

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

<b>Submission date</b> 30/08/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

**ORCID ID**

<http://orcid.org/0000-0003-0401-4058>

**Contact details**

The Anna Freud Centre and University College London  
12 Maresfield Gardens  
London  
United Kingdom  
NW3 5SU

## 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?
<a href="#">Protocol article</a>	protocol	03/11/2017	06/11/2017	Yes	No
<a href="#">Results article</a>	results	02/05/2019	07/05/2019	Yes	No