Qualitative Protocol Development Tool

This protocol has regard for the HRA guidance, the order of the content has been altered

FULL / LONG TITLE OF THE STUDY

Using digital technology to increase activity during inpatient rehabilitation: initial evaluation of Virtual Engagement Rehabilitation Assistant (VERA)

SHORT STUDY TITLE / ACRONYM

Evaluation of the Virtual Engagement Rehabilitation Assistant (VERA)

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 (28th Feb 2022)

RESEARCH REFERENCE NUMBER

IRAS Number:	293744
SPONSORS Number:	5626 - Grants and Funding 5741 - Legal and Governance
FUNDERS Number:	C2N-SA.06.A

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 requirement.

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

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

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

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Joint-sponsor(s) / co-sponsor(s)	Not applicable
Funder(s)	Stroke Association / MedCity Collaborate to Innovate award Stroke association contact: Dr Richard Francis, Head of Awards research@stoke.org.uk MedCity contact: Rikesh Patel, Strategic Partnerships Lead rikpatel@medcityhq.com

Key Protocol Contributors	Research staff: Dr Kathryn Jarvis, Dr Rachel Stockley, Dr Clare Thetford, Julie Cook. The Walton Centre NHS Foundation Trust (The Walton Centre) staff: Dr Andrew Rose, Nicola Branscombe, Jo Haworth, Dr Ganesh Bavikatte. Steering Committee including: Margaret Ogden (PPI), Dr Sue Hunter (research expert), Prof. Fiona Rowe (research expert), Suzanne Simpson (clinical expert), and Suzanne Clarke (User Experience expert). Staff from Citrus Suite: Chris Morland, Steve Donovan. Staff and service users who contributed to workshops.
Committees	VERA Working Party (Project Management Group) Chair: Dr Ganesh Bavikatte (Ganesh.Bavikatte@the waltoncentre.nhs.uk) Study Steering Committee Chair: Suzanne Simpson (suzanne.simpson12@nhs.net)

STUDY SUMMARY

Study Title	Using digital technology to increase activity during inpatient rehabilitation: initial evaluation of Virtual Engagement Rehabilitation Assistant (VERA)
Internal ref. no. (or short title)	Evaluation of Virtual Engagement Rehabilitation Assistant (VERA)
Study Design	Mixed methods, single site implementation evaluation
Study Participants	Inpatient service users and medical, nursing and allied health professional staff on a complex rehabilitation unit
Planned Size of Sample (if applicable)	Up to 20 service users Up to 20 medical, nursing, and allied health professional staff

Follow up duration (if applicable)	None
Planned Study Period	Once all ethical and organisational approvals are in place, the study will take place over an 8-month period. It is anticipated that the study will be complete by 30th April 2022.
Research Question / Aim(s)	This study aims to evaluate the implementation process and outcomes of placing the VERA digital technology in a complex neurological inpatient rehabilitation setting, and to explore the adoption of the technology by service-users and staff.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and / or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Stroke Association / MedCity	£59,916.59

ROLE OF STUDY SPONSOR AND FUNDER

The Funder will not be involved in the study design, conduct, data analysis, interpretation or manuscript writing. Kathryn Jarvis and Chris Morland will meet with the Funder on a regular basis (anticipated to be once every one / two months). The purpose of this meeting will be to track progress against the planned timeline.

The study sponsor is the University of Central Lancashire (UCLan), assuming overall responsibility for the initiation and management of the study.

The research team will have control over decisions about study design, interpretation and reporting of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES / GROUPS & INDIVIDUALS

Initial service user and staff workshops

The study design is based on findings from workshops undertaken with service users and staff in 2019 at The Walton Centre, Liverpool, UK. This NHS Foundation Trust provides specialist neurology, neurosurgery, spinal injury and pain management services. In the workshops, service users on a complex rehabilitation ward were asked about their average day on the ward and what they would like a digital system to offer in this environment. The staff were asked separately about their hopes and expectations of digital technology to support increased activity on the ward. The workshops were facilitated by Dr Rachel Stockley, a UCLan researcher, and the findings were instrumental in the initial design brief of VERA.

Study Steering Committee

A Study Steering Committee (SSC) has been convened comprising: Patient and Public Involvement (PPI) representative, experienced researcher, clinical staff member and an expert in technology user experience. The SSC will meet once every two months throughout the duration of the study (6 virtual meetings expected). The role of the SSC will be:

- To provide advice, including PPI, through its Chair, on all appropriate aspects of the project
- To concentrate on progress of the project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments
- To provide advice to the investigators on all aspects of the project.

VERA Working Group (Project Management Group)

The VERA Working Group (PMG) is responsible for the day-to-day management of the project. The role of the PMG is:

- To enable the delivery of the project objectives
- To facilitate and promote the aims of the project
- To take responsibility for the creation, refinement and adjustment of the project work plan
- To identify issues that arise within the project which may affect delivery and act on these accordingly, informing and seeking advice from the Steering Committee where necessary.
- Provide regular update reports as required for co-applicants, collaborators, key stakeholders and funders
- To manage the resources and budgets for the project, advising on best use of funding and staffing
- To lead on the practical arrangements for project meetings and other activities
- To discuss, agree and offer solutions to issues that arise focussed on avoiding and solving problems
- To act as a source of support and advice for those involved in the project.

PROTOCOL CONTRIBUTORS

A range of people have contributed to and reviewed the study protocol. The contributors are summarised below:

Research team members from UCLan:

Dr Kathryn Jarvis, Senior Lecturer in Occupational Therapy, UCLan, Chief Investigator.

Dr Rachel Stockley, Senior Research Fellow, UCLan, Original Chief Investigator.

Dr Clare Thetford, Senior Research Fellow, UCLan.

Julie Cook, Research Fellow, UCLan.

The Walton Centre Team:

Dr Andrew Rose, Head of Commercial Engagement and Marketing

Dr Ganesh Bavikatte, