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

i-Minds Feasibility Clinical Trial

This protocol has regard for the HRA guidance and order of content.

(Template Version 1.2, March 2016)

FULL/LONG TITLE OF THE TRIAL

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

SHORT TRIAL TITLE / ACRONYM

i-Minds Feasibility Clinical Trial

PROTOCOL VERSION NUMBER AND DATE

Version 3.0. 09/05/2022

This project is funded by the National Institute for Health Research (NIHR) (Health Services and Delivery Research) programme (NIHR131848 - 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 study with a mixed-methods design). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

This project is also supported by the NIHR Clinical Research Network.

RESEARCH REFERENCE NUMBERS

IRAS Number:	301517
ISCRTN Number:	ISRCTN43130832
SPONSORS Number:	x531s
FUNDERS Number:	NIHR131848

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature:

.....

Date:
...../...../.....

Name (please print): Sarah Leo

Position: R&I Manager

Chief Investigator:

Signature:

Date:
...../...../.....

Name: (please print): Sandra Bucci

(Optional)

Statistician:

Signature:

.....

Name: (please print):

.....

Position:

.....

KEY TRIAL CONTACTS

Chief Investigator	Professor Sandra Bucci NIHR Research Professor; Professor of Clinical Psychology Division of Psychology and Mental Health, School of Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester Address: The University of Manchester, 2nd Floor, Zochonis Building, Brunswick Street, Manchester, M13 9PL Email: sandra.bucci@manchester.ac.uk
Project Manager	Dr Amanda Larkin Research Associate Complex Trauma and Resilience Research Unit Address: Research and Innovation, 3rd Floor, Rawnsley Building, Manchester Royal Infirmary, Oxford Road, M13 9WL Email: amanda.larkin@gmmh.nhs.uk
Sponsor	Greater Manchester Mental Health NHS Foundation Trust Representative of the Sponsor: Sarah Leo Address: 1st Floor, Harrop House, Bury New Road, Manchester, M25 3BL Email: researchoffice@gmmh.nhs.uk
Funder	National Institute for Health and Care Research (NIHR), Health Services and Delivery Research (HS&DR) Email: enquiries@nihr.ac.uk / julie.wright@nihr.ac.uk (Research Manager, Southampton NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)
Key Protocol Contributors	Professor Sandra Bucci, Dr Kim Cartwright
Statistician	Professor John Norrie Email: J.Norrie@ed.ac.uk
NHS Trust Collaborators	Pennine Care NHS Foundation Trust, England Manchester Universities NHS Foundation Trust, England NHS Lothian, Scotland
HEI Collaborators	The University of Manchester, England

	The University of Edinburgh, Scotland
Committees	**Project Management Group (PMG)** Name: Professor Sandra Bucci Position / Role: NIHR Research Professor; Professor of Clinical Psychology / Chief Investigator & Lead for Manchester site Address: The University of Manchester, 2nd Floor, Zochonis Building, Brunswick Street, Manchester, M13 9PL, UK Telephone: +44 (0)161 306 0422 Email: sandra.bucci@manchester.ac.uk Name: Dr Kim Cartwright Position / Role: Research Associate & Co-Investigator (PPI Lead) Address: Research & Innovation, Greater Manchester Mental Health NHS Foundation Trust, 3rd Floor, Rawnsley Building, Manchester Royal Infirmary, Oxford Road, Manchester, M13 9WL Email: kim.cartwright@gmmh.nhs.uk Name: Dr Filippo Varese Position / Role: Senior Lecturer in Clinical Psychology; NIHR Advanced Fellow / Co-Investigator Address: The University of Manchester, 2nd Floor, Zochonis Building, Brunswick Street, Manchester, M13 9PL Email: filippo.varese@manchester.ac.uk Telephone: 0161 3060434 Name: Professor Matthias Schwannauer Position / Role: Professor of Clinical Psychology; Head of School for Health Science / Co-Investigator & Lead for Edinburgh site Address: Room 2.14, Doorway 6, Medical Quad, Teviot Place, Edinburgh, EH8 9AG Email: m.schwannauer@ed.ac.uk

	Name: Professor Ethel Quayle Position / Role: Professor of Forensic Clinical Psychology / Co-Investigator Address: Room 2.1, Old Medical School, Teviot Place, Edinburgh, EH8 9AG Email: ethel.quayle@ed.ac.uk Name: Professor John Norrie Position / Role: Professor in Medical Statistics and Trial Methodology & Director of Edinburgh Clinical Trials Unit / Co-Investigator (Trial Statistician) Address: 9 Little France Road, Edinburgh BioQuarter, Edinburgh, EH16 4UX Email: j.norrie@ed.ac.uk Name: Mr Matthew Machin Position / Role: Information Systems Programme Manager / Co-Investigator (Digital Co-Lead) Address: The University of Manchester, Room 2.007, Vaughn House, Portsmouth Street, Manchester, M13 9GB Telephone: 0161 306 7381 Email: matthew.machin@manchester.ac.uk Name: Dr Pauline Whelan Position / Role: Information Systems Manager & Co-Director CAMHS Digital Research Unit / Co-Investigator (Digital Co-Lead) Address: The University of Manchester, Room 2.007, Vaughn House, Portsmouth Street, Manchester, M13 9GB Email: pauline.whelan@manchester.ac.uk Name: Professor Prathiba Chitsabesan Position / Role: National Advisor CYPMH – NHS England Improvement & Consultant Child Psychiatrist – Pennine Care

	NHS Foundation Trust & Honorary Professor – Manchester Metropolitan University / Co-Investigator Address: Healthy Young Minds Stockport, The Forum, Tameside House, Tameside Business Park, Windmill Lane, Denton, Manchester, M34 3QS Email: p.chitsabesan@nhs.net Name: Dr Cathy Richards Position / Role: Lead Clinician & Head of Psychology CAMHS – NHS Lothian & Honorary Professor – University of Edinburgh / Co-Investigator Address: Child and Adolescent Mental Health Service, Royal Edinburgh Hospital, Morningside, EH10 5HF Email: cathy.richards@nhslothian.scot.nhs.uk Name: Ms Victoria Green Position / Role: Acting CEO Marie Collins Foundation / Co-Investigator Address: Marie Collins Foundation, Unit 5a, Well Hall Farm, Bedale Road, North Yorkshire, DL8 2PX Email: victoriagreen@mariecollinsfoundation.org.uk **Project Steering Committee (PSC)** Professor Sam Cartwright-Hatton Role: Chair Address: Department of Psychology, Pevensey 2, University of Sussex, Brighton, BN1 9QH Email: S.Cartwright-Hatton@sussex.ac.uk Dr Peter Fuggle Role: Academic (Member) Email: peter.fuggle@annafreud.org Dr Suzie Black

	Role: Clinician (Member) Email: suzie.black@nhslothian.scot.nhs.uk Mrs Simone Spray Role: PPI representative (Member) Email: simone.spray@42ndstreet.org.uk Dr Alexandra Wright-Hughes Role: Statistician Email: a.wright-hughes@leeds.ac.uk Prof Sandra Bucci Role: Principal Investigator (Member) Email: See above Dr Amanda Larkin Role: Project Manager (Observer) Email: See above Prof John Norrie Role: Trial Statistician (Observer) Email: See above **Data Monitoring and Ethics Committee (DMEC)** Professor David Kingdon Role: Chair Address: University of Southampton, 60 Priory Road, Southampton, SO17 2HS Tel: 0740 306 1969 Email: d.kingdon@soton.ac.uk Professor Ulrich Reininghaus

	Role: Digital health intervention expert (Member) Email: ulrich.reininghaus@zi.manheim.de Dr Pollyanna Hardy Role: Statistician (Member) Email: pollyanna.hardy@npeu.ox.ac.uk
Research Assistants	Name: Cindy Chan Site: Manchester Address: Research & Innovation, Greater Manchester Mental Health NHS Foundation Trust, 3rd Floor, Rawnsley Building, Manchester Royal Infirmary, Oxford Road, Manchester, M13 9WL Email: cindy.chan@gmmh.nhs.uk Name: Alice Newton-Braithwaite Site: Manchester Address: Research & Innovation, Greater Manchester Mental Health NHS Foundation Trust, 3rd Floor, Rawnsley Building, Manchester Royal Infirmary, Oxford Road, Manchester, M13 9WL Email: alice.newtonbraithwaite@gmmh.nhs.uk Name: Will Hewins Site: Edinburgh Address: Room 2.1, Old Medical School, Teviot Place, Edinburgh, EH8 9AG Email: whewins@exseed.ed.ac.uk / will.hewins@nhslothian.scot.nhs.uk

i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
AMUsED	Analyzing and Measuring Usage and Engagement Data
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
DSUR	Development Safety Update Report
EC	European Commission
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LEAG	Lived Experience Advisory Group
MS	Member State
NSAC	National Stakeholders Advisory Committee
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PMG	Project Management Group
PPAC	Parents and Professionals Advisory Committee
PSC	Project Steering Committee

QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

iii. TRIAL SUMMARY

Trial 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	
Internal ref. no. (or short title)	i-Minds Feasibility Clinical Trial	
Clinical Phase	Phase 1	
Trial Design	This is a mixed-methods trial involving a non-randomised feasibility clinical trial to test a digital intervention (app) for young people who have experienced online sexual abuse (YP-OSA) and a nested qualitative interview study.	
Trial & Nested Qualitative Study Participants	YP-OSA aged 12-18 years who are receiving support from an NHS Child and Adolescent Mental Health Service or Sexual Assault Referral Centre or e-therapy healthcare provider, Kooth. Health professionals involved in referring young people to the trial and managers of referring services.	
Planned Sample Size	60 young people to take part in the feasibility clinical trial and 20 of these to take part in the nested qualitative interview study. 20 healthcare professionals and 10 service managers to take part in the nested qualitative interview study.	
Treatment duration	6 weeks	
Follow-up duration	7-9 weeks post-baseline	
Qualitative interviews	8-10 weeks post-baseline or upon trial participant terminating using the app	
Planned Trial Period	15 months (May 2022 – July 2023)	
	Objectives	Outcome Measures
Primary	To test the feasibility of delivering a digital intervention (app) for YP-OSA including the extent to which services refer to the study / intervention. To test the usability, safety and acceptability of the app.	Recruitment and retention data congruent with all relevant fields of the CONSORT statement for feasibility studies. Usability – proportion of participants completed intervention, dropout rates, reason for withdrawal, app usage and engagement (guided by AMUsED

		framework); software embedded in app to record usage. Safety - detailed adverse events / serious adverse events reports. Acceptability – in-depth interviews 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, perceived changes, barriers to participation / engagement.
Secondary	To explore whether the app brings about clinically meaningful change in outcomes. To explore differences in engagement and potential clinical benefit across key demographic groups. To explore what are the barriers and enablers to integration and uptake into existing NHS CAMHS & SARC and e-therapy healthcare provider pathways	Battery of questionnaires measuring mentalisation, problematic internet use, emotional distress, online abuse-related stress, emotion regulation, interpersonal sensitivity, close interpersonal relationships and resilience. Registration form requesting demographic (gender, ethnicity, age, sexual orientation, level of social deprivation) and clinical (diagnosis, treatment regime in referring service, other sources of support) details. 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.

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN (in the case of I-Minds, membership of advisory groups and dissemination support)**
National Institute for Health and Care Research Health Services and Delivery Research Programme	Marie Collins Foundation
	Childnet International
	NCA-CEOP
	Facebook USA
	Tik Tok
	Manchester University Hospitals NHS Foundation Trust
	Kooth
	Barnardo's
	42nd Street
	Manchester Health and Care Commissioning
	Lancaster University (Academic member)
	University of Birmingham (Academic member)

v. ROLE OF TRIAL SPONSOR AND FUNDER

The proposed project has been reviewed by an NIHR funding panel as part of the NIHR HS&DR panel and was recommended for funding. The project's Sponsor is Greater Manchester. Mental Health NHS Foundation Trust (GMMH). The GMMH (R&I) office will oversee study set up, delivery and close out to ensure research governance compliance. An individual from the study team will be identified and delegated by the Sponsor to act in a quality/compliance capacity on behalf of the sponsor in line with the sponsorship oversight framework. The NIHR and the Sponsor have no direct involvement in the selection of the study design, conduct of the research, data analysis and interpretation or dissemination of results. The analysis, interpretation and preparation of outputs will be the responsibility of the chief investigator (CI) (Professor Bucci) and the project team. The views expressed will be those of the authors and not necessarily those of the NIHR, the Department of Health and Social Care or UoM.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

General project management. Greater Manchester Mental Health NHS Foundation Trust is the primary sponsor for the trial. All researchers will receive training in the International Conference on Harmonisation (ICH) Guidelines-Good Clinical Practice. Independent oversight will be provided by a Project Steering Committee (PSC) and a Data Monitoring and Ethics Committee (DMEC). Overall responsibility and management for the project will be with the CI (SB), also the Manchester site Lead. MS will be Edinburgh site lead. MM and PW will be responsible for the development of the digital platform. AL is the project manager and will be responsible for the day-to-day running of the project under the supervision of the CI (SB) and will also co-ordinate all PPI activities. The project manager will conduct weekly supervision with the RAs in Manchester (via Microsoft Teams or in-person depending on COVID restrictions) and MS and EQ will do the same with the RA in Edinburgh. Supervision will focus on recruitment, liaison with referrers, compliance to follow-ups and adherence to research procedures. AL will chair a monthly remote meeting with RAs across sites to share best practice. Supervision from site leads (SB, Manchester; MS, Edinburgh) focussed on problem-solving, risk management and local issues will supplement this supervision plan. MM will supervise the software staff. Each site will have regular team meetings.

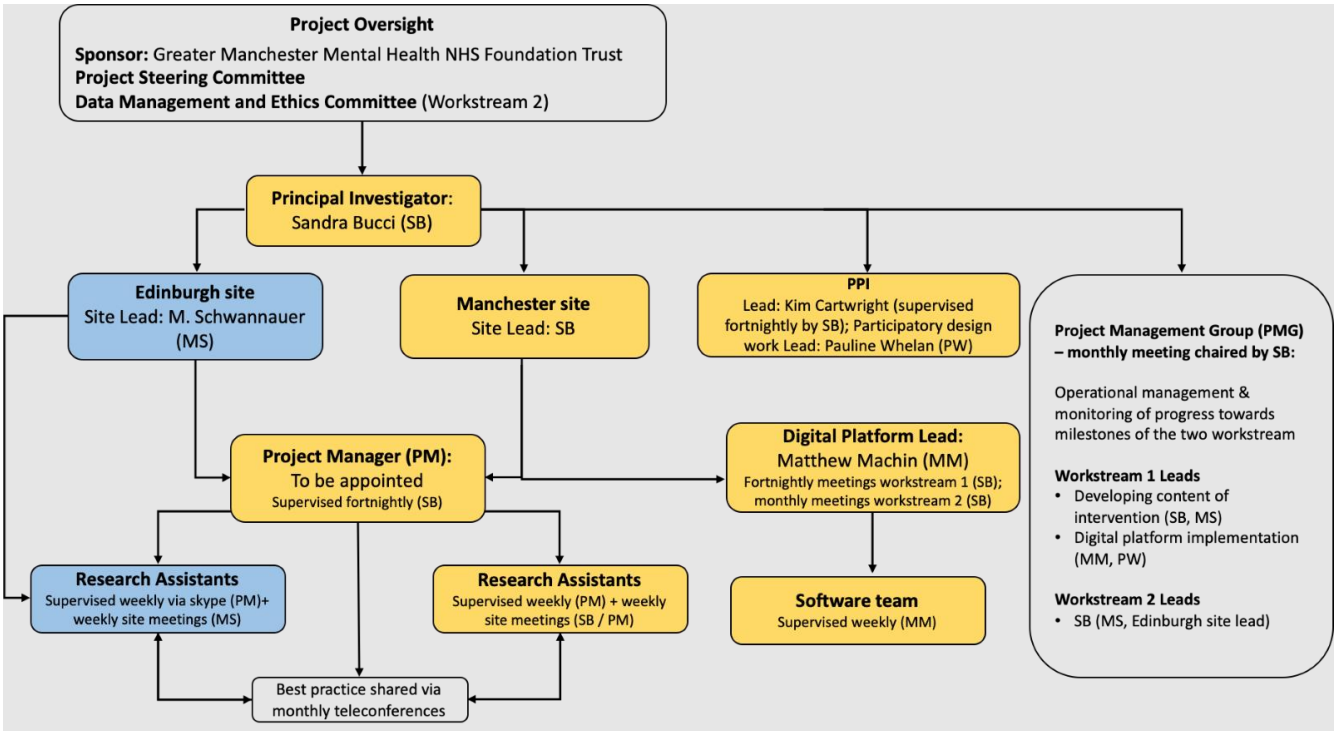


Figure 1. Management structure of i-Minds

Project Management Group (PMG)

Operational management and governance of the feasibility clinical trial and nested qualitative study will be through monthly meetings of the Project Management Group (PMG). The PMG will be chaired by the CI (SB) and attended by all Co-Is. Meetings will be held mostly remotely, with approx. 3

planned in-person meetings (COVID restrictions dependent) per year at key milestones in the project where possible. The PMG will monitor progress towards the planned milestones and outputs, identify risks to achieving milestones, plus solutions for managing risks to ensuring the project will be delivered in a timely manner and within budget.

Project Steering Committee (PSC)

In line with NIHR guidance, an independent Project Steering Committee (PSC) has been assembled to provide independent oversight of the project. The members of the PSC are independent from the Sponsor and Investigators (i.e., they are not involved in other funded research collaborations with the Investigators and will not be affiliated with Greater Manchester Mental Health NHS Foundation Trust, NHS Lothian, The University of Manchester, The University of Edinburgh or any of the Investigators' substantial employers, in addition to other independence criteria outlined in relevant NIHR guidance). The PSC has been approved by the funder and therefore conforms to NIHR guidance and includes: 1) an independent chair with experience of management of research projects in clinically applied areas; 2) an independent statistician; 3) an independent clinician; 4) an independent academic; 5) an independent person able to provide relevant PPIE perspectives and 6) the project CI (Bucci). Other members of the project team including the project manager, Co-I JN, who is a statistician, may attend meetings if required in a non-voting capacity. Other members of the research team, as well as a representative of the Sponsor, may also attend PSC meetings in a non-voting capacity, on an ad-hoc basis when their contribution is deemed necessary or beneficial by the members of the PSC. The PSC Charter has been approved by all members and observers.

The PSC is responsible for the independent oversight of the project on behalf of the Sponsor and the NIHR and will ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The PSC will: 1) provide advice on all appropriate aspects of the project; 2) review the progress of research against the project timeline, monitor adherence to the protocol and the consideration of new information of relevance to the research question; 3) review issues related to patient safety (e.g. any AE or SAE) and ensure that, throughout the project, the rights as well as safety and well-being of the participants will be prioritised over the interests of science and society; 4) agree proposals for substantial protocol amendments and provide advice to the Sponsor and NIHR regarding approvals of such amendments.

Membership to the PSC has been approved by the NIHR and the PSC Charter has been reviewed and signed by all members and observers.

Data Monitoring and Ethics Committee (DMEC)

A DMEC has been established and will meet prior to commencing the feasibility clinical trial to monitor ethical issues of consent and confidentiality, data quality and completeness, incidence of adverse events, monitor compliance with the protocol by participants and investigators, and any other issues relevant to the transparent and ethical delivery of the project. The DMEC will meet on 2-3 occasions in (e.g. study set up, trial end) and will comprise an independent chairperson, independent statistician and independent expert on digital health interventions. The role of its members is to monitor these

data and make recommendations to the PSC on whether there are any ethical or safety reasons why the trial should not continue. The safety, rights and well-being of the trial participants are paramount.

Advisory Groups

The project will be guided by ongoing consultations with YP, parent/caregivers and practitioners and overseen by our PPI Lead KC. We have established three advisory groups to meet throughout the life of the project to help steer and oversee it, and contribute to dissemination and implementation: i) Lived Experience Advisory Group (LEAG) (n=8-10) convened for 2 hours every month during critical periods and every other month outside of this; ii) National Stakeholders Advisory Committee (NSAC) (n=8-10) convened for 2 hours every 6 months, and iii) Parents and Professionals Advisory Committee (8-10) convened for one hour every other month, drawn from our extensive network of collaborators and contacts (see PPI Section for further details). Advisory group feedback will directly inform the running of the project and development, delivery and evaluation of the intervention as illustrated in our project flowchart. The PPI Co-I (KC) will further ensure that the views and values of YP-OSA will be represented across the lifetime of the project. In accordance with NIHR guidance, KC will develop and shape the PPI plans with public contributors, set and refine the overall PPI strategy, provide appropriate induction and training to advisory group members and ensure that involvement is aligned to UK Standards for Public Involvement and monitored using a PPI impact log aligned with the GRIPP2 guidance.

vii. Protocol contributors

Professor Bucci and the Dr Cartwright were responsible for the drafting of the protocol on the basis of the Detailed Project Plan of the grant application submitted to NIHR as part of the NIHR HS&DR application submission.

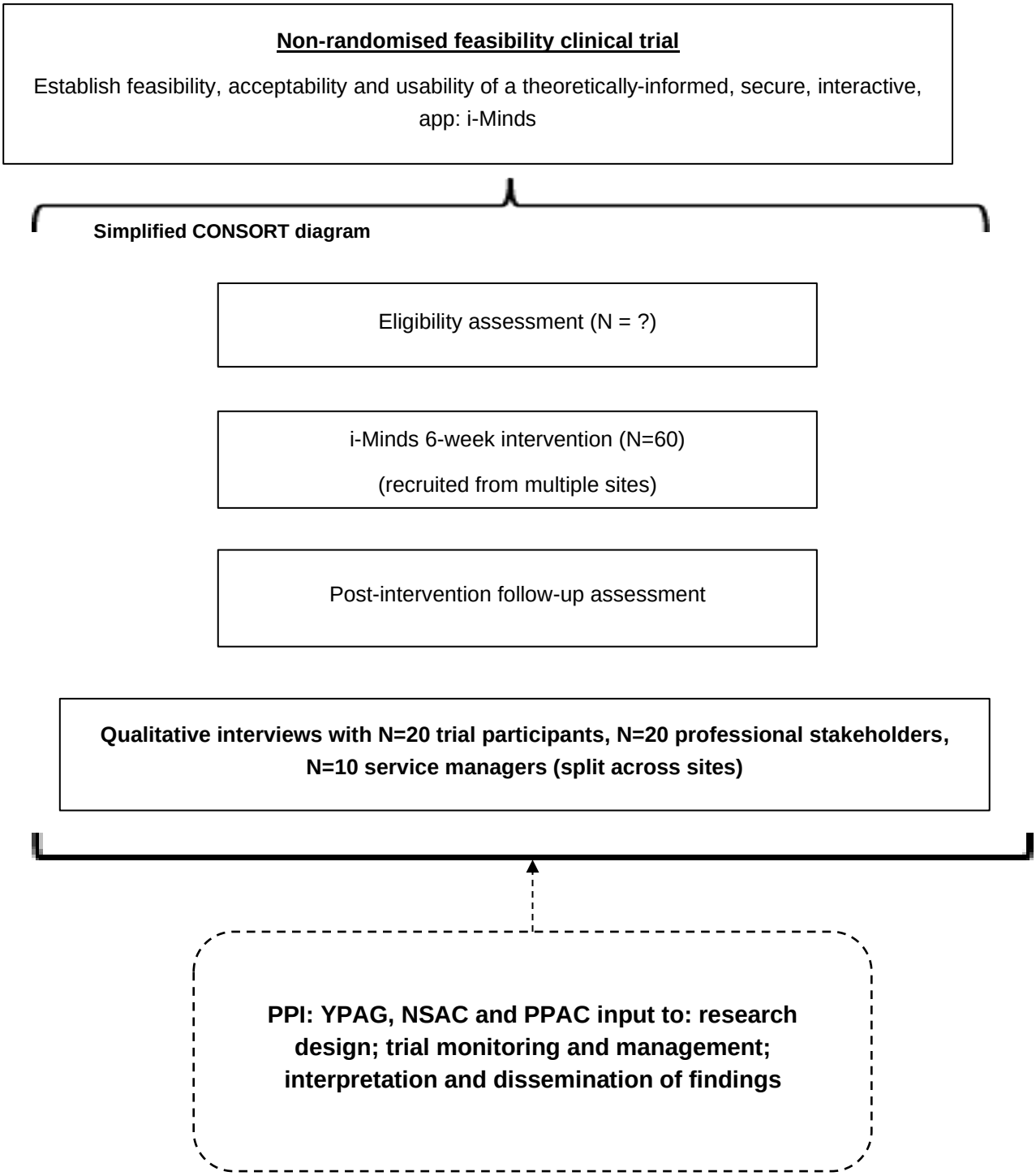
viii. Key Words

online sexual abuse; digital; young people; abuse; eHealth; mHealth

ix. TRIAL FLOW CHART

Mixed-Methods Feasibility and Acceptability Study

(13 months; May 2022 – July 2023)



1.1 LAY SUMMARY

Online sexual abuse (OSA) of young people (YP) has increased, can have serious effects on YP's development and mental health, and has become an important priority for health and social care services. YP can report this abuse to government agencies and social media companies, but there are currently few tried and tested or helpful treatments available. The NHS urgently needs an accessible intervention to support YP who have experienced OSA (YP-OSA).

We have been working in partnership with YP, caregivers and professionals to develop an app that: i) YP find easy to use, ii) has a positive effect on YP's mental health, interpersonal resilience and wellbeing, and helps them stay safe on the Internet, and iii) could be used in the context of NHS and online services that already provide mental health and / or sexual abuse support to YP. This is the first phase of the 27-month project.

In the current feasibility clinical trial, the second phase of the project, we will ask 60 YP-OSA to use the app. The app is designed to help young people better understand their own thoughts and feelings, and the thoughts and feelings of others. This feasibility clinical trial will allow us to test whether YP actually use the app, if they like using it, and if it is safe to use. They will also be asked to complete questionnaires about their well-being and internet use at different time points in the study (before and after they have used the app) to monitor whether the app was helpful or not. In addition, we will interview: i) 20 YP who took part in the trial to find out what they liked/did not like about the app, what improvements we can make; and ii) 30 professionals to understand how the app could be used in existing NHS and online services.

We will share findings with as many people as possible, including YP themselves, caregivers, mental health services, police, schools and education services, industry and voluntary sector organisations, and the general public.

1.1.1 SCIENTIFIC ABSTRACT

There is no evidence-based support offered to young people who have experienced online sexual abuse (YP-OSA). NICE (2017) has recognised as a research priority the identification of effective interventions for improving the wellbeing of YP-OSA and preventing further harm. Interventions aimed at improving mentalisation (the ability to understand the mental states of oneself and others) are increasingly applied to treat young people with varied clinical issues. YP-OSA are reluctant to seek in-person support and are generally comfortable receiving support online. A digital intervention aimed at improving mentalisation in YP-OSA may reduce risk for re-victimisation and future harm and make young people more resilient and able to manage distress that might result from OSA experiences. We are currently working in partnership with YP, caregivers and professionals to develop a theoretically-informed app that: i) YP find easy to use, ii) has a positive effect on YP's mental health, interpersonal resilience and wellbeing, and helps them stay safe on the Internet, and iii) could be used in the context of NHS and online services that already provide mental health and / or sexual abuse support to YP.

AIMS: To determine the feasibility, acceptability and usability of the digital intervention and how to best integrate the intervention into existing routine care pathways.

METHODS: We will conduct a mixed-methods non-randomised study to determine the feasibility, acceptability and usability of the intervention. We will conduct interviews with YP-OSA who use the app to assess their impressions of the intervention and identify areas for improvement. Informed by

Normalisation Process Theory (NPT), we will examine barriers and enablers relevant to the future integration of the intervention into existing care pathways, including traditional clinic-based NHS services and NHS e-therapy providers.

PATIENT AND PUBLIC INVOLVEMENT: We will build on our existing partnerships with YP-OSA, parents/caregivers and relevant agencies. Regular consultations with YP-OSA and other stakeholders will ensure our work is relevant and meaningful. Project workstreams will be informed by bespoke advisory groups comprising YP-OSA, their parents/caregivers, and practitioners/professionals from a range of statutory and third sector organisations. Our PPI consultations have already indicated that a digital intervention for YP-OSA is welcomed and needed.

ANTICIPATED IMPACT AND DISSEMINATION: We will develop an evidence-based intervention that can be embedded in existing services to support YP-OSA. We will ensure digital outputs can be scaled-up to provide an accessible intervention. Our confirmed stakeholder partnerships, including law enforcement (NCA-CEOP), industry (Facebook), third sector (Marie Collins Foundation), NHS CAMHS services, and e-therapy providers (Kooth) will ensure outputs meet the intended beneficiaries. Our wide-reaching dissemination strategy, supported by our partners and track-record of world-leading research, will ensure maximum impact, longevity, and integration of outputs into existing infrastructure.

2 BACKGROUND

Child sexual abuse (CSA) constitutes a major risk factor for many health risk behaviours as well as physical and mental health problems. CSA negatively impacts developmental trajectories, education attainment, occupational prospects and communities more broadly, at huge societal and economic costs (e.g. 1–3). For YP, using the internet is a routine part of daily life, but it can place them at risk of various forms of CSA. Online sexual abuse (OSA) can happen through any device connected to the Internet and across multiple platforms and applications. YP can be coerced into sharing sexual images of themselves, take part in sexual activities via a webcam or smartphone, or have sexual conversations by text (‘sexting’). Online grooming, abuse and exploitation may also lead to contact abuse; increasingly, contact abuse cases involve online elements (e.g. the production and distribution of images). Offline and online sexual abuse are not mutually exclusive in terms of risk behaviours or harm, but there is evidence of additional risks of OSA afforded by the Internet, and unique social and psychological harms associated with OSA (4–6).

The distinctive nature of OSA relative to other forms of abuse is recognised in the current NICE guidelines for responding to child abuse and neglect (1). NICE found no evidence-based interventions for improving the mental health and well-being of YP-OSA and recommended further research for the efficacy of interventions aimed at improving well-being, relationships and preventing further harm following online facilitated abuse. Rapid reviews conducted as part of the HS&DR Commissioned Call on OSA (2018) confirmed the lack of evidence and ongoing primary research on specific interventions for YP-OSA. In June 2020, we conducted a PROSPERO search and found no published/ongoing reviews relevant to OSA. We also conducted rapid searches of databases (the Cochrane Library; Medline) to identify relevant clinical trials or trial protocols published since 2016 (the date of last search of the NICE guidelines above). We searched trial registers for relevant ongoing primary research (the UK Clinical Trials/‘Be Part of Research’ Gateway; WHO trials; ISRCTN registry) and found no ongoing/recently published trial that addresses this NICE research recommendation. **The**

efficacy of interventions that could improve wellbeing and prevent further harm in YP-OSA remains an unmet research need.

Multiple factors are likely to be involved in the vulnerability to being exposed to OSA; a relevant risk factor is a YP's ability to accurately estimate others' intentions and motivations when engaging in online environments. **This ability to understand what is going on in our own mind as well as in other people's minds (in terms of thoughts, intentions, desires and beliefs) is known as 'mentalisation'** (7). More specifically, mentalisation (or 'mentalising') is the ability to attend to and reflect on the mental states in ourselves and in others and consequently understand our own actions and those of others on the basis of intentional mental states. A clear inverse relationship exists between emotional arousal and failure in mentalisation (8). YP who are distressed or have difficulties with affect regulation as a result of having been victimised, abused, and/or exploited online, may be at greatest risk of developing difficulties in mentalising, increasing the likelihood of repeated victimisation and harm (9). Furthermore, social anxiety (often experienced by YP who are groomed online) has also been found to be associated with mentalisation difficulties (10). People's assumptions about the intentions and motives of others is usually based on the verbal and non-verbal cues of real-life interactions. When we communicate in an online environment, signals of empathy and understanding are transmitted more opaquely (11–13), and mentalising, already compromised in vulnerable YP, can be even further affected. The inability to mentalise can compromise evaluation of risk and assumed trust in online communications (14) and might therefore represent a valuable target for interventions aimed at reducing risk in YP who have already been exposed to OSA.

