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'Our Digital Health': A Longitudinal Modelling and Digital Diary Study of the digital participation of people with intellectual disabilities

PROTOCOL

Version 1.4 February 2024

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief 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 requirements.

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 publicly available through publication or other dissemination tools without any unnecessary delay, 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: Liverpool John Moores University

Name:	Position:	Signature:	Date:
Professor Keith George	Head of Research		
Chief Investigator:			
Name:	Position:	Signature:	Date:
Dr. Darren Chadwick	Senior Lecturer in Psychology		14/12/23

General Information: This protocol describes the Digital Health Participation of People with Intellectual Disabilities study and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the study should be referred, in the first instance, to the study management group.

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Study Co-ordination

The Digital Health Participation Project is being coordinated by the project team based at John Moores University, Dundee University, Warwick University, Kent University, Gloucestershire University & Dudley Voices for Choice.

This protocol has been developed by the Digital Health Participation Project Study Management Group (SMG).

For all queries please contact the Digital Health Participation team through the main study email address. Any queries will be directed through the Study Manager to either the Chief Investigator or Co-Investigators.

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GLOSSARY OF ABBREVIATIONS

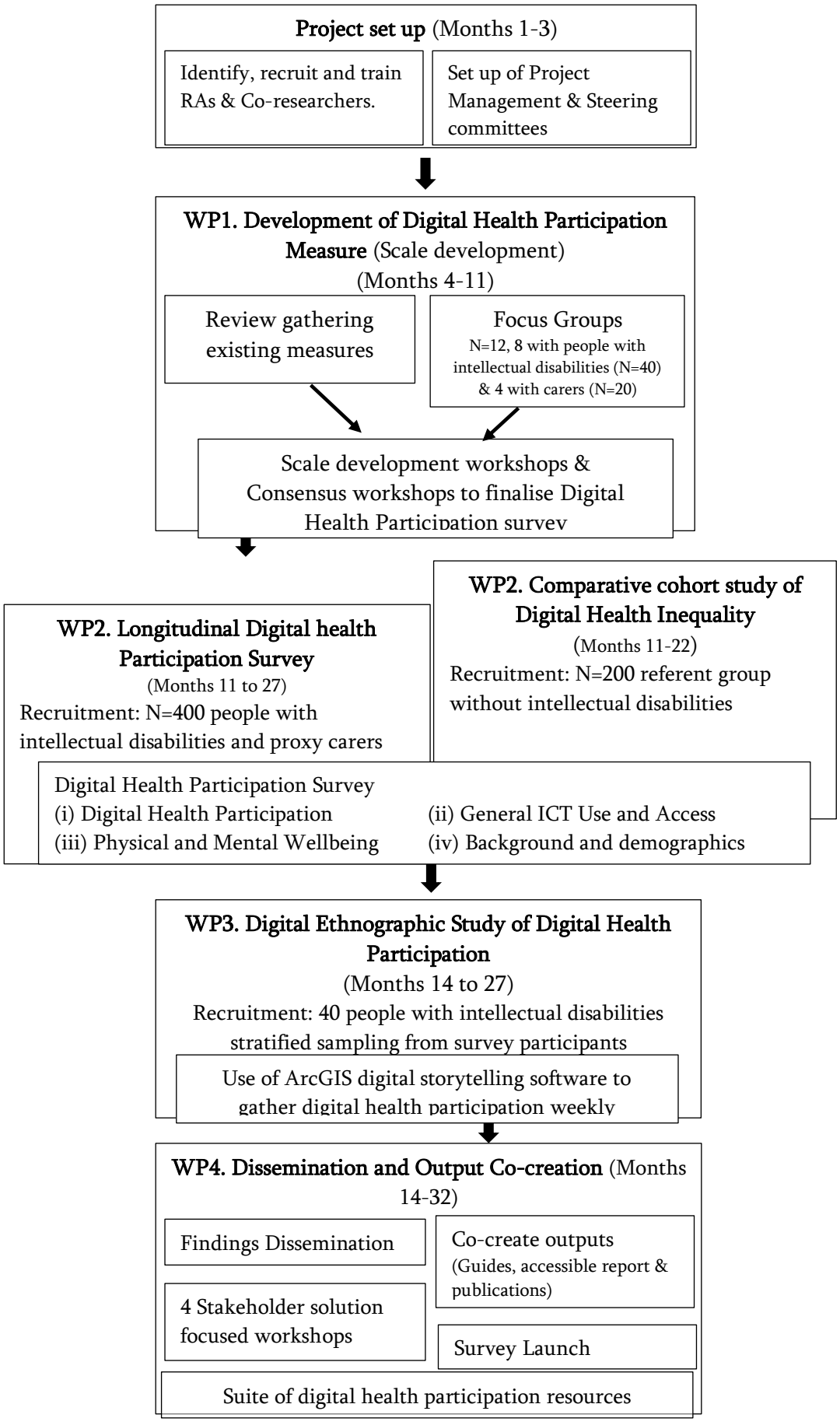
AE	Adverse Event
CF	Consent Form
CI	Chief Investigator
CR	Co-researcher
GAfREC	Governance Arrangements for NHS Research Ethics Committees
GCP	Good Clinical Practice
HSCD	Health & Social Care Delivery
IC	Informed consent
IEC	Independent Ethics Committee
ISF	Investigator Site File
LJMU	Liverpool John Moores University
MMU	Manchester Metropolitan University
NHS	National Health Service
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QL (QoL)	Quality of Life
RAs	Research Associates / Fellows
R&D	Research and Development
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SMF	Study Master File
SMG	Study Management Group
SSC	Study Steering Committee
UD	University of Dundee
UoK	University of Kent
WP	Workpackage

Amendment History

Amendment Number	Protocol Version	Date Issued	Summary of Changes made since previous version
1	**1.2**	**04/08/23**	Added in the funder acknowledgement to the following - National Institute for Health and Care Research as part of the Health and Social Care Delivery Research (HSDR) Programme. This has been added into the publication policy 7.1j section. Updated the funder ref from NIHR – HS&CD – 153571 to HSDR NIHR153571.
2	**1.2**	**01/09/23**	Changed titled from 'Digital Health Participation of People with Intellectual Disabilities: A Longitudinal Modelling and Digital Diary Study' and ''Our Digital Health': A Longitudinal Modelling and Digital Diary Study of the digital participation with intellectual disabilities'
3	**1.3**	**14/12/23**	Additional information requested by ethics committee added to the safeguarding section 4.1.2: For WP3 researchers working on the project will review the diary uploads on a monthly basis as part of data collection monitoring and will contact participants weekly or fortnightly to chat about what data has been collected. Should any data indicate a safeguarding concern this will be referred to the relevant people (local safeguarding team or individual) at the participants location and standard operating procedures for safeguarding at that location will be followed.
4	**1.4**	**26/02/24**	Changed the NIHR logo on title page to the latest NIHR logo Changed version number and date in the header so it is consistent throughout the document Removed the gantt chart in Appendix 2. This is because the NIHR advised that this should be removed as every time there is a change to the timeline, an updated protocol would need to be created.

Study Summary & Flow Diagram

Study Flow Diagram



Study Plain English Summary

People with intellectual disabilities are often excluded from online health provision due to their disabilities and lack of support in using technology to improve and manage their health. This can increase health inequality. It is important that people with intellectual disabilities and their families are included in decisions about health. This research focuses on how people with intellectual disabilities take part in online health provision (called digital health participation). This includes how well people are able to use technology, including the internet, and how people are able to understand and use health information (called health literacy).

The research will take place in four different parts of the UK (in England and Scotland). It will have four parts (called work packages). Part 1 explores how best to measure digital health participation for people with intellectual disabilities. We will review the literature to gather information on current measures. Group discussions will be held with people with intellectual disabilities and their paid and family carers. The information gathered in Part 1 will be used to develop a Digital Health Participation Survey.

In Part 2, a survey will be completed by 400 people with intellectual disabilities, either alone or with support or by their carers. This will include questions about their digital health participation, wellbeing and their background. This survey will be repeated by each person after 8 months. This will tell us about their levels of digital health participation at two time points. We will also survey 200 people without intellectual disabilities to understand their levels of digital and health inequality.

In Part 3, 40 people with intellectual disabilities or carers will be supported to use tablets as a diary to understand their everyday experiences of using digital technology for their health. We will use this information to identify what influences their digital health participation and what it is that excludes them on a day-to-day basis.

Finally, in Part 4, we will run workshops with researchers, people with intellectual disabilities and carers. These will enable us to share our findings and find solutions to improve digital health. We will gather recommendations to inform guidance for improving digital health. The project will end with a large-scale online launch to promote and share the work we have done.

Study Easy read summary

Digital Health Participation Summary

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Digital Health Participation Summary

This project is about how we can include people with learning disabilities better in using technology (the internet, smartphones for example) to support them to feel healthy and well.

The first part of the project we will make a questionnaire to find out how people with learning disabilities do this.

We will do this by:

Finding out how people have done this before. We will do research to find out. This is called a literature review.

Talking to people with learning disabilities and people who support them in focus groups.

These are called group interviews.

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In the second part of the project, we will look at the surveys to see how well people with learning disabilities understand their own health and how much they use technology for their health.

This will include looking on the internet for information about health, e.g. using social media.

Looking online for doctor's appointments and health appointments.

We will ask people to do a survey at two different times. There will be an 8 month gap between the two surveys. This is called longitudinal research.

Dudley Voices for Choice

In the third part of the project, we will talk to people and collect **software** on tablets to see what information they do online.
Software is information.

This will include what health information people have looked at and what activities people access online.

This is called a digital diary study.

We will collect this information over 5 months.

In the fourth part of the project, we will use the information we have collected to make a guidance document, which will offer advice on using technology to stay healthy.

People who support people with learning disabilities will be able to use this to improve people's health, wellbeing and digital access.

NIHR Reference:
HSDR/153571 Digital Health Participation
v1.2 04/08/23

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Research Summary

Background: People with intellectual disabilities experience greater digital exclusion and have poorer health literacy. In the absence of good quality research, health inequalities are likely to worsen leading to poorer health outcomes. Research is needed to better understand digital health participation in people with intellectual disabilities. Via the creation of a valid measure, this investigation will identify the predictors, outcomes and experiences of digital health participation and exclusion among adults with intellectual disabilities.

Primary Aim: To determine levels of digital health participation and inequality among adults with intellectual disabilities.

