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Developing an app to help young people self-manage when feeling overwhelmed during lessons

Submission date
30/08/2016

Recruitment status
No longer recruiting

Registration date
23/09/2016

Overall study status
Completed

Last Edited
07/05/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In England, between 3-7% of school aged children experience behavioural difficulties. Behavioural difficulties can have a negative long-term impact. For example, evidence shows that behavioural difficulties may predict worse academic attainment and higher levels of school dropout. Recent policy calls for schools to help students to manage behavioural difficulties. ReZone is a smartphone app for young people to use when they feel overwhelmed, stressed or anxious in class. The app aims to help students manage how they are feeling so they can ReZone and return to learning. It contains a series of tools which are designed to improve concentration, help relieve stress and help students to reflect and think through problems logically, through use of mentalisation based therapy (a type of therapy that helps people separate their thoughts and feelings from those around them) and cognitive behaviour therapy (a type of therapy aiming to help people to change negative behaviour patterns) techniques. The aim of this study is to test the effectiveness of ReZone at reducing emotional and behavioural difficulties in young people in need of targeted support to engage with school.

Who can participate?
Young people aged 10-15 years who attend alternative provision or mainstream primary schools.

What does the study involve?
Classes are randomly allocated to one of two groups. Students in the first group are given access to the ReZone app, which are downloaded on school tablets, for 12 weeks. They are able to use the app whenever they are feeling overwhelmed, stressed or anxious, either of their own accord or be directed by teachers to use it in class. The app contains tools based on cognitive behavioural therapy, mindfulness, and attention bias modification training to help students calm and re-focus quickly, enabling them to re-engage with their learning. Students in the second group continue as normal for the duration of the study. At the start of the study and then again after 12 weeks, students in both groups complete a range of questionnaires to measure their emotional and behavioural difficulties, mental wellbeing and self-management.

What are the possible benefits and risks of participating?
There is no guaranteed benefit in taking part. One advantage is that participants will get to help shape an app that will benefit young people in future. Most people find taking part in research rewarding, as they contribute to the development of knowledge that may benefit other people in the future. After the study has ended, all classes in schools taking part in the project will be able to use ReZone if they wish. There are no notable risks involved with participating in this study.

Where is the study run from?
The study is run by University College London and the Anna Freud National Centre for Children and Families and takes place in alternative provision or mainstream primary schools in England (UK)

When is the study starting and how long is it expected to run for?
August 2016 to June 2017

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

Who is the main contact?
Dr Julian Edbrooke-Childs

Contact information

Type(s)
Scientific

Contact name
Dr Julian Edbrooke-Childs

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7969/001

Study information

Scientific Title
Cluster randomized control trial of ReZone: helping young people to self-manage when feeling overwhelmed

Study objectives
Primary aim:
To examine the effectiveness of an mHealth intervention (ReZone) in reducing emotional and behavioural difficulties in young people in need of targeted support to engage with school.

Secondary aim:
To examine the effectiveness of ReZone in improving self-management, well-being, and health-related quality of life in young people in need of targeted support to engage with school.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCL Ethics Committee, 27/09/2016, ref: 7969

Study design
Cluster randomised control study

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Emotional and behavioural difficulties in young people

Interventions
Current Interventions (as of 17/01/2018):
Classes are randomly allocated to the intervention or control arm using a random sequence generator by an independent trials unit.

Intervention arm: Students will be given access to the ReZone app for 12 weeks on school tablets. Students can use ReZone of their own accord or be directed by teachers to use it during

classes at times the students is becoming overwhelmed. ReZone contains six tools based on attention bias modification training, art therapy, metallisation based therapy, and cognitive behaviour therapy techniques: the ‘stress bucket’ exercise, ‘time out’ incident clock, art zone, mindfulness breathing, happy faces and games.

Control arm: Students continue as normal for the duration of the study.

Participants in both groups complete measures of emotional and behavioural difficulties, mental wellbeing, self-management, and health-related quality of life at baseline and 12 weeks.

Previous interventions:
Classes are randomly allocated to the intervention or control arm using a random sequence generator by an independent trials unit.

Intervention arm: Students will be given access to the ReZone app for 12 weeks. They are able to download the ReZone app from the iTunes, Google play, and Windows app stores. Students can then use the app as much as they like, using the tools on the platform as well as being able to download flat graphics of tools. Students can use ReZone of their own accord or be directed by teachers to use it during classes at times the students is becoming overwhelmed. ReZone contains four tools based on art therapy, metallisation based therapy, and cognitive behaviour therapy techniques: the ‘stress bucket’ exercise, ‘time out’ incident clock, art zone, and mindfulness breathing.

Control arm: Students continue as normal for the duration of the study.

Participants in both groups complete measures of emotional and behavioural difficulties, mental wellbeing, self-management, and health-related quality of life at baseline and 12 weeks.

Intervention Type
Other

Primary outcome measure
Emotional and behavioural difficulties are measured using the 16-item Me and My School (M&MS) at baseline and 12 weeks completed by students.

Secondary outcome measures
1. Mental wellbeing is measured using the 7-item Short Warwick-Edinburg Mental Well-being Scale (SWEMWBS) at baseline and 12 weeks completed by students
2. Self-management is measured using the 6-item “self” subscale of the Youth Empowerment Scale-Mental Health (YES-MH) at baseline and 12 weeks completed by students
3. Health-related quality of life is measured using the 6-item EQ-5D-Y at baseline and 12 weeks completed by students

Overall study start date
01/08/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Current participant inclusion criteria (as of 17/01/2018):
1. Young people aged 10-15 years
2. Attending alternative provision or mainstream primary schools
3. Able to understand English sufficiently to take part

Previous participant inclusion criteria:
1. Young people aged 11-14 years
2. Attending alternative provision schools
3. Able to understand English sufficiently to take part

Participant type(s)
Other

Age group
Child

Lower age limit
10 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
Current participant exclusion criteria (as of 17/01/2018):
1. Children (<10 years)
2. Adults (>15)
3. Not attending alternative provision or mainstream primary schools
4. Not able to understand English sufficiently to take part

Previous participant exclusion criteria:
1. Children (<11 years)
2. Adults (>15)
3. Not attending alternative provision schools
4. Not able to understand English sufficiently to take part

Date of first enrolment
01/02/2017

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
United Kingdom
WC1E 6BT

Study participating centre
Anna Freud National Centre for Children and Families
United Kingdom
NW3 5SU

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/11/2017	06/11/2017	Yes	No
Results article	results	02/05/2019	07/05/2019	Yes	No