Improving mentalisation is also expected to lead to improved mental health and well-being of YP-OSA. Growing evidence has confirmed that mentalisation abilities are central to effective emotional regulation and mental well-being. The ability to mentalise one's own experiences and those of others allows for adequate coping with external and internal stressors, regulation of affect, and the formation of stable and safe interpersonal relationships (15). In turn, difficulties in mentalising processes have been linked to greater vulnerability for a range of mental health problems that are common amongst OSA survivors, including depression, anxiety, eating disorders and shame (16). Recent systematic reviews (16) have highlighted Mentalisation-Based Therapy (MBT), a therapeutic approach that specifically aims to improve mentalising capacity, and consequently affect regulation and psychological distress, is a promising treatment approach across a wide range of clinical presentations, including groups that have previously shown limited response to psychological therapy (e.g. adolescents who self-harm). The efficacy of MBT has been more extensively trialled in adult mental health, but a growing evidence base is emerging for the efficacy of MBT in YP. For example, in a randomised controlled trial (RCT) with adolescents who self-harm, Rossouw and Fonagy (17) found that MBT for adolescents (MBT-A) was more effective than TAU, with a recovery rate of 44% in comparison to 17%. In a recently published pilot RCT conducted by the Edinburgh co-applicants, a brief (12 weeks) mentalisation-based intervention has been found to be acceptable in YP in receipt of CAMHS treatment and associated with significant treatment effects across a range of outcomes relevant to the present application (e.g. anxiety, self-harm behaviours, ability to regulate distressing emotions) (18). Therefore, **improved mentalisation capacity following a mentalisation-based psychological intervention might result in improvements in two key intervention targets for YP-OSA: 1) reducing risk for re-victimisation and future harms, and 2) improve the emotional and mental wellbeing of users that might experience current distress as a result of OSA experiences.**

There has been a dramatic expansion of digital health tools for YP. Whilst psychological interventions for YP can be delivered across multiple modalities (individual face-to-face interventions, group interventions), digitally-mediated interventions represent an acceptable way to support YP and overcome some central limitations of traditional "clinic-based" services. Recent systematic reviews and meta-analyses have demonstrated that **digitally-mediated psychological interventions represent effective treatment options for improving the mental health and well-being of YP** across a range of problems (19), including computerised cognitive behaviour therapy (cCBT) targeting depression and anxiety, which have been most commonly examined. Existing feasibility, acceptability and efficacy studies of digital interventions indicate that they are acceptable across genders (20), impact on behaviour as well as mood (21), and are safe with vulnerable YP (22).

A digitally-mediated intervention would help address several key limitations in relying solely on routine clinic-based service delivery to support the needs of YP-OSA. Most services are only available during business hours, yet distress and the need for support are not bound in this way. Long waiting times in CAMHS services (23) mean there are significant delays in help being offered, preventing timely access to support, the potential exacerbation of problems brought about by OSA exposure, and the increased risk for repeated victimisation in the interim. When effectively integrated within existing care pathways for YP, a digital intervention for YP-OSA would add value by: i) scaling up access to support and tackling the overwhelming demand on services to provide timely therapeutic input; ii) ensuring the support could be implemented 'in the flow of daily life' and in a format that is both familiar to YP and unconstrained by location and time, allowing access to therapeutic strategies even when traditional means of support are not available (e.g. in the event of repeated and ongoing lockdown restrictions), and iii) achieve clinical benefit using relatively fewer resources compared to clinic-based services. **As most YP have access to and use the internet, a digital intervention would significantly scale-up and accelerate access to therapeutic support for YP-OSA**.

Our project specifically addresses NICE (1) research recommendations calling for research evaluations of interventions for improving the well-being of YP who have been exposed to online-facilitated abuse, and reducing the likelihood of future harm. We will expand on the above body of knowledge by adapting the manual of an existing brief mentalisation-based intervention for YP (18), integrating knowledge from the literature on OSA (as per NICE recommendations) and through extensive design input from YP-OSA, their parents/guardians and practitioners. We will build an engaging digital-platform for delivering the intervention and conduct a mixed-methods non-randomised trial to evaluate the feasibility and acceptability of our digital intervention, and gather knowledge on the barriers and enablers for its effective integration into relevant NHS care pathways for YP (CAMHS services, Sexual Assault Referral Centres, NHS e-therapy providers). In doing so, our project is aligned to the NHS Long Term Plan (in particular the priority of making digitally-enable care a mainstream reality in the NHS; (24)), a NICE research priority (the evaluation of interventions to support the wellbeing of YP-OSA; (25)), the NHS England Strategic Direction for Sexual Assault and Abuse Services: lifelong care for victims and survivors: 2018-2023 (26)), and UK Home Office recommendations (27) highlighting that support and protection of YP-OSA is a national priority.

3 RATIONALE

Evidence explaining why this research is needed now

The COVID-19 crisis has exacerbated the already present risk and vulnerability of YP being victimised, abused and exploited online. There is substantial evidence demonstrating the extent of OSA both before and during COVID-19. Before COVID-19 took hold, the National Crime Agency (NCA) saw a 700% increase in CSA images referred to them from 2014 to 2017 (28); its most recent intelligence showed there are at least 300,000 people in the UK alone who pose a threat to YP. Concerns around the increase in OSA over the last decade (and in recent months) (28) have resulted in a UK government White Paper (29) and a recent coalition of 18 of the world's 'tech giants' with the goal of preventing and eradicating OSA (30). Since the UK government announced lockdown and social restriction rules, YP are spending significantly more time online, often unsupervised. For example, there has been a 40% increase in WhatsApp use (31). Research by the NSPCC with 2000 YP indicates that those who rely on social media, and who are unhappy, extroverted and lonely, are more exposed to online grooming. NCA recently reported that offenders are discussing opportunities to abuse children during the crisis. Europol (32), who has been assessing the impact of COVID-19 on child exploitation, has seen an increase in the number of attempts to access illegal websites featuring OSA material and a surge in attempts by offenders to contact YP on social media sites (33). The Internet Watch Foundation revealed that it had blocked and filtered at least 8.8 million attempts by UK internet users to access OSA videos and images during April alone (34). COVID-19 has led child protection organisations to urge governments, tech companies, educators and parents to be alert, take urgent measures to mitigate potential risks and ensure YP engagement online in a safe and positive way.

The sharp increase in YP-OSA, even before COVID-19, had already caused increased pressure on health and care services, education and government systems. Generalist services (e.g. CAMHS) are overstretched and insufficiently resourced to meet the expanded demands for therapeutic input (35); the additional impact of COVID-19 has meant that health and social care services have been under considerable pressure because traditional means of delivering face-to-face support have been limited or impossible. Recent data shows an increase of 34% in the demand for mental health support from YP during the pandemic (36). Child protection organisations have released recommendations on how to keep YP safe from OSA, but there remains no evidence-based provision for YP-OSA that does not rely on face-to-face delivery, making it impossible in lockdown conditions or in future crises that may disrupt once again the ability to deliver traditional clinic-based services.

The widespread requirement for digital technologies due to current lockdown has shown the value and urgent need for digital therapeutic support and has fuelled a renewed interest in digital health given the unconstrained opportunities digital means afford for accessing healthcare. Indeed, digital technology capabilities and the current climate of increased uptake of remote ways of working by clinicians and services means a digital intervention is perfectly positioned to support YP-OSA. **Our project will address the challenge of services delivering timely and effective support to YP-OSA that remains deliverable in further potential crises.**

4 ASSESSMENT AND MANAGEMENT OF RISK

4.1 Participants – young people who have experienced online sexual abuse

Sensitive / potentially upsetting topics

Participants will be asked to complete some questionnaires asking them questions about their mental health and wellbeing, traumatic life experiences, problematic and risky internet use and interpersonal relationships. These measures have been used as part of other funded studies we have conducted involving similar vulnerable client groups. In our experience, participants tolerate well completing these measures, and in most cases, welcome opportunities to discuss how their mental health was influenced by distressing and potentially traumatic life experiences.

Participants will also be invited to take part in an interview after using the app. Questions will focus on asking participants about 1) taking part in the study, for example, how they found the research assessment procedures, and 2) the intervention, for example, whether it met their expectations, their overall impressions, what they liked and / or did not like about it, how it helped and / or did not help, what changes they would make. The questions are not designed to include sensitive or potentially upsetting topics.

If for any reason participants become distressed whilst completing the questionnaires, using the app, or being interviewed, we will follow distress protocols adapted from our previous studies involving vulnerable young people who have experienced trauma and / or mental health difficulties and which have been reviewed by our lived experience and professional advisory groups / committees (Lived Experience Advisory Group (LEAG); National Stakeholders Advisory Committee (NSAC); Parents and Professionals Advisory Committee (NSAC). Data collection will be stopped immediately and will only continue if the participant feels comfortable doing so. Participants will also be reminded that they can withdraw from the study at any time. The research assistant will debrief the participant after the assessment and interview and discuss whether the participant might wish to arrange a meeting with the project lead (a clinical psychologist with extensive experience in the topic area) or another member of staff they feel comfortable with. We will liaise with the participant's clinical teams to handle any significant risk and signpost participants to appropriate sources of support in their locality. The Safeguarding and Distress Management Protocol outlines the process that will be followed should participants become distressed.

Confidentiality and management of disclosures

If a participant discloses something which raises serious concerns about their safety or the safety of others, it may be necessary to break confidentiality and inform relevant parties. This will be made clear in the Participant Information Sheet and discussed with participants during the consenting process. Please see the Safeguarding and Distress Management Protocol for the process we will follow should an issue with safety occur.

Consent

Feasibility clinical trial: All participants will be aware of the aims and intentions of the non-randomised feasibility clinical trial and what it will involve. They will be provided with an age relevant Participant Information Sheet (i.e., 12-15 or 16-18 years) to read and this will be explained verbally to

participants over the telephone or via Trust-approved remote platforms (e.g., Microsoft Teams / Zoom / NEARME) prior to them consenting. All participants will give fully informed consent. Prospective participants aged 12-15 years will be asked to give the Participant Information Sheet for parents / caregivers to at least one of their parents / caregivers. Parents / caregivers of young people in England will be given the opportunity to opt their child out (by contacting the research team or a member of the child's clinical team or completing an opt out form) should they not wish their child to take part in the study. As research assessments and interviews may be completed in person, remotely or via telephone, consent may be obtained either through participants returning a signed hard copy via post, audio-recorded verbally or by returning a signed photographed or scanned copy via email. Three copies of the consent form will be produced: 1 original for the research team, 1 copy for the participant, and 1 electronic copy to be uploaded to medical notes. Our consent procedures will also be reviewed by our lived experience and professional advisory groups / committees.

Nested qualitative interview study: All participants will be aware of the aims and intentions of the nested qualitative study and what it will involve. This includes young people who take part in the non-randomised feasibility clinical trial and healthcare professionals who have referred to the feasibility clinical trial. Young people, sampled purposively via age and gender, will be provided with information about the qualitative study in the Participant Information Sheet provided to them for the feasibility clinical trial. They will be asked to consent to taking part in the qualitative study as part of the consent process for the feasibility clinical trial. As interviews with healthcare professionals will be completed in person, remotely or via telephone, consent may be obtained either through participants returning a signed hard copy via post, audio-recorded verbally or by returning a signed photographed or scanned copy via email. Three copies of the consent/assent form (for YP participants) will be produced: 1 original for the research team, 1 copy for the participant, and 1 electronic copy to be uploaded to medical notes. As above, consent procedures will be reviewed by our lived experience and professional advisory groups / committees.

Distress experienced while using the app

The Participant Information Sheet and app will have an emergency contacts section so that, should YP become distressed whilst using the app, they will be able to contact a relevant organisation. The contact list will include information to out-of-hours emergency contacts (e.g., A&E services; NHS contacts; charity helplines; charity helplines and websites) as well as local organisations that can provide support during business hours.

Risk management

We will employ stringent adverse events standard operating reporting procedures. Research staff will liaise immediately with clinical staff and services to ensure provision of appropriate support, should risk be identified. We will develop a robust process for informing the clinical team, based on tried-and-tested procedures (which will be further developed in consultation with our advisory groups) we have already employed in other trials of digitally-mediated and face-to-face psychological interventions for YP with trauma, severe mental difficulties and ongoing risk (e.g. the MRC-funded *Actissist* and NIHR-funded *EASE* trials (IRAS Refs: 234090 and 250744). We will liaise closely with a participant's clinical keyworker and share information relevant to the participants' welfare, clinical support needs and

safety. At the point of referral, we will collect the contact details of both the YP's General Practitioner and keyworker from the referring service, who will be our primary point of contact for subsequent liaison with the clinical team / key worker. Once a YP has consented to taking part in the study, we will swiftly inform the referring clinician / keyworker from the referring service of the participants' decision to take part in the i-Minds study and write a letter to the clinical team / healthcare provider to inform them about the YP's participation in the study so that this information can be included in relevant electronic notes accessible to all team members involved in their care. We will follow the study's Safeguarding and Distress Management Protocol included in this application. We will report risks where needed according to the relevant Trust risk reporting procedure.

4.2 Participants - healthcare professionals

Sensitive / potentially upsetting topics

Professionals will be interviewed once young person participants have used the app. Healthcare professionals and practitioners will only be asked questions about the uptake and integration of the intervention into existing NHS and online young person service care pathways. They will not be asked to discuss specific cases or highly sensitive, emotive or distressing topics. If for any reason participants do become distressed during the interviews, as per our distress protocol, data collection will be stopped immediately and will only continue if the participant feels comfortable doing so. Participants will also be reminded that they can withdraw from the study at any time. The research assistant will debrief the participant and discuss whether the participant might wish to arrange a meeting with the project lead / lead for Manchester or lead for Edinburgh (both qualified clinical psychologists) or another member of staff they feel comfortable with.

4.3 Research assistants

Sensitive / potentially distressing topics

The questions the researchers will be asking in the research assessments can include sensitive and emotive distressing topics, and this may have an impact on members of our research team involved in the planned data collection activities. All research assistants will have weekly supervision with the project manager, and monthly joint supervision with the project lead and lead for Manchester, a clinical psychologist with extensive expertise in severe mental health and working with trauma survivors, and / or lead for Edinburgh (MS), a clinical psychologist with extensive experience in mental health in young people and works for the Child and Adolescent Mental Health Service. They can also request additional meetings with the site leads should they need support more urgently. These systems will ensure appropriate opportunities for raising, discussing and resolving any emotive or challenging issues arising from the assessments conducted as part of this study, and the implementation of steps for ensuring that all research workers will be optimally supported. The research assistants will also receive appropriate training in distress management from their local Trusts and from the clinical team members of the project team.

Safety during research assessments and interviews

Participants may complete research assessments online, via telephone or in person. For those who complete the research assessments online or via telephone, the research assistants will be available via telephone should a participant need support. Research assistants may conduct interviews in person at the home or another convenient place for the participant, over the telephone or online from their own home or from their place of work. For assessments and interviews that take place in person, the Lone Working Policy will be adhered to.

5 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The main aim of the study is to determine whether: i) it is feasible to deliver a secure, theoretically-informed and interactive multi-media digital intervention (an app, with the goals of reducing the risk of re-victimisation and improving the mental health, interpersonal resilience and wellbeing of YP-OSA); ii) the app is usable and acceptable to users; and iii) how best to integrate the app into existing NHS and online mental health and / or sexual abuse service care pathways.

5.1 Primary objective

The primary objective of the trial is to determine the feasibility and acceptability of delivering a digital intervention (app) for YP-OSA including the extent to which services refer to the study / intervention and the usability, safety and acceptability of the app.

Key questions to be addressed include:

1. To what extent do services refer YP-OSA to an intervention of this kind?
2. What are the levels of engagement and patterns of use among YP?
3. How safe is the digital platform for YP-OSA to use?
4. How complete are the data collection measures?
5. How usable and acceptable is the app to YP-OSA?

5.2 Secondary objectives

The secondary objectives of the trial are to explore whether the app brings about clinically meaningful change in outcomes, the differences in engagement and attrition and potential clinical benefit across key demographic groups (e.g., LGBTQ & BAME), the demographics and service differences across recruitment sites (Manchester / Edinburgh / Kooth) and what are the barriers and enablers to integration and uptake into existing NHS CAMHS & SARC and digital youth mental healthcare provider pathways.

5.3 Outcome measures/endpoints

5.3.1 Primary endpoint/outcome

The focus of the study is feasibility. No formal attempt to test the effectiveness of the intervention will be conducted. To establish the extent to which services refer to i-Minds, we will collect detailed

recruitment and retention data congruent with all relevant fields of the CONSORT statement for feasibility studies (52), including:

i) number of eligible participants consenting;

ii) total number recruited, including information about recruitment setting to inform sampling strategy of a future definitive trial;

iv) completeness of outcome measures;

vi) number lost to follow-up;

vii) number of services that were offered the intervention, including dates and content of all site communication; dates of meetings and staff present; decisions on adoption/referrals made by sites, with reasons when available.

To evaluate the extent to which YP-OSA engage with i-Minds, we will collect data on:

i) proportion of participants completing the intervention;

ii) dropout rates, reason for withdrawal; and

iii) platform usage and engagement data using secure software analytics guided by the AMUsED framework for analysing and measuring usage and engagement data in digital interventions (53).

Automated software analytics embedded in the digital platform will record, for example, each visit by registered users, number of times visited the programme, aspects of the platform used, length of use, which can be viewed by the researcher using a (web-interface) dashboard.

To evaluate the safety of the intervention, we will collect detailed adverse events / serious adverse events reports using standardised operating procedures used in our previous trials and in line with NIHR and HRA Safety Reporting procedures.

To understand how i-Minds is experienced and its acceptability, we will conduct in-depth qualitative interviews with 20 YP-OSA (10 per site) who complete and/or do not complete the intervention. Participants will be selected according to a sampling framework to capture varied demographics, experiences of OSA and levels of engagement in the intervention. Interviews will be in rounds of approx. 5 participants to allow for iterative analysis to inform further sampling. Topic guides developed with input from our YPAC and PPAC will be used to examine: i) whether i-Minds met expectations; ii) what level of support is needed to facilitate engagement with i-Minds; iii) overall impressions of i-Minds (enjoyable, usability, satisfaction); iv) what participants liked and/or did not like about the intervention in terms of content and usability of the platform; v) how it helped and/or did not help; vi) what changes they would make; vii) barriers to participation/engagement, including perceived burden of the research assessment procedures.

5.3.2 Secondary endpoints/outcomes

To determine which outcomes are sensitive to change in this group and are specific to the problems experienced by YP-OSA, participants will be asked to complete measures assessing relevant outcomes of the intervention both before (Week 1) and after using the app (Weeks 7-9 post-baseline). Prior to their use in the trial, the battery of measures will be thoroughly piloted with the aid of members of our advisory panel to ensure the measures collected will be meaningful to the target group, and that

the overall assessment procedure will not be excessively burdensome. Based on our prior research on mentalisation interventions in YP, we will assess the following outcomes: mentalisation (Reflective Functioning Questionnaire for Youths, RFQ-Y; (54), problematic internet use (Problematic and Risky Internet Use Screening Scale, PRIUSS; (55)); emotional distress (Revised Child Anxiety and Depression Scale – 25 item version, RCADS-25; (56)); online-abuse related distress (by anchoring the Child Revised Impact of Events Scale, CRIES; (57) to the YP's OSA experience). We will also administer psychosocial measures relevant to mentalisation that are expected to be associated with improved outcome, including: emotion regulation (Difficulties in Emotion Regulation Scale – Short Form, DERS-SF; (58)); interpersonal sensitivity (Interpersonal Sensitivity Measure, ISM; (59)); views/attitudes towards close interpersonal relationships (short version of the Experiences in Close Relationships Scale–Revised Child version, ECR-RC; (60)) and resilience (Connor-Davidson Resilience Scale – 10 item version, CD-RISC-10; (61). We will administer an app satisfaction questionnaire (at follow-up only). We will omit the views/attitudes towards close interpersonal relationships (short version of the Experiences in Close Relationships Scale–Revised Child version, ECR-RC and the Problematic and Risky Internet Use Screening Scale at follow up as these measures are not sensitive in the time between baseline and follow up.

To examine differences in engagement and potential clinical benefit across key demographic groups, at study entry participants will complete information relating to demographic data, and clinical and contact details (including study site). To understand the characteristics of users, demographic data will include date of birth, gender, whether their gender matches with their sex assigned at birth, ethnicity, highest completed level of education, who they live with, whether they have any children or people they care for, and if so, who, employment status, job and relationship status as well as information to identify their relevant level of social deprivation using the Scottish/English Index of Multiple Deprivation (62,63). Clinical data about accessing services will be obtained from participants who take part in the feasibility clinical trial at baseline including: service currently supporting them, other services currently supporting them and for how long, whether they use any apps to help with their mental health, whether they have been a patient in a child and adolescent psychiatric hospital / ward, and if so, what for, whether they receive any therapy from a psychologist or counsellor for a mental health problem, whether they have received a diagnosis for a mental health problem, and if so, what diagnosis, whether they are able to access the internet when they or need to, internet use (how and frequency), whether anything has happened online or on a phone that bothered or upset them (past year), what sorts of things might have happened to them and how often (past year) and whether they talked to someone about what happened (the last time something happened).

To examine barriers and enablers (and unintended consequences) to integration and uptake of the intervention into existing care pathways, we will build on the findings of the qualitative interviews with professional stakeholders in workstream 1 and extend our understanding in workstream 2 to further clarify questions around the integration and uptake of i-Minds in existing care pathways (when YP participants and healthcare professionals have used and interacted with the digital platform). We will conduct qualitative interviews, informed by PPAC consultations, with 20 healthcare professionals who referred to the trial (10 per site) and 10 service managers (5 per site) to examine specific questions around: i) ways in which we can maximise uptake, utility, user experience, acceptability, satisfaction and reach of the platform; ii) how the platform can be locally adapted and translated into practice; iii) professionals' views about referral routes to a digital intervention within existing care pathways; iv) strategic perceptions about the relative advantage of the digital platform and its wider transactability (whether it can be scaled up).

5.4 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To test the feasibility of delivering the digital intervention (app) for YP-OSA including the extent to which services refer to the study / intervention To test the usability, safety and acceptability of the app	Recruitment and retention data congruent with all relevant fields of the CONSORT statement for feasibility studies Usability – proportion of participants completed intervention, dropout rates, reason for withdrawal, app usage and engagement (using secure software analytics guided by AMUsED framework) Safety - detailed adverse events / serious adverse events reports Acceptability – in-depth interviews 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, perceived changes, barriers to participation / engagement	
Secondary objectives To explore whether the app brings about clinically meaningful change in outcomes To explore differences in engagement and potential	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. Registration form requesting demographic (e.g. gender,	Baseline and 7-9 weeks post-baseline

clinical benefit across key demographic groups	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.	
To explore what are the barriers and enablers to integration and uptake into existing NHS CAMHS & SARC and digital youth mental healthcare provider pathways	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	

6 CLINICAL TRIAL DESIGN

This trial will use a mixed-methods design comprising two components: i) non-randomised feasibility clinical trial with 60 YP-OSA recruited across two sites and via a national e-therapy provider. To evaluate who might benefit from the intervention, we will recruit participants with varied characteristics wherever possible (e.g. ethnicity, sexual orientation, gender, OSA experiences); ii) combination of quantitative data on adoption, uptake and use (aligned with the AMUsED framework for analysing and measuring usage and engagement data in digital interventions) and qualitative data from semi-structured interviews guided by NPT exploring YP (n=20), healthcare professional (n=20) and service managers (n=10) perceptions of the app across two sites (Manchester; Edinburgh) and via a national e-therapy provider.

7 TRIAL SETTING

This is a multicentre feasibility trial which will take place across two key sites: Manchester, Edinburgh. In Manchester, the trial will take place at three NHS Trusts including Greater Manchester Mental Health NHS Foundation Trust (GMMH), Pennine Care NHS Foundation Trust (PCFT) and Manchester University NHS Foundation Trust (MFT). In Edinburgh, the trial will take place in one NHS Trust, NHS Lothian. Within these NHS Trusts, the trial will involve Child and Adolescent Mental Health Services (CAMHS) and Sexual Assault Referral Centres (SARC). We will also recruit participants from the NHS commissioned nationwide (England) youth e-therapy provider, Kooth.

8 PARTICIPANT ELIGIBILITY CRITERIA

8.1 Inclusion criteria

Young People

YP will be included in the trial if they meet the following inclusion criteria:

i) aged 12 to 18 years;

ii) have been exposed to OSA and report associated distress;

iii) 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;

iv) willing to use an app designed to support YP-OSA;

v) proficient in speaking and writing in English;

vi) have capacity to consent;

vii) consent to providing their username to the research team (Kooth participants only).

For those who do not own/have access to a smartphone or computing device, they will be provided with a phone handset to facilitate access to the app. Data network charges will also be covered for all participants for the 6-week duration of the app intervention window.

For the nested qualitative study, a proportion of participants who take part in the feasibility clinical trial (20 YP-OSA; 10 per site) and who consent to take part in the qualitative study will be asked during the second assessment (post-intervention), or at the point they discontinue from using the intervention (if they do not complete it in its entirety) if they still consent to take part in the interview study.

Healthcare Professionals

Healthcare professionals will be included in the nested qualitative study if they are: i) the member of the YP's direct care team who referred the YP to the feasibility clinical trial, ii) the manager within the service that referred the YP to the feasibility clinical trial, and ii) able to understand and speak English.

8.2 Exclusion criteria

Young People

YP participants will be excluded from the feasibility clinical trial if they: i) have insufficient verbal and written command of English, ii) have moderate learning difficulties (as assessed by their direct care team), or iii) are at risk of current or recent (past month) suicidality.

Healthcare professionals

Healthcare professionals will not be eligible to take part in the nested qualitative study if they do not meet the inclusion criteria, but there are no other exclusion criteria.

9 TRIAL PROCEDURES

9.1 Recruitment

Feasibility clinical trial

We will recruit 60 YP-OSA from NHS Child and Adolescent Mental Health Services (CAMHS) and Sexual Assault Referral Centres (SARC) and an NHS commissioned national (England) e-therapy provider (Kooth). Participants with varied characteristics wherever possible (e.g., ethnicity, sexual orientation, gender, OSA experiences) will be recruited to determine who might benefit from the digital intervention. The research team will liaise with CAMHS, SARC and Kooth teams to provide information about the study via presentations at team meetings and the provision of study information leaflets and copies of the Participant Information Sheets. Clinical staff will be encouraged to identify potentially eligible participants (e.g., young people aged 12-18 years who have experienced online sexual abuse). They will be informed by the research team about what the inclusion and exclusion criteria are. Clinicians will be encouraged to approach eligible prospective participants in their caseloads. If potential participants meet the eligibility criteria, they will be given a Participant Information Sheet to read. Prospective participants aged 12-15 years will be provided with a Participant Information Sheet to give to at least one of their parents / caregivers. Additional participants may be identified via placing a poster advert in waiting rooms or via digital spaces (e.g. Kooth's website). The poster will invite interested prospective participants to ask for information about the study from a member of their clinical team. If prospective participants express an interest in taking part in the study, their clinician will obtain the individual's written or verbal consent to pass on their name and contact details to the research team.

Nested qualitative study

YP-OSA

A proportion of participants who take part in the feasibility clinical trial (20 YP-OSA) and who consent to take part in the qualitative study will be asked during the second assessment (post-intervention), or at the point they discontinue using the app (if they do not complete it in its entirety) if they still consent to take part in the interview study. The interview study aims to understand how the intervention is experienced and its acceptability.

Healthcare professionals and service managers

Twenty healthcare professionals who referred YP-OSA to the feasibility clinical trial and 10 service managers) from the referring service will be invited to take part in a semi-structured interview (after YP-OSA have taken part in the feasibility clinical trial) as part of an in-person or remote meeting with a research worker. Only healthcare professionals and service managers who referred to the feasibility clinical trial will be included; this may or may not include those who took part in the qualitative study already conducted with healthcare professionals as part of the development of the intervention (IRAS Ref: 301335).

9.1.1 Participant identification

Feasibility clinical trial

Potential participants will be identified and initially approached by members of their clinical team currently supporting them at a CAMHS or SARC or Kooth. Clinicians will be provided with information on eligibility to check individuals meet the inclusion criteria. A poster advertising the study will placed in clinic waiting rooms / digital spaces (e.g., for digitally run services such as Kooth). The poster will ask prospective participants to speak with a member of their clinical team should they be interested in taking part. The clinical team will then assess their eligibility. The clinical team will provide eligible prospective participants with an age-appropriate Participant Information Sheet. Prospective participants aged 12-15 years will be provided with a Participant Information Sheet to give to at least one of their parents / caregivers. If prospective participants are interested in taking part, their written or verbal consent will be taken to refer them to the study, including passing on their name and contact details to the research team. A phone conversation will be arranged between a research worker and the referring clinician to complete a Referral to Study Form. Potential participants will never be directly approached by members of the research team. Once it has been established that a prospective participant is interested in taking part in the study, has given permission to be contacted by the research team, and the researcher and referring clinician have spoken, the researcher will have a phone conversation with the prospective participant to explain the study to them in detail and give them the opportunity to ask questions. The researcher will explain to prospective participants that participation is voluntary, that they can withdraw consent at any point during the study without giving a reason and this will not impact on them continuing to access standard care within the referring service (as the digital intervention is in addition to not in replace of standard care), or other sources of support they might access simultaneously. Potential participants will be given at least 48 hours to decide if they would like to take part in the study. Parents / caregivers in England will be given the option to opt their child out (by contacting the research team or the child's clinical team or completing an opt out form) should they not wish their child to take part.

Nested qualitative study

YP-OSA

Participants who take part in the feasibility clinical trial, and as part of this who complete the baseline assessment and access and use the intervention, will be eligible to take part in the qualitative interview study. Participants will be informed about and asked to consent to the qualitative interview study when information is provided and consent taken for the feasibility clinical trial. Participants will be approached directly by the research team to take part in the interview upon discontinuation from accessing and using the app or completion of using it. Therefore, both participants who do and do not complete the feasibility clinical trial in its entirety will be asked to take part in the interview. Participants will be selected according to a sampling framework to capture varied demographics, experiences of OSA and levels of engagement in the intervention.

Healthcare professionals and service managers

NHS and Kooth staff, including healthcare professionals and service managers, who referred participants to the feasibility clinical trial will be identified and approached directly via telephone or email by the research team to take part in the qualitative interview study.

9.1.2 Screening

There are no screening assessments or procedures being used to assess the eligibility of prospective participants in the feasibility clinical trial or qualitative study.

9.1.3 Payment

Young people who take part in the trial will be remunerated £40 for their time for completion of the baseline assessment (£20) and the follow-up (post-intervention) assessment (£20). Young people who also take part in the nested qualitative interview study will receive a further £20 for their time. We will give participants the choice of either cash, vouchers or BACS (in line with local Trust approved methods). The amount was decided upon based on NIHR INVOLVE guidelines.

Young people who do not have access to a smartphone will be provided with one and their data network charges will be covered for the 6-week intervention period.

Healthcare professionals who take part in the nested qualitative interview study will not receive any payments for their participation.

9.2 Consent

Consent will be taken by trained members of the research team. In no cases participants will be recruited if their capacity to consent is in doubt (e.g., as indicated by the member of the clinical team who has referred participants).

In both the quantitative feasibility clinical trial and nested qualitative interview study, fully informed consent will be sought from YP and healthcare professionals and obtained prior to data collection and participants accessing and using the app. Prospective participants will be provided with HRA/REC approved copies of the Participant Information Sheet. Age-appropriate Participant Information Sheets and consent forms will be used for prospective young people including for 12-15 year olds and 16-18 year olds. Prospective participants aged 12-15 years who are recruited in England will be provided with a Participant Information Sheet to give to at least one of their parents / caregivers, who will be given the opportunity to opt their child out (by contacting either a member of the research team or their child's clinical team or completing an opt-out form) should they not wish their child to take part in the study. Prospective participants aged 12-15 who are recruited from Scottish site will be asked if they would like their parents to be given a Participant Information Sheet. Parents of prospective participants aged 12 – 15 years in Scotland will not be able to opt their child out of the study, if the prospective participant is Gillick competent. All prospective participants will be provided with a verbal explanation of the study and given opportunities to ask questions about the study during in-person or remote meetings with a member of the research team.

Young people will be provided with information about both the feasibility clinical trial and the qualitative study in one Participant Information Sheet provided to them prior to taking part in the feasibility clinical trial. They will be asked to consent to taking part in the qualitative study as part of the consent process for the feasibility clinical trial, but continued consent will be checked if they are invited to take part in the interview.

The researcher will explain to all potential participants that participation is voluntary and that they can withdraw their consent at any point during the study without giving a reason. It will be made clear to YP that, as the intervention is not in replace of standard care (it is in addition to standard care), withdrawal from the intervention will not impact on YP's ability to continue to access standard care within the referring service, or other sources of support they might access contemporaneously. The participants will continue to be actively supported by the service during their participation in the study and using the app will not affect any form of therapeutic support participants receive.

Prospective participants in both the feasibility clinical trial and qualitative study (i.e., YP and healthcare professionals) will be given multiple options for documenting their informed consent including:

- Signed hard copy of the consent form by standard mail
- Returning a digitally signed copy of the consent form by email (encrypted)
- Recording their consent on an encrypted audio file that will be stored separately from any research data collected from them

Three copies of the consent form will be produced: 1 original for the research team, 1 copy for the participant (electronic or printed copy), and 1 electronic copy to be uploaded to medical notes. The participant's GP / care team will be provided with a letter to inform them that the young person is taking part in the study.

We will strive in all cases to obtain a record of informed consent in writing. However, for participants taking part using remote means only it may be necessary to obtain verbal consent via audio-recordings as outlined above. We will not be able to share audio-recordings of consent.

Participants will be given at least 48 hours to decide whether or not to take part.

Parents / caregivers of 12-15 year olds recruited in England will be given the opportunity to opt their child out if they do not wish their child to take part in the study. Parents / caregivers of 12-15 year olds recruited from Edinburgh sites will be given a copy of Participant Information Sheet if the young person wishes.

If a participant, who has given informed consent, loses capacity to consent during the study, the participant would be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to the participant.

9.3 Baseline and follow up data

Following consent being obtained, at baseline, participants will be asked to complete a battery of self-report questionnaires that assess relevant outcomes of the intervention as part of in-person or remote meetings with a research worker. These include: mentalisation, problematic internet use, emotional distress, online abuse related distress, emotion regulation, interpersonal sensitivity, attitudes/views

towards close interpersonal relationships and resilience. The measures will provide an opportunity to determine which outcomes are sensitive to change in this group and are specific to the problems experienced by YP-OSA. Prior to their use in the study, this battery of measures will be thoroughly piloted with the aid of members of our advisory panels to ensure the measures collected are meaningful to the target, and that the overall assessment procedure is not excessively burdensome. Based on prior research on mentalisation-based interventions with YP, the measures will include: the Reflective Functioning Questionnaire for Youths, the Problematic and Risky Internet Use Screening Scale, the Revised Child Anxiety and Depression Scale – 25 item, the Child Revised Impact of Events Scale, the Difficulties in Emotion Regulation Scale – Short Form, the Interpersonal Sensitivity Measure, the short and child version of the Experiences in Close Relationships Scale – Revised, the Connor-Davidson Resilience Scale – 10 item version and relevant demographic (e.g. age, gender, ethnicity) and clinical details (e.g. diagnosis, treatment regime in referring service, other sources of support.

At follow up, participants will be invited to complete an app satisfaction rating scale, as well as the following measures: Reflective Functioning Questionnaire for Youths, the Revised Child Anxiety and Depression Scale – 25 item, the Child Revised Impact of Events Scale (anchored to experiences of onlise sexual abuse), the Difficulties in Emotion Regulation Scale – Short Form, the Interpersonal Sensitivity Measure, the Connor-Davidson Resilience Scale – 10 item version. The Experiences in Close Relationships Scale – Revised is not repeated at follow up as it is not sensitive to change in the period between baseline and follow up. The Problematic and Risky Internet Use Screening Scale is not required at follow up as it captures internet use over a 6 month period; we would not expect to see change within the period from baseline to follow up assessment.

The demographic, clinical, and impact of events scale will be administered at the outset with the support of the research worker. The assessments of reflective function and emotion regulation will be administered next, with the remaining measures completed in a randomised order.

9.4 Trial assessments

As described above, following consent, participants will complete a battery of questionnaires. This will take about 50 minutes plus 10 minutes for a full debrief. Completion of the measures will be via an online survey system, capturing all the measures in our CRF, or, where this is not possible, a paper/hard copy version of the CRF will be used. Following baseline questionnaire completion, participants will then be set up on and shown how to access and use the app. The app is intended to be used for 6 weeks. Upon completion of the intervention (i.e. at 6 weeks), in Weeks 7-9, participants will be asked to complete the same battery of questionnaires they were asked to complete at baseline. This will take about 50 minutes plus 10 minutes for a full debrief. Assessments will take place remotely via local Trust approved platforms (e.g. via telephone or Microsoft Teams / Zoom / NEARME) or in person. In-person meetings will only take place after satisfactory risk assessments (COVID-19 and other risks) and appropriate risk mitigation procedures have been put in place (e.g., ensuring meetings in sufficiently ventilated rooms / locations). In-person meetings will take place at locations that are mutually convenient for research workers and participants (these can include the participant's home, NHS premises, University premises). Meetings will take approximately 1 hour, depending on the extent to which the participant requires breaks or further support / guidance. Participants will be fully debriefed at the end of each meeting; the research aims of the study will be explained to them, and in addition, upon completion of the second assessment (after completing the intervention) how the

results of the study will be used will be explained to them. If they consented to receiving a summary of the study findings, receiving invitations to participate in further studies conducted by the research team and taking part in the qualitative interview study, continued consent will be sought and how they will receive a summary of the results and participation in the interview will be explained. They will also be provided with information about sources of support they could access in their locality, should they wish to in addition to the support they are already receiving from the referring service.

9.5 Long term follow-up assessments

There are no long-term follow-up assessments for this project.

9.6 Qualitative assessments

YP-OSA: A proportion of participants who take part in the feasibility clinical trial (20 YP-OSA) and who consent to take part in the qualitative study will be asked during the second assessment (post-intervention), or at the point they discontinue from using the app (if they do not use it for the intended 6 weeks) if they still consent to take part in the interview study. The interview study aims to understand how the intervention is experienced and its acceptability. Participants will be selected according to a sampling framework to capture varied demographics, experiences of OSA and levels of engagement in the intervention. Participants who consent to take part will be asked to complete a qualitative interview as part of an in-person or remote meeting with a research worker. Participants will be asked questions that seek to find out: i) whether the intervention met expectations; ii) what level of support is needed to facilitate engagement with the intervention; iii) overall impressions of the intervention (enjoyable, usability, satisfaction); iv) what participants liked and/or did not like about the intervention in terms of content and usability of the platform; v) how the intervention helped and/or did not help; vi) what changes they would make; vii) barriers to participation / engagement, including perceived burden of the research assessment procedures (see topic guide for examples of specific questions that will be asked). In-person meetings will only take place after satisfactory risk assessments (COVID-19 and other risks) and appropriate mitigation procedures have been put in place (e.g. ensuring meetings take place in sufficiently ventilated rooms / locations). In-person meetings will take place at locations that are mutually convenient for research workers and participants (these can include the participant's home, NHS premises, University premises). The topic guide will be developed in collaboration with our lived experience, parent / caregiver and professional advisory groups. The interviews will be audio-recorded for transcription and analytic purposes using devices enabling password protection at the point of recording. Meetings will take approximately 1 hour, depending on the extent to which the participant requires breaks or further support / guidance and to include a full debrief.

Healthcare professionals: Twenty healthcare professionals who referred YP-OSA to the feasibility study and 10 service managers will be invited to take part in a semi-structured interview (after YP-OSA have taken part in the feasibility clinical trial) as part of an in-person or remote meeting with a research worker. Only healthcare professionals who referred young people to the study or managers from the referring service will be included; this may or may not include those who took part in the qualitative study already conducted with healthcare professionals as part of the development of the app (IRAS Ref: 301335). The interviews will build on the findings from the completed qualitative study to further clarify questions around the integration and uptake of i-Minds in existing care pathways

(when YP participants and healthcare professionals have used and interacted with the digital platform). Specific questions will focus on: i) ways in which we can maximise uptake, utility, user experience, acceptability, satisfaction and reach of the platform; ii) how the platform can be locally adapted and translated into practice; iii) professionals' views about referral routes to a digital intervention within existing care pathways; iv) strategic perceptions about the relative advantage of the digital platform and its wider transactability (i.e., whether it can be scaled up) (see topic guide for examples of questions). In-person meetings will only take place after satisfactory risk assessments (COVID-19 and other risks) and appropriate mitigation procedures have been put in place (e.g. ensuring meetings take place in sufficiently ventilated rooms / locations). In-person meetings will take place at locations that are mutually convenient for research workers and participants (these can include the participant's home, NHS premises, University premises). The topic guide will be developed in collaboration with our advisory groups. The interviews will be audio-recorded for transcription and analytic purposes using devices enabling password protection at the point of recording. Meetings will take approximately hour. Prior to taking part in the interview, healthcare professionals will be asked to complete some brief demographic questions (e.g. age, profession, years of professional experience), which will take 5 minutes.

9.7 Withdrawal criteria

A participant will be withdrawn if they express either to a member of the research team or to their clinical key worker that they wish to withdraw from the intervention, or the trial, or both. If a participant withdraws from the study, we will follow procedures such as completion of a withdrawal form, suspension of data collection activities, and retention and analysis of anonymised data collected up to the point of withdrawal. If a participant withdraws from the intervention, we will cease their use on the app but still invite them to complete follow-up measures and a qualitative interview to understand their reasons for withdrawal to the intervention (but only if the participant consents to this).

The PSC, following reports from the DMEC, will decide whether to close the trial down after reviewing adverse event data.

9.8 End of trial

The end of the trial will be when the last participant has completed the interview for the nested qualitative study.

10 TRIAL TREATMENTS

10.1 i-Minds digital intervention (app)

The app is in addition to not in replace of standard care or any other source of support participants might be accessing at the time. Participants will continue to be actively supported by the referring service whilst they are accessing and using the digital intervention and any form of therapeutic support participants are receiving will not be affected.

Following the overall structure and content of a mentalisation-based manual developed by members of our team in a previous trial with YP, the i-Minds app will involve several tasks that not only provide psychoeducation about mentalisation but also encourage the application of mentalisation principles to

a range of scenarios presented to the YP. Our PPI work has shown that YP would prefer the intervention to be developed in the form of an app (software application). As such, the digital intervention will be delivered on an app and will be made available over a 6 week intervention window. The aim of the intervention is to help YP understand more clearly the motives of adults and peers, help protect them from future abuse, and help them feel more confident in ambiguous and challenging interpersonal interactions. The app includes modules aiming to: introduce the concept of mentalisation and relate it to scenarios that YP find distressing; encourage emotional and cognitive literacy in interpersonal interactions; encourage reflection on interpersonal relationship patterns and their development, and explore how these concepts affect emotional expression, behaviour and mental health (e.g. anxiety, mood, trauma responses, self-esteem, self-harm behaviour), and perspective taking. This content will be organised in three modules organised around Psychoeducation (Module 1), Emotional and Mental Health (Module 2) and The Impact of Trauma (Module 3). The app will comprise multi-media material designed to support learning and promote engagement, including (but not limited to) video clips, audio exercises, diary function; podcasts; real-life stories of recovery; emergency and safeguarding contacts, interactive-based scenarios and exercises.

The app will be designed to enable the delivery of the intervention on computers, tablets and smartphones. For the purpose of this trial, the i-Minds app will either be downloaded onto a person's own smartphone or a YP will be loaned a smartphone with the i-Minds app pre-loaded. As in our other successful digital platform builds, we will adhere to an Agile development process, which supports close collaboration between the software engineers and the clinicians and clinical academics developing the content of the intervention and enables changing requirements to be incorporated throughout the development.

App development will be supported by a series of PPI consultations. This enables the end users to influence the design and functionality of the app, leading to the development of an intervention that is more likely to be acceptable, have better uptake and be effective. By working together, developers and users can learn together and optimise platform functionality, with designers being responsible for pointing out technical options, and users providing information about their needs, practices and how they will use the system. When building the app, working software will be delivered on a regular basis and reviewed by the clinical team and advisory groups who will provide interim feedback on the user interface developed, the software performance and its usability. Any changes required are then incorporated into the next iteration of platform development and continue until the fully functioning system is available.

The participant will be able to configure certain features of the app themselves during a single, 'Onboarding' session with the researcher. If the app is downloaded onto a YP's own smartphone, the researcher will guide the participant through the set-up process either over the phone or in-person. The app 'Onboarding' session will include a series of features such as personalising the app (e.g. choose wallpaper, colour scheme-various options; customise the avatar; customise the intervention backdrop, goal setting, and orientation to the different features within the app). All interactions with the platform (e.g. clicks, etc.) will be date and time-stamped to help us understand how a YP uses the platform – a key question for our feasibility clinical trial.

There will be no limits to how often or when a participant can use the app. That is; we will not limit how people interact with the platform, and interaction is not conditional on a participant's response to screening items.

If the participant has received a loaned phone, the researcher will collect the handset at the follow-up assessment. If the app was downloaded onto a participant's own handset, the researcher will either delete the app from the participant's phone so that they can no longer interact with it, or if the functionality allows, the app will automatically stop working/be de-commissioned after the intervention window.

A daily prompt, in the form of an auditory notification will appear on the app home screen to support engagement and invite people to use the app. Participants can also self-initiate use with the app at any time of the day, as many times as they choose. A research worker will also call the participant after a week of using the app to troubleshoot potential technical difficulties.

Software User and Usability testing: We will undertake formal user and usability testing on the near-final (Beta) version of the digital platform with 5 end-users to ensure defects are fixed and the platform is accessible, clear, usable and functional prior to deployment in the feasibility clinical trial. Emphasis in user and usability testing will be on assessing the ease with which test users can navigate the platform and perform simple tasks. Think Aloud usability sessions will be recorded using screen capture and audio-recording software. The data from these sessions will be reviewed by the software team to optimise the navigation, look and feel of the intervention and improve the usability of the platform.

Software security features.

- **App:** Use of the app will require a PIN code on the users phone and this will be checked and enforced when the app starts. Data collected within the app will be sent to the server over HTTPS using secure ciphers.
- **Server:** The server will be part of the University of Manchester's research virtual machine infrastructure and is secured inside the University's network. Operating system and related security patches are applied on a regular basis to these servers by the University's infrastructure team.
- **Web-based interface:** Each member of the research team will be allocated a username and password to use to access the web-based interface. All accounts will require approval by the CI. An audit log of user activity will be stored. The software team will have administrative access to the web-based interface to enable them to maintain the system and manage accounts for the researchers. All members of this team have current data protection training.

Participant data (app).

In order to minimise security risks, no parts of the system will collect identifiable information. A pseudonymised identifier will be used to identify each participant. Only the research team will know the link between this identifier and the actual participant. This link will not be stored anywhere in the system and the software team will only have access to the pseudonymised identifiers.

App usage analytics.

User interactions with the app will be captured using Matomo. The statistics will help the study team to understand how visitors interact with the app by collecting and reporting information anonymously. The data will be used to analyse our traffic and how the features are used. We can improve the app based on the analysis. The data collection and analysis are compliant with GDPR. We will not collect

written input or answers to do analysis, only interaction data (e.g. pages visited, buttons clicked) will be collected. Users can choose to opt out of this data collection as part of the informed consent process.

10.2 Trial restrictions

The PSC, following reports from the DMEC, will decide whether to close the trial down after reviewing adverse event data. A member of the research team will reach out to each participant currently enrolled in the trial and inform them that all trial activities will be suspended. This will occur in writing, followed by a phone call. The content of this communication will depend on the nature of the trial closure and will be carefully agreed by the oversight groups.

10.3 Assessment of compliance with treatment

As this is a feasibility clinical trial, we have no *a-priori* hypotheses or intentions about level of compliance with the app. We seek to explore and understand how participants use the app and the way in which they use it. Platform usage and engagement data collected using secure software analytics whilst participants are using the app will be guided by the AMUsED framework for analysing and measuring usage and engagement data in digital interventions (53).

11 ADVERSE EVENTS

AEs are defined by the Health Research Authority (HRA) as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in trial participants, whether or not related to the intervention which require additional support or input from health professionals. We will take all appropriate steps during the conduct of the trial for ensuring participant safety. Any adverse event observed over the course of the research will be documented and reported according to a bespoke SOP that will fully comply with appropriate HRA safety reporting procedures for non-CTIMP studies, Sponsor's requirements and local R&D policies of participating NHS organisations.

AEs will be recorded and initially assessed for severity and seriousness by site researchers. Level of severity will be categorised as mild, moderate and severe, which reflect the impact of the event on the person at the time. Please note there is a distinction between "severe" and "serious". Seriousness is the criterion for defining regulatory reporting obligations. An adverse event will be classified as serious if it results in: death, injury or permanent impairment to a body structure or body function; serious deterioration in the health of the subject; or foetal distress, foetal death, or a congenital abnormality or birth defect. However, in this study any AE rated as 'severe' will automatically be classified as a SAE and will be reported immediately to the PI.

