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i-Minds: a digital intervention for young people exposed to online sexual abuse

Submission date
21/03/2022

Recruitment status
No longer recruiting

Registration date
12/04/2022

Overall study status
Completed

Last Edited
25/11/2024

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
Online sexual abuse (OSA) of young people has increased, can have serious effects on their development and mental health, and has become an important priority for health and social care services. The National Institute for Health and Care Excellence (NICE) has recognised the identification of effective interventions for improving the wellbeing of young people who have experienced OSA and preventing further harm as a research priority. Young people can report OSA to government agencies and social media companies, but there are currently few tried and tested (evidence-based) or helpful treatments available. The NHS urgently needs an accessible intervention to support young people who have experienced OSA. Interventions aimed at improving mentalisation (the ability to understand one's own thoughts and feelings and those of others) is increasingly applied to treat young people with varied mental health difficulties. Young people who have experienced OSA are reluctant to seek in-person support and are generally comfortable receiving online support. A digital intervention aimed at improving mentalisation in OSA may reduce the risk for future harm and help young people become more resilient and able to manage distress that might result from OSA experiences.

Who can participate?
Young people aged 12-18 years who have experienced OSA that has led to distress who are receiving support from a service such as the NHS or Kooth for their mental health, though OSA does not necessarily have to be the primary focus of their support.

What does the study involve?
Participants use an app-based intervention over the period of 6 weeks. The intervention is largely based on mentalisation approaches which aim to boost the ability to understand the mental states of oneself and others. This approach has seen increasing application in the support of young people's mental health. The purpose of the i-Minds app is to help people better mentalise and therefore make them less vulnerable to the ongoing risk of online harm and further re-victimisation online. It is not intended to prevent or treat a medical condition.

What are the possible benefits and risks of participating?
The study hopes that the intervention may reduce distress by supporting young people to develop their mentalisation capacity and gain valuable psychoeducational insight into OSA and

how best to avoid further re-victimisation in the future. Whilst all possible steps have been implemented to ensure the safety of young people taking part in the study, it is possible that when accessing the materials in the app, young people may become upset due to reliving memories of the OSA. Appropriate support will be provided throughout the study and there are a number of methods used in the app to help calm and soothe young people if they start to feel upset.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2018 to April 2023

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

Who is the main contact?
Prof. Sandra Bucci
sandra.bucci@manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Sandra Bucci

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301517

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 301517, CPMS 51349

Study information

Scientific Title
i-Minds: a digital intervention to improve mental health and interpersonal resilience for young people who have experienced online sexual abuse - a non-randomised feasibility clinical trial and nested qualitative study

Acronym
i-Minds

Study objectives
As this is a feasibility clinical trial, there are no a-priori hypotheses. Instead, the study aims to determine the feasibility, acceptability and usability of the digital intervention (an app) and how to best integrate the app into existing routine care pathways.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/12/2021, West of Scotland Research Ethics Committee 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WestofScotland.ResearchEthicsCommittee4@ggc.scot.nhs.uk), ref: 21/WS/0160

Study design
Multi-center non-randomized mixed methods feasibility clinical trial and nested qualitative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
App-based support for young people who have experienced distress associated with online or technology-facilitated sexual abuse

Interventions
Non-randomised mixed methods feasibility clinical trial with all participants receiving the intervention (novel app-based intervention using a mentalisation-based approach to improve resilience and reduce risk of re-victimisation and further harm associated with online sexual abuse). The intervention window is 6 weeks.

Intervention Type
Other

Primary outcome(s)
1. Feasibility of delivering the app will be assessed via recruitment and retention data congruent with all relevant fields of the CONSORT statement for feasibility studies. Assessment will take place across the recruitment and data collection period (months 1-11 of trial).
2. Usability, safety and acceptability:
2.1. Usability assessed by the proportion of participants who complete intervention, dropout rates, reason for withdrawal, app usage and engagement (using secure software analytics guided by AMUsED framework)
2.2. Safety assessed using detailed adverse events/serious adverse events reports
2.3. Acceptability assessed using in-depth interviews with trial participants (YP-OSA) to examine whether expectations met, level of support needed to engage with the app, overall impressions, likes/dislikes about the app, how it helped/did not help, changes required, barriers to participation/engagement.

Assessment will take place across the recruitment and data collection period (months 1-11 of trial).

Key secondary outcome(s))
1. Exploration of whether the app brings about clinically meaningful change in outcomes, measured via a battery of questionnaires measuring mentalisation, problematic internet use, emotional distress, online abuse-related stress, emotion regulation, interpersonal sensitivity, views/attitudes towards close interpersonal relationships and resilience, app satisfaction. Assessment will take place at baseline (pre-app use) and post 6-week intervention window (post-treatment).
2. Exploration of differences in engagement and potential clinical benefit across key demographic groups, measured by a registration form requesting demographic (e.g. gender, ethnicity, age, sexual orientation, internet use, level of social deprivation) and clinical (e.g. diagnosis, treatment regime in referring service, other sources of support) details. Assessed at baseline.
3. Exploration of barriers and enablers to app integration and uptake into existing National Health Service (NHS) Child & Adolescent Mental Health Services (CAMHS) & Sexual Assault Referral Centres (SARC) and e-therapy provider pathways, assessed with qualitative interviews with healthcare professionals and service managers from referring services to examine ways to maximise uptake, utility, user experience, acceptability, satisfaction, reach of the app; how the app can be locally adapted and translated into practice; referral routes to the app via existing care pathways; strategic perceptions about whether the app can be scaled up. This will be assessed throughout the data collection period.

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. 12-18 years old
2. Have been exposed to online sexual abuse and report associated distress
3. Are receiving support from NHS CAMHS, SARC or e-therapy providers (Kooth) and will continue to be actively supported by the service over the duration of the trial
4. Willing to use an app designed to support YP-OSA
5. Proficient in speaking and writing in English

6. Have the capacity to consent
7. Consent to providing their username to the research team (Kooth participants only)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Have insufficient verbal and written command of English
2. Have moderate learning difficulties (as assessed by their direct care team)
3. Are at risk of current or recent (past month) suicidality

Date of first enrolment
01/05/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich

Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Kooth Digital Health Limited
2 Eastbourne Terrace
London
United Kingdom
W2 6LG

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

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

Individual participant data (IPD) sharing plan
Future requests to access data will be via the project's CI (Prof. Sandra Bucci; sandra.bucci@manchester.ac.uk) and will be only approved on a case-by-case basis when sharing of data will not incur any risk of participant identification, and only when secondary users will be from a bona fide research organisation and have been granted suitable regulatory approval to further interrogate the data. The exact procedures for accessing the final datasets, as well as relevant meta-data and statistical code used in all quantitative analyses, will be approved by the PSC and made available to prospective future users upon request addressed to the CI and in keeping with our ethical approvals.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/03/2023	24/03/2023	Yes	No
Basic results			25/11/2024	No	No
HRA research summary			28/06/2023	No	No

Other publications		28/03/2024	02/04/2024	Yes	No
Participant information sheet	Participant information sheet version 3	11/11/2025	11/11/2025	No	Yes
Protocol file		09/05/2022	07/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes