

# Improving mental health literacy among children and young people aged 12-14 years in the United Kingdom

<b>Submission date</b> 23/06/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/08/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Mental health problems are estimated to affect 10-20% of children and adolescents worldwide. Research shows that the prevalence of depression rises sharply after puberty and that over half of depressed adolescents have a recurrent episode within five years. Mental health literacy can be defined as knowledge and beliefs about mental disorders which help people to prevent, recognise and manage problems. We know that low levels of mental health literacy significantly increase the risk of adolescents developing moderate to severe depression and that improving mental health literacy may be a useful way to reduce the future burden of depression amongst young people.

We have co-adapted with young people, parents, professionals and other stakeholders an existing digital application (the intervention), originally developed for young people aged 11-15 years in Indonesia to improve mental health literacy and self-management skills, for use in the UK with young people aged 12-14 years. We have also co-designed an additional third book for the application, designed specifically for young people in the UK.

The study aim is to determine the feasibility of delivering and evaluating the use of the digital application in education and community settings in the UK. We will explore how many young people want to take part in our study, how much they use the intervention and what sort of follow-up data they are willing to provide. We will also speak to young people about their experiences with the intervention. We will use these findings to collaboratively design a larger study to explore the costs and impacts of the intervention.

### Who can participate?

Young people aged 12-14 years old, of all genders, attending educational and community settings and with access to a smartphone or tablet

What does the study involve?

The study will take place over a 3-month period at four study sites across Greater Manchester (two schools and two community venues). The sites will be initially approached through existing contacts of the study team. Ten young people aged 12-14 years will be recruited at each site.

To test the feasibility of the digital application, a cluster randomised control trial will be used. In this study, an equal number of clusters (two per arm) will be allocated to the intervention and control arms. The young people in the intervention arm will have access to the digital application and the young people in the control arm will not have access to the digital application. Following recruitment and the completion of demographic and baseline questionnaires at all sites, randomisation will then decide which of the two clusters (sites) have access to the intervention. This will be achieved by using a blocked randomisation list. The study statistician will produce the randomisation list. A cluster will not be allocated until the full set of 10 young people has been recruited at that cluster, to prevent allocation bias. The allocation sequence will not be revealed to the other study investigators.

The outcome data will predominantly be self-reported using quantitative questionnaires that measure mental health literacy and other mental health-related measures. At each site, all the young people will complete these questionnaires in a similar timeframe; at baseline, post-intervention (or about a month after baseline for the control group) and follow-up (at 3 months). At the intervention arm sites, we will collect qualitative data through semi-structured interviews /focus groups with young people. This will focus on the experiences of using the application.

What are the possible benefits and risks of participating?

The possible benefit is that the digital application could help young people learn about their mental health and develop self-management techniques, and the study will help improve the app for future use. The possible risk is that talking and thinking about mental health can be difficult for young people.

Where is the study run from?

University of Manchester (UK)

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

May 2022 to May 2023

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Dr Helen Brooks

[helen.brooks@manchester.ac.uk](mailto:helen.brooks@manchester.ac.uk)

## Contact information

**Type(s)**

Principal Investigator

**Contact name**

Dr Helen Brooks

**ORCID ID**

<http://orcid.org/0000-0002-2157-0200>

**Contact details**

University of Manchester  
Oxford Road  
Manchester  
United Kingdom  
M13 9PL  
+44 (0)7837471975  
[helen.brooks@manchester.ac.uk](mailto:helen.brooks@manchester.ac.uk)

**Type(s)**

Scientific

**Contact name**

Dr Jack Wilkinson

**ORCID ID**

<http://orcid.org/0000-0003-3513-4677>

**Contact details**

University of Manchester  
Oxford Road  
Manchester  
United Kingdom  
M13 9PL  
+44 (0)161 3066000  
[jack.wilkinson@manchester.ac.uk](mailto:jack.wilkinson@manchester.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## Study information

**Scientific Title**

A cluster-randomised controlled feasibility trial for a digital mental health literacy intervention for young people aged 12-14 years in the United Kingdom

**Acronym**

IMPETUS

## **Study objectives**

1. The IMPETUS app improves mental health literacy of young people aged 12-14 years
2. Rolling out the IMPETUS app to educational and community settings is feasible

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 28/06/2022, University of Manchester Research Ethics Committee (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)161 306 6000; research.ethics@manchester.ac.uk), ref: 2022-14361-24300

## **Study design**

Multi-centre interventional cluster-randomized feasibility trial

## **Primary study design**

Interventional

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

Community

## **Study type(s)**

Prevention

## **Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Improvement of mental health literacy

## **Interventions**

Forty children and young people aged 12-14 years will be recruited across four study sites (community and educational settings). Ten young people will be recruited per site (cluster).

The intervention arm is participants having access to a digital application, the 'IMPETUS app'. This is an immersive storyline digital game in which young people play as a character facing mental health challenges. Their decisions affect the direction of the game and eventual outcomes. The control arm is participants not having access to the 'IMPETUS app.'

An equal number of clusters (two per arm) will be allocated to the intervention and control arms. This will be achieved by using a blocked randomisation list. The study statistician will produce the randomisation list. A cluster will not be allocated until the full set of 10 participants has been recruited at that cluster, to prevent allocation bias. The allocation sequence will not be revealed to the other study investigators.

## **Intervention Type**

Device

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

IMPETUS application

**Primary outcome measure**

1. Feasibility measured using children and young people recruitment and retention rates, intervention uptake and engagement rates, and the variability and potential floor/ceiling effects in our proposed patient outcome measures at baseline (prior to randomisation), post-intervention (or at approximately 6 weeks post-randomisation for control group participants) and 3-month follow-up.
2. Mental health literacy is measured using the Knowledge and Attitudes to Mental Health Scale (KAMHS) at baseline, post-intervention and 3-month follow-up

**Secondary outcome measures**

1. Core depressive symptoms measured using the short version of the Mood and Feeling Questionnaire (MFQ) at baseline, post-intervention and 3-month follow-up
2. Well-being measured using the World Health Organisation Five Well-Being Index (WHO-5) at baseline, post-intervention and 3-month follow-up
3. Levels of anxiety measured using the Revised Children's Anxiety and Depression Scale (RCADS) at baseline, post-intervention and 3-month follow-up
4. Family cohesion and adaptability measured using the Family Cohesion and Satisfaction with Communication sub-scales of the Family Adaptability and Cohesion Evaluation Scale (FACESIV) at baseline, post-intervention and 3-month follow-up
5. Health status measured using the SF-36 questionnaire at baseline, post-intervention and 3-month follow-up

**Overall study start date**

01/05/2022

**Completion date**

15/05/2023

**Eligibility**

**Key inclusion criteria**

1. Aged between 12 and 14 years old
2. Attending the study site
3. Access to a smartphone/tablet to use the application

**Participant type(s)**

Healthy volunteer

**Age group**

Child

**Lower age limit**

12 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

4 clusters, 10 children and young people per cluster

**Total final enrolment**

19

**Key exclusion criteria**

1. Aged under 12 years old and over 14 years old
2. Not attending the study sites
3. No access to smartphone/tablet

**Date of first enrolment**

01/07/2022

**Date of final enrolment**

31/01/2023

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Manchester**

Oxford Road

Manchester

United Kingdom

M13 9PL

## **Sponsor information**

**Organisation**

University of Manchester

**Sponsor details**

Faculty of Biology  
Medicine and Health  
5.012 Carys Bannister Building  
University of Manchester  
Oxford Road  
Manchester  
England  
United Kingdom  
M13 9PL  
+44 (0)161 275 5436  
FBMHethics@manchester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.manchester.ac.uk/>

**ROR**

<https://ror.org/027m9bs27>

## **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

1. Planned publication in a high-impact peer-reviewed journal
2. A lay summary of the findings will be sent to participants

### **Intention to publish date**

31/12/2024

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the Mendeley repository (<https://data.mendeley.com/>). Anonymised quantitative study data from questionnaires will be stored and shared. This data will be available following publication of the study and stored in perpetuity, on the grounds that it may be used to reproduce the results of the study. This data will be accessible to anyone without restriction. Consent from participants will be obtained to share this data. Data will be anonymised and participant ID numbers will be used in the dataset.

### **IPD sharing plan summary**

Stored in publicly available repository

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 5	23/06/2022	18/07/2022	No	Yes
<a href="#">Protocol file</a>	version 2	11/04/2022	18/07/2022	No	Yes
<a href="#">Statistical Analysis Plan</a>	version 1.0	12/07/2022	18/07/2022	No	Yes