Urgent actions concerning participant and staff safety, communication with others, and clinical care will be immediately addressed by the PI and reported to the PMG. SAEs will be further reviewed for unexpectedness and relatedness to the investigational device and/or trial procedures by the PI initially, and additionally by the chair of the DMEC.

All 'reportable' events (SAEs, Device Deficiency that might have led to a SAE, or new findings/updates in relation to already reported events) will be reported to the Research Ethics Committee (REC) immediately, but not later than 7 calendar days after awareness, by the PI. However, any reportable events that indicate an imminent risk of death, serious injury, or serious illness will be reported no later than 2 calendar days after awareness.

All AEs and SAEs (from each site) will be pooled and reported quarterly to the PMG and for each meeting of the DMEC, or at any time at the request of the DMEC Chair. The DMEC will be responsible for investigating further if there are any concerns about unexpectedly high rates of SAEs, which may include seeking further data on adverse events and will advise the PSC on any ethical or safety reasons why the trial should be prematurely ended. The Funder will immediately be notified on receipt of any information that raises material concerns about safety or efficacy, and of any recommendations from the DMEC to end the trial.

An Adverse Event Log file will be created to systematically record occurrences, with reference to an a priori defined list of anticipated and unanticipated adverse events. The list is adapted from the adverse effects of a digital therapy app (Actissist) reported by the PI (Bucci).

Responsibilities

Chief Investigator (CI):

Checking for AEs and ARs whilst participants are using the app and followed-up.

1. Using judgement in assigning seriousness, causality and whether the event/reaction was anticipated using the Reference Safety Information approved for the trial.
2. Using judgement in assigning seriousness and causality and providing an opinion on whether the event/reaction was anticipated using the Reference Safety Information approved for the trial.
3. Ensuring that all SAEs are recorded and reported to the sponsor within 24 hours of becoming aware of the event and provide further follow-up information as soon as available. Ensuring that SAEs are chased with Sponsor if a record of receipt is not received within 2 working days of initial reporting.
4. Ensuring that AEs and ARs are recorded and reported to the sponsor in line with the requirements of the protocol.

Chief Investigator (CI) / delegate or independent clinical reviewer:

1. Clinical oversight of the safety of patients participating in the trial, including an ongoing review of the risk / benefit.
2. Using judgement in assigning the SAEs seriousness, causality and whether the event was anticipated (in line with the Reference Safety Information) where it has not been possible to obtain local medical assessment.
3. Using medical judgement in assigning whether and event/reaction was anticipated or expectedness in line with the Reference Safety Information.
4. Immediate review of all SUSARs.
5. Review of specific SAEs and SARs in accordance with the trial risk assessment and protocol as detailed in the Trial Monitoring Plan.

Sponsor: Sponsor responsibilities for safety oversight is delegated to the CI.

1. Central data collection and verification of AEs, ARs, SAEs, SARs and SUSARs according to the trial protocol onto a database.
2. Reporting safety information to the CI, delegate or independent clinical reviewer for the ongoing assessment of the risk / benefit according to the Trial Monitoring Plan.
3. Reporting safety information to the independent oversight committees identified for the trial (Data Monitoring and Ethics Committee (DMEC) and / or Project Steering Committee (PSC)) according to the Trial Monitoring Plan.
4. Expedited reporting of SUSARs to the REC within required timelines.
5. Notifying Investigators of SUSARs that occur within the trial.
6. Checking for (annually) and notifying PIs of updates to the Reference Safety Information for the trial.
7. Preparing standard tables and other relevant information for the DSUR in collaboration with the CI and ensuring timely submission to the REC.

11.5 Notification of deaths

All deaths will be reported to the sponsor within 24 hours irrespective of whether the death is related to using the app or an unrelated event.

12 STATISTICS AND DATA ANALYSIS

Statistical aspects of the feasibility clinical trial have been reviewed by a statistician within the research team, Prof John Norrie. A pre-specified analysis plan will be developed by the trial statistician (JN) and approved by the Project Steering Committee (PSC).

12.1 Sample size calculation

The total sample size for the project is 90 participants. 60 young people who have experienced online sexual abuse (YP-OSA) will be recruited to take part in the feasibility clinical trial over 9 months. Of these 60 participants, a subsample of 20 will take part in in-depth qualitative interviews. 20 healthcare professionals who referred YP-OSA to the study and 10 service managers will be recruited to take part in a qualitative interview after young people have accessed the intervention.

The proposed sample size is in line with other NIHR-funded feasibility studies and is sufficient for establishing feasibility. Formal power calculations are not appropriate for a study primarily aimed at establishing feasibility; statistical significance (p-values from hypothesis tests) of any findings are not the primary study focus. Our recruitment targets are realistic based on other YP-OSA studies conducted by members of our team (49–51). Our trial methodologist (JN), a world-leader in feasibility studies and in evaluating complex mental health interventions (including digital interventions), has advised that this number is sufficient to report on response rates, follow-up rates, safety information and attrition, as well as the clinical characteristics of our study population at the beginning of the study and follow-up.

12.2 Planned recruitment rate

It is estimated that 6-7 participants will be recruited per month over a 9-month recruitment period across two large NHS Trust sites and via the national e-therapy provider Kooth.

12.3 Statistical analysis plan

A pre-specified statistical analysis plan will be prepared by the trial statistician (Prof Norrie). Appropriate descriptive statistics (mean and standard deviations for continuous data; counts and percentages for categorical data) will be used to summarise: 1) recruitment and retention data in line with CONSORT statement standards and the extent to which services refer into trial; 2) data usage patterns (frequencies; data visualisation) using secure software analytics in line with the AMUsED framework for analysing and measuring usage and engagement data in digital interventions (53); 3) completeness of study measures; and 4) the number and nature of adverse events observed over the course the trial.

Pre- and post-intervention questionnaire data will be analysed using the Leeds Reliable Change Indicator (64), or other approaches for the evaluation of reliable/clinically significant changes in secondary outcome measures (e.g. when conditions for the application of the Leeds RCI are not met) to determine the number and proportion of participants who achieve significant improvement on clinical measures and who achieve no significant worsening on clinical measures at post-treatment.

12.3.1 Summary of flow of participants

The flow of trial participants in the study is shown in section ix.

12.3.2 Primary outcome analysis

See Section 5.4 for a summary of outcomes and measures to be reported and Section 12.3 for details of the planned statistical analysis and Section 12.4 for the planned qualitative data analysis.

12.3.3 Secondary outcome analysis

See Section 5.4 for a summary of outcomes and measures to be reported and Section 12.3 for details of the planned statistical analysis and Section 12.4 for the planned qualitative data analysis.

12.4 Qualitative data analysis plan

All qualitative interviews will be audio-recorded with consent, transcribed and thematically analysed using a modified Framework approach (65) and end-to-end encrypted Trust or University approved qualitative data analysis software. Analysis of qualitative interviews will occur alongside transcription and data collection so that we can iterate our topic guide and develop the intervention alongside the qualitative work– these tasks will not be sequential but will occur in parallel. We will initially use the Framework method to take an inductive approach to theme generation. Subsequent theme refinement will be deductive and guided by NPT. NPT is a widely used (47,48) theory to explain the processes by

which an intervention becomes, or fails to become, normalised into routine practice; it offers a framework for assessing the conditions in which interventions become practically workable in healthcare. NPT comprises four constructs (coherence, cognitive participation, collective action, reflexive monitoring) which are a set of propositions that we will use to explore perceptions, expectations, attitudes, challenges and unintended consequences towards integrating a digital intervention for YP-OSA in existing NHS service and e-therapy provider pathways. This approach will enable us to answer our research questions whilst allowing important insights to be iteratively produced. The coding framework will then be applied to analysis of subsequent transcripts, with ongoing adaptations as new themes emerge. Data will then be charted into a matrix with illustrative extracts and interpretive themes refined through discussion at regular analysis meetings. We will engage the wider research team, our advisory groups and stakeholders in the analysis process.

12.5 Subgroup analyses

As the study aims to evaluate feasibility and acceptability, we will not conduct formal subgroup analyses (whether estimated treatment effects vary significantly between subcategories of trial participants). To explore whether how different participants engage with the app, attrition and clinical benefit across key demographic groups (e.g., LGBTQ & BAME) and potential service differences across recruitment sites (Manchester / Edinburgh / Kooth), we will use descriptive analysis to inform future work; we will not test for differences as the study is not powered for this.

12.6 Interim analysis and criteria for the premature termination of the trial

As this study is feasibility, there are no planned interim analyses. We will only stop the trial if the DMEC reviews the safety data and recommends (and the PSC decides) to stop the trial.

12.7 Missing Data

For partial missing data (i.e. a subject has completed a questionnaire but has not completed all elements of that questionnaire) we will be using validated instruments, and will follow the established procedures for calculating overall scores in the presence of partially missing data.

When data are completely missing for a whole questionnaire, we will – in the context of this feasibility clinical trial – record the occurrences of this, and if the prevalence of such missing data permit, use multiple imputation assuming these data are missing at random. We may also, if we think these data may be informatively missing i.e., missing not at random, investigate appropriate sensitivity type analyses to see whether our findings are robust to these missing data.

12.8 Participant population

The participant population whose data will be subjected to the feasibility trial analysis with be young people who have experienced online sexual abuse and are receiving support via a CAMHS or SARC or Kooth (inclusion and exclusion criteria are specified in Sections 8.1 and 8.2). Participants are not being randomised in the feasibility clinical trial; all participants will have access to use the app and all participants will be included in all analyses for the feasibility clinical trial.

12.9 Economic evaluation

No economic evaluation will be carried out for this project.

13 DATA MANAGEMENT

13.1 Data collection

Robust data security measures will be implemented throughout the study, in full compliance with national policies and relevant data management and information governance policies and procedures of the participating Universities and NHS organisations.

The processing of names, personal addresses, telephone numbers and other contact details are necessary to inform participants about the study, obtain consent, arrange research assessments and meetings to give them access to use the app, to arrange interviews, and after their participation, to keep them informed about the study findings and other research opportunities they might want to be approached about (only for participants who consent to this). All personally identifiable data will be stored separately from research data. All research data will be pseudo-anonymised and unique study IDs will be assigned to participants and used instead of participant names / personally identifiable data. The pseudo-anonymised key linking unique study ID numbers to participants names will be stored electronically in an encrypted and password protected file only accessible to members of the research team with necessary privileges. Contact information will be kept securely from the research data using unique study ID numbers and will not contain names.

Any hard copies of data including personal and research data will be transferred to a secure NHS or University of Manchester / Edinburgh location as soon as possible. Within NHS and University of Manchester / Edinburgh locations, data will be kept in lockable storage and research and personal data will be stored separately. Hard copies of signed consent forms will be stored in a similar way and will be kept separate from research data collected as part of the study. Any hard copies of participant questionnaire data will be stored in safe lockable cabinets on University of Manchester or University of Edinburgh or NHS premises.

Digital / electronic copies of extracts from clinical notes (e.g. diagnosis, treatment regime in referring service and other sources of support), demographic information (captured via a questionnaire), and outcome measures / questionnaires included in the case report form, interview transcripts and audio recordings will be password protected and stored on secure and automatically backed-up services available at the Universities and participating NHS sites.

Interviews will be conducted using recording devices enabling encryption at the point of data collection, to provide additional data security. All interviews will be anonymised at the point of transcription, and all identifying details removed. Audio-recorded consent (including participants' names) will be recorded on a separate audio file so that this information cannot be directly linked with the interview transcripts or audio-recordings. Digitally encrypted audio recordings of the interviews (but not identifying consent data, see above) will be transferred to an external company (approved by the Universities and NHS Trust organisations / Sponsor) or a University or NHS member of staff (who is

an approved transcriber) for transcription. Personal identifiable information will be removed at the point of transcription. Transcripts will then be returned to the central research team using digitally encrypted files.

Electronic transfer of data is necessary as data collection will be undertaken across several, geographically dispersed NHS sites, and pseudo-anonymised research data will require transfer to the Universities for analysis. The transfer of research data amongst participating sites will be managed via a secure web-based database system hosted on University of Manchester servers (REDCAP), or an alternative safe data transfer system approved by the Sponsor. Access to the database will be restricted to members of the project team involved in data entry and analysis, using an in-built secure system to grant access and data management privileges that can be authorised only by the project CI.

Research assistants at each participating site will input data collected via Qualtrics on the REDCAP database. In the case of paper/hard copy-completed questionnaires, research assistants will: i) scan paper copies for digital preservation of all research completed as part of the study; and ii) enter questionnaire scores on the REDCAP database. Paper copies of questionnaires will be destroyed using confidential waste services at participating NHS sites at the end of the study.

Data may need to be looked at by individuals from the Universities of Manchester and Edinburgh, from regulatory authorities or from participating NHS Trusts, including the Sponsor, for monitoring and auditing purposes, and this may well include access to personal information. Prospective participants will be informed about this in the Participant Information Sheets and via the consent process.

Storage and use of data after the end of the study

Quantitative data generated by the study will be analysed using NHS or University computers by the research assistants, the Chief Investigator Sandra Bucci and Co-Investigator Matthias Schwannauer (who is the lead for the Edinburgh site) with support from methodologist Co-Investigator Prof John Norrie.

Qualitative data generated by the study will be analysed using NHS or University computers by the research assistants, Chief Investigator Sandra Bucci and Co-Investigator Ethel Quayle.

Personally identifiable data will be stored and accessed for up to 5 years after the study has ended (as determined by relevant information governance policies) at which point all identifiable data will be destroyed.

Research data generated by the study will be stored for 5 years.

Long-term arrangements for storage of research data

Retention periods are subject to the Sponsor's (i.e., GMMH's) records retention schedule policies. All research data will be kept in anonymised format and retained for 5 years following the end of the study. All final locked datasets will be kept in encrypted files on robust and automatically backed up on University or NHS Trust servers. Prof Sandra Bucci will act as data custodian. Local PIs will be responsible for the safe disposal of data collected at participating sites once these are no longer needed. Hard copy data will be safely destroyed using confidential waste management systems at participating NHS Trusts and Universities, and electronic data will be permanently deleted from

computers and servers. At the end of the study, all study data, the Trial Master File, and all site files will be forwarded for archiving with the study Sponsor.

13.2 Data handling and record keeping

Refer to Data Management Plan.

13.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections - in line with participant consent.

14 MONITORING, AUDIT & INSPECTION

The Project Core Team has been established to oversee the day-to-day running of the project and ensure tasks completed / deadlines met and comprises the CI, SB (who is also the Manchester Lead), FV (Co-I, Manchester), MS (Co-I, Edinburgh Lead), EQ (Co-I, Edinburgh), KC (Co-I), a Research Assistant (RA) in Edinburgh and 2 RAs in Manchester. AL (Project Manager) will be supervised fortnightly by CI SB and AL will supervise the RAs weekly.

In line with NIHR guidance, an independent Project Steering Committee (PSC) has been assembled to provide independent oversight of the project. The members of the PSC are independent from the Sponsor and Investigators (i.e., they are not involved in other funded research collaborations with the Investigators and will not be affiliated with Greater Manchester Mental Health NHS Foundation Trust, NHS Lothian, The University of Manchester, The University of Edinburgh or any of the Investigators' substantial employers, in addition to other independence criteria outlined in relevant NIHR guidance). The PSC has been approved by the funder and therefore conforms to NIHR guidance and includes: 1) an independent chair with experience of management of research projects in clinically applied areas; 2) an independent statistician; 3) an independent clinician; 4) an independent academic; 5) an independent person able to provide relevant PPIE perspectives and 6) the project CI (Bucci). Other members of the project team including the project manager, Co-I JN, who is a statistician attend meetings in a non-voting capacity. Other members of the research, as well as a representative of the Sponsor, may also attend PSC meetings in a non-voting capacity, on an ad-hoc basis when their contribution is deemed necessary or beneficial by the members of the PSC.

The PSC is responsible for the independent oversight of the project on behalf of the Sponsor and the NIHR and will ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The PSC will 1) provide advice on all appropriate aspects of the project; 2) review the progress of research against the project timeline, monitor adherence to the protocol and the consideration of new information of relevance to the research question; 3) review issues related to patient safety (e.g. any AE or SAE) and ensure that, throughout the project, the rights as well as safety and well-being of the participants will be prioritised over the interests of science and society; 4) agree proposals for substantial protocol amendments and provide advice to the Sponsor and NIHR regarding approvals of such amendments.

Thorough training of all research workers at the study onset and subsequent weekly supervision of all RAs throughout their involvement in the study will minimise risk of deviations from protocol. However, accidental deviations from protocol can happen at any time; these will be documented and recorded in a protocol deviations log, which will be saved in the Trial Master File. All deviations from protocol will be brought to the attention of the project CI, and promptly communicated to the study Sponsor (GMMH), so that corrective actions could be promptly implemented. The protocol deviations log will also be reviewed at regular meetings with the PSC for additional scrutiny and suggestions of corrective actions.

The study will also be subject to the audit and monitoring regime of the Sponsor and all participating NHS sites including the University of Manchester, the University of Edinburgh, Pennine Care NHS Foundation Trust, Manchester Universities NHS Foundation Trust and NHS Lothian.

15 ETHICAL AND REGULATORY CONSIDERATIONS

15.1 Research Ethics Committee (REC) review & reports

Before the start of the trial, approval will be sought from REC/HRA for the trial protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters. Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial (note that amendments may also need to be reviewed and accepted by NHS R&D departments before they can be implemented in practice at sites). All correspondence with the REC will be retained in the Trial Master File/Investigator Site File. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the trial. If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

15.2 Peer review

The application has been peer reviewed, and approved by, the funder and the protocol has been approved by the Sponsor. The trial has been reviewed in multiple rounds by an independent national panel of experts appointed by the NIHR HS&DR (the funder), involving an independent statistician/methodologist. Important documents such as the Safeguarding and Distress Management Protocol have been independently reviewed by our independent National Stakeholder Advisory Group.

15.3 Public and Patient Involvement (PPI)

The design of the current feasibility and nested qualitative study and application for funding for the entire project (including intervention development and its evaluation) included input from YP-OSA and professionals who work within services that support YP. Our resolve to develop a digital intervention as opposed to an "offline" one was directly influenced by the views and preferences of YP-OSA. Prior to our application for funding, Co-I EQ had led two relevant EU-funded projects: the Risk-taking Online Behaviour Empowerment through Research and Training project and the Self-Produced Images Risk

Taking Online project. Both projects involved consultation and in-depth interviews with YP-OSA, covering their views on the consequences of abuse, factors that influenced their ability to disclose/seek support, and factors that facilitate recovery and adjustment in the aftermath of OSA. These lived experience accounts highlighted the current lack of resources available to YP-OSA, and the urgent importance of addressing this unmet need. In 2019, to inform a previous version of our funding application, we carried out consultations with YP-OSA from the Marie Collins Foundation's, a charity that specifically supports YP-OSA. In 2020, we continued engagement and involvement activities with both professional stakeholders and YP to update and develop further our funding application, including meetings with NHS clinicians, third sector organisations that support survivors of childhood sexual abuse and exploitation (e.g. Bernardo's), NHS e-therapy providers (Kooth) and a consultation meeting with the Young Persons' Advisory Panel of the Manchester 'CAMHS.Digital Research Unit" – an NHS-funded research unit specialising in the development and evaluation of digital mental health interventions co-produced with young people. The main themes that emerged from these consultations and how they informed our funding application included:

1) "YP-OSA-specific support is extremely limited; educational materials about reducing OSA risk are available; existing services don't provide tailored support that addresses our needs". Our current PPI strategy is ensuring that we are co- producing the intervention and delivery of its evaluation.

2) "Developing a new resource for YP-OSA is very important and should be done as quickly as possible". To accelerate the development of our digital intervention, we opted to use a mixed method design that will allow us to maximise the collection of evidence to effectively guide the future integration of the intervention into existing care pathways in NHS mental health services and via youth digital mental health providers.

3) "The intervention should aim to help YP-OSA feel that what has happened to them is not their fault, they are not to blame and reduce negative feelings of shame, guilt and loneliness, improve self-esteem, how to talk to adults about what has happened to them, understanding mainstream media and how to continue using the internet and social media safely". These areas are being targeted through the intervention we are developing and will evaluate in the current feasibility and nested qualitative study. The overarching aim of the digital intervention is to improve YP-OSA ability to 'mentalise', meaning the ability to make sense of their own and other people's thoughts, beliefs, wishes and feelings and to link these to their actions and behaviour. This will empower them to continue using social media and other platforms safely, whilst also improving emotional difficulties that are common among YP-OSA.

In line with NICE (2017) research recommendations for developing interventions to improve wellbeing following OSA, we have continued to seek extensive feedback from YP-OSA, parents and practitioners via our three advisory groups, who we will work with for the lifetime of the feasibility and nested qualitative studies. Active involvement of YP-OSA, their parents/caregivers and relevant professionals is at the core of this project and is ensuring active input into the development of the intervention, including its content, format and structure, and linked procedures to ensure the safety of our participants, as well as to delivery of its evaluation and dissemination of the findings to maximise impact.

Our Lived Experience Advisory Group (LEAG), with capacity for up to 10 members with lived experience of childhood OSA, has been established and meets monthly. Feedback has already been sought on the development of the intervention to be evaluated in this project, including both the

content of the intervention and design of the digital platform via which it will be delivered, and associated software requirements. The group has already influenced the Participant Information Sheet, for example, explaining that not all sexual experiences online are unwanted and some may be wanted by in fact go wrong – as such, we have reflected this important point in our patient-facing documents. This group will be consulted about the software performance and its usability and the procedures for the feasibility and nested qualitative studies including, for example, developing participant documents such as participant information sheets and consent forms. They will also provide feedback on the running of the project (i.e., delivery and evaluation of the intervention), for example, strategies for feasibility study recruitment and possible solutions to any difficulties that might arise, and interpretation of the findings and dissemination. As in our other projects, we will train interested members of the group in qualitative methods so they can support data analysis (e.g., critically reading interview transcripts; commenting on data analyses).

A National Stakeholders Advisory Committee (NSAC) has been established and comprises professionals from national law enforcement and child protection/safeguarding organisations, academic institutions, online sexual abuse support services and social media organisations. These professionals have expertise in child protection/safeguarding and online child sexual abuse and have been and will continue to provide feedback via 6-monthly meetings on the safeguarding protocol for and content of the intervention currently being developed and to be evaluated, the delivery of the feasibility clinical trial and its dissemination.

A Parents and Professionals Advisory Committee (PPAC) has also been established and comprises clinicians from relevant services that provide mental health and/or online sexual abuse and/or safeguarding support to young people in Greater Manchester and Edinburgh. This Committee has and will continue to provide feedback on the development of the intervention and safeguarding issues and delivery of the feasibility clinical trial and its dissemination via bi-monthly meetings.

Our advisory groups will provide feedback on initial findings and critically review the final report we will produce.

The NSAC and PPAC are being overseen by Co-Is EQ and KC and the LEAG by KC and a research assistant with lived experience. They will ensure that the views and values of the groups are represented across the lifetime of the project. In accordance with NIHR guidance, KC has developed and shaped the PPI plans with public contributors, set and refined the overall PPI strategy and will provide appropriate induction and training to group / committee members and ensure that involvement is aligned to UK Standards for Public Involvement and monitored using a PPI impact log aligned with the GRIPP2 guidance.

15.4 Regulatory Compliance

Before any site can enrol patients into the study, the CI or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the CI or designee, in agreement with the Sponsor will submit information to the appropriate body (REC, HRA, Sponsor and participating sites) in order for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS

sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

All correspondence with the HRA / REC will be saved in the Trial Master File. The CI or designee will be responsible for the submission of annual reports and safety reports to the REC, the final REC project report / end of study notification and the prompt notification of the premature interruption of the study, should this be warranted.

The sponsor and the University of Manchester regulatory approvals advisor have reviewed and assessed the study and acknowledged that the app is not a medical device as described in the MHRA decision tool. Whether an app (or other piece of software) is a medical device depends on the intended purpose. The purpose of the i-Minds app is to help people better mentalise and therefore make them less vulnerable to ongoing risk of online harm and further re-victimisation online. It is not intended to prevent or treat a medical condition. Working through the flow chart on page 6 of the MHRA guidance document (Guidance: Medical device stand-alone software including apps (including IVDMDs) v1.08) indicates that the app is not a medical device.

15.5 Protocol compliance

Thorough training of all research workers at the study onset and subsequent weekly supervision of all RAs throughout their involvement in the study will minimise risk of deviations from protocol. However, accidental protocol deviations can happen at any time. They must be adequately documented on a protocol deviations log, which will be saved in the Trial Master File. All deviations from protocol will be brought to the attention of the project CI, and promptly communicated to the study Sponsor, so that corrective actions could be promptly implemented. The protocol deviations log will also be reviewed at regular meetings with the PSC for additional scrutiny and suggestions of corrective actions.

15.6 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The PSC and DMEC will be notified within 7 days of any case where the above definition applies during the trial conduct phase.

15.7 Data protection and patient confidentiality

Throughout the study, all trial investigators and site staff will comply with the requirements of the Data Protection Act 2018 / GDPR and the NHS Confidentiality Code with regards to the collection, storage, processing and disclosure of personal information and will uphold these Acts’ core principles. Any personal information will be deleted and/or safely destroyed at the end of the study e.g. through confidential waste management services available at our HEIs and NHS organisation. This will include

pseudonymisation keys, i.e. data will be fully anonymised at the end of the study. All anonymised research data will be kept in anonymised format and retained for a minimum of 10 years following the end of the study. All final locked datasets will be kept in encrypted files on robust and automatically backed up on UoM servers. The CI (Bucci) will act as data custodian.

Robust data security measures will be implemented throughout the study, in full compliance with national policies and relevant data management and information governance policies and procedures of the participating HEIs and NHS organisations. To protect participant's confidentiality for participants who will undertake remote / digitally mediated meetings with staff, we will employ steps to ensure that documents shared with research participants (e.g., electronic copies of consent forms) will be password protected, and emails from participants will be immediately deleted once received and returned documents are safely stored. Audio recordings of consent will be encrypted using specialist software and will be accessible only to members of the research team. Consent forms returned by standard mail will be via pre-stamped and self-addressed envelopes provided the research team – as the risk of accidental misplacement of this mail correspondence cannot be completely controlled, we will always advise participants to employ methods of documenting their consent that will minimise risk to their confidentiality and will use standard mail options only as a last resort or when participants express a strong preference for such methods.

In the quantitative feasibility clinical trial, all research data will be pseudo-anonymised at the point of data collection, whereas in the nested qualitative interview study, data will be pseudo-anonymised at the point of transcription and audio recordings will be deleted as soon as transcription of data is complete. Pseudo-anonymisation keys will be stored as password protected and encrypted files on NHS and University of Manchester / Edinburgh computers, and will only be accessible by members of the research team. Data will become fully anonymised at the end of the study, when the pseudo-anonymisation keys will be permanently deleted.

The custodian of the data generated by the feasibility clinical trial and nested qualitative study will be the Chief Investigator, Professor Sandra Bucci.

The transfer of research data amongst participating sites will be managed via a secure web-based database system hosted on University of Manchester servers (Research Electronic Data Capture; REDCAP), or alternative safe data transfer systems approved by the Sponsor. Access to the database will be restricted to members of the project team involved in data entry and analysis, using an in-built secure system to grant access and data management privileges that can be authorised only by the project CI (Professor Bucci).

At the end of the study, all study data, the Trial Master File, and all site files will be forwarded for archiving with the study Sponsor.

Security of app and web-interface data is described on pp. 43-44.

15.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

There are no competing interests to declare for the co-investigators or committee members responsible for the overall trial management of the project. The CI (Bucci) is Director of CareLoop Health Ltd., a spin-out of The University of Manchester to make digital therapeutics related to severe mental illness commercially available.

15.9 Indemnity

Greater Manchester Mental health NHS Foundation Trust (GMMH) is the project sponsor. NHS indemnity applies for this NHS Trust sponsored trial. The Universities involved in this project also have insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15.10 Amendments

For any amendment to the study, the CI or designee, in agreement with the Sponsor will submit information to the appropriate body (REC, HRA, Sponsor and participating sites) in order for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended. The views from members of the PMG will be sought on any proposed amendments to the i-Minds protocol. The PSC will agree proposals for substantial protocol amendments and provide advice to the Sponsor and NIHR regarding approvals of such amendments where appropriate. Protocol amendments will be added to the i-Minds Protocol and to clinicaltrials.gov.

15.11 Post trial care

Post-trial, participants will be encouraged to continue to receive support from their referring care team / clinician / keyworker. As taking part in this trial does not replace usual care, and as all participants will be involved with a clinical service throughout the duration of the trial, participants post trial will continue to be supported by the referring healthcare provider.

15.12 Access to the final trial dataset

Future requests to access our data will be via the project's CI (Prof Bucci) and will be only approved on a case-by-case basis when sharing of data will not incur in 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 our 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.

16 DISSEMINIATION POLICY

16.1 Dissemination policy

This will be the first evidence-based intervention for YP-OSA available on a digital platform. We aim to develop a digital platform that is accessible, user-friendly and positively impacts YP. We intend to make i-Minds widely available and will work with our partnering organisations to ensure the learnings from the project are incorporated into further developments of the intervention.

The research has the potential for broad-ranging impact. We anticipate that addressing the needs of this vulnerable group will reduce the potential for re-victimisation and ongoing distress and harm and improve coping and resilience, thereby reducing the need for reactive care. By reducing self- blame and shame about OSA, and by helping YP recognise and manage online risk, we anticipate YP will feel more empowered to access support when needed. If the intervention is feasible, acceptable and demonstrates signs of clinical benefit, we anticipate there being two non-mutually exclusive routes to impact: i) direct uptake by any organisation that wishes to implement the platform (NHSE, SARC/CAMHS services, e-therapy providers), especially if secondary viral waves occur; and/or ii) application for funding to run a powered test of efficacy over a longer follow-up period with more participants. At the end of the project, we will be ready for a Phase III trial. In line with NICE (2017) research recommendations, we will be in a position to conduct a fully powered parallel group RCT comparing i-Minds to either TAU or a wait-list control group, with sufficient follow-up (e.g. 6 to 12 months) to better evaluate efficacy and cost effectiveness of the intervention.

The team has an excellent track record in translating research into improvements in NHS provision. Our advisory groups, NHS management Co-Is and industry partners (Facebook USA; Kooth) will play a significant role in ensuring the project has impacts for both users and service providers. Barriers to these impacts being achieved include poor engagement with the project (e.g. due to the shame/stigma felt by YP-OSA) and/or the digital intervention itself, and inability to integrate the digital platform into existing health / e-therapy provider pathways. It is for these reasons our platform will be co-produced and that we include qualitative work in our project design to explore the barriers and enablers to integrating i-Minds into existing care pathways. Our research team comprises team members who are ideally placed to advise how this intervention should interface with existing care pathways. Our partnership with CAMHS services across two sites, and the national CCG-commissioned e-therapy provider Kooth, will help to achieve maximum exposure when the intervention is ready for full scale implementation.

Anticipated outputs:

1. A digital intervention for YP-OSA available on computers, tablets and smartphones. We will build a standalone digital intervention that will not rely upon the use of third-party IP/software. No IP restrictions will be placed on the platform and there will be no implementation barriers. We will work with stakeholders to take the platform forward as appropriate.
2. Mixed-method feasibility and acceptability study that could be used to shape clinical practice / recommendations / further research.
3. Academic publications (we expect to produce at least 5 peer-reviewed publications).
4. Stakeholder conferences and presentations at academic conferences (virtual where needed).

5. HS&DR final report.
6. Project website, digital media animations / videos to promote the visibility of the project.

Our dissemination strategy includes:

Project website: regularly updated over the course of the research making available publicly accessible and youth-friendly reports (co-written with our YPAG), including a monthly blog from the team and invited experts on directly-related topics;

Social media platforms: Facebook account and Twitter feed. We also have the backing and support of Facebook USA, not only to act in an advisory role but also to help with dissemination through their social media platform. Facebook is invested in giving direction to YP as to where they may seek evidence-based help. Members of our team have an existing advisory relationship with Facebook USA and have presented annually at their conferences.

Practitioner and public forums: NSPCC's CASPAR (NSPCC's Knowledge and Information Service), which provides access to child protection research, policy and practice. The goals of the project are closely aligned with the Model National Response of the #WeProtect Global Alliance, a UK Government led initiative that seeks to tackle and prevent OSA. Co-I EQ is a member of the Child Dignity Alliance Working Group (aligned to the #WeProtect Global Alliance), providing a route to disseminate our findings in the wider international child protection community and influence the potential for scaling up the research outputs to a global audience.