Secondary Aims: (i) To co-create and produce a digital health participation scale for use with people with intellectual disabilities and their carers; (ii) To identify influences, consequences and support needs of people with intellectual disabilities in their digital health participation; (iii) To longitudinally model factors affecting digital health participation and wellbeing of people with intellectual disabilities; (iv) To determine levels of digital health inequality by comparing digital health participation between people with intellectual disabilities and a referent group of non-disabled people; (v) To explore processes of everyday digital health participation; (vi) To develop interventions to enhance digital health participation of people with intellectual disabilities.

Methods: This is a mixed methods study comprising 4 work-packages (WP) conducted across four study sites (West Midlands (Dudley), North West (Manchester & Liverpool), South East England (Kent), and East Central Scotland (Dundee)): (WP1) Development of a valid and reliable measure of digital health participation via thematic analysis and synthesis of findings from a scoping review of extant measures and 12 focus groups with 40 people with intellectual disabilities and 20 carers; (WP2) Longitudinal survey of 400 people with intellectual disabilities to: a) identify levels of digital health participation; b) determine changes over time and identify causal relationships between aspects of digital health participation and wellbeing, utilising a cross-lagged path analysis, while controlling for demographic and background characteristics; and c) compare digital health participation of people with intellectual disabilities with a non-disabled reference group of 200 people using General Linear Model; (WP3) Digital diary study utilising ArcGIS to thematically explore challenges, facilitators and experiences of digital health participation for 40 adults with intellectual disabilities weekly over 5 months; (WP4) Dissemination and output co-creation

workshops to develop a suite of digital health participation guidance, interventions and supports.

Patient & Public Involvement & Engagement: Patient and public involvement and engagement (PPIE) are meaningfully embedded throughout the lifespan of the project. Partner organisations influenced and informed development of the study plans. A co-researcher at each study site will be recruited to provide ongoing contribution to the project. We have partnered with: Dudley Voices for Choice (Dudley), Advocating Together (Dundee); East Kent Mencap (Kent) and People First (Manchester) who will collaborate with us throughout the project to develop the measure of digital health participation. These partners will also support us to produce study documentation and materials, recruit participants, and co-create and disseminate the outputs from the study. People with intellectual disabilities, carers and other key stakeholder groups will sit on the study Steering Committee and provide oversite of the project. They will also review participant-facing study materials, including the recruitment, training, data collection and dissemination materials.

Anticipated impact and dissemination: Dissemination comprises publication of findings, a national project launch of outputs and international academic conference presentations. Findings will enhance understanding of how digital health participation and exclusion operate for people with intellectual disabilities, antecedents, and the impact on wellbeing. Longer term impacts include improved digitally mediated health related behaviour by people with intellectual disabilities and their carers, and use of the measure of digital health participation and suite of digital health participation support materials in clinical and social care practice.

Keywords

Intellectual disabilities, digital inclusion, health literacy, mixed methods, scale development, longitudinal survey, digital diary

1. Background

1.1 Introduction

People with intellectual disabilities are a heterogeneous group and face a range of challenges in communication, literacy, abstract thinking, reasoning and decision making, and often need support to be included in society (APA,2013).

This population are entitled to healthcare access as a human right without disability discrimination (UNCRPD, 2007). If the UK is to meet its obligations, ascribe to the social inclusion of people with intellectual disabilities, and better enable them to obtain the highest standards of healthcare, then digital health inequalities must be addressed (7,8). People with intellectual disabilities have greater unmet health needs (Emerson, 2021; Krahn & Fox, 2014; Berkman *et al.*, 2011), and are more vulnerable to digital exclusion (Alfredsson Ågren *et al.*, 2020; Chadwick *et al.*, 2022). Despite this, digital participation and its relationship with health literacy has not been adequately investigated (Vázquez et al., 2018), and existing measurements of health literacy are inadequate for those with intellectual disabilities (Geukes *et al.*, 2018). There is increased societal expectation for digital participation and health literacy (i.e. digital health participation) (van Kessel *et al.*, 2022). People with intellectual disabilities are likely to have difficulties engaging with digitally delivered healthcare due to the nature of their disabilities and lack of support to facilitate access (Chadwick *et al.*, 2022). This may unduly impact on both their ability to access digital healthcare and their wellbeing (Chadwick *et al.*, 2022), potentially leading to greater morbidity and mortality. To prevent this, and to inform intervention development, valid, inclusive assessment of digital health participation is needed alongside larger scale research to identify influences, levels, outcomes and processes of digital health participation and inequality.

1.2. Theoretical Framework

People diagnosed with intellectual disabilities are cognitively, genetically and clinically extremely heterogeneous (e.g. Maia *et al.*, 2021; Sajewicz-Radtke *et al.*, 2022). People with intellectual disabilities with more severe and profound levels of cognitive impairment will need greater support to engage with all aspects of life, including healthcare, information and communication technologies (ICT), and research (APA,2013). Similarly, the intersection of

intellectual disability with other characteristics including ethnicity, mental and physical health conditions, advancing age, residential and financial circumstances etc. can also exacerbate social and health exclusion and exclusion from research (Dhamoon & Hankivsky, 2011). To enable full consideration of digital health participation across the population of people with intellectual disabilities strategic research recruitment should be enacted to incorporate heterogeneity and intersectionality (NIHR, 2020; NIHR, 2022).

This study takes a strengths-based approach to digital health participation (Niemiec *et al.*, 2017), to understand the demands of digital health environments that people with intellectual disabilities encounter. In addition, self-determination theory (Deci & Ryan, 1985), a theory of intrinsic motivation which posits that humans are motivated to engage in activities where they experience mastery, autonomy and a sense of relatedness (Wehmeyer, 2020a), is the primary theoretical lens underpinning the study. Self-determination has been strongly linked to quality of life and wellbeing in people with intellectual disabilities (Wehmeyer, 2020b). Teaching of skills related to self-determination has been linked to the achievement of desired outcomes for people with intellectual disabilities (Wehmeyer, 2020a). It is essential that the self-determination of people with intellectual disabilities in relation to digital health participation is enhanced and better understood. Through better understanding of experiences of mastery, autonomy and interactions pertaining to digital literacy and health participation, interventions to support digital health participation can be devised.

People with intellectual disabilities are more likely to experience both digital exclusion (Chadwick *et al.*, 2022; Alfredsson Ågren *et al.*, 2020) and lower levels of health literacy (20). The digital inclusion (16) and health literacy (Latteck & Bruland, 2020; Geukes *et al.*, 2018; Sørensen *et al.*, 2012) of people with intellectual disabilities are influenced by individual (e.g. cognitive, literacy, understanding, self-awareness), interpersonal (e.g. support, communication, education), contextual and societal (e.g. accessibility, residence, employment, finances, attitudes) factors. Taken together, digital inclusion and health literacy demonstrate how effectively people with intellectual disabilities can participate in decisions about their own health. Health literacy refers to the motivation, knowledge, appraisal and application of health information to make healthcare decisions (Vetter *et al.,* 2021). It influences health behaviour, is associated with positive healthcare outcomes, and is a pre-requisite for patient empowerment (Berkman et al., 2011; Crondah & Karlsson, 2016; Chinn, 2014). Measures of health literacy have thus far not adequately considered the experiences of people with intellectual disabilities (Latteck & Bruland, 2020; Chinn, 2014) or the utilisation

of health-related information and communication technologies (ICT) for this population (Sørensen *et al.*, 2012).

Health participation has been highlighted as challenging to define but has been defined as being involved in performing societally expected roles within certain health related domains (Eyssen *et al.*, 2011). Within health participation the expectation for performance is influenced by and impacted on by levels of health literacy, as defined above, and includes health behaviours (e.g. physical activity, maintenance of a healthy diet moderation, abstinence of alcohol intake etc.) (Berkman et al., 2011; Sørensen *et al.*, 2012). More widely, it incorporates processes of engagement with health-related provision and negotiating support (health and dental check-ups and use of primary and tertiary healthcare) (Sørensen *et al.*, 2012; Eyssen *et al.*, 2011; Rifkin, 2014).

Digital inclusion and inequalities have been viewed in relation to technology access, use, and, more recently, participation (Chadwick *et al*., 2019; Chadwick *et al.*, 2022; Alfredsson Ågren *et al.*, 2020). Digital participation refers to people's active involvement as digital citizens in society through the use of ICT (Alfredsson Ågren *et al.*, 2020) and is increasingly being viewed as a human right (Chadwick *et al.*, 2022). Adults with intellectual disabilities are heterogeneous in their internet use (Anrijs *et al.*, 2022), but have been found to seldom use ICT to seek information for themselves or to organise and arrange their own healthcare and support (Alfredsson Ågren *et al.*, 2020). Nonetheless, there is evidence of increasing successful use and motivation to use ICT among people with intellectual disabilities (Chadwick *et al.*, 2022; Alfredsson Ågren *et al.*, 2020). Family carers providing support also experience challenges using ICT to find health information and arrange healthcare support (Chadwick *et al.*, 2022).

For people with intellectual disabilities, measurement of digital participation has tended to focus on digital skills and the frequency of participation in digitally mediated activities (Alfredsson Ågren *et al.*, 2020), with no specific focus on digitally mediated health activity. Due to low methodological quality of existing measures, assessment of intervention efficacy is difficult (Geukes *et al.*, 2018). Thus, there is an urgent need for a valid, reliable and inclusively developed self-report measure of digital health participation (Geukes *et al.*, 2018; Latteck & Bruland, 2020; Kooijmans *et al.*, 2022), incorporating both digital participation and health literacy.

The move towards hybrid (a mix of online and offline) health provision is expected to remain following its increase during the COVID-19 pandemic (Feijt *et al.,* 2020). Such provision offers many advantages (i.e. convenience, efficiency, client disinhibition and greater adherence to treatment) (Feijt *et al.*, 2020). The trajectory of technology is such that, without greater understanding and development of interventions to attenuate the disability digital divide, health inequalities faced by people with intellectual disabilities are likely to widen and worsen (van Kessel *et al.*, 2022). This, in turn, will lead to poorer health outcomes for a group already disproportionately disadvantaged, often having undiagnosed, untreated and unmanaged healthcare needs (Emerson, 2021). There is a need to promote people with intellectual disabilities to become more autonomous, competent actors, with support, in both their digital participation and their health literacy (Latteck & Bruland, 2020; Chadwick et al., 2022). Without valid tools to assess digital health participation it is not possible to determine levels of digital health inequality or to identify factors which influence digital health participation levels to inform interventions and their efficacy (Geukes *et al.,* 2018).

1.3 Study Rationale

It is not currently known what impact increasing use of digital technology in health is having on the wellbeing of people with intellectual disabilities or how digital participation and health literacy interact to affect engagement with health activities. No large-scale comparative studies to identify inequality in relation to digital health participation exist (Geukes *et al.* 2018; Vetter *et al.*, 2021). Empirical evidence to inform interventions by identifying causal factors in reduced digital health participation for people with intellectual disabilities is also lacking (Geukes *et al.,* 2018). Recently, some understanding has been gathered from interview-based studies (Oudshoorn *et al.*, 2020), which, do not provide sufficient information about how the processes of digital health participation operate in daily life. Nonetheless, there is a clear need for further research to provide valid measurement of digital health participation in people with intellectual disabilities, to determine how digital health participation influences wellbeing and to better understand factors influencing digital health participation in the lives of people with intellectual disabilities.

1.4 Aims and objectives

1.4.1 Aim

To determine levels of digital health participation and inequality among adults with intellectual disabilities

1.4.2 Objectives:

Work package 1 (Development of Digital Health Participation Measure**)**

i. To conduct co-production focus groups and workshops to identify areas salient to digital health participation in the lives of people with intellectual disabilities and their carers.
ii. To conduct a literature review to identify existing measures, surveys and interview questions used to elicit information about digital health participation.
iii. To use information from the focus groups and literature review to co-produce a psychometrically valid and inclusive measures of key components of digital participation and health literacy appropriate to people with intellectual disabilities and a proxy measure for carers

Work package 2 (Digital Health Participation Survey – Longitudinal and Comparative Studies)

iv. To use longitudinal data to model factors influencing the digital health participation and wellbeing of people with intellectual disabilities
v. To compare levels of digital health participation between people with intellectual disabilities and a referent group of non-disabled people
vi. To identify influences on digital health participation and the factors that increase the likelihood of digital health inclusion and exclusion

Work package 3 (Digital Diary Study)

vii. To explore processes of digital health participation in the lives of people with intellectual disabilities and their carers day-to-day
viii. To identify processes and sources of support that influence digital participation and health literacy in the lives of people with intellectual disabilities and their carers and identify common support needs
ix. To explore the consequences of digital health inclusion and exclusion the lives of people with intellectual disabilities and their carers

Work package 4 (Dissemination and output co-creation)

x. To synthesise the findings in four solution focussed workshops to co-develop a suite of guides and resources for key stakeholders to enhance digital health participation of people with intellectual disabilities
xi. To provide a psychometrically valid and accessible measure of digital health participation
xii. To disseminate findings to key stakeholders in health and social care and more widely via the launch events and study website

2. Study Design and Methods of Data Collection and Analysis

2.1 Design / Approach

This investigation is a mixed methods study comprising:
(i) Digital health participation scale development and validation via a scoping review of extant measures and focus groups and workshops with people with intellectual disabilities and carers (WP1);
(ii) Longitudinal survey to: (a) identify levels of digital health participation; (b) determine changes over time and identify causal relationships between aspects of digital health participation and wellbeing, utilising a cross-lagged path analysis, while controlling for demographic and background characteristics; and (c) determine levels of digital health inequality of people with intellectual disabilities compared with a non-disabled referent group (WP2);
(iii) Digital diary study utilising ArcGIS storytelling software to explore the challenges, facilitators and experiences of digital health participation.
(iv) Co-creation of resources to better support the digital health participation of people with intellectual disabilities and their carers.

This study will adopt a nuanced approach to digital health participation incorporating: (i) a strengths based approach, drawing on self-determination theory, to discern the skills, independence, and supports pertaining to successful digital health participation (Niemiec *et al.*, 2017; Wehmeyer 2020a, 2020b); (ii) a digital participation framework, including ICT use, access and digital participation; and (iii) a health literacy framework, assessment of which includes access to health information, functional appraisal skills, communicative and social influences and critical health decision making (Chinn, 2014) and should involve people with intellectual disabilities (Chinn, 2014; Geukes et al., 2018; Latteck & Bruland, 2020).

A logic Model for the proposed study is presented in Appendix 1.

The project will be delivered over 32 months across 4 study sites (East Central Scotland – DU; North West England – LJMU & MMU; South East England – UoK; West Midlands England – LJMU). With 3 months for project set up, 8 months for WP1,19 months for WP2, 12 months for WP3 and 13 months for WP4 with overlapping work across 4 sites for WPs 2, 3 and 4. A detailed project plan (Appendix 2), and a summary of key timelines and milestones is provided: Set-up of management and steering groups (m1-3) and staff recruitment (m1-3 and m9-11); WP1 Survey Development (m4-11); WP2 Longitudinal survey (m11-30); WP3 Digital Diary Study (m14-27); WP4 Dissemination & Output Co-creation (m14-16 and 24-32). A schedule of procedures is presented in Appendix 3.

2.2 Project Set up (Months 1-3)

Preliminary and start up tasks will be carried out in the first 3 months of the project. These include the following tasks:
Task 1. Preparation of Ethical Approval and Study Documentation
Task 2. Recruit research associates/fellows (RA) and co-researchers (CR) with intellectual disabilities
Task 3. Provide preliminary project training to RAs and CRs
Task 4. Set up 4 monthly project steering committee (comprising representation from key stakeholder groups: people with intellectual disabilities, staff and family carers, healthcare providers and professionals, digital content providers).
Task 5. Set up monthly management group (comprising the chief and co-investigators and RAs).

2.3 Development of the Digital Health Participation Measure (Months 4-11) - Work Package 1 (WP1).

2.3.1 Scale Development Process

A validated assessment of digital health participation will be developed. This will incorporate recommended stages of scale development (Kooijmans *et al.*, 2022): (i) item generation (via a review of pre-existing scales of digital participation and health literacy and focus groups with people with intellectual disabilities and carers); (ii) creation of the content incorporating adaptations (Kooijmans *et al.*, 2022) to language, response formats and supportive media layouts (enabled by pictorial representations of key aspects of digital health participation

drawn by an illustrator working alongside the co-researcher with intellectual disabilities); (iii) piloting the draft-seeking consensus from people with intellectual disabilities, carers and professional experts; and (iv) psychometric analysis.

2.3.2 Item Identification & Selection

Two parallel processes will be undertaken: (i) a full review of the extant literature and broader practice-based resources and (ii) a series of focus groups with key stakeholder groups.

Review of the literature – Search Strategy

A full review of the literature (Heyvaert et al., 2016) will be conducted to gather existing measures of: ICT use and access (Chadwick *et al.*, 2022); digital literacy; online support; functional, interactional and critical health literacy (Chinn, 2014); and online health activity, access and use. Key words will be generated pertaining to these components of digital health participation for the review. Use of databases (CINHAL, Psychinfo, Medline), hand-searching of references, and communication with authors will all be utilised in the review. Keywords will be adapted for use with each database. In addition, we will put out a call to online networks of service providers and those interested in digital inclusion of people with disabilities to gather existing practice measures.

Studies will be identified via an initial title and abstract screening conducted by the RA and CI. Paper will be included for full screen if they address or incorporate conceptualisations salient to digital health participation and if they have developed or utilised a measure relevant to digital health participation. The search will consider both literature focusing on people with intellectual disabilities and measures and conceptualisations from the broader literature.

Papers included following full screening will be categorised into conceptual papers, empirical papers investigating qualitative and quantitative aspects of digital health participation and papers developing or using existing measures of key concepts detailed above. Conceptual and empirical articles will be tabulated and synthesised into core aspects of digital health participation using thematic analysis (Heyvaert *et al.*, 2016). The psychometric quality (reliability, validity, factor structure) of pre-existing gathered measures will be tabulated and used to inform decision making regarding item inclusion. Full versions of literature and

practice-based measures will be gathered and items will be thematically analysed and grouped conceptually in readiness for scale construction.

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis has been conducted and no current or underway systematic reviews or scoping reviews on the topic of measurement of digital health participation in people with intellectual disabilities have been identified.

Focus Groups with Key Stakeholders

Adults with a diagnosis of intellectual disabilities, their families and paid carers (as proxy participants for people with higher support needs) are the target participant populations. For WP1 focus groups will be conducted at a single time point for each participant at the site University or partner organisation.

Eight focus group meetings with 4-6 people with intellectual disabilities (N=40) and 4 focus groups with 4-6 (N=20) carers, equally split across the four study sites, will be conducted. Data gathered will be analysed inductively to identify digital health participation skills, support processes and contextual influences not considered within existing scales. This equates to a moderately large sample for a qualitative study (Clarke & Braun, 2013). Recruitment into the focus groups will be facilitated by our partner organisations and Birmingham Community Health Care NHS Foundation Trust and maximum variation sampling to provide a breadth of experiences of digital health participation will be employed. Our overall planned accrual rate is 10 participants per month over six months to reach our aim of a final sample size of up to 60.

Participants in these workshops will be offered the opportunity to return for the digital health participation measure co-creation workshops.

2.3.3 Data synthesis and analysis

Items from prior scales and focus group data will be collated and analysed using thematic framework analysis (Gale *et al.*, 2013) to identify key components of digital health participation for people with intellectual disabilities and generate accessible items to assess them. Trustworthiness strategies will be embedded in the qualitative analyses for both WP1 and WP3 (Amankwaa, 2016; Shenton 2004), along with dialogue and checks conducted with research partners (Nyirenda *et al.*, 2020).

2.3.4 Scale Construction

Preliminary scale items will be shared in two co-creation workshops, one with people with intellectual disabilities and another with carers, to develop and work towards reaching consensus (Kooijmans *et al.*, 2022). From these, a long list of items will be generated for the Digital Health Participation Survey (self/supported completion) and Carer Proxy Digital Health Participation Survey. Items in these two measures will mirror each other with the latter containing third person rather than first person text. This measure of digital health participation will comprise: (i) Digital participation: access and use; skills and literacy; self-efficacy; (ii) Support for digital participation; (iii) Health literacy: functional; interactional; critical decision-making; (iv) Frequency and success of engagement in digital health activity (e.g. information seeking, video-consultation, health appointment and communications, use of digital health monitoring devices); (v) Additional inductively derived aspects of digital health participation which do not readily fit with the utilised frameworks. Piloting of the survey will occur with focus group participants prior to roll out in WP2.

