4. History of repeated self-harm assessed using the self-harm subscale of the Risk Taking and Self Harm Inventory for Adolescents (has intentionally harmed him/herself more than once)
5. Able to provide written informed consent or, for under 16s, written informed assent and parent/guardian consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Key exclusion criteria
1. Currently receiving inpatient treatment or specific psychological intervention
2. Moderate/severe learning disability
3. Current psychotic disorder (those with sub-threshold psychotic symptoms will not be excluded) or substance dependence requiring care planned treatment (substance abuse will not be an exclusion criterion)

Date of first enrolment
01/01/2019

Date of final enrolment
01/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
City College Norwich
Ipswich Rd
Norwich
United Kingdom
NR2 2LJ

Study participating centre
East Coast College
Suffolk Rd
Great Yarmouth
United Kingdom
NR31 0ED

Study participating centre

Dereham Neatherd High School
Norwich Rd
East Dereham
United Kingdom
NR20 3AX

Study participating centre
Acle Academy
South Walsham Rd
Acle
Norwich
United Kingdom
NR13 3ER

Study participating centre
Catch 22 Include
27 Hurricane Way
Norwich
United Kingdom
NR6 6HE

Study participating centre
East Norfolk Sixth Form
Church Lane
Gorleston-On-Sea
Great Yarmouth
United Kingdom
NR31 7BQ

Study participating centre
Hellesdon High School
187 Middleton's Lane
Norwich
United Kingdom
NR6 5SB

Study participating centre
Jane Austen College
46-48 Colegate

Norwich
United Kingdom
NR3 1DD

Study participating centre
Ormiston Victory Academy
Middleton Crescent
Norwich
United Kingdom
NR5 0PX

Study participating centre
Taverham High School
Beech Avenue
Norwich
United Kingdom
NR8 6HP

Study participating centre
Thorpe St Andrew School
Laundry Lane
Norwich
United Kingdom
NR7 0XS

Sponsor information

Organisation
Norfolk and Suffolk NHS Foundation Trust

Sponsor details
Hellesdon Hospital
Drayton High Road
Norwich
England
United Kingdom
NR6 5BE
+44 (0)1603 421255
RDOfficeMailbox@nsft.nhs.uk

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/03400ft78

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/09/31

Results and Publications

Publication and dissemination plan
The trialists plan to publish the study protocol. This is currently being prepared for publication. Findings will be disseminated to participants and other key stakeholders, including commissioners, CAMHS managers and service-users, academics and practitioners in mental health and education. Dissemination vehicles will include study newsletters, a dissemination event, publications in peer-reviewed journals and presentation at scientific conferences. We intend to publish the key study findings in a high-impact peer reviewed journal by the end of 2021.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publically available repository on Norfolk and Suffolk NHS Foundation Trust's electronic servers for a period of 10 years in accordance with the Trust's research archiving policies. Data will be shared for future research if agreed by the Trial Management Group and subject to any necessary ethical or legal approvals.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2022	22/03/2023	Yes	No
HRA research summary			28/06/2023	No	No