Decision Aid for young people who Self--Harm (DASH)

Submission date	Recruitment status	[X] Prospectively registered		
13/05/2015	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/05/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
20/09/2018	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Self-harm is when a person deliberately hurts or injures their body, often as a way to punish themselves. Self-harm is a serious mental health problem that is usually carried out to help the individual cope with or express extreme emotional distress. It is also the strongest predictor of suicide and is especially common among young people, a group in whom rates of self-harm appear to be rising. There is evidence to suggest that young people who self-harm can find it hard to reach a decision about where and how to get help. While young people may be reluctant to seek help from healthcare professionals when distressed, many turn to the internet as a way of coping with psychological distress. A growing number of studies involving children and adolescents suggest positive effects of treatment programmes that make use of web-based technology. Therefore, a safe and effective, internet-based intervention for young people who self-harm could be of benefit to a large numbers of individuals. The aim of this study is to test the practicality, acceptability and potential effectiveness of a newly developed internet-based decision aid (DA) programme. The DA aims to help young people reach decisions regarding where they can go for help or support for their self-harm issues.

Who can participate?

Children aged 12-18 attending secondary school in Southwark, London.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given access to the DA programme. Those in group 2 (control group) are given standard information from their school counsellor. All participants are followed up 4 weeks after the start of the study to answer questions about their experiences during the study period.

What are the possible benefits and risks of participating? Not provided at time of registration.

Where is the study run from? The Charter School (UK)

When is the study starting and how long is it expected to run for? April 2015 to April 2016

Who is funding the study? Guy's and St Thomas' Charity (UK)

Who is the main contact? Dr S Rowe (public) Dr P Moran (scientific)

Contact information

Type(s)

Public

Contact name

Dr Sarah Rowe

Contact details

David Goldberg Building De Crespigny Park London United Kingdom SE5 8AF

Type(s)

Scientific

Contact name

Mr Paul Moran

Contact details

David Goldberg Building De Crespigny Park London United Kingdom SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Decision Aid for young people who Self--Harm (DASH): a feasibility trial

Acronym

DASH

Study objectives

The principal research objective of this trial is to assess the feasibility of undertaking a randomised controlled trial of the decision aid (DA), with respect to the following predefined parameters:

- -1. Recruitment of young people and consent rates
- -2. The feasibility and acceptability of randomisation procedures
- -3. Follow-up rates and response rates to questionnaires

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Camberwell St Giles Research Ethics Committee, 00/02/2015

Study design

Randomised single-centre feasibility/pilot study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Self-harm

Interventions

We invite young people (aged 12--18) to complete a questionnaire about their feelings and any self--harm behaviour they may have engaged in the previous year. Participants who report self-harm in the previous year will then be randomised to one of two groups:

- 1. Intervention group receiving the web-based DA
- 2. Control group receiving general information about feelings and emotions Both groups will be asked to complete some research scales about decision-making and help-seeking behaviour. Participants in both groups will be followed up at 4- weeks when we will

repeat the scales. The researcher administering the 4-week scales will be blind to the original allocation status of the participants.

Intervention Type

Behavioural

Primary outcome measure

- 1. Recruitment of young people and consent rates
- -2. Feasibility and acceptability of randomisation procedures
- -3. Follow--up rates and response rates to questionnaires

Secondary outcome measures

Descriptive data on candidate outcome measures, in order to inform the design of an adequately powered, future efficacy study.

Overall study start date

17/03/2015

Completion date

31/12/2016

Eligibility

Key inclusion criteria

- 1. Aged 12-18
- 2. Attending secondary school within the London borough of Southwark
- 3. Basic proficiency in English language

Participant type(s)

Other

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

Lacking capacity to consent

Date of first enrolment

Date of final enrolment 01/08/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Charter School

Red Post Hill London United Kingdom SE24 9JH

Sponsor information

Organisation

King's College London (UK)

Sponsor details

Institute of Psychiatry/South London & Maudsley P005
R & D Office, De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type

University/education

Website

http://www.gsttcharity.org.uk/

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

Charity

Funder Name

Guy's and St Thomas' Charity

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	28/09/2016		Yes	No
Results article	results	30/01/2018		Yes	No