Greater Manchester Mental Health
NHS Foundation Trust

Health Research Authority

EN-CAMHS 2: Enhancing CAMHS Referrals Protocol

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RESEARCH REFERENCE NUMBERS

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Principal Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation without the prior written consent of the Sponsor

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

For and on behalf of the Study Sponsor:

Date: .2/12/2025

Signature: 

Name (please print): Natalie Garratt

Position: Head of Research & Innovation GMMH

Principal Investigator:

Signature: 

Date: 29/10/2025

Name: (please print): Prof Kathryn Abel

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Committees	Study Steering Committee (SSC) – as before? Project Management Group – if different from above?

STUDY SUMMARY

Study Title	EN-CAMHS 2: Enhancing CAMHS Referrals
Internal ref. no. (or short title)	EN-CAMHS 2
Study Design	Mixed methods: Qualitative (focus groups and semi-structured interviews) and quantitative (usage/engagement rates of digital referral tool)
Study Participants	Child and Adolescent Mental Health Services (CAMHS) Stakeholders who have had experience with the CAMHS referral process, including: • CAMHS staff • Collaborators • Children and young people (CYP) • Key referrers (e.g., GPs, teachers, SENCOs, community paediatricians, social workers) • Parents/carers • CAMHS commissioners • Mental Health Leads • Senior national stakeholders (e.g. NHS England senior leaders) Trust staff members from different departments, for example, clinical IT, digital strategy, Chief Clinical Information Officers (CCIOs), research.
Planned Size of Sample (if applicable)	WP1 - 6 focus groups - we aim to recruit 60 stakeholders (6-10 per group) WP2 - onboard 5-8 CAMHS providers, 1-hour workshop with each provider (n=25), Accessibility working group n=10, 2 digital co-design workshops (n=50) WP3 - 60 referrers to use the tool, semi-structured interviews with 25 referrers
Follow up duration (if applicable)	N/A
Planned Study Period	01/06/2024 – 30/11/2026 (30 months)
Research Question/Aim(s)	We aim to develop a simple, clear way for children to get the right support for their mental health problems when they need it. We aim to solve the problems people told us about in EN-CAMHS 1 (NIHR 131379) and to improve the quality of referrals made to CAMHS. Research Questions: 1. Using the findings from NIHR HS&DR-funded EN-CAMHS 1 and stakeholder consultation, can we develop a set of national standards for digital CAMHS referral processes?

	2. Can we translate the prioritised features from EN-CAMHS 1 of a digitally-led, intelligent CAMHS referral process into a usable, acceptable and widely accessible platform that is nationally standardised, locally adaptable and sustainable? 3. Can we address concerns about digital health equity through the newly developed CAMHS referral mechanisms? 4. How do referrers, including GPs, school staff and children/young people/families perceive the usability and acceptability of the digital tool? 5. How do referrers use and engage with the tool? 6. How do rates of successful referrals with the tool compare to traditional modes of referral?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Health Services and Delivery Research Programme	£1,259,268.30

ROLE OF STUDY SPONSOR AND FUNDER

Department of Health definition of a sponsor: An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them, by agreement, amongst the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study.

Summary of Sponsor Responsibilities:

- Taking responsibility for putting and keeping in place arrangements to initiate, manage and fund the study.
- Confirming that everything is ready for the research to begin.
- Satisfying itself the research protocol, research team and research environment have met the appropriate scientific quality assurance standards.
- Satisfying itself the study has ethical approval before relevant activity begins.
- Allocating responsibilities for the management, monitoring and reporting of the research.

- Ensuring that appropriate arrangements are in place to approve any modifications to the design, obtaining any regulatory authority required, implementing such modifications and making them known.
- Satisfying itself that arrangements are kept in place for good practice in conducting the study and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions.

For full details of sponsor definitions and responsibilities please refer to the Department of Health's Governance Framework for Health & Social Care (2nd Edition 2005).

Sponsor: Greater Manchester Mental Health NHS Foundation Trust (GMMH) will assume overall responsibility for the project. GMMH sponsorship regulations are outlined in RD SOP14 Trust Sponsorship of Research (GMMH) https://www.gmmh.nhs.uk/search/text-content/ri-standard-operating-procedures-sops-and-guidance-documents--1739

Funder: National Institute for Health Research Health Services and Delivery Research Programme. The role and responsibilities of the funder are outlined in the contract between the Secretary of State for Health and Greater Manchester Mental Health NHS Foundation Trust Version number: 2/18 NHS Feb 18.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Committee (SSC): The role of the SSC is to provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to 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 main features of the SSC are as follows:

- To provide advice, through its Chair, to the Project Funder, the Project Sponsor, the Principal Investigator, the Host Institution and the Contractor on all appropriate aspects of the project.
- To concentrate on progress of the trial/project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question.
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society.
- To ensure appropriate ethical and other approvals are obtained in line with the project plan.
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments.
- To provide advice to the investigators on all aspects of the project.

Project Management Group (PMG): The Project Management Group will consist of the co-Principal Investigators, the Project Manager, and PPIE representatives (a parent, and a young person). The group will hold monthly meetings throughout the study to review progress against the Project Management Plan.

Patient and Public Involvement Groups: There will be two Patient and Public Involvement (PPI) groups during this study, a Young Persons Advisory Group (YPAG) and a Parents/carers and Professionals Advisory Group (PPAG). These groups will meet bimonthly and quarterly, respectively,

to review and feedback on the study and ensure young people and their parents/carers/families influence decision making. Training will be provided, where necessary, to support members of the advisory groups.

PROTOCOL CONTRIBUTORS

Professor Kathryn Abel, (KMA) is Professor of Psychological Medicine and Director of the Centre for Women's Mental Health at the University of Manchester. She is Honorary Consultant Psychiatrist and Co-Director of the GM.Digital Research Unit at Greater Manchester Mental Health. GM.Digital has the specific scope of working to develop scalable and valued digital solutions to improvemental health and wellbeing. She has many years' experience leading and successfully completing large scale mental health research trials. KMA will have overall responsibility for the project and oversee all work packages of the project.

Dr Pauline Whelan (PW)**,** is Co-Director of the GMMH GM.Digital Research Unit at Greater Manchester Mental Health NHS Foundation Trust which aims to develop and evaluate evidence-based technologies to improve mental health and wellbeing. She is Senior Research Fellow in Digital Health at the University of Manchester. She has 20+ years' experience developing and deploying digital solutions across a range of research, healthcare and industry projects and is also an experienced PPI facilitator and mixed methods researcher. PW will have joint lead-applicant responsibilities, attend all PMG meetings, and advise on the potential for digital health technologies to support the range of potential solutions in WP1.

Dr Julian Edbrooke-Childs (JEC), is Head of Digital Development and Evaluation at Anna Freud National Centre for Children and Families, Associate Professor of Evidence Based Child and Adolescent Mental Health at University College London, and Deputy Director of the Evidence based Practice Unit. His research covers three main areas: empowering young people, implementation science, and digital innovations. He has extensive experience of developing and evaluating digital mental health interventions for young people, publishing in leading journals in this field (e.g., the Journal of Medical Internet Research) and computer science conferences. JEC will attend all PMG meetings and advise on YP inequalities across the project.

Dr Rachel Elvins, (RE), MD, FRCPsych is a Consultant Child and Adolescent Psychiatrist working in central Manchester. Clinically she has worked in a wide range of CAMH settings from community outreach to specialist inpatient facilities. Her research interests focus on eating and mood disorders in adolescents, treatment of autistic spectrum conditions, digital treatments in mental health and process measures in treatment trials, particularly the therapeutic alliance. Rachel co-leads the CAMHs research hub in MFT Trust which produces a range of high-quality research, and in collaboration with other research and clinical institutions. RE will attend all PMG meetings, provide clinical input into all work packages and coordinate local trial site in MFT.

Dr Lesley-Anne Carter (LAC), is a Lecturer in Biostatistics at the University of Manchester, specialising in clinical trials methodology. She has a particular focus on the design and analysis of cluster trials and has expertise in multilevel modelling. In addition, she has experience with feasibility studies and is a member of the North West RfPB Regional Advisory Committee. LAC will attend all PMG meetings and lead on the analysis of the referral data.

Professor Bernadka Dubicka (BD), is chair of child and adolescent psychiatry at the University of York, Honorary Professor at the University of Manchester and a consultant child and adolescent

psychiatrist at Greater Manchester Mental Health Trust. She has been a consultant for an adolescent unit for over a decade, and recently moved to a new post in Greater Manchester where she is helping develop intensive community and crisis services for young people and is also a research lead. In 2015 she was elected vice-chair of the RCPsych Child and Adolescent faculty, and became chair in June 2017. She campaigned actively for improved CAMHS on taking up this post. Dubicka will provide expertise from a CAMHS clinical and research perspective.