A manual for the finalised scales will be developed. This will detail administration for people with intellectual disabilities from independent self-completion, through differing levels of support needs through to full proxy completion for participants with higher support needs, for example, those who are minimally verbal or have profound intellectual and multiple disabilities. Guidance on decision making regarding whether independent, supported or proxy completion is most appropriate will be included within the manual. This decision will be based on level of support needs, literacy, information processing and comprehension considerations. This will enable the measure to be applicable to all people with intellectual disabilities addressing the considerable heterogeneity within this population.

In addition, filtered administration logic will be developed, whereby initial screening by particular overarching questions can remove the need to subsequently answer sub-questions. This will both to reduce participant burden and administration time.

2.3.5 Psychometric Analyses

Validation via exploratory and confirmatory factor analyses and reliability analysis will occur concurrent to WP2 following steps 5 to 9 in Boateng et al. (2018), who also suggest a sample size between N=200-450 is sufficient for psychometric analysis. The analyses will assess items and the underlying factor structures among them. On this basis, some items

may be refined or removed. Confirmatory factor analysis will be used to determine if the hypothesised underlying structure of items is captured by the items (Wang & Wang, 2012). If the hypothesed structure does not provide sufficient model fit, models with different numbers of factors will be compared using likelihood ratio tests (specifically, using AIC and BIC criterion) to establish the most appropriate structure. All models will be reported with robust standard errors and model fit will be evaluated using the comparative fit index (CFI >0.9), Tucker-Lewis Index (TLI >0.9), standard root mean squared residual (SRMR <0.08) and root mean square error of approximation (RMSEA <0.08), (see Wang & Wang, 2012; Hu & Bentler, 1999; Schreiber *et al.*, 2006). We will report the internal consistency of items in the measure using McDonald's Omega (Andrew *et al*., 2020).

2.4 Longitudinal Digital health Participation Survey Study (Months 11-30) and Comparative Study of Digital Health Inequality (Months 11 to 22) - Work Package 2 (WP2).

In this work package we will conduct two inter-linked investigations: A longitudinal survey study to identify factors influencing the digital health participation and wellbeing of people with intellectual disabilities and a comparative study contrasting levels of digital health participation between people with intellectual disabilities and a referent group of non-disabled people.

2.4.1 Longitudinal Survey Study

The digital participation survey (Proxy or Self/supported completion as appropriate) will be administered to a convenience sample of 400 people with intellectual disabilities at two time points eight months apart (+/-1 month). This sample size will enable digital health participation for people with intellectual disabilities to be adequately understood across the breadth and heterogeneity inherent in this population. It will also enable a sufficiently powered analysis to identify moderate effect sizes in relation to predictors of digital health participation.

Survey sampling & recruitment

Adults with a diagnosis of intellectual disabilities and the family and paid carers (as proxy participants for people with higher support needs) are the target population. Taking a whole population approach, and to increase geographical diversity, a self-selecting sample of 400 adults with intellectual disabilities will be recruited equally from the four study sites.

Recruitment will be facilitated by partner organisations with established groups of people with intellectual disabilities and links with additional community groups and agencies which contain under-represented groups of people with intellectual disabilities. Birmingham Community Healthcare NHS Foundation Trust will also act as a recruitment centre. Our overall planned accrual rate is 50-60 participants per month across the four study sites (12-15 per site) over seven months to reach our aim of a final sample size of 400 (Note we expect some of the 60 participants from WP1 to participate in WP2 and WP3).

Partner organisations will ensure adequate oversampling to offset participant drop out. The organisations will also support sample replenishment in the case of non-completion of the survey at time 1. Levels of dropout in longitudinal studies with individuals with intellectual disabilities is approximated at 13% (McCarron *et al.,* 2020); however, we will conservatively allow for up to 15% via oversampling (McCarron *et al.,* 2020). To ensure inclusion of under-represented groups (e.g. people with intellectual disabilities from: ethnic minority/global majority groups, with autism, who are older, and who have underlying physical health problems) and groups more at risk of digital exclusion (older; unemployed; living in group settings supported by paid staff; people with greater support needs (via carers) (Anrijs *et al.*, 2022), sample characteristics will be reviewed after 25% of initial survey data collection has been achieved. If insufficient at initial recruitment, a purposive/targeted sampling strategy, facilitated by partner organisations, will be implemented to ensure adequacy of representation. This review process will be repeated once 75% of initial survey data collection is complete.

Longitudinal survey data collection

Prior to data collection, participants and their carers will be invited to attend online training workshops provided within the project to support the survey data collection (Work package 2). Training will be provided by the CI and site/regional PIs alongside the RAs and the CRs with intellectual disabilities.

Participants will choose their preferred modality for survey completion (Paper-based, online completion (housed on Qualtrics), telephone completion, face-to-face completion as an interview with the geographically closest researcher or a known carer). Where appropriate, the survey will be administered by RAs and CR at each study site. Self and carer supported completion will also be offered for data collection. Survey methods are viable for use with people with intellectual disabilities and have been used successfully by applicants previously and in recent large-scale studies (e.g. Caton *et al.*, 2022). Guidance on completion will be

provided in the manual with individualised support offered by RAs and co-researchers on an as needed/requested basis. The manual will provide guidance on deciding whether independent completion, supported completion or, proxy completion is most appropriate. The survey digitally housed (Qualtrics), printed versions of the survey will also be available if requested for subsequent entry by RAs. Carers proxy completing the survey will also be offered the same range of completion options (Paper-based, online completion (housed on Qualtrics), telephone completion, face-to-face completion as an interview with a researcher).

The survey will comprise: (i) The Digital Health Participation Survey developed in WP1; (ii) General ICT Use and Access (Anrijs *et al.*, 2022); (iii) Physical and Mental Wellbeing (EQ-5-3L, (Herdman *et al.*, 2011)); (iv) Salient Demographic (Gathered from participants in accordance with PROGRESS-plus criteria) (Oliver et al., 2008; O'Neill et al., 2014) and Background information (Current and historical health conditions, ongoing health involvement, day activities, levels of support need, literacy and communication, level of cognitive impairment and postcode to enable gathering of deprivation indices).

Longitudinal survey statistical analysis

Descriptive analysis of levels and frequency of digital health participation. A cross-lagged path analysis (CLPM) will investigate changes over time and identify causal relationships between aspects of digital health participation and physical and mental wellbeing, while controlling for demographic and background characteristics (Kenny & Harackiewicz, 1979). By fitting the model with causal crossed lagged pathways in both directions, we can address whether aspects of digital health participation causally precedes physical and mental wellbeing or vice versa in individuals with intellectual disabilities. Sample sizes N=100 - 400 are sufficient for structural equation modelling; more specifically, N=150 for models including seven or fewer variables with modest communalities (below 0.5) and zero under identified constructs (Hair *et al*., 2014). We will fit models with and without cross lagged effects and use likelihood ratio tests (specifically, AIC and BIC criterion) to compare these nested models to determine which better fits the data (Kenny & Harackiewicz, 1979). If data is found to be missing at random (MAR), CLPM analyses will default to using full-information maximum likelihood. All models will be reported with robust standard errors and model fit will be evaluated using the comparative fit index (CFI >0.9), Tucker-Lewis Index (TLI >0.9), standard root mean squared residual (SRMR <0.08) and root mean square error of approximation (RMSEA <0.08), (see Wang & Wang, 2012; Hu & Bentler, 1999; Schreiber *et al.,* 2006).

2.4.2 Comparative study of Digital Health Inequality

A cross sectional comparative study will contrast digital health participation of people with intellectual disabilities to a reference group people without disabilities.

Comparator

A reference group of 200 participants without disabilities will be recruited across the study sites via local advertisement and social media. This referent group will concurrently complete the same Digital Health Participation survey online via Qualtrics. A referent sample of 200 will allow detection of a group difference, d=0.2812 (small-medium effect) at 90% power, 2:1 group ratio, and alpha=0.05. Sample size calculations were conducted using G*Power 3.1.9.7. Our overall planned accrual rate for the referent group is 25-30 participants per month across the four study sites (6-8 per site) over seven months to reach our aim of a final sample size of 200.

Primary outcome

Digital health participation levels as developed from the work in WP1 will be used as the primary outcome measure.

Secondary outcome

Level of mental and physical wellbeing will be measured using the EQ5 (Herdman *et al.* 2011).

Comparative study statistical analysis

Descriptive analysis of levels and frequency of digital health participation of the groups (N=600). Between group comparison using general linear model (GLM) of digital health participation of people with intellectual disabilities.

The study will use propensity score weighting (inverse probability weights) to reduce the bias due to confounding variables and ensure sufficient balance across groups. The propensity scores will be generated on the basis of the following variables: geographic region, sex, age band, ethnicity, and deprivation index. In the event that models including the probability weights do not converge, we will explore other approaches to resolve (i.e. direct adjustment as the number of covariates is relatively small).

We will test whether the data is missing completely at random (MCAR) using Little's test for missing completely-at-random (MAR) (Little, 1988) if more than 10% of data is missing. Data is MCAR if the test is not significant, meaning the estimates will be sufficiently unbiased to not need any adjustments. If data is found to be MAR, GLMs will use multiple imputation via chained equations and up to 10 imputation sets will be generated, then pooled following Rubin's Rules (following Granger *et al.*, 2019). All parameter estimates will be reported with 95% confidence intervals. Both imputed and complete case model estimates will be reported for comparison.

A more detailed Statistical Analysis Plan (SAP) will be developed once WP1 is completed and the digital health participation survey which will be administered as part of WP2 is developed.

2.5 Digital Diary Study of Digital Health Participation (Months 14-16 and 24-32) - Work Package 3 (WP3).

To gain a deeper understanding of how digital health participation operates in the lives of people with intellectual disabilities, WP3 employs principles used in digital ethnographic research. This prioritises prolonged collection of rich, unstructured data through observations and accounts of participants (Hammersely, 2019) in contexts and environments which are predominantly digital (Jensen *et al.*, 2022; Pink *et al.,* 2016). Qualitative digital diaries offer a useful way to explore everyday experiences (Volpe, 2019) by utilising the benefits 'new mobilities' technology offers, enabling the ability to record textual, visual or digital diary information that is located in both time and space (Shellen & Urry, 2006).

We will conduct a digital diary study using tablets housing the ArcGIS software package (Jung & Elwood, 2020), which contains digital storytelling software and story mapping. ArcGIS enables generation of verbal, visual and survey data linked to specific community places. Real-time ArcGIS demographic, verbal, visual and narrative data generation about experiences, thoughts and feelings about using the technology in relation to their health will be gathered from participants, with support and prompting provided weekly by RAs and co-researchers. Concurrent to WP2 accessible 'easy-read' study materials will be developed.

2.5.1 Digital diary study sampling

In order to gain a breadth and depth of digital health participation experiences from participants, we will recruit a subsample of 40 people, split evenly across the four study

sites, using stratified sampling from a sampling frame developed in WP2. Sample sizes in qualitative research are commonly between 15-30, hence 40 participants is considered to be a large sample (Hennink *et al.*, 2017; Clarke & Braun, 2013). Stratification will be based on geographical location, and to ensure representation of the heterogeneity within the study population and inclusion of digitally disadvantaged groups (Older age, unemployed, living in group settings supported by paid staff, with greater support needs and higher levels of cognitive impairment (Anrijs *et al.*, 2022)).

2.5.2 Digital diary study data collection

For WP3, participants with intellectual disabilities (with support from carers should they wish it) and participant carers will attend a training workshop. In this they will be trained and given an opportunity to practice appropriate use of the tablets and ArcGIS digital storytelling software to record their digital health participation diaries (Janssens *et al.*, 2018). ArcGIS allows demographic and real time verbal, visual and narrative data to be recorded about their experiences, thoughts and feelings of using technology for health. Hence, the diary can be typed, audio, video / vlogging, pictorial etc. or a combination of these modalities can be used by participations to record their digital health participation activities. Geographical data, linked to specific community places, can also be recorded. Participants will make their diary recordings weekly using tablets over 5 months (Janssens *et al.*, 2018). Support from RAs and co-researchers, via pre-arranged brief check-in chats, will be provided weekly throughout the 5 months of data collection. They will also record the brief check in chats as a record of participant experiences of using the technology and participating in the study. Site RAs will also provide ad hoc support in use of the tablets and ArcGIS software over the 5 months. RAs will also facilitate collation and synthesis of the individual stories.

2.5.3 Qualitative Analysis

The longitudinal digital diaries in WP3 will produce a large corpus of verbal, textual, visual and geographical data regarding digital health participation over the period of data collection. This qualitative data will be entered and analysed in NVIVO, a useful tool for managing large longitudinal data sets (Jackson & Bazeley, 2019; Saldana, 2003). The data analysis process will primarily involve using thematic framework analysis (Gale *et al.*, 2013), but will also draw on a number of established approaches for narrative analysis (Willis, 2019), qualitative longitudinal analysis (Lewis, 2007) and for analysing visual and geolocation data (Reavey, 2020).

Thematic framework analysis (Gale *et al.*, 2013) will be applied to the qualitative story data to provide deeper insight into the cross-case influences, processes and consequences of digital health participation and exclusion. The framework approach allows both deductive and inductive thematic coding of data, has been successfully applied in qualitative longitudinal research (Lewis, 2007), and is sufficiently flexible (Gale *et al.*, 2013) to allow incorporation of qualitative data collected that differ from the usual textual data analysis (e.g. visual (photograph & video) and geolocation data) (Reavey, 2020). Deductive analysis will align with the following theoretical frameworks: (i) self determination theory (experiences of mastery, autonomy and interaction) (Wehmeyer 2020a, 2020b), (ii) digital inclusion (individual, interpersonal, contextual and societal influences on technology access, use and participation) (Chadwick *et al.*, 2019; Chadwick *et al.*, 2022) and (iii) health literacy (experiences of different online health behaviours and their appraisal and functional, interactional and critical decision-making) (Sørensen *et al.*, 2012; Chin, 2014).

Stages of data analysis using the framework approach will follow Gale *et al.* (2013) and include: transcription of verbal data and collation of additional forms of data e.g. textual, visual and geolocation; familiarisation with the data; Coding; development of a working analytical framework; application of the analytical framework to the data; charting of the data into a framework matrix; and interpretation of the data (Gale *et al*., 2013). Working with participants, data will be co-constructed into individual digital health participation stories. When considering the data longitudinally, developments in digital health participation will be investigated via consideration of different types of change: narrative, reinterpretation by participants, researchers' interpretation, absence of change (Saldana, 2003; Lewis, 2007).

Findings from these analyses will be collated and developed into archetypal composite thematic narratives pertaining to the digital health participation of people with intellectual disabilities. This approach allows complex, situated accounts of digital health participation to be presented in a format that is both anonymous and accessible outside academia (Willis, 2019). The composite narratives will be reported at the workshops for discussion, alongside the findings from the survey. Strategies will be embedded within the analysis process to ensure rigour and trustworthiness (Amankwaa, 2016; Shenton 2004; Nyirenda *et al.*, 2020, White *et al*., 2012).

2.6 Dissemination & Output Co-creation (Months 14-32) - Work Package 4.

The process and synthesis of this complex mixed methods programme of work is best visualised in the project flow diagram for the study. An iterative process is employed within the programme of work with work packages building on each other to enhance understanding of digital health participation. The findings from WP1 will be used to develop the measure of digital health participation used in WP2. The quantitative findings from WP2 (e.g. barriers and facilitators of digital health participation) and the qualitative findings from the digital diary study in WP3 (e.g. the digital health participation related support needs of people with intellectual disabilities) will be collated to provide a rich insight into the nature of digital health participation in the lives of the participants, the factors that influence it and how digital health participation is related to wellbeing.

Workshops will be conducted as part of WP4. These will be solution focused and will co-produce recommendations and actions to enhance digital health participation for people with intellectual disabilities. Via the four solution focussed workshops, the findings from WP1, WP2 and WP3 will be contrasted and synthesised into key findings, recommendations and guidance. These will be collated into a suite of digital health participation resources and interventions which will be made publicly available on a study website.

Four site-specific workshops will be held to disseminate findings to stakeholders (researchers, people with intellectual disabilities, carers and steering committee members). Academic papers will be published in high impact intellectual disability and cyberhealth related journals, an accessible summary of digital health participation stories will be produced, and guidance documents will be developed for people with intellectual disabilities, digital health content provider and those providing support. A preliminary suite of digital health participation interventions will be developed. This work package will culminate in a launch of the study outputs and digital health participation survey on an accessible interactive website containing findings and guidance videos presented by co-researchers with intellectual disabilities and project staff. All accessible outputs will be co-developed with the co-researcher with intellectual disabilities and in consultation partner organisations. All dissemination events will be co-presented with the co-researcher with intellectual disabilities.

2.7 Study Setting and Context

Participants recruited into the WPs will live in a variety of support settings including their own homes, family homes, supported living accommodation, group homes and other congregate settings.

Study site partners for the project (and associated Universities) are:

- Dudley Voices for Choice & The West Midlands Self Advocacy Network, West-Midlands England (LJMU)
- Advocating Together, East-Central Scotland (DU)
- East Kent Mencap, South-East England (UoK)
- People First, North-West England (MMU)

- Birmingham Community Health Care NHS Foundation Trust (BCHCFT) (LJMU)

These partner organisations employ and facilitate self-advocacy in people with intellectual disabilities and will serve as links and contacts with these settings for recruitment and will negotiate and ensure cooperation by supporting organisations for each participant.

3. Participant Selection & Recruitment

3.1 Eligibility Criteria

Inclusion criteria will maximise the scope of the project to include as wide and heterogeneous a group of people with intellectual disabilities as is practicable. Eligible participants with intellectual disabilities and their carers from across the UK, in urban and rural settings, with varying levels of communication, health, support needs and deprivation, including geographical regions where research participation opportunities for this population have historically been limited. Every effort will be made to ensure inclusivity and reach. Prior to participant recruitment, we will seek specific input from our identified NHS and third sector organisational partners and members of the Project Steering Committee to determine how best to maximise inclusivity. Demographic and background information will be collected following consent procedures at the point of recruitment to enable reviewing of inclusivity of recruitment for each of the work packages where data will be collected (WP1-3). Reach

across under-represented groups (e.g. people with intellectual disabilities from: ethnic minority/global majority groups, with autism, who are older, and who have underlying physical health problems) and groups more at risk of digital exclusion (older; unemployed; living in group settings supported by paid staff; carers of people with greater support needs will be assessed as part of these review meetings which will occur at regular intervals throughout the data collection processes (See sampling and recruitment in WP2 in Section 2.4).

3.2 Inclusion and exclusion criteria

3.2.1 Inclusion criteria

We have two main participant groups for the study which are detailed below with their respective inclusion criteria:

1. People with intellectual disabilities

- Has a diagnosis of intellectual disabilities
- Over 18 years of age
- Has capacity to give informed consent
- Has a carer or family member able to support participation in the relevant aspect of the study (if this is necessary for the participant to successfully take part)

2. Carers of people with intellectual disabilities

- Providing daily support to people with intellectual disabilities who are unable to consent to participate in research.

3. Adults without intellectual disabilities (Referent Group)

- For WP2 we will also recruit a third group of participants who will be the comparison referent group. The criteria for inclusion for these participants is that they are an adult, have the capacity to consent to take part and do not have intellectual disabilities.

3.2.2 Exclusion criteria

- Not in either a member of either of the above two groups
- Has a court order which bans internet access

In preliminary meetings chief officers at the advocacy groups and the site PI at BCHCFT will be made aware of the inclusion and exclusion criteria for participation for the two groups. Those identifying potential participants for the study (People working at the 4 advocacy groups and clinicians and staff in BCHCFT) will be instructed not to select any people for inclusion in the study that they know have a court order which bans or restricts internet access. It will be made clear that these need to be a court order not restricted access due to gatekeeping, monitoring or control in the perceived interests of safeguarding by carers (Seale & Chadwick, 2017) or self exclusion due to negative online experiences (Chadwick, 2019, 2022).

Following recruitment and inclusion in the study a previously unknown exclusion criteria may be identified. Should this occur and information regarding an exclusionary order comes to light the site PIs will inform the study management team about this. The study management team will then review the case and exclude such participants.

3.3 Recruitment strategy

Our approach to recruitment and retention has been developed in line with the INCLUDE Ethnicity Framework (Treweek *et al.*, 2021) and INCLUDE guidance (NIHR, 2020; NIHR, 2022). Information regarding the sample sizes, sampling strategies and associated justifications are detailed for each of the WPs within sections 2.3, 2.4 and 2.5 of this protocol.

3.3.1 Ensuring equality, diversity and inclusion within the project

In consultation with West Midlands Self Advocacy Service, Dudley Voices for Choice and our other partner organisations we have confirmed that access to a diversity of people with intellectual disabilities across all strata laid out in the NIHR INCLUDE guidance is viable (Treweek *et al.*, 202; NIHR, 2020; NIHR, 2022). This includes diversity of ages, sex, sexual identities, sexual orientation, ethnicity, religious beliefs, marital, parental, residential, health access and socio-economic status. Having four study sites ensure inclusion of geographical diversity and inclusion of people living in both urban and rural locations.