Events: Conferences, network meetings, webinars and symposia (e.g. Digital Health World Congress; MCF Annual Conference). We will host two one-day PPI engagement conferences in Manchester and Edinburgh in partnership with our advisory groups, and a stakeholder conference / cross-sectoral workshop to present and discuss the findings of this research. We will invite several national-level NHS representatives (Public Health Leads, DoH Directors of Mental Health, Public Health England) and agencies that have an online presence to explore avenues for potential uptake. Should further lockdown restrictions be in place over the life of the project, we will carry out this work remotely (e.g. online webinars; remote conferences).

Leverage stakeholder contacts: we will share results in accessible digital formats through partner sites and activities, youth-led initiatives and influence policy and practice through direct contact with NHS partners and governments (Co-I PC is the CYP Health and Justice Steering Group Co-Chair and will facilitate discussion about deployment and uptake of i-Minds during network meetings). We will mobilise our collaborator YP and digital collaborators to share project findings through their multimedia channels and networks (e.g. CAMHS.Digital podcast series and Alexa app mental health updates).

Government/ Policy Development: our proposal addresses established NHS and government priorities. We will engage with the Home Office Child Protection Groups and the Scottish Government during stakeholder/network events as well as reporting findings into the revised national strategy on sexual assault referral centres (SARCs) through NHSE CYP Mental Health Policy Team and the Health and Justice Team. We already have membership of key online child protection working groups within the Home Office and the Scottish Government that will enable this (Co-I's TP; EQ). Importantly, our collaborators include NCA–CEOP who play a central role in disseminating information to YP/practitioners on online safety and well-being, and Childnet International who work directly with YP, parents/caregivers, teachers and professionals and are the UK Safer Internet Centre Hub. We will

meet with local commissioners to discuss the impact of our findings. We will invite a commissioner to be a member of our advisory group to help shape the study for scale-up, if successful.

NHS Trusts / NHS commissioned e-therapy providers: Two of our Co-Is are NHS Strategic Leads for CAMHS and our collaboration with online e-therapy provider Kooth will help to facilitate immediate dissemination in the clinical community to promote its future uptake (should this be indicated) in routine clinical practice through regional strategic clinical networks. Our NHS Co-Is and our collaborator Green (Chief Clinical Officer, Kooth) have access to extensive and well-established networks. We will use local and national contacts within these networks to facilitate dissemination. Through local CYPMH transformation plans (LTPs) in each Borough and regional health and justice programmes, there is an opportunity for commissioners and multi-agency providers to consider how to effectively deliver the intervention platform locally.

16.2 Authorship eligibility guidelines and any intended use of professional writers

No professional writers will be involved in the production of the final project report and other peer-reviewed publications that will result from the research activities conducted as part of the project. Authorship of various project outputs will be informed by authorship criteria proposed by The International Committee of Medical Journal Editors or equivalent criteria endorsed by specific peer-reviewed journals where manuscripts will be submitted. Exact authorship decisions, including any time limits and review requirements by co-authors, will be agreed by the research team over the course of the project.

All publications and outputs arising from the project will comply with the NIHR's publication requirements, including advance output notifications to NIHR, standard NIHR funding statements and NIHR / disclaimers.

Following completion of the study, participants will be provided with an accessible summary of the study findings (if they consented to this). The findings of the project will be written-up as a series of papers to be submitted for publication in peer-reviewed journal. Further dissemination will be via conference presentations at national and international academic conferences, as well as training seminars / lectures provided by the research team following the completion of the project.

17 REFERENCES

1. NICE. Child abuse and neglect: NICE guideline ng76. NICE; 2017. Available from: https://www.nice.org.uk/guidance/ng76/resources/child-abuse-and-neglect-pdf-1837637587141
2. NSPCC. Estimating the costs of child sexual abuse in the UK. London: NSPCC; 2014.
3. Letourneau EJ, Brown DS, Fang X, Hassan A, Mercy JA. The economic burden of child sexual abuse in the United States. Child Abus Negl. 2018;79:413–22.
4. Gewirtz-Meydan A, Lahav Y, Walsh W, Finkelhor D. Psychopathology among adult survivors of child pornography. Child Abus Negl. 2019;98:104189.
5. Pashang S, Khanlou N, Clarke J. The Mental Health Impact of Cyber Sexual Violence on Youth Identity. Int J Ment Health Addict. 2019;17(5):1119–31.
6. Marie Collins Foundation. A systematic review of the recovery needs of children exposed to online sexual abuse. Author; Report available from MCF on request; 2016.
7. Bateman A, Fonagy P. Mentalization-based Treatment for Borderline Personality Disorder: A Practical Guide. Oxford: Oxford University Press; 2006.
8. Sharp C, Vanwoerden S, Wall K. Adolescence as a Sensitive Period for the Development of Personality Disorder. Vol. 41, Psychiatric Clinics of North America. W.B. Saunders; 2018. p. 669–83.
9. Penner F, Gambin M, Sharp C. Childhood maltreatment and identity diffusion among inpatient adolescents: The role of reflective function. J Adolesc. 2019.76:65–74.
10. Ballespí S, Vives J, Debbané M, Sharp C, Barrantes-Vidal N. Beyond diagnosis: Mentalization and mental health from a transdiagnostic point of view in adolescents from non-clinical population. Psychiatry Res. 2018;270:755–63. https://doi.org/10.1016/j.psychres.2018.10.048
11. Bleiberg E, Rossouw T, Fonagy P. Adolescent breakdown and emerging borderline personality disorder. In: Handbook of mentalizing in mental health practice. American Psychiatric Publishing, Inc.; 2012. p. 463–509.
12. Sharp C, Pane H, Ha C, Venta A, Patel AB, Sturek J, et al. Theory of mind and emotion regulation difficulties in adolescents with borderline traits. J Am Acad Child Adolesc Psychiatry. 2011;50(6):563-573.e1.
13. Heyes CM, Frith CD. The cultural evolution of mind reading. Science (80-). 2014;344(6190):1243091–1243091.
14. Debbané M, Salaminios G, Luyten P, Badoud D, Armando M, Solida Tozzi A, et al. Attachment, Neurobiology, and Mentalizing along the Psychosis Continuum. Front Hum Neurosci. 2016;10:406.
15. Fonagy P, Target M. Early intervention and the development of self-regulation. Psychoanal Inq. 2002;22(3):307–35.
16. Malda-Castillo J, Browne C, Perez-Algorta G. Mentalization-based treatment and its evidence-base status: A systematic literature review. Psychol Psychother Theory, Res Pract. 2019;92(4):465–98.
17. Rossouw TI, Fonagy P. Mentalization-based treatment for self-harm in adolescents: A randomized controlled trial. J Am Acad Child Adolesc Psychiatry. 2012;51(12).
18. Griffiths H, Duffy F, Duffy L, Brown S, Hockaday H, Eliasson E, et al. Efficacy of Mentalization-based group therapy for adolescents: the results of a pilot randomised controlled trial. BMC Psychiatry. 2019;19(1):167.
19. Hollis C, Falconer CJ, Martin JL, Whittington C, Stockton S, Glazebrook C, et al. Annual Research Review: Digital health interventions for children and young people with mental health problems - a

systematic and meta-review. J Child Psychol Psychiatry. 2017;58(4):474–503.
20. Widman L, Kamke K, Evans R, Stewart JL, Choukas-Bradley S, Golin CE. Feasibility, Acceptability, and Preliminary Efficacy of a Brief Online Sexual Health Program for Adolescents. J Sex Res. 2020;57(2):145–54.
21. Bevan Jones R, Thapar A, Rice F, Mars B, Agha SS, Smith D, et al. A Digital Intervention for Adolescent Depression (MoodHwb): Mixed-Methods Feasibility Evaluation (Preprint). JMIR Ment Heal. 2019
22. Bailey E, Alvarez-Jimenez M, Robinson J, D'alfonso S, Nedeljkovic M, Davey CG, et al. An enhanced social networking intervention for young people with active suicidal ideation: Safety, feasibility and acceptability outcomes. Int J Environ Res Public Health. 2020;17(7).
23. Moore A. Revealed: Hundreds of children wait more than a year for specialist help [Internet]. Health Service Journal. 2018 Aug 30. Available from: https://www.hsj.co.uk/quality-and-performance/revealed-hundreds-of-children-wait-more-than-a-year-for-specialist-help/7023232.article
24. NHS England. The NHS Long Term Plan. 2019. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf
25. NHS. Five Year Forward View. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf
26. NHS England. Strategic direction for sexual assault and abuse services: Lifelong care for victims and survivors 2018-2023. London: NHS England; 2018. Available from: https://www.england.nhs.uk/wp-content/uploads/2018/04/strategic-direction-sexual-assault-and-abuse-services.pdf
27. Javid S. Keeping our children safe. Home Office; 2018. Available from: https://www.gov.uk/government/speeches/keeping-our-children-safe
28. Bowcott O. Online child sex abuse referred to Met increased by 700% since 2014 [Internet]. The Guardian. 2018 Jan 22. Available from: https://www.theguardian.com/uk-news/2018/jan/22/online-child-sex-abuse-referred-to-met-increased-by-700-since-2014
29. HM Government. Online harms white paper. Author. 2019. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/793360/Online_Harms_White_Paper.pdf
30. Technology Coalition. The Technology Coalition Announces Project Protect [Internet]. Author. 2020 June 10. Available from: https://www.technologycoalition.org/2020/05/28/a-plan-to-combat-online-child-sexual-abuse/
31. Perez S. Report: WhatsApp has seen a 40% increase in usage due to COVID-19 pandemic. Tech Crunch. 2020 Mar 26. Available from: https://techcrunch.com/2020/03/26/report-whatsapp-has-seen-a-40-increase-in-usage-due-to-covid-19-pandemic
32. Europol. Catching the virus: Cybercrime, disinformation and the COVID-19 pandemic [Internet]. Author. 2020 April 3. Available from: https://www.europol.europa.eu/sites/default/files/documents/catching_the_virus_cybercrime_disinformation_and_the_covid-19_pandemic_0.pdf
33. NSPCC. Lonely children are twice as likely to be groomed online [Internet]. Author. 2020 April 23. Available from: https://www.nspcc.org.uk/about-us/news-opinion/2020/coronavirus-children-groomed-online/
34. Grierson J. Watchdog reveals 8.8m attempts to access online child abuse in April [Internet]. The Guardian. 2020 May 20. Available from:

https://www.theguardian.com/society/2020/may/20/watchdog-reveals-88m-attempts-to-access-online-child-abuse-in-april

35. Rocks S, Fazel M, Tsiachristas A. Variation in spend on young mental health across Clinical Commissioning Groups in England: A cross-sectional observational study. BMJ Open. 2019;9(10):e030011.
36. Kooth. How has COVID-19 affected the mental health of children and young people in the United Kingdom? [Internet]. Author. 2020. Available from: https://about.kooth.com/covid19-data/
37. Bucci S, Barrowclough C, Ainsworth J, Machin M, Morris R, Berry K, et al. Actissist: Proof-of-Concept Trial of a Theory-Driven Digital Intervention for Psychosis. Schizophr Bull. 2018 Aug 20;44(5):1070–80.
38. Liu RT, Scopelliti KM, Pittman SK, Zamora AS. Childhood maltreatment and non-suicidal self-injury: a systematic review and meta-analysis. The Lancet Psychiatry. 2018;5(1):51–64. http://dx.doi.org/10.1016/S2215-0366(17)30469-8
39. Sharp C, Ha C, Carbone C, Kim S, Perry K, Williams L, et al. Hypermentalizing in adolescent inpatients: Treatment effects and association with borderline traits. J Pers Disord. 2013;27(SPL.ISS.1):3–18.
40. Fonagy P, Allison E. What is mentalization? The concept and its foundations in developmental research. In: Midgley N, Vrouva I, editors. Minding the child: Mentalization-based interventions with children, young people and their families. 2012. p. 11–34.
41. Rising L, Janoff NS. The Scrum Software Development Process for Small Teams. IEEE Softw. 2000;17(4):26–32.
42. Bucci S, Ainsworth J, Barrowclough C, Lewis S, Haddock G, Berry K, et al. A Theory-Informed Digital Health Intervention in People with Severe Mental Health Problems. Stud Health Technol Inform. 2019;264:526–30.
45. UK Government. User Research Service Manual [Internet]. 2020. Available from: https://www.gov.uk/service-manual/user-research
46. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, et al. Development of a theory of implementation and integration: Normalization Process Theory. Implement Sci. 2009;4:29.
47. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. Sociology. 2009 Jun;43(3):535–54.
48. May CR, Cummings A, Girling M, Bracher M, Mair FS, May CM, et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: A systematic review. Implement Sci. 2018;13(1):1–27.
49. Quayle E, Jonsson L, Lööf L. Online behaviour related to child sexual abuse: Interviews with affected young people. European Union & Council of the Baltic Sea States; 2012. Available from: http://childrenatrisk.eu/robert/public/Interviews_with_affected_young_people.pdf
50. Quayle E, Cooper K, Hervy K, Svedin C-G, Jonsson L, von Weiler J, et al. SPIRTO Self Produced Images Risk Taking Online. 2013. Available from: http://www.spirto.health.ed.ac.uk/wp-content/uploads/FINAL_Public-Annual-Report.pdf
51. Quayle E, Cariola L. Youth-produced sexual images: A victim-centred consensus approach [Internet]. University of Edinburgh; 2017. Available from: http://www.spirto.health.ed.ac.uk/
52. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
53. Miller S, Ainsworth B, Yardley L, Milton A, Weal M, Smith P, et al. A Framework for Analyzing and Measuring Usage and Engagement Data (AMUsED) in Digital Interventions: Viewpoint. J Med

Internet Res. 2019;21(2):e10966.
54. Fonagy P, Luyten P, Moulton-Perkins A, Lee YW, Warren F, Howard S, Ghinai R, Fearon P, Lowyck B. Development and validation of a self-report measure of mentalizing: The reflective functioning questionnaire. PLoS One. 2016 Jul 8;11(7):e0158678.
55. Jelenchick LA, Eickhoff J, Christakis DA, Brown RL, Zhang C, Benson M, et al. The Problematic and Risky Internet Use Screening Scale (PRIUSS) for adolescents and young adults: Scale development and refinement. Comput Human Behav. 2014;35:171–8. http://dx.doi.org/10.1016/j.chb.2014.01.035
56. Ebesutani C, Reise SP, Chorpita BF, Ale C, Regan J, Young J, Higa-McMillan C, Weisz JR. The Revised Child Anxiety and Depression Scale-Short Version: scale reduction via exploratory bifactor modeling of the broad anxiety factor. Psychological assessment. 2012 Dec;24(4):833.
57. Perrin S, Meiser-Stedman R, Smith P. The Children's Revised Impact of Event Scale (CRIES): Validity as a Screening Instrument for PTSD. Behav Cogn Psychother. 2005;33(04):487.
58. Kaufman EA, Xia M, Fosco G, Yaptangco M, Skidmore CR, Crowell SE. The Difficulties in Emotion Regulation Scale Short Form (DERS-SF): Validation and replication in adolescent and adult samples. Journal of Psychopathology and Behavioral Assessment. 2016 Sep;38(3):443-55.
59. Boyce P, Parker G. Development of a scale to measure interpersonal sensitivity. Aust N Z J Psychiatry. 1989;23(3):341–51.
60. Marci T, Moscardino U, Altoè G. The brief Experiences in Close Relationships Scale - Revised Child version (ECR-RC): Factor structure and invariance across middle childhood and early adolescence. Int J Behav Dev. 2019;43(5):409–23.
61. Campbell-Sills L, Stein MB. Psychometric analysis and refinement of the connor–davidson resilience scale (CD-RISC): Validation of a 10-item measure of resilience. Journal of Traumatic Stress: Official Publication of The International Society for Traumatic Stress Studies. 2007 Dec;20(6):1019-28.
62. Scottish Government. Scottish Index of Multiple Deprivation 2020.
63. McLennan D, Noble S, Noble M, Plunkett E, Wright G, Gutacker N. The English Indices of Deprivation 2019. Ministry of Housing, Communities, and Local Government. 2019.
64. Morley S, Dowzer C. Manual for the Leeds Reliable Change Indicator: Simple Excel(tm) applications for the analysis of individual patient and group data. Leeds, UK: University of Leeds; 2014. Available from: https://dclinpsych.leeds.ac.uk/wp-content/uploads/sites/26/2018/09/Manual-for-Leeds-RCI-CSC-calculators.pdf
65. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. Analysing qualitative data. Routledge; 1994. p. 173–94.