John Sainsbury (JS), is the Innovation Manager, in Research and Innovation at Greater Manchester Mental Health NHS Foundation Trust. He has worked as an Allied Health Professional in Mental Health services, in CMHTs and as a clinical service manager in EITs. He holds an MSc in Continuous Improvement in the Public Sector and has acted as the Principal Investigator for digitally enabled therapies in CYP and Psychosis Services, and has enabled the Trust to be an early adopter of digital therapies for example: VR for agoraphobia and psychosis, and internet based therapeutic interventions for a range of mental health conditions.

Charlotte Stockton-Powdrell (CSP)**,** is an Information Systems Programme Manager and Co-Lead of the Digital Health Software team who will be involved in the design and development of the digital CAMHS referral tool. She has many years of experience in overseeing the development, delivery and implementation of digital health technologies, with a particular expertise in digital mental health. She was also heavily involved in EN-CAMHS 1.

Professor Penny Bee (PB)**,** is a Professor of Applied Mental Health Research, Deputy Theme Lead for Mental Health in the NIHR ARC-GM, Coproduction Lead in the NIHR rapid evaluation Unit, REVAL and NIHR Senior Investigator. She is a world-renowned qualitative researcher with an awarding winning track record in PPI (Young people and adults) and over £13 million active funding pertaining to patient experiences, support needs and barriers to care. She is Co-director of NIHR Global Health Research Group for mental health and has developed and evaluated mental heath digital applications for Young People in the UK Indonesia.

Dr Lamiece Hassan (LH)**,** is a Research Fellow, based at University of Manchester. She specialises in using participatory approaches from the social sciences, health informatics and computer science to explore user experiences, acceptability, preferences and ethical issues relevant to digital and data-driven health interventions. She has experience in leading public involvement and engagement initiatives for large, health informatics research centres. LH will attend all PMG meetings and lead on all PPI activities.

Heidi Tranter (HT) the Project Manager, is a Research Associate at Greater Manchester Mental Health NHS Trust (GMMH). She will be responsible to the day-to-day project management and oversight. She is an experienced research associate who has conducted research with healthy and vulnerable populations, and was extensively involved in EN-CAMHS 1.

Abbreviations

CAMHS	Child and Adolescent Mental Health Services
CCIO	Chief Clinical Information Officer
CYP	Children and Young People
DHSC	Department of Health and Social Care
EDI	Equality, Diversity and Inclusion
ICB	Integrated Care Board
ICS	Integrated Care System
IM&T	Information Management and Technology
NASSS	Non-adoption, Abandonment, Scale-up, Spread, Sustainability
NASSS-CAT	Non-adoption, Abandonment, Scale-up, Spread, Sustainability Complexity Assessment Tool
NHS	National Health Service
NHSE	National Health Service England
PMG	Project Management Group
PPAG	Parent's and Professional's Advisory Group
PPI	Patient and Public Involvement
SSC	Study Steering Committee
WP	Work Package
YPAG	Young People's Advisory Group

KEY WORDS: CAMHS, mental health, digital mental health, referral, stakeholder consultation

EN-CAMHS 2: Enhancing CAMHS Referrals

1 BACKGROUND

Children and young people's mental health is a national priority for the Department of Health and Social Care [1] and all major national funders. This research addresses critical problems in the referral processes to Child and Adolescent Mental Health Services (CAMHS) that we identified during our qualitative research program during our NIHR HS&DR-funded EN-CAMHS 1 project.

1. **CAMHS cannot cope with the growing numbers of referrals.** Nearly 500,000 children and young people (CYP) were referred to CAMHS in 2021/2022 [2], and this number has risen steadily since 1999 [3,4]. CAMHS providers are overwhelmed by the number of referrals [5,6].

2. **Rising demand** is **coupled with high levels of rejection**. Almost a quarter of the referrals made into CAMHS are unsuccessful because they are deemed inappropriate or do not reach the threshold for treatment [2]. This results in **longer delays for children who need the specialist care,** which is exacerbating mental health difficulties [7].

3. The **experience of the referral process is poor** [8,9]. The high rate of inappropriate referrals causes **unnecessary distress to children, their families and to referrers,** who can wait many weeks if not months for a decision [10]. The family upset is compounded by **a lack of communication throughout the long process** [11]. When a referral is rejected, it typically goes to the 'back of the queue', resulting in further delays for children and families.

4. **The quality of CAMHS referrals is poor** and is often the first and only, service referred to by families (who see this as the gold standard) and **referrers struggling to know what else is available** in primary care [7,10]. This leads to an increased number of referrals, which are often not completed to the standard needed by CAMHS.

5. Clear **information** about what CAMHS can and cannot provide is **not readily available and suitable alternative sources of mental health support are often not explained** to children and their families at the point of referral rejection [12,13].

6. Non-CAMHS support is **poorly understood** [14] and not widely valued as a helpful source of support. People who could be helped better by non-CAMHS support are **not signposted elsewhere early enough** in the process, except in a minority of places.

7. Rejected referrals incur a **significant cost for CAMHS** who must triage often incomplete and/or inaccurate, referral documentation. Receiving a rejection is also **frustrating and costly to referrers** (GPs, school staff) who spend valuable time preparing referral documentation [15,16].

Our NIHR funded EN-CAMHS project ("EN-CAMHS 1", NIHR131379) consulted with 110 CAMHS stakeholders (CYP, parents/carers, GPs, mental health school staff and CAMHS professionals) [17]. EN-CAMHS 1 confirmed and extended previous research: stakeholders reported widespread confusion about the kinds of support CAMHS can and cannot provide. Referrers reported poor support during the

referral process, lack of transparency about the process and a lack of knowledge and low confidence in other sources of support. Services reported poor quality of referrals such that many were 'rejected'. Families described using 'workarounds' to get to CAMHS (e.g. going to A&E). This is concerning not least because it highlights families' difficulties, but also because it disrupts the goals of referral and triage: i.e. to provide timely, appropriate care and to prioritise those in most need. We identified overwhelming problems with the current referral processes resulting in high levels of unnecessary additional cost to services; and widespread despair for referrers and for children and families.

2 RATIONALE

Direct changes to CAMHS resourcing and staffing are the domain of DHSC and not something we can change. However, by improving referrals, our work can relieve additional pressure on services, make the process work better and create greater satisfaction for users. We can also increase understanding of what CAMHS is and does; and create confidence in CAMHS alternatives. Our research has demonstrated an urgent **health and care need** to provide a straightforward referral process to ensure that children most in need are prioritised for treatment, and that all children are signposted to appropriate help in a timely manner. Such a process needs to be scalable, low cost, widely accessible and sustainable over time.

Our 110 CAMHS stakeholders in EN-CAMHS 1 [18] repeatedly **expressed** a clear **preference** for a digital solution that could simplify and improve the CAMHS referral process. Stakeholders unanimously advised that we should create a national, standardised referral process which could also be tailored to local CAMHS' configurations. To date, there has been no national collaboration to improve the referral process; rather, piecemeal attempts across CAMHS providers have adopted different approaches. Our audit of such approaches unfortunately suggests they **do not meet the requirements of CAMHS stakeholders** identified in EN-CAMHS 1. For example, none has been rigorously co-developed with stakeholders; none provides a mechanism for people to track 'where they are' in the referral journey once a referral is submitted. From a technical perspective, the digital tools currently developed are not interoperable with core NHS infrastructure (e.g. NHS app; NHS website). There is patchy sharing of digital referrals in geographically-aligned providers, but it is fragmented and again lacks most of the recommendations we bring from EN-CAMHS 1 stakeholders for what the digital referral should 'look like'.

EN-CAMHS 1 stakeholders recommended we implement a digital solution to address the current problems of poor communication, missing information, poor data quality and lack of guidance for families about what to expect of the referral journey. The design and development of the digital tool will specifically address the accessibility needs of referrers. We intend to explore issues of digital accessibility in the consultations (WP1) and in the co-design workshops with participants. We shall also consider the three key elements of digital exclusion: lack of digital access; lack of digital skills; lack of confidence to use digital. We will explore these challenges in the co-design workshops, with stakeholders in consultation and with our advisory groups. The digital tool will supplement rather than supplant traditional modes of referral; traditional (e.g. paper based) modes of referral will remain. However, we anticipate that our digital tool will enable more people to make more successful referrals than before.

We shall also **generate new knowledge** about the patterns of referrals into CAMHS, by automating data collection through the digital tools and thereby enabling services and NHS England to understand referral and treatment data in greater detail than ever before. We see **enormous potential** in this project and its learnings/outputs for cross-pollination to **other services experiencing similar problems**.

1. **Referrals overwhelming CAMHS**
- We **cannot** increase CAMHS staff levels or change what it can provide.
- We **can** make the referral process work better and with greater satisfaction for referrers and for those being referred.
- We **can** increase confidence in CAMHS alternatives and increase follow-through into CAMHS alternatives.
- We **can** help CAMHS prioritise the needs of those it is designed to help.

2. **Quality of referrals is poor**
- We **can** provide clear, accessible guidelines to make appropriate referrals.
- We **can** validate input on the referral form and ensure all required information is completed pre-submission.
- We **can** raise awareness about what a good referral is.
- We **can** educate people about common referral mistakes.