Membership and extended networks held by partner organisations include potential participants from subgroups of people with intellectual disabilities who represent people with all of the above characteristics, which present risks in terms of exclusion from the study. Participation by a diverse range of people with intellectual disabilities will be assured for

each work-package and will be embedded with recruitment in WP1-3 and in advertisement of dissemination activities for WP4. Embedded checks in recruitment to the survey for WP2 are detailed in section 2.4.

Translation of study materials in WP2 will be conducted to encourage representation from participants from a diversity of ethnic backgrounds.

3.3.2 Recruitment method

Partner organisations (See 2.7) at the fours study sites will act as gatekeepers and facilitators of recruitment for the project and will develop sampling frames which will be used to identify and recruit participants into the study and to monitor accrual. They will identify people from within their own organisations (e.g. advocacy service, NHS, Charitable or private service provider) and will also act as links with additional organisations supporting under-represented groups or other potential gatekeepers to increase the inclusivity and reach of recruitment (e.g. those supporting people in more rural locations, people with profound and multiple intellectual disabilities, supporting people with global majority ethnic backgrounds and carer groups). Within BCHCFT who are acting as a PIC site, the site PI will coordinate members of the existing clinical care team to identify eligible adults with intellectual disabilities for contacting using the inclusion criteria. Partner organisations will share accessible study information and contact details for the research team with eligible people within their organisations and their extended networks.

Participant information materials

Easy-read information sheets, data collection handbooks, consent forms and capacity checks (for those appearing to lack capacity or need additional support to fully understand what participation in the study involves) will be developed for all work packages. These will be developed in consultation with the project steering group, partners, co-researchers and PPIE leads. Participant facing materials will adhere to accessibility and Health Research Authority (HRA) guidance. Different modalities (e.g. video and image based presentation of participant facing materials will be incorporated). Materials will be approved by the REC.

Partner organisations will send easy read Participant Information Sheet (PIS) and an ‘Expression of Interest’ (EOI) form to be completed and returned directly to the research team (either via an online portal or in paper format, returned via a FREEPOST envelope). In additional online and in person meetings will be arranged where site PIs will provide information about, and provide an opportunity to discuss, the project and answer any

questions people have. At these meetings those wishing to participate in data collection for each WP will be supported to complete an EOI form. We will also consult PPIE advisors on alternative formats of presentation of information to carers (e.g., video presentation of participant information; use of QR codes instead of an EOI). Those who indicate they wish to participate will have their contact details passed on to the study team to arrange initial discussion of participation and begin consent procedures. The research team will then contact participants and where appropriate their carers by telephone to gather preliminary demographic information and explain the purpose of the study, answering any additional questions that may arise.

3.4 Consent

Respect for participant is paramount within this study, and our procedures for gaining consent to include someone within this study will be completed before enrolment. Respect for the rights of participants and ensuring their ongoing wellbeing within the context of participation is paramount within this study. All participants will have the option to provide informed consent for each WP. Procedures for gaining consent or permission to include someone within this study will be completed before participants join the study. The team is experienced in informing, consenting and conducting mental capacity checks with research participants with intellectual disabilities. In line with the Mental Capacity Act (2005), British Psychological Society guidance and Project Assent (BPS, 2021; Heywood et al., 2019), prior to participation, consent for those with mild to moderate intellectual disabilities will be taken. Where viable, ongoing assent will be observed and monitored throughout the study.

Screening and checks will be conducted to determine support needs for consenting and that participants understand what participation involves. For self-advocates and participants screened and found able to provide consent independently or with support, adapted consent procedures will be administered. For those with moderate to profound intellectual disabilities who are unable to provide informed consent, paid and family carers will be approached to participate in the study and provide consent. PIS and consent forms will be developed for carers in line with HRA guidance.

Consent will be able to be taken electronically or via a paper form posted to their home address (returned via a FREEPOST envelope) should participants wish to complete the consent process independently or with support by their carer. Participants will be given time after the initial invitation to participate before being asked to sign the Consent Form should

they wish, we will offer 1 to 7 days and respect participant selection of a consideration time duration.

3.4.1 Withdrawal

The right of the participant to refuse to participate in the study without giving reasons will be respected. Participants will be informed that they can withdraw from the study (either from participation in the focus group, survey and digital diary study) at any time without giving a reason. Any reasons that are given voluntarily for withdrawal will be recorded on a withdrawal form.

3.5 Retention Strategy

Both the longitudinal survey in WP2 conducted with a gap of 8 months between survey completions and the digital diary study where the diary is collected weekly over 5 months the retention of participants is an important consideration.

3.5.1 Retention

Monitoring of retention is detailed above and in section 2 for WP2 and 3. A number of strategies will be employed to promote retention. These include: (a) maintaining regular contact with participants, and minimising the time between contacts, this will be implemented for all WPs, (b) promoting service-user involvement at all stages of the study, (c) using co-creation to develop the measure in WP1 which will subsequently be administered in WP2 to help encourage retention, (d) working effectively with our partner organisations to help encourage continued engagement, (e) enabling participants and carers to contact RAs (via telephone or dedicated study email address) at any point during the study for additional information or support with study processes including data collection.

3.5.2 Participant incentives

Participants with intellectual disabilities and proxy carers will be offered vouchers (£10 per activity in WP1 and WP2) to thank them for their participation. Participants in WP3 will be allowed to keep the tablets provided at the end of the study as an incentive for their extensive support and involvement for this part of the study. Travel costs and refreshments will be provided to participants for all visits they attend in relation to the project.

3.5.3 Lost to follow up

For the longitudinal elements of WP2 and WP3, a participant will be considered lost to follow up if they have not responded to three attempts to schedule the survey completion or digital diary check-in, where at least one of these attempts was sending a letter to their home asking them to contact the research team.

3.5.4 Methods for sharing study progress and findings

Study progress information, such as number of recruits/study stage, will be shared via the study website and on social media (Twitter). Participants will also be updated regularly via electronic newsletters or can request that any communication is sent directly to them by post. Study findings will be shared in solution focused workshops, easy read report and study outputs will be shared at a launch event. Updates on progress and findings will also be shared, where appropriate, at 4 monthly steering committee meetings.

4. Ethical and Regulatory Considerations

4.1 Assessment & Management of Risk

4.1.1 Monitoring of distress

It is possible that both carers and people with intellectual disabilities could become distressed during survey and diary data collection, given the nature of measures and the potential for prior negative online experiences and health issues to be raised, relating to mental well-being and quality of life, during data collection for WP1-3. Researchers and co-researchers with intellectual disabilities will receive study-specific training in dealing with distress should this arise, and participants will be signposted to local sources of help and support if indicated. The views of both the Project Steering Committee and partner organisation regarding potential ethical issues will be sought during study set-up and development of ethical approval documentation for submission to REC.

4.1.2 Safeguarding

Should participants during the course of the study raise concerns that there is potential risk to themselves or others this will trigger local adult safeguarding procedures.

For WP3 researchers working on the project will review the diary uploads on a monthly basis as part of data collection monitoring and will contact participants weekly or fortnightly to chat about what data has been collected. Should any data indicate a safeguarding concern this will be referred to the relevant people (local safeguarding team or individual) at the participants location and standard operating procedures for safeguarding at that location will be followed.

4.1.3 Adverse & Serious Adverse Events

The risk involved in the study are viewed as low as this is a non-interventional investigation.

We will mitigate the risks of using the internet during the study and owning technology via support, guidance and monitoring of technology use integrated within the study. See below:

Support for safe usage of technology within WP3 of the study

All participants given a tablet and internet access for the purposes of the study will be provided with the following guidance, training and support:

- Training in the access and use of the device
- Training in how to collect and upload data for the study
- Training in acceptable and unacceptable use of the provided technology
- Training will provide information about online risks and what constitutes pro and anti-social technology/internet use and contact. It will also provide guidance about how to manage and report this to the study team and to those providing them with support should it occur.
- A support team will be developed for each participant in relation to the digital diary study. This will include one or more of the following people: The Site PI, RA working at the site, Chief officer or worker at the advocacy service which supported recruitment, family carer, staff support, friends. Lines of support and communication will be made clear to participants.
- Researchers at the study site will contact each participant weekly/fortnightly to check in and see how they are getting on with using the technology and gathering data for the project.
- At the end of the study the participants will need to provide their own network connection - this will be explained at the start and repeated at the end of the study. Researchers will have a final meeting with each participant to explain the end of the study and what happens next, they will also reiterate safe and pro-social technology

use guidance and ongoing support for using the tablet will be identified from within the participants support network.

For all of these activities understanding will be checked and additional support and reminders provided on an individual as needed basis until the study end.

Occurrence of adverse events during the study

Should any adverse or serious adverse events be identified during the course of the study, these should be passed to the Site PI who should then inform the study management team within 72 hours. The CI or other representative of the SMG will pass this information using the appropriate channels within IRAS and the sponsor LJMU.

An adverse event within the context of this study is defined in line with Table 1 below.

Table 1: Definitions

Term	**Definition**
Adverse Event (AE)	Any untoward medical occurrence in a participant or study participant administered an intervention which are not necessarily caused by or related to that product
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect • Other medically important condition***

*Note: The term 'life-threatening' in the definition of serious refers to an event in which the study participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.
** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.
*** Note: other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

As this is not an interventional study, we will not routinely collect adverse or serious adverse events. The study team will, however, collect risk related behaviours salient to having the tablet provided as part of the study. This includes the conduct or experience of negative and

antisocial behaviour online or offline due to technology/internet use (i.e. Contact, Content, Conduct and Contract Risks (Livingstone & Haddon, 2009; Livingstone & Stoilova, 2021) and assault or theft of the tablet when used in public).

For any risks of this nature identified post inclusion in the study the Sponsor and IRAS Standard Operating Procedure (SOP) will be initiated. Within the study the process for management is detailed below.

1. If risk of harm is identified for the participant or anyone else this will trigger local adult safeguarding procedures
3. The project management group, once informed, will review and decide if the participant can continue participation in the study
4. If excluded an exit interview will be conducted with the participant to ensure adequate handover and support
5. If participation continues a review meeting to identify what support, guidance and monitoring is needed to manage future risk will be held. This will be documented.