3. **Poor experience of referral**
- We **can** explain the referral process clearly.
- We **can** outline key steps in the referral journey and inform people about the expected waiting times for the local CAMHS triage process.
- We **can** update referrers and CYP/families as their referral moves through the system.
- We **can** signpost to local and national resources that may help during the waiting period.

4. **Costs for CAMHS**
- We **can** reduce **CAMHS clinical** time wasted by automating the checking of referral documents before they are submitted.
- We **can** improve referral success by ensuring alternative non-CAMHS support is signposted appropriately and explained.

5. **Poor information**
- We **can** provide straightforward accessible information translated into multiple languages.
- We **can** signpost to phoneline support for those who are not comfortable with technology.

6. **Lack of confidence in non-CAMHS**
- We **can** make non-CAMHS support more understandable and transparent to people using services by linking to **real-life case studies** / CYP stories and working with CAMHS stakeholders.
- We **can** help build trust between referrers and services.

7. **Timeliness of Assessment by CAMHS**
- We **can** divert CYP to alternative services which may free CAMHS to see those who need them most, sooner.
- We **can** reduce the workload of CAMHS staff in triaging inappropriate referrals.
- We **can** free up CAMHS clinical time for more complex appropriate referrals.

- We **can** make referrals faster and more reliable.
- We **can** make them 'recyclable' so re-referrals do not 'fall out' of the system and need to 'start from scratch'/'go back to the back of the queue.'

Evidence

The number of children and young people (CYP) waiting longer than 12-weeks for mental health treatment in England is at a five-year high [19]. The challenge for CAMHS improvement is complex, but a review of the current literature has identified how the referral process represents an important aspect of this leading to children waiting until they are very unwell to access care [10,19]; possibly needing more prolonged and intensive treatment as a result and leading to lack of trust in services [20,21]. Simple, practical problems already identified in the literature include lack of transparency in the referral process; incomplete information in referral forms; poor communication with referrers/families throughout the process; lack of information about where else to seek help and who can refer into CAMHS [e.g. 22-25]. The NIHR HS&DR-funded EN-CAMHS 1 extended this understanding of the challenges for referrals into CAMHS.

Existing evidence suggests potential solutions include: a 'single point of access' (SPoA) within CAMHS [e.g. 26-28] referrer-friendly guidelines with training to support referrers [14]; increasing, and ring-fencing funding available to CAMHS [6]; clarity about CYP mental health support available for referrers that is separate from CAMHS and which may be more readily and repeatedly available in the community [9,27]; and a call for policymakers to improve collaboration between professionals involved in supporting CYP mental health [11]. However, our audit of CAMHS referral processes found that only 11 providers (out of 78) have online, interactive referral forms, many of which have poor user interfaces and are difficult to navigate. Most have no online referral mechanism and provide lengthy documents that need to be downloaded, printed and/or emailed individually to each different provider. Referrers told us these forms were often hard to find, confusing and difficult to complete. **Easy-win opportunities** to provide online referral forms that automatically validate information and support accessibility (e.g. translations) have not been exploited. Other helpful information, such as: **overviews of what CAMHS can and cannot provide**, indicative waiting times, signposting to alternative local sources of help and other support mechanisms are not available in a standardised format. Children and families told us **they did not know where to find information** about CAMHS and that **they did not know which** sources of information **to trust**. Opportunities for co-designed, patient-centred communications accessible to this (and other) marginalised and under-represented groups have been missed.

EN-CAMHS 1 engaged widely with children and families, policymakers, commissioners, mental health staff, NHS England and other CAMHS stakeholders to identify the key problems and the tractable solutions to the CAMHS referral problems. Stakeholders advocated for a digitally-led referral process that would support completeness of submitted information; signpost to alternative help and resources (where applicable); real-time updates about where a child is on the referral pathway and approximate waiting times to referral outcomes and treatment. Mental health staff identified time-savings that would accrue from receiving correct and accurate information at the point of referral review. GPs and school staff advised that the system needs to guide them through the referral process and advise on

alternative sources of help; the current processes are simply not fit for purpose and often cause distress to children and families.

Another key benefit of a standardised referral system is the ability to **automatically** collect data for **onward reporting to national bodies** (e.g. waiting times to NHS England). This automatic data collection would further **enable benchmarking of CAMHS referral processes** widely across and within Trusts in the UK. This monitoring of service performance in turn can provide a means for responding to problems quickly, as well as targeting support to areas where there are clear challenges.

3 RESEARCH QUESTION/AIM(S)

Our overarching aim is to improve the CAMHS referral process for CYP, their families and carers, as well as for health, education and CAMHS professionals so that CYP receive the help they need as quickly as possible.

Research questions:

1. Using the findings from EN-CAMHS 1 and stakeholder consultation, can we develop a set of national standards for digital CAMHS referral processes?

2. Can we translate the prioritised features from EN-CAMHS 1 of a digitally-led, intelligent CAMHS referral process into a usable, acceptable and widely accessible platform that is nationally standardised, locally adaptable and sustainable?

3. Can we address concerns about digital exclusion and other identified health inequalities through the newly developed CAMHS referral mechanisms?

4. How do referrers, including GPs, school staff and children/young people/families perceive the usability and acceptability of the digital tool?

5. How do referrers use and engage with the tool?

6. How do rates of successful referrals with the tool compare to traditional modes of referral?

There are no primary nor secondary outcome measures for this study as this is a feasibility study to evaluate usage and acceptability of the co-created tool using data collected from referrers. These data will be a combination of quantitative data on usage and engagement and qualitative data from semi-structured interviews with 25 referrers.

3.1 Objectives

1. To develop national standards for digital referrals into CAMHS that have sufficient flexibility to support the diversity of CAMHS configurations locally and regionally (WP1).
2. To co-develop with key stakeholders a standards-compliant digital CAMHS referral tool that maximises the use of digital technologies to support inclusion (e.g. translation support, text to speech, culturally-relevant service information and imagery) (WP2).

3. To implement, test and refine the newly developed standards and digital tool in 5-8 CAMHS providers (WP3), with CAMH sites purposively selected for diverse contextual characteristics.
4. To develop a blueprint for implementation of the new referral process at CAMHS.
5. To develop a robust sustainability plan for standards-compliant CAMHS referral processes so that the platforms developed through the funding remain relevant, usable and useful beyond the lifetime of this grant funding (WP4).

3.2 Outcome

To our knowledge, this is the first study designed specifically to develop a solution to the challenge of rejected/inappropriate CAMHS referrals. Through our extensive consultation with all key stakeholders on the referral process throughout EN-CAMHS 1, we are now positioned to build a solution to the problems of referral that addresses the needs of all types of referrers, including notably young people and their families. Our broad network of collaborators and partners on the project will support widespread dissemination of the work. Our partner MQ will work closely with us throughout the project to ensure that our dissemination, outputs and impact are maximised for the benefit of young people who require mental health support. As in EN-CAMHS 1, we shall leverage our extensive mental health networks to influence and support policy change to bring benefit to CYP and their families through an enhanced referral process. We will aim to share findings as soon as possible and tailor these to the audience. We shall do this through ongoing updates through our social media channels and those of our partners (critically, MQ) and through ongoing presentations, conferences, seminars and informal events across the full lifetime of the project. MQ is our dissemination partner and we shall hold events with stakeholders throughout the project as part of our parallel work on implementation.

The project has the potential for far-reaching and sustained impact. Specifically, we anticipate and will aim for the following effects:

- Reduced proportion of inappropriate referrals to CAMHS.
- Greater proportion of successful referrals.
- Reduced clinical costs for use by CAMHS assessing CYP and families in need.
- Reduced waiting times for first appointments.
- Flattening of recent increases in referral rates.
- Improved quality of referrals and information therein.
- Reduction in length of initial referral meetings.
- Fewer delays in decision-making.
- Improved information about alternative services or self-help.
- With swifter processes, it will help reduce the number of young people who get to assessment stages and then get rejected for becoming eligible for adult services [9].
- Improved patient experience through transparency of progress during referral.
- Potentially more time made available for face to face appointments when needed due to more efficient and complete referral process.
- In services where dedicated time to discuss referrals are not routine, greater availability can be carved out for direct contact (phone, email) to prevent inappropriate and rejected referrals, and to ensure those CYP who need be seen do so. This remains an essential clinical activity to ensure patient safety. It would reduce the need for lengthy, and weekly referral meetings freeing up resource internally.

- Having the necessary sources of information and complete investigations prior to the initial assessment will improve throughput and waiting times within the CAMHS system leading to increased patient and clinician satisfaction and earlier interventions/diagnosis as appropriate Clinicians would be freed up from chasing further information to supplement their assessment and formulation and this will improve efficiency and release their time for clinical duties.
- We shall facilitate NHS England's ability to benchmark and monitor referrals into CAMHS and the information from the digital referrals process will also aid ICBs to commission services best suited to support local need.
- We shall influence policy and practice through direct contact with NHS partners and governments and by feeding information about referral over time and different regions. Many of our project team and collaborators are influencers at national and regional policy level (e.g. Abel; Chitsabesan; Ranote; Jiva). We shall also input directly to professional groups (e.g. Faculty of Child and Adolescent Psychiatry).

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

The study uses a mixed method design, including: :

- Extensive stakeholder consultation relating to design information for the digital tool through focus groups, workshops and semi-structured interviews (Qualitative).Analysis of how people use and engage with the newly developed CAMHS referral tool (Quantitative – engagement and usage metrics; qualitative – semi-structured interviews.
- Analysis of successful referral rates compared to traditional modes of referrals.
- Designing, developing and testing a digital referral tool using Agile approaches.

4.1 Data Collection

Work Package 1 (WP1), Months 3-12 (Leads: MQ, PW, PB) - Requirements Prioritisation

Aims:

- We shall hold 2 x roundtable events (Manchester and London) to gather feedback and input from senior stakeholders (e.g. NHS England senior leaders; commissioners, CAMHS leaders).
- With our partner MQ, we shall conduct 6 stakeholder focus groups with CYP, families/carers and professionals including GPs, to collaboratively prioritise requirements (identified in EN-CAMHS 1) for the revised digital tool. We aim to recruit up to 10 stakeholders per group, therefore 60 participants in total. We shall use the MoSCoW prioritisation method [29] collaboratively as we have done in a number of other NIHR funded digital health projects. As part of this prioritisation process, each of the existing 11 interactive CAMHS referral forms created by individual CAMHS in England will be rated using the System Usability Scale [30] and using criteria from the EN-CAMHS 1 focus groups (e.g. navigability, clarity of language, accessibility).

The technical project team will use the information from the roundtable and stakeholder meetings about the broader technical mental health landscape alongside their expert digital health software knowledge to develop a set of technical standards relevant for the CAMHS referral process. The costed software engineer will align with and extend existing NHS referral standards and interoperability standards to achieve this aim.

Work Package 2 (WP2) (PW, RE, JEC, Digital Health Software Team, VB): Months 3-12 - Co-Design and Tool Implementation

Aims:

- Onboard 5-8 CAMHS providers (with different characteristics and served populations) who are willing and can support an evaluation of the digitally-enhanced CAMHS tool in collaboration with our partners, NHS England.
- Workshops with 5-8 Trust staff from each provider.
- Co-design the tool with CAMHS stakeholders (2 x 1-hour workshops with 25 referrers).
- Ensure accessibility support (WCAG2.2 and assistive technology, translations of the tools etc) is extensive and supports needs identified by stakeholder consultation (Digital Accessibility Working Group n=10) and in collaboration with PPIE, YPAG and PPAG. This group will be formed from the project with characteristics derived from accessibility needs identified in the stakeholder codesign groups and from ENCAMHS 1. This group shall meet twice during the co-design process to review the tool and suggest accessibility enhancements. Every effort will be made to incorporate suggestions made by this group into the digital tool.

National and locally relevant content (e.g. links to alternative sources of help) will be developed in collaboration with CAMHS professionals at each of the providers and in collaboration with the CAMHS professionals on our research team. We shall run a workshop at each of the chosen providers with 5-8 Trust staff members from different departments, for example, clinical IT, digital strategy, CCIOs, research. These workshops will undertake a full assessment of the capability of the Trust to implement, identify risks to implementation, and create a plan to manage and mitigate them. We have costed a professional content designer to ensure the quality and accessibility of content developed. We have provisional confirmation from the following CAMHS providers for WP2 and WP3: Manchester University NHS Foundation Trust (South Manchester, North Manchester); Greater Manchester Mental Health NHS Foundation Trust (Bolton, Wigan); East London NHS Foundation Trust (South Bedfordshire and Luton).

Our team has worked across many NIHR funded digital mental health projects. We shall use the same approach in this project, developing with an iterative Agile and a user-centred design approach to co-develop the platform. This approach enables the software team to work closely with and respond to the needs of the end user. This will be delivered through (a) user research (b) moderated usability testing with end users. This design approach will follow the below stages:

- Discovery [38]: The discovery phase will draw heavily on the findings of EN-CAMHS 1 and of Work Package 1 of this project. We shall translate these findings into outputs that can be disseminated widely including User Personas (to indicate the profiles of different referrers who will use the system) and User Journey Maps (to show how people will interact with the system at each stage of the process).
- Alpha [39]: Our senior designer will produce prototypes and wireframes to demonstrate the flow of the digital tool in this phase for feedback and review by workshop participants.
- Beta [40]: During this phase, we shall ask at least 5 healthy volunteers to try out the newly-developed tool to ensure it has no critical or major defects and is ready for use in the evaluation in WP3.
- Live [41]: The live version of the platform will be demonstrated in a co-design workshop available for participants to try and provide feedback.

A priority for the digital tool is to be inclusive and accessible to all. We will work collaboratively with our stakeholder groups during the co-design phase to ensure we maximise the accessibility of the tool. From EN-CAMHS 1 we already know that supporting access to translated materials is an important requirement. We aim to go well above and beyond the WCAG 2.2 standards [31] to ensure that the tool we develop has as wide a reach as possible. We shall also beta-test the accessibility with a Digital Accessibility Working Group.

Work Package 3 (WP3): (KMA, PW, VB, LAC, PB, RE, PB) Months 12-24 - Evaluation of Implementation

We aim to:

- Evaluate implementation of the new digitally-enhanced referral process with 60 key referrers.
- Explore the potential, enablers and barriers of embedding a new CAMHS referral mechanism via semi-structured qualitative interviews with 25 referrers.
- Develop a blueprint and toolkit for CAMHS to implement the referral tool.
- Understand if and how the tool enhances the CAMHS referral process.

A mixed-methods, non-randomised evaluation of implementation with 60 CAMHS referrers across 5-8 CAMHS. CAMHS sites and referrers will be chosen to reflect the diversity of the current CAMHS landscape. 9 CAMHS sites have indicated their support for working with us on the evaluation. We shall evaluate usage and acceptability data collected from referrers which combine quantitative data on engagement and usage with qualitative data from semi-structured interviews with 25 referrers.

We shall use the NASSS-CAT toolkit [32] to guide the implementation and evaluation of the digital tool across CAMHS sites. This entails running a NASSS-CAT workshop with key stakeholders from each CAMHS service in order to introduce and complete the assessment as well as create a risk management and mitigation plan. The workshop will identify gaps in information that will need to be identified and incorporated. Once this is done, the risk plan will be regularly reviewed throughout the implementation process. Insights from this will be turned into an implementation toolkit that sets out a standardised evidence-based approach along with common risks and how they can be managed or mitigated. We shall also use the NASSS-CAT implementation toolkit to explore the potential, enablers and barriers of embedding a new CAMHS referral mechanism across different types of referrers and across CAMHS with various configurations. The NASSS-CAT toolkit will be used to guide implementation discussions with key stakeholders. Specifically, we will use the NASSS framework to address key considerations for the implementation digital transformation covering the key NASSS areas: the illness/condition in question; the technology; the value proposition; the intended adopters; the organisation; external context for innovation. The questions from the NASSS-CAT toolkit on these areas will be tailored for the EN-CAMHS project and used to structure the topic guides for interviewers with referrers.

We shall collect referral data from each referrer and from the CAMHS site referred into. We shall collect number of referrals made via the digital tools and numbers made by traditional referral mechanisms. We shall collect usage and engagement data with the tool, including numbers of referrals completed to an endpoint (either referral sent to CAMHS or to alternative help). We shall collect data on accepted/rejected referrals made by participant referrers to CAMHS using a) the tool and b) traditional modes of referral. Co-design workshops with each CAMHS provider will help us understand which data can be captured, and how each provider records the data.

We shall conduct semi-structured qualitative interviews with 25 referrers (including CYP and their families/carers as well as professional referrers) to understand the usability and acceptability of the new referral process. Interview schedules will be developed in collaboration with our YPAG and PPAG to explore experiences of using the new referral process: usability, content quality, barriers/enablers and any future refinements. The interview schedules will be informed by two recognised theoretical frameworks to assess intervention development, implementation and sustainability (NASSS, NPT [33]) and will focus on how the intervention becomes/does not become incorporated and sustained in practice. We shall use the mechanisms defined by NPT (coherence, cognitive participation, collective action and reflexive action) to structure the topic guides for interviewers with referrers. This will enable us to explore and analyse the implementation of the digital tool collaboratively. Interviews will be conducted by a Research Associate trained and experienced in qualitative methods. Consenting participants will be interviewed for up to one hour at a convenient location and transcribed verbatim.

Work Package 4, (WP4): (MQ, KMA, PW) Months 6-30 - Sustainability Planning

The charity MQ Mental Health Research was a key partner to EN-CAMHS 1. We plan to continue this successful partnership in EN-CAMHS 2. In this WP4, MQ will drive the sustainability of the EN-CAMHS tools. MQ are actively engaged in discussions with the Prudence Trust about longer-term sustainability support for the platform. MQ aim to collaborate to drive and support the tools' implementation, nationally if possible. This will require lobbying key national stakeholders (including senior policymakers, regional ICB leads, mental health professional bodies) to support implementation of the platform for the medium and longer terms, beyond the lifetime of this grant. MQ have secured funding from the Prudence Trust to support longer term sustainability for the referral tool and enhanced referral processes developed through this project. MQ will work to secure alternative longer term sustainability solutions through a piece of work called 'FORESIGHT' which will be delivered in three overlapping phases, complementing deliverables within ENCAMHS 2.

PPIE

PPIE is deeply embedded across all elements of the project. EN-CAMHS 1 achieved a national award for the breadth and depth of PPIE activities. We shall expand this achievement in EN-CAMHS 2. Our YPAG and PPAG alongside widespread consultation with CAMHS stakeholders will ensure we engage extensively with diverse CAMHS stakeholders, including CYP, parents and families. Our recruitment to PPIE activities will aim for contributors from across key demographics aiming to include groups typically under-represented especially those parents with mental illness as well as parents and families living in deprivation and some Black and migrant ethnic minority groups. The YPAG and PPAG will be consulted bi-monthly throughout the project and advise across all work packages. We will leverage the extensive networks of underserved local communities and networks of the Greater Manchester Applied Research Collaboration as well as the Young People's Panel and the GM Forum (CoI Bee is a lead of the mental health theme of the GM ARC). CYP, parents/carers and professionals involved in the YPAG, PPAG and PMG will have substantial involvement across the project. PPIE contributors will be reimbursed for their time and expenses and will have access to UoM training for public contributors (and/or we will support with our own induction . There will be at least 2 members (1 from YPAG, 1 from PPAG) invited to attend the PMG monthly meeting. A PPI impact log will be used throughout to support team-wide discussion and reflection on levels of engagement/involvement, thus ensuring the level of contribution is appropriate.

See below breakdown of involvement at every stage of the project, as illustrated in the flow diagram:

Set up phase: YPAG and PPAG formed; contributing to focus group topic generation; regular input at PMGs, YPAG and PPAG meetings.

WP1: YP, parent & stakeholder input to prioritise 'wants'; input to focus groups; regular input at PMGs and PPAG, YPAG meetings.

WP2: CAMHS referrers (including children and young people, parents & families) co - design tool; regular input at PMGs & PPAG, YPAG meetings.

WP3: YP, parent and stakeholder input to emerging data analysis; regular input at PMGs and PPAG, YPAG meetings.

WP4: regular input at PMGs & PPAG, YPAG meetings.

Analysis and write up phase: YPAG & PPAG will be consulted in the analysis process, interpretation and dissemination of findings; regular input at PMGs, YPAG and PPAG meetings.

4.2 Data Analysis

In WP1, data from the roundtables shall not be formally analysed but insights gained will be developed into a report and used throughout the project, and specifically to inform the background context for the prioritisation and standards development of the digital referral tool. Where a consensus on priorities cannot be reached within or across workshops, the research team, in close collaboration with the advisory groups, will make the final decisions using a Consensus Voting approach.

In WP2, we shall design a standards-compliant technical architecture for the system, emphasising the need for interoperability with NHS systems. This will include consideration of how the tool complies with NHS referral standards (e.g. BaRS standard [34]) and with the NHS app [35]. We shall also undertake an assessment of each CAMHS service's capacity and capability to implement the referral tool using the empirical NASSS framework [36]. We will employ a light touch version of the framework to assess CAMHS site's suitability to participate in the programme. We will then run a workshop with each of the chosen sites to undertake a full assessment of their capability to implement, identify risks to implementation, create a plan to manage and mitigate them.

Our user-centred co-design approach will follow the UK's Government Digital Standards approach across the four stages of User Research: Discovery, Alpha, Beta, Live [37]. Each of the first two phases, described above, will involve a 1-hour co-design workshop with key stakeholders (n=25 key referrers, including GP, school and health professionals, CYP, families and carers). Our aim to include a diversity of referrers (including diversity of: referrer type; demographics; urban/rural; CAMHS configuration – where applicable; personal characteristics of CYP referred – key diversity elements are drawn from our work in EN-CAMHS 1.)

WP3 Quantitative data analysis: We shall evaluate how referrers engage with the referral tool analysing engagement / usage analytics from the digital tool following the AMUsED framework [42]. Specifically, we will summarise usage over time to evaluate whether it is an acceptable referral

method and we will explore whether this differs between type of referrer. We shall explore 'effective engagement' with the tool: the ability of referrers to complete a successful referral with the tool. A successful referral can mean either a referral to CAMHS or to an alternative source of support for the CYP. We shall analyse the rate of successful referrals made using the tools against those made using traditional referral processes.

Qualitative data analysis: We will conduct qualitative interviews (n=25) with referrers who have used the digital tool to highlight any potential barriers to implementation. Additionally, WP3 Qualitative data analysis: Anonymised transcripts will be analysed using NATCEN Framework Analysis methodology set out by Ritchie and Spencer [43], outlined in Ritchie et al. [44], and using Nvivo 12, as this has a Framework Matrices Tool [45], allowing for both inductive and deductive coding. Coders will meet regularly to discuss codes and develop a provisional framework. During constant comparison of new data, this provisional framework will be amended to accommodate new codes and remove old codes that become superfluous. The final coding framework will be presented to the study advisory group to ensure interpretations of data remain grounded in the experience of mental health services. Analysis will occur in parallel to data collection. The whole team will agree when data saturation has occurred.

5 STUDY SETTING

This is a multi-site study. The referral data collection will involve 5-8 CAMHS sites from various regional providers. The collaborating sites will be selected to: target the areas of high need for CYP mental health; reflect diversity in terms of urban/rural locations; ethnicity of service user population; diversity in configuration of CAMHS services/CAMHS offer.

The stakeholder and Trust staff consultations, i.e. roundtables, focus groups, workshops and semi-structured interviews, will be held both virtually and face-to-face. Virtual consultations will be facilitated via Microsoft Teams. If any sessions are held in person, these will be held at different locations to ensure they are as accessible as possible, for example, central locations in both the South and North of England.

Quantitative data reflecting usage and engagement will be collected using inbuilt analytics.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

6.1.1 Inclusion criteria

Throughout the project, participants will be included if they are:

- Aged 16+.
- CAMHS Stakeholders who have experience with the CAMHS referral process since 2019, these may include:
    - CAMHS Staff: we will include any staff who currently work in CAMHS services.
    - Collaborators: We will include collaborators who have direct experience of the current referral process for CAMHS.
    - CYP: We will be recruiting CYP who have been referred to CAMHS regardless of whether they were accepted into the service or not.

- Key referrers: We would ask that these individuals have had experience referring CYP to CAMHS, regardless of how many times.
- Parents/carers: we will ask parents/carers who have experience of their child or a child in their care having been referred to CAMHS, regardless of the outcome of the referral.
- CAMHS Commissioners: We will ask Commissioners who understand the current CAMHS referral processes locally or nationally, and who are involved in the funding process.
- Mental Health Leads: We will invite people with a strategic overview of the CAMHS referral process locally or nationally to share their experiences of the referral process.
- Any individuals identified through earlier WPs as key to the CAMHS referral process.

- Able to provide informed consent.
- Be proficient in English.

6.1.2 Exclusion criteria

- Participants must be able to speak English at a basic level.
- Participants must have good internet access to take part in the online consultations.
- Participants have not had experience with the CAMHS referral process.

We will inform participants during the consent process (i.e. in the PIS and subsequent discussions) that there may be discussion which they could find upsetting, and we have a distress protocol in place for if anyone needs additional support, but that this should be considered when agreeing to take part in the study.

6.2 Sampling

6.2.1 Size of sample

In WP1, we shall recruit 60 key CAMHS stakeholders (CYP, parents and carers, key referrers and CAMHS professionals) to 6 focus groups (10 participants per group).

In WP2, we shall recruit 5-8 CAMHS providers, with 5-8 members of Trust staff from each provider to participate in a workshop (25-64 staff in total). 2 1-hour co-design workshops will also be held with 25 key referrers in each group. A maximum of 10 stakeholders shall be recruited to form the Digital Accessibility Working Group (n=10 CYP/families and professional referrers); a group formed from the project with characteristics derived from accessibility needs identified in the stakeholder co-design groups and from EN-CAMHS 1. This group shall meet twice during the co-design process to review the tool and suggest accessibility enhancements. Every effort will be made to incorporate suggestions made by this group into the digital tool, within the time and resource limitations of the project

In WP3, we shall recruit 60 key referrers across all sites for quantitative data collection. 25 of the key referrals will also participate in qualitative semi-structured interviews.