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

Before the start of the study, a favourable ethical opinion will be sought from Liverpool John Moores University and also, via the IRAS ethical approval process, from a Research Ethics Committee (REC) that is legally “recognised” by the United Kingdom Ethics Committee Authority for review and approval, and approval from the Health Research Authority.

This process will incorporate approval for the study protocol, informed consent forms and other study documentation. All correspondence with the REC will be retained. It is the Chief Investigator’s responsibility to produce the annual reports as required. 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 study is declared ended.

This research investigation will also be conducted in accordance with British Psychological Society guidance for both research with human participants and internet mediated research.

4.2.1 Regulatory and review compliance

The Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place prior to enrolment of any participants into any of the

workpackages within the study. A Non-Commercial Participant Identification Centre Agreement will be approved by the REC prior to BCCHCFT acting as a recruitment site for the study.

4.2.3 Amendments

The decision to amend aspects of the protocol and study materials will be made by the PMG in consultation with the PSC and partner organisations as appropriate.

It is the responsibility of the study management group to ensure that new documents have the associated correct approvals. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the REC in order for them to issue approval for the amendment.

During the study, should amendments be made to the study documentation. The study management group will circulate the latest version of the documents as soon as they become available. The Chief Investigator or designee will work with partner advocacy organisations and BHCHFT so they can put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

4.3 Peer Review, Funding & Project Registration

4.3.1 Peer Review

This protocol has been reviewed by the sponsor, research support office within LJMU and the funders representative.

4.3.2 Funding

This study is adopted on the NIHR portfolio and is funded by the National Institute for Health Research – Health and Social Care Delivery awarded to Dr. Darren Chadwick, Liverpool John Moores University.

4.3.3 Registration

The study has been registered with the Research Registry [Ref: researchregistry9220]

4.4 Patient & Public Involvement

Though much digital inclusion, digital health literacy, health inequality and health need research has been conducted by governments, organisations and researchers, the majority of this has excluded people with intellectual disabilities (Latteck & Bruland, 2020). Quantitative and mixed methods studies often establish cognitive impairment as a participatory exclusion criteria. Studies which have included people with intellectual disabilities have done so without involving them in the processes and decision-making of the research. This has led to findings which are remote from and often not applicable to people with intellectual disabilities, overlooking key aspects salient to their lives (Geukes *et al*., 2018). Underpinning this investigation is the tenet that people with intellectual disabilities and, where appropriate proxy family and paid carers, will be centrally and fully involved.

4.4.1 PPIE in Project Development

Prior to developing this research protocol the CI conducted a number of smaller scale unfunded qualitative pieces of research which provide underpinning empirical support for the continuation of this work. The PI attended meetings of the West Midlands Self-Advocacy Network and Dudley Voices for Choice to talk through the best focus for the next stages of this digital inclusion research. Finding out about health, health appointments and staying healthy were raised as the most important things that people wanted to be able to do more independently.

During design of the project, four PPI meetings were undertaken, facilitated by the CI and workers within our partner organisations. Three meetings were with people with intellectual disabilities (Total N=21 at Dudley Voices for Choice and West Midlands Self Advocacy Network). Participants at these three PPIE consultations included self-advocates living in a range of settings including with family, in supported living, co-habiting with partners, in congregate settings. Most of these self-advocates had low support needs and were white British. Three members were non-British and non-white and four had high support needs. Young adults and older adults were also represented. Paid and family carers were also included and contributed to one of the PPIE events. The fourth PPIE meeting was facilitated by Birmingham Community Health Care NHS Foundation Trust, held with health and social care practitioners (N=3) working with people with intellectual disabilities.

Information shared at these meetings influenced the project in the following ways: increased the orientation towards health literacy; supported the inclusion of people with intellectual

disabilities with higher support needs (and their carers) who are more likely to be digitally excluded; the incorporation of digitally mediated health behaviour as a factor beyond seeking health information; the importance of the inclusion of co-researchers; the need to focus on gaining a deeper understanding of day-to-day digital health participation; and the need to focus on empowerment of people and to shed light on factors, such as support seeking, confidence and self-efficacy, that they reported had influenced their digital and health participation.

4.4.2 Ongoing PPIE within the project

Patient and public involvement and engagement (PPIE) are embedded throughout the lifespan of the project. This aspect will be led by Dr. Susan Buell who has extensive experience of PPIE activities and our co-applicant partner organisation Chief Executive Ms. Sarah Offley.

In line with the working together and communication standards of the UK Standards for Public Involvement, partner organisations comprising people with intellectual disabilities and a co-researcher at each study site will provide ongoing guidance to the project. Dudley Voices for Choice which, as a representative for the West Midlands Self-Advocacy Network, is a co-applicant.

Study site partners for the project (and associated Universities) are:

- Dudley Voices for Choice & The West Midlands Self Advocacy Network, West-Midlands England (LJMU)
- Advocating Together, East-Central Scotland (DU)
- East Kent Mencap, South-East England (UoK)
- People First, North-West England (MMU)

These third sector study site partner organisations will facilitate identification and recruitment of co-researchers. Partners will also provide recruitment support in developing sampling frames at each study site, for representativeness and adequacy of the sampling.

Co-researchers with intellectual disabilities will be established at each study site and will be involved in all aspects of the study throughout its duration. They will bring expertise from lived experience and be trained in research skills while on the project (Iriarte Garcia *et al.*, 2014). Throughout the course of the study they will contribute alongside the site PIs and RAs

in recruitment (WP1-4), co-facilitating the item generation and measurement consensus discussions (WP1), focus group (WP1) and survey data collection (WP2), co-training in the use of tablets and ArcGIS storytelling software (WP3), data analysis, preparation of guides, accessible summary and journal articles and co-presentation at dissemination events (WP4). Site PIs will provide weekly supervision to their RAs and Co-researchers with intellectual disabilities, the latter will be facilitated by Offley and representatives from each partner organisation from which co-researchers were recruited. Offley and Buell will be overall co-leads for the PPIE within the project, supported by site leads and partner organisations at each study site.

Prior to participant recruitment a project steering committee will be recruited. In line with the UK Standards for Public Involvement (UK Public Involvement Standards Development Partnership, 2019), this will consist of key stakeholder groups including a diverse mix of self-advocates with a range of intellectual disabilities with differing communication support needs from each of our partner organisations and other key groups. Our partners will support inclusivity within the steering committee. Although it is not possible to consult people with more severe and profound intellectual disabilities directly, carers of these groups will be included as participants in the study and PSC members. The steering committee will review all participant facing study materials for each work package including the recruitment, training, data collection and dissemination materials.

Via focus groups and co-creation workshops in Work Package 1, stakeholders will be heavily involved in the development of the core measure of digital health participation, in particular, in relation to survey conceptualisation and administration.

In line with the support and learning standard set out in the UK Standards for Public Involvement the co-researchers, project steering committee members and partner organisations will be asked about their training and support needs. Training will be provided on an ad hoc basis as an adjunct to management group meetings.

Co-researchers will be provided with mentoring and support by partner organisations, site PIs and RAs to enable them to fulfil their role as experts by experience throughout the study. Participants and stakeholder members of the public will also be involved in solution focused workshops which will underpin the outputs of the study.

4.5 Protocol Compliance

The Principal Investigator should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice to the study team in writing as soon as they become aware of it.

4.6 Data protection and participant confidentiality

4.6.1 Data Protection

The study management group will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and in accordance with the General Data Protection Regulation 2016. The data custodian for this study is Liverpool John Moores University.

4.6.2 Archiving

The Master Folder and associated files for the study which contain essential documents that will be archived by the sponsor for a minimum of 10 years digitally. This will include copies of signed documents that have been digitised.

4.7 Indemnity

Liverpool John Moores University will act as Sponsor and provide indemnity in the event of negligent harm.

4.8 Access to the final study dataset

Dr. Darren Chadwick at Liverpool John Moores University will be the custodian of the data. The study team will have access to the data and will make a decision during the course of the study, In consultation with partner organisations regarding whether the anonymised quantitative and qualitative data will be made open access. We will seek participant consent for this should open access be agreed. Should data be made freely available, any use of study data beyond the PMG must be subject to prior approval from the PMG, which must include the CI.

4.9 End of study definition

The end of the study is defined as the date of final data capture to meet the study endpoints. In this case end of study is defined as the date that the last participant completes the digital diary study and/or time point two of the survey.

The sponsor must notify the main REC of the end of a study within 90 days of its completion or within 15 days if the study is terminated early.

5. Quality Control & Assurance

5.1 Monitoring

Study related monitoring, including audits, by providing direct access to source data/documents as required may be required. Participant consent for this will be obtained. Findings generated from any central monitoring will be shared with the Sponsor, Chief Investigator and Principal Investigator.

5.2 Audits & inspections

The study is participant to inspection by NHS Research Governance departments. The study may also be participant to inspection and audit by Liverpool John Moores University under their remit as Sponsor.

6. Study Management

Project oversight will be provided by both the Project Team, who will form the Project Management Group, and also the Project Steering Committee formed from key stakeholder groups. Membership charters will be drawn up for the Project Management Group and the independent Project Steering Committee.

Project Management Group (PMG): The PMG will comprise Principal and Co-Investigators, and directly employed staff. The full PMG will meet 4-6 weekly to set up the study, monitor progress and deal with issues as they arise, paying particularly attention to timescales. This group will deal with the day-to-day running of the project and will report to the Project

Steering Group. The CI will also be responsible for organising weekly project team meetings, inclusive of the site PIs and directly employed staff, to set out weekly project tasks and goals ensure the ongoing progress of the project.

The Project Steering Committee (PSC): The PSC will meet four monthly and will comprise 6-11 members with representation from key stakeholder groups: people with intellectual disabilities, staff and family carers, healthcare providers and professionals, and digital content providers and will have an independent Chair. The project steering group will have supervisory responsibility for the study. The Chief investigator, co-investigators, co-researchers and directly employed staff will attend to report on progress and observe the meeting.

Mentoring of PI by Professor Langdon will occur six to nine times per year with ad hoc mentoring support provided as required. This will facilitate the PI to build research leadership and project management skills.

7. Publication & Dissemination Policy

A number of people will contribute to the Digital Health Project during its course. This document addresses how individuals contribute to the publication process to ensure timely outputs that are produced in an equitable, efficient and transparent manner.

7.1 Publication policy

A publication is defined as a research paper published in a peer review journal, presentations inclusive of posters, at conferences, and other material detailing the methods or findings using data obtained from participants during this study placed in the public domain (e.g. websites, book chapters).