The sample size across the project will be made up of:

- WP1 - 6 focus groups - we aim to recruit 60 stakeholders (6-10 per group).
- WP2 - onboard 5-8 CAMHS providers, 1-hour co-design workshop with each provider (n=25), Accessibility working group n=10. 2 co-design workshops with up to 25 participants in each (n=50).
- WP3 - 60 referrers to use the tool, semi-structured interviews with 25 referrers.

6.2.2 Sampling technique

In WP1 and WP2, we shall use purposive sampling to recruit a diverse group of CAMHS stakeholders and Trust staff for focus groups.

In WP3, we shall use purposive sampling to include a diversity of referrers. We shall aim for diversity in terms of: type of referrer (GP, school, self-referrer, social care); CAMHS configuration (provision of service; location of CAMHS urban/rural) and by key individual characteristics of the referrer (age, ethnicity, spoken language etc). We shall aim to make the sample of referrers representative of the proportions of the different referers that refer into CAMHS. That would mean more GPs than other referrers. The diversity of CAMHS configuration will be drawn from the data from EN-CAMHS 1 and with respect to relevant recent changes to the CAMHS landscape identified in WP1.

6.3 Recruitment

6.3.1 Sample identification

In WP1, we shall hold a combination of stakeholder specific and mixed stakeholder groups. Attendees can choose which type of group they feel most comfortable attending. Across the 6 focus groups we aim to recruit 60 participants representing a diversity of referrer type (CYP, GP, health, social care, educational professional, CAMHS workers, families), and also designed to incorporate the diversity within each referrer type found in EN-CAMHS 1. Identification and recruitment of stakeholders will be extensively supported by our partner MQ.

In WP3, we shall recruit referrers from across the study CAMHS sites. Senior stakeholder collaborators will be consulted to ensure the project achieves the most appropriate mix of CAMHS providers to optimise widespread applicability of the new tool. We shall work with 60 referrers to test the new referral process. We shall specifically aim to ensure appropriate diversity to test if the translated and culturally-sensitive materials we develop are fit for purpose.

We have not used power calculations for detecting effect sizes in this evaluation, as hypothesis testing is not the aim. Our aims are to 1) recruit participants to test different user experiences (opportunities and challenges) that arise as a result of using tool and; 2) to capture a diversity of: referrer types (GPs, school staff, social care professionals, parents/carers); within-referrer characteristics (age, gender, ethnicity, dis/ability); CAMHS provider (CAMHS configuration; rural/urban). Our purposive sampling approach will be targeted at maximising the diversity of referrers and CAMHS sites and supporting accessibility testing of the tool. Our sampling strategy will be informed by our diversity data from EN-CAMHS 1 and by the stakeholders consultations in WP1.

Identification and recruitment of CAMHS professional stakeholders will be supported by our extensive network of CAMHS collaborators. Recruitment of key referrers is supported by our school and primary care collaborators, as well as links to key referrers provided by our CAMHS sites. We will not directly target individuals, just share adverts about the study around collaborating organisations and networks.

Recruitment of CYP and their families will be supported by our CAMHS networks, adverts on social media and websites, and our third sector collaborators (MQ, Calm Connections, Anna Freud Centre).

We shall extend our focus group invitations beyond our collaborating sites to ensure we capture a wide diversity of CAMHS stakeholder perspectives.

6.3.2 Consent

All potential participants will be asked to provide informed consent to participate in any of the data collection stages i.e. roundtables, focus groups, workshops, testing the tool, quantitative data collection, or semi-structured interviews. They will be provided with a Participant Information Sheet and Consent Form.

Once a potential participant has expressed interest in taking part in the relevant data collection stage they will have the opportunity to review the Participant Information Sheet and Consent Form which are integrated into the referral form. The Information Sheet will detail the nature and objectives of the study and has been developed in accordance with NHS guidance. The information sheet and the consent form will be developed in consultation with both our YPAG and PPAG.

Participants will be given sufficient time to understand the information they are given and to weigh up the information in order to make an informed decision. They will be given the opportunity to ask any questions about the research if they want to and will be given the option of a Microsoft Teams meeting or telephone call with a member of the study team to ask any questions about the research. The Consent Form will be collected prior to the relevant data collection stage through the digital referral tool, therefore only written, electronic consent will be sought and obtained. Participation is voluntary and participants will be informed that they have the right to withdraw at any time without giving a reason. As per the Consent Form, any previous information collected from research activity participation before withdrawal will still be used in the study. As the Consent Form is integrated in the digital referral tool, participants will have 24 hours to decide whether or not to take part.

6.3.3 Payment

PPI Payment will follow the NIHR INVOLVE recommended rates. CYP and parents/carers will be paid for their involvement in the focus groups, at a rate of £25 per hour of activity. Professional CAMHS stakeholders will not be offered payment, unless agreed otherwise. We will be asking professional stakeholders to join focus groups during the working day for which they are paid, and therefore we will not be paying them for their time. We have included ‘unless agreed otherwise’ to allow for a discussion for any individuals who may have to take time out of work to participate, as then we will pay them for their involvement.

7 ETHICAL AND REGULATORY CONSIDERATIONS

The project will require NHS Ethics and HRA approvals, and UREC approval for WP1. As a project team, we have extensive experience completing ethical applications. All our previous NHS Ethics and HRA applications have received approval. We shall address a number of ethical issues throughout the study, including: informed consent, data confidentiality, safety, burden, distress and risk.

7.1 Assessment and management of risk

7.1.1 Consent and Safeguarding

We have extensive experience of obtaining informed consent from participants in digital health research. We shall follow standard ethical procedures for gaining informed consent from participants in research studies. An information sheet and consent form approved by the ethical committee describing the study will be provided to all potential participants.

Consent will be confirmed at the beginning of the focus groups, roundtables, workshops and semi-structured interviews, and participants will be reminded that they can leave the discussion at any time, without giving an explanation. The consultations will be facilitated by at least 2 researchers who will aim to ensure that a friendly and positive environment is created.

Participants may be asked about their experiences with the CAMHS referral system, either as professionals, referrers, parents/carers or CYP themselves.

We do not envisage that the consultations will be distressing for professional participants. For parents/carers or CYP who have had difficult experiences with the referral process, discussing their experiences may be distressing. For this reason, we have developed a distress protocol which the research team will follow if people are affected by the topics within the focus groups and want to seek help. Participants will also have the option to leave to join a breakout room with one researcher if needed. We do not expect there to be significant safety, burden or distress and risk issues to address, therefore research activities are unlikely to cover topics which result in distress. Our digital tool is a supportive referral tool to enable appropriate CAMHS referrals to be made. The tool will contain links to local sources of mental health support, and will clarify that it is not to be used for crisis support. It will contain links to emergency support lines and advise users in distress to contact the relevant support services (GP, A&E, 111).

We do anticipate some CYP and their parents might want to discuss their problems and get advice. We have included in our Information sheet that we are not asking anyone to share details of their own mental health, but based on this feedback, we have made this clearer and included that we will not be offering advice or guidance on the referral process or about people's mental health issues. We will also make sure to include this statement at the beginning of all stakeholder consultations, to remind participants that we are not asking them to share their mental health problems.

7.1.2 Data security, protection and confidentiality

Data security, data protection and confidentiality are particularly relevant to the development and implementation of our CAMHS referral digital tools. The following issues will be addressed:

- Information and research governance and data protection/GDPR compliance will be overseen by the University of Manchester Information Governance team, supplemented by specialist health informatics data security and confidentiality guidance from the Centre for Health Informatics, University of Manchester.
- A data management plan, following University of Manchester policy, will be developed by the project team, and reviewed and updated throughout the lifetime of the project.
- Data access will be strictly controlled and only available to authorised users.
- Data sharing agreements will be established between organisations and sites as required. This will be overseen by the Sponsor (GMMH) and also supported by the University of Manchester Information Governance and Contracts team.
- Embedding the CAMHS referral tools within CAMH sites will be through close collaboration with the IM&T teams at the 5-8 Trusts. All appropriate NHS Information Governance data security standards will be complied with.

- The importance of respecting each other will be discussed with all participants at the start of stakeholder consultations, it will be made clear that they should not talk about what other people have said outside of the discussion. Participants will not be asked to share specific personally identifiable information during the consultations, but they may spontaneously share information.
- The semi-structured interviews will be recorded and transcribed. During transcription, all identifiable information will be removed, and the recording deleted permanently afterwards.
- Focus groups, workshops and roundtables will not be recorded, and members of the research team will take notes during these consultations.

7.1.3 Safety, Burden, Distress and Risks

We do not expect there to be significant safety, burden or distress and risk issues to address: our digital tool is a supportive referral tool to enable appropriate CAMHS referrals to be made. As we have done in other studies, we have developed a distress protocol which the research team will follow if people are affected by the topics within the focus groups and want to seek help. It will contain links to emergency support lines and advise users in distress to contact the relevant support services (GP, A&E, 111).

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC on the study protocol, informed consent forms and other relevant documents e.g. advertisements. The Chief Investigator will produce progress reports as required and the Principal Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Principal Investigator will notify the REC, including the reasons for the premature termination. All correspondence with the REC will be retained.

Within one year after the end of the study, the Principal Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

7.2.1 Amendments

For substantial amendments to the REC application or the supporting documents, the research team shall submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the responsibility of the Sponsor to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Substantial amendments that require review by the Sponsor will not be implemented until the Sponsor returns an approved amendment form which will then be submitted via IRAS. Any substantial change to an approved project should be submitted for approval as a project amendment. This will be done by the Project Manager via the IRAS system and will be reviewed by the PI. Guidance for how to submit an amendment can be found on the IRAS website under the heading of Amendment guidance - all review bodies. Any substantial amendments will be communicated to the relevant stakeholders at project meetings or via email.

A log of all amendments will be tracked in the protocol to identify the most recent protocol version.

7.3 Peer review

The study underwent independent peer review by research experts in the area by the National Institute for Health Research prior to the Principal Investigator receiving funding for this project.

7.4 Patient and Public Involvement

We will hold bimonthly 1-hour meetings with our Young Persons Advisory Group (YPAG, n=6-10) and quarterly meetings with our Parents/Carers and Professionals Advisory Group (PPAG; n=6-10). We will establish mechanisms for incorporating feedback from these groups into our work, ensuring young people and their parents/carers/families influence decision making.

All potential Young Person's advisory group members will be provided with an Information Sheet and Consent Form via email. The Information Sheet will detail the nature and objectives of the study and will be developed in accordance with NHS guidance. Members will be given sufficient time to understand the information they are given and to weigh up the information in order to make an informed decision. They will be given the opportunity to ask any questions about the research if they want to. The Consent form will be collected prior to them joining the advisory group via email or post. Participation is voluntary and members will be informed that they have the right to withdraw at any time without giving a reason.

PPAG members will not need to complete a consent form.

YPAG and PPAG members will be paid £25 for their attendance at each advisory group meeting (a maximum of 10), both based on the NIHR INVOLVE's guidance.

We will work with our YPAG and PPAG to develop the topic guide for the stakeholder focus groups. We will feed back the discussions of the advisory groups for consideration at the focus groups in an iterative manner to allow the topic content to evolve. Process/pathway mapping outcomes and data analysis will be discussed at the YPAG/PPAG meetings. This will a) ensure the advisory groups are informed about emerging findings b) identify any gaps/problems in the data and analysis c) ensure the direction of the research remains aligned with their priorities. Our PPI groups and activities will be fully supported throughout the project.

7.5 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Principal Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Principal Investigator 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. Different arrangements for NHS and non NHS sites are described as relevant.

For any amendment to the study, the Principal Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Principal Investigator 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.

7.7 Indemnity

This study is sponsored by Greater Manchester Mental Health NHS Foundation Trust and standard GMMH insurance and indemnity will apply.

7.8 Access to the final study dataset

The co-PIs, the Project Manager, the project researchers, the statistician, and the qualitative analyst will have access to the final study dataset. Other members of the research team will be allowed access if a formal request describing their plans is approved by the steering group.

8 DISSEMINATION POLICY

8.1 Dissemination policy

The datasets arising from the study will be protected by know-how, copyright and database rights (which are automatic rights and do not need to be registered). The copyright for the foreground IP will be held by GMMH.

The draft final report will be due to the NIHR two weeks after the end of the contract. The NIHR will contact the team at least three months before this time with more specific advice. Further guidance on writing the draft final report can be found on the Information for Authors webpage. This guidance is regularly updated and will change during the lifespan of the project. We must make sure to use the most up to date guidance when drafting the report.

8.2 Outputs

Key indicators of success will be defined by the following criteria:

- Digital referral platform successfully tested across minimum 5 CAMHS.
- Stakeholders successfully recruited to roundtable events and prioritisation of features consultation.
- CAMHS referral technical standards defined.
- Co-design of digital tool completed with outputs produced and published.
- Quantitative referral data collected and analysed from CAMHS sites. A reduction in the proportion of unsuccessful referrals is achieved when made through the ENCAMHS platform compared to the usual referral processes.
- Following AMUsEd framework, engagement and usage metrics with the digital platform demonstrate that the platform is usable and acceptable to referrers.
- Qualitative intervention data successfully collected and analysed. Qualitative interviews demonstrate usability and acceptability of the platform to referrers and key stakeholders, including GPs, school staff, health and educational professionals and CYP and families/carers themselves. Qualitative interviews demonstrate a preference for the platform by referrers and key stakeholders, including GPs, school staff, health and educational professionals and CYP and families/carers themselves.
- Evaluation successfully completed.
- Sustainability plan developed that secures future plan for the CAMHS digital tool supported for use within the NHS.

Specific outputs for WP1

- Report detailing the changing CAMHS landscape (from roundtables) and how the digital tool aligns with newly configured CAMH services.
- Clear set of priorities and requirements for the revised CAMHS referral process, ranked by Must Have, Should Have, Could Have and Won’t Have (MoSCoW) to enable the technical build in Work Package 2.
- A set of technical referral standards for the digital tool for development in WP2.

Finally, we aim to produce 4 peer-reviewed academic publications during the project.

8.3 Dissemination Strategy

Policy Input: We shall influence policy and practice through direct contact with NHS partners and governments and by feeding information about the digital referral platform over time and different regions. Many of our project team and collaborators are influencers at national and regional policy level (e.g., Abel; Chitsabesan; Ranote; Jiva). We shall also input directly to professional groups (e.g., Faculty of Child and Adolescent Psychiatry).

Website: A page on the GM.Digital Research Unit website will be established and updated regularly throughout the project. It will link to social media feeds which will keep the content fresh and will include project updates in engaging formats accessible for lay audiences. Our collaborator network (particularly the CAMHS.Digital Research Advisory Group) and advisory groups (YPAG and PPAG) will contribute materials (blogs, vlogs, podcasts) which can be shared widely with lay audiences.

Social media: We will not set up a specific media (Twitter, Facebook) account for the project, but instead leverage the combined extensive social media networks of our project team and collaborators including: MQ, Anna Freud Centre, Youth Connection, Calm Connections, GMMH media team. All partners have agreed to help with social media dissemination. We shall also mobilise our collaborator YP and digital collaborators to share project findings through their multimedia channels and networks (e.g., the CAMHS.Digital podcast series).

Dissemination via MQ: Our collaborator MQ, the leading charity for mental health research in the UK, are fully committed partners in this project and costed to support with stakeholder recruitment through their extensive networks, conducting engagement activities such as focus groups and roundtables and dissemination activities, for example, engaging key stakeholders. MQ are also leading WP4 which involves the sustainability of the digital tool, their role within this is to 1) understand how to drive and support implementation nationally and, 2) lobby national stakeholders for support and implementation. MQ collaboration will be coordinated by the project PM and the funded RA.

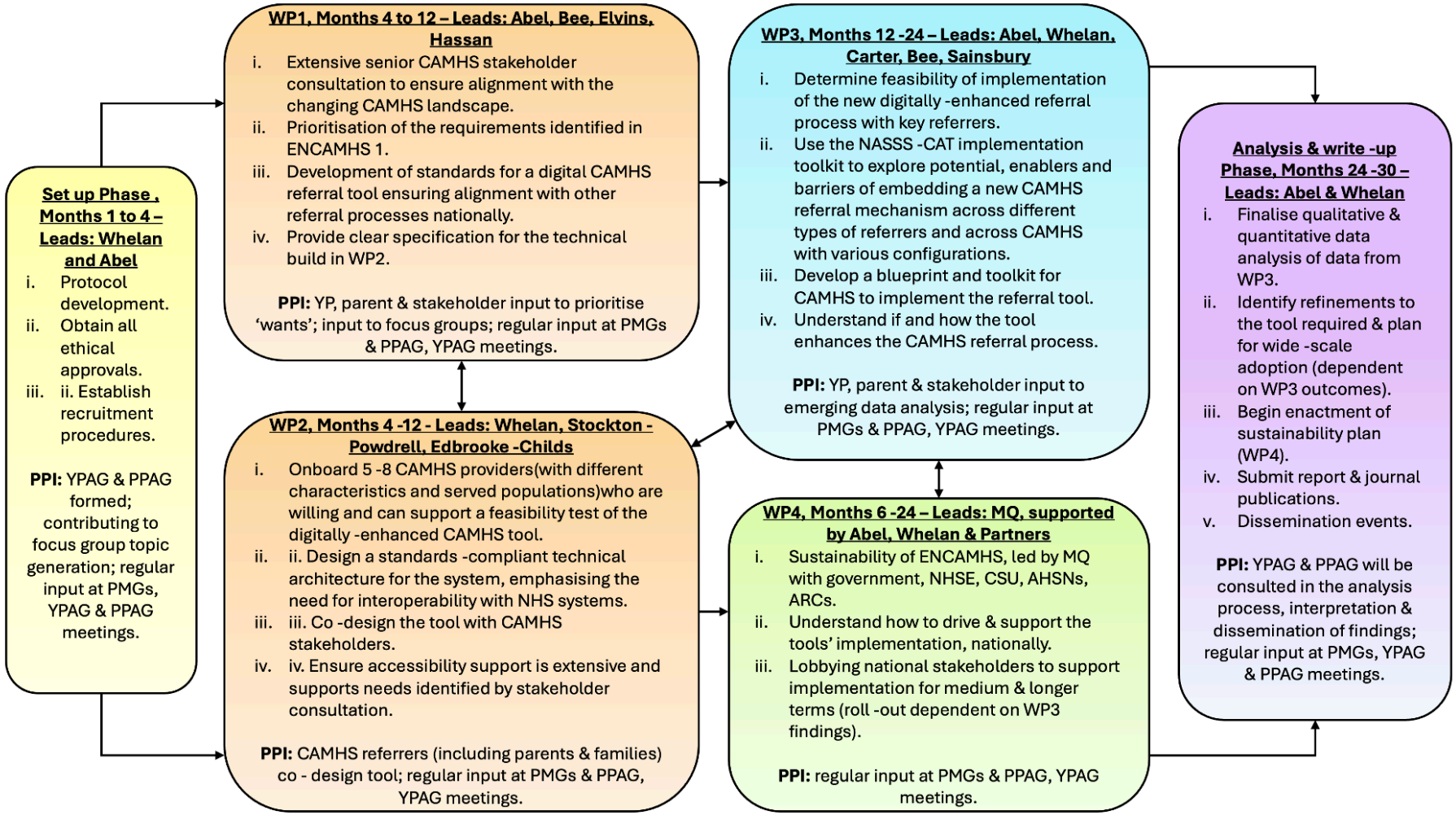
Conference/Webinars/Events: We shall host a series of conferences, webinars and events throughout the duration of the project. We shall host a PPI engagement conference in partnership with our YPAG and PPAG to convey our findings to a public and lay audience. We shall host a stakeholder workshop to present and discuss the findings of this research. We shall exploit our longstanding and extensive connections with national-level NHS representatives (Public Health Leads, DoH Directors of Mental Health, NHS England CAMHS Leads, MQ and Wellcome MH Lead) to convene a round table discussion about how our findings present new avenues for service improvements.