The roles of various members of the research team for ensuring that publications are effectively manged are detailed below:

a. Chief Investigator – responsible for agreeing which papers will be written, assigning a lead author to each paper, agreeing the co-author list, acting as a guarantor of the paper when the lead author is unable to accept this responsibility, and approving the

use of any of the data arising from this study after study has ended and committees cease to exist.

b. Lead Authors – responsible for deciding who are the co-authors, draft contribution statements and make appropriate acknowledgements, lead the drafting of the publication, circulate drafts for review and enforce deadlines, liaise with SMC or Study Manager about status and organise and requests for funder approval of publications, and act as a guarantor of the paper.
c. Co-authors – support lead authors in writing and reviewing manuscripts in a timely manner, sign any authorship agreements. Further adjustments or adaptations may be needed for PPI members and the lead author should discuss and agree this with PPI co-authors. Principal investigators may be co-authors if their contribution is justifiable. Reviewing and contributing to a manuscript is mandatory to qualify for co-authorship.
d. Study Manager – develop, update and maintain publication plan, maintain records of each publication, submit any papers to funder for approval before submission, maintain records of authorship agreements, identify any publication costs in collaboration with the Chief Investigator.
e. Study Management Group – approves papers for submission, and approves requests for data analysis.

Authorship

a. A lead author and wider writing team will be established and agreed for each identified paper.
b. All potential contributors shall have the opportunity to opt into the writing team.
c. PPI members should be included on relevant publications as authors where appropriate.
d. It is the responsibility of the Chief Investigator in conjunction with the lead author to decide authorship order in consultation with agreed co-authors. If any disputes arise, the Chief Investigator will take responsibility for reaching a resolution.
e. All named authors must meet the authorships criteria as detailed within the Authorship Statement below.
f. Each author must take appropriate public responsibility for the content of publications.
g. All authors must sign the Authorship agreement (Appendix).
h. An author is defined as someone who meets the following four criteria based upon the ICJME rules:

1. Substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of the data for the work, and
2. Drafting the work or revising it critically for important intellectual content, and
3. Final approval of the version to be published, and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriate investigated and resolved. An author should also be able to identify which co-authors are responsible for specific parts of the work and have confidence in the integrity of the contributions of their co-authors.

Note that special consideration will be given to co-researchers with intellectual disabilities and PPI members who will be contributing in a specialist manner. They must be included appropriately where they have contributed.

i. Those who have made a contribution but do not fulfil the criteria for authorship will be acknowledged. The lead author of papers will take responsibility for acknowledgements.

j. All outputs must acknowledge the funder and include any appropriate disclaimer that is required by the funder. The funder acknowledgement is 'National Institute for Health and Care Research as part of the Health and Social Care Delivery Research (HSDR) Programme'.

7.2 Presentations

- Submission of abstracts for conference presentation should be agreed in advance with the TMG. Authors should allow sufficient time for their request to be reviewed. This may be completed via email.
- However, if there is insufficient time for the TMG to review such a request, the CI can make a decision on behalf of the TMG.
- The body of the presentation (including posters) should be reviewed by the TMG prior to presentation. This may be completed via email.

7.3 Dissemination

Dissemination for the project is embedded within WP4. Dissemination activities will be manifold and will aim to reach and engage as many individuals who will be affected by or can affect change through the research findings as is feasible. Important findings will be shared with stakeholders at various stages of the project, for example via four site specific

dissemination events. The research and practitioner community will also be kept informed of key research findings, recommendations of good practice and innovations via a project e-newsletter which will be circulated at 6 monthly intervals, conference presentations, published outputs of project data within targeted journals and practitioner publications which are likely to have the widest reach, e.g. open access journals will be selected where appropriate to ensure findings are freely accessible and available as early as possible to affect change. Guides detailing how to best support and facilitate digital health participation for online health providers and ICT providers who develop digital health resources will be made freely available via a project website. In addition, an accessible report summarising findings, digital participation stories and key recommendations will be shared in order to facilitate digital health participation and will be circulated via advocacy groups (e.g. West Midlands Self Advocacy Network), networks of people with intellectual disabilities (e.g. Choice Forum) and to organisations working with people with intellectual disabilities (e.g. Foundation for People with Learning Disabilities; Learning Disability England; Mencap, BILD) and cascaded down to their members. Key findings and outputs will also be shared with press offices at each site and via social media with the intention of engaging local and national and international media with our research and raising public awareness. Also, an accessible project website will be developed.

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Appendix 1: Digital Health Participation of People with Intellectual Disabilities Logic Model

CONTEXT			AIMS	
Digital participation & its relationship with health literacy has seldom been considered empirically for this group. Existing measurement of digital participation & health literacy are currently inadequate for those with intellectual disabilities to enable assessment of this key healthcare quality indicator. The facilitators, barriers & outcomes of digital health participation & levels of digital health participation and inequality are currently not well understood for this population.			To determine levels of and factors which influence digital health inequ digital health participation occurs in the lives of adults with intellectual distribution of psychometrically valid & accessible measures of digital p influences on digital health participation & via comparison with referen levels of inequality (WP2). A diary study will also explore processes of	
INPUTS (resources invested)	**PROCESSES**		**OUTCOM**	
	Activities (what is done)	**Outputs (what will be achieved by activities)**	**Short-term**	**Medium-te**
Project Team: PI, Site Leads, Research assistants (RAs), Co-researcher (CR) with intellectual disabilities. Partner organisation support & facilitation for project. Support from carers (paid staff & family members) & professionals. Illustrator to provide pictures to enhance accessibility of data collection & dissemination materials.	WP1. Development of Digital Health Participation Scale & focus group topic guides; Scoping review to gather existing digital participation & health literacy measures; Focus groups with people with intellectual disabilities & their carers to identify salient aspects of digital participation & health literacy. Workshops to select scale items & response formats.	Development of initial Digtial health participation survey for use in WP2 and associated manual.	Co-development of an accessible, psychometrically valid measure of components of digital health participation & health literacy which can be utilised in both research & practice to better understand how digital health participation operates in the lives of people with intellectual disabilities.	Use by researchers of the psychometrically valid mea components of digital hea & health literacy for use a of healthcare quality for a excluded from digital inclu health literacy & participat
Financed Project Resources: iPads (& Sim cards), Laptops, ARCgis, Qualtrics licence. Participant renumeration for time, payment for RAs, third sector partner organisations & co-researcher(s) with intellectual disabilities. PPIE Payment for steering committee members. Translation costs.	WP2. Longitudinal Digital Health Participation Survey. Collation of measures of background, social determinants of health & wellbeing alongside bespoke digital participation survey. Participants across four sites with intellectual disabilities (N=400) complete survey twice (8 month follow up). Workshop to provide survey completion training. Carers, RAs & CR to support survey completion. Quantitative analysis (Cross-lagged PA, CFA).	Analysis of pychometric properties of Digital Health Participation Survey. People with intellectual disabilities to complete survey to provide digital health participation information at two time points. Longitudinal modelling of causal factors influencing digital health participation & wellbeing of people with intellectual disabilities. Development of sampling frame from survey cohort and recruitment of sample of participants with intellectual disabiltiies for WP3.	Enhanced understanding of how background characteristics, social determinant of health, digital participation & health literacy interact to influence wellbeing amongst people with intellectual disabilities.	Illumination of digital heal needs of the participants
Supervision & Training: Regarding data collection processes & methods provided to RAs and Co-researcher(s). Training, guidance & ongoing support in survey completion & use of ArcGIS storysharing software. Qualitative analysis training for RAs from PI.	WP2. Comparative survey study. Recruitment of matched referent group of people without intellectual disabilities. Completion of Digital Health Participation Survey by referent group. Comparative analysis to identify inequalities in digital health participation (GLM).	Identification of levels of inequality in digital health participation.	Enhanced understanding of levels of digital & health inequality for people with intellectual disabilities and the factors specific to people with intellectual disabilities which perpetuate & alleviate inequalities and exclusion.	
	WP3. Digital Diary study. Training of 40 participants in use of ArcGIS & use of iPads for health related activities. RA & carer support & monitoring of weekly qualtitative data collection. Thematic framework analysis of collated qualitative accounts / stories.	Identification of nature and processes of support, interdependence & independence in digital health participation via qualitative diary accounts to be compiled into stories of people's day-to-day lived experiences of digital health participation.	Deeper understanding of the ways digital health participation operates in the lives of people & the barriers & facilitators of participation and good practice in supporting digital health participation.	Greater awareness of digi participation possibilities b intellectual disabilities & th involved in WP3.
	WP4. Dissemination & Output Co-creation activities. Write up of findings. Solution focussed workshops with all stakeholders to identify next steps & develop preliminary intervention components to ameliorate barriers to digital health participation	(i) Guides detailing how to support & facilitate digital health particiaption for (ia) people with intellectual disabilities; (ib) carers / online health providers; (ic) digital health resource developers; (iii) Accessible report summarising findings, digital participation stories & recommendations; (iv) Final 'Digital Health Participation' survey.	Enhanced evidence about digital health participation of people with intellectual disabilities. Development of a suite of interventions from this work that sit alongside natural supports to be evaluated in future research work following funding.	Providers of digital health health ICT platforms will b of adaptations needed to people with intellectual dis Empirical evidence to guic research, social care & he policy.
ASSUMPTIONS			**EXTERNAL FACTORS**	
Digital health exclusion: People with intellectual disabilities are at risk of digital exclusion and reduced opportunity to engage in health decision making due to reduced health literacy. Much health provision and information are now delivered digitally, thus people with intellectual disabilities are doubly disadvantaged in relation to ongoing involvement in their health. **Measurement Development:** It is possible to co-create a psychometrically valid measure of digital health participation for completion by people with intellectual disabilities.			**Support for Participants to complete data collection:** Completion of reliant for many participants on the support of their carer(s) and the va health decision making. Also the health of individual participants may collection.	

Appendix 2: Schedule of Procedures[1]

Procedures	Number of Visits / Contacts			
	WP1 Scale Development	WP2 Longitudinal Survey	WP3 Digital Diary Study	WP4 Dissemination & Output Co-creation
Informed consent	1	1	1	1
Demographics	1	1	1	1
Focus Groups	1			
Scale Development Co-creation Workshop	1			
Piloting of Survey	1			
Survey Completion		2		
Digital Diary completion Training			1	
Weekly short check in Interviews			20 remote 5-10 min check ins over 5 months	
Solution focussed finding synthesis workshops				1
Dissemination events				1
Output launch				1

[1] Taken from the HRA Qualitative Protocol Development Tool (2016).