Guidance on disseminating research can be found here: https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research- studies/manage-my-study/How-to-disseminate-your-research/dissemination- guidance.pdf

8.3 Authorship eligibility guidelines and any intended use of professional writers

All study team members who make a substantive contribution to reading and writing the final report will be granted authorship on the final study report.

STUDY FLOW CHART



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10. APPENDICIES

10.1 Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site:

1. CVs of the research team
2. Participant Information Sheet (PIS)
3. Consent Form
4. Demographics Questionnaire

10.2 Appendix 2 – Schedule of Procedures

Procedures	**Visits**				
	Screening	**Baseline**	**WP1**	**WP2**	**WP3**
Informed consent	x		x	x	x
Demographics		x	x	x	x
Focus Group			x		
Workshops				x	
Interview					x

10.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**
	0.1	**08/02/2024**	**HT**	
1	**1.0**	**02/05/2024**	**HT, CSP, LH, LAC**	**Updated version number, changed Principal Investigator phrase to be used consistently throughout, phrase of research question 3 updated, CSP and LH updated their protocol contributors section, small changes to sections 1, 2, 3.2, 4.1 (reviewed by LAC, statistician), 6.3.2, 7.1.2, 8.3, one reference updated.**
2	**1.1**	**24/06/2024**	**KMA**	**PI KMA added comments and made small changes throughout document for HT to address.**

3	**1.2**	**03/07/2025**	**HT, PW**	**Addressed KMA's comments, formatting, changes in sections 2, 3, 4, 6.2.1, 6.3.1, 8.1 (comment from PW), 8.3**
4	**1.3**	**17/07/2025**	**HT, PW**	**PI PW updated protocol contributors, comments on study summary, keywords, 4.1 – comment about formatting of references, additions in WP4, comments on sections - 7.2, 7.4, 8.1, 8.3**
5	**2.0**	**01/09/2025**	**HT**	**HT addressed all comments in sections on previous versions, apart from 1 comment in section 2 (PW) and 1 comment in section 4 (LAC) which needed to be discussed further.**
6	**2.1**	**28/02/2025**	**HT**	**Resolved comments from previous version.** **Sponsor review feedback responded to (Table 1).**
7	**2.2**	**31/03/2025**	**HT**	**Further feedback from Sponsor responded to (Table 2).**

Table 1

Protocol (ensure safety section states all SAEs must be reported to the sponsor)		p. viii - Research questions do not correspond with research questions in the IRAS – please ensure these are consistent Page numbers missing from contents page and incorrect in footers. References to page numbers based on Word toolbar at bottom of page. **1 BACKGROUND** Please clarify how poor quality referrals link to CAMHS being seen as gold standard by families and referrers being unaware of alternative primary care services – perhaps clearer to say that these two factors lead to *inappropriate* referrals. **2 RATIONALE** Incomplete sentence in point 4.

		3 RESEARCH QUESTIONS/AIM(S) Please distinguish between primary and secondary questions/objectives **SECTION 4 STUDY DESIGN (etc.)** p.20 - correct 'realting' to 'relating' p.21 – when listing CAMHS providers please specify which Trust they belong to and then list the locations (e.g. GMMH – Bolton and Wigan CAMHS; Black Country and Healthcare – Sandwell and Dudley) p.22 – please resolve Lesley-Ann Carter's comment p.22 – is this section complete? Stray colon at end of last sentence? p.23-24 - Please remove any content from this paragraph which is not specifically about data analysis and move it to the relevant sections where work packages are described **SECTION 5 STUDY SETTING** p. 25 – please use Teams for video conferencing **SECTION 6 SAMPLE AND RECRUITMENT** p. 26 – please specify which languages are 'supported' p.27 – please clarify sentence 'We shall aim to make the referrers included representative of the propositions of different refers that happens in clinical practice.' p.28 – will participants be given the opportunity to discuss the research with someone over the phone prior to consent, or will all communication be via written media? Please confirm (for clarity) that only written consent is being sought. **7 ETHICAL AND REGULATORY CONSIDERATIONS** p. 29 As per IRAS review, we will need to discuss appropriate IG/GDPR arrangements

		p.30 It is CI's responsibility to produce progress reports, rather than PI. The HRA no longer requires submission of annual reports so please remove relevant sentence. p. 31 – please rephrase sentence so that 'Principal Investigator/Principal Investigator' is removed **STUDY FLOW CHART (p.34)** Should WP2 also have a connector to WP3?

Table 2

Protocol (ensure safety section states all SAEs must be reported to the sponsor)		p. viii - Research questions do not correspond with research questions in the IRAS – please ensure these are consistent addressed Page numbers missing from contents page and incorrect in footers. References to page numbers based on Word toolbar at bottom of page. Addressed Please add page numbers to the table of contents **1 BACKGROUND** Please clarify how poor quality referrals link to CAMHS being seen as gold standard by families and referrers being unaware of alternative primary care services – perhaps clearer to say that these two factors lead to *inappropriate* referrals. Addressed **2 RATIONALE** Incomplete sentence in point 4. addressed **3 RESEARCH QUESTIONS/AIM(S)** Please distinguish between primary and secondary questions/objectives addressed **SECTION 4 STUDY DESIGN (etc.)** p.20 - correct 'realting' to 'relating' addressed p.21 – when listing CAMHS providers please specify which Trust they belong to and then list the locations (e.g. GMMH – Bolton and

		Wigan CAMHS; Black Country and Healthcare – Sandwell and Dudley) addressed Please remove Bedfordshire and Luton NHS Foundation Trust and replace with East London NHS Foundation Trust p.22 – please resolve Lesley-Ann Carter's comment addressed p.22 – is this section complete? Stray colon at end of last sentence? - addressed p.23-24 - Please remove any content from this paragraph which is not specifically about data analysis and move it to the relevant sections where work packages are described addressed **SECTION 5 STUDY SETTING** p. 25 – please use Teams for video conferencing addressed **SECTION 6 SAMPLE AND RECRUITMENT** p. 26 – please specify which languages are 'supported' addressed p.27 – please clarify sentence 'We shall aim to make the referrers included representative of the propositions of different refers that happens in clinical practice.' addressed p.28 – will participants be given the opportunity to discuss the research with someone over the phone prior to consent, or will all communication be via written media? addressed Please confirm (for clarity) that only written consent is being sought. addressed **7 ETHICAL AND REGULATORY CONSIDERATIONS** p. 29 As per IRAS review, we will need to discuss appropriate IG/GDPR arrangements – discussed in meeting with ethics. p.30 It is CI's responsibility to produce progress reports, rather than PI. addressed The HRA no longer requires submission of annual reports so please remove relevant sentence. addressed p. 31 – please rephrase sentence so that 'Principal Investigator/Principal Investigator' is removed addressed

		STUDY FLOW CHART (p.34) Should WP2 also have a connector to WP3? Addressed Some of the original flowchart is visible underneath, please try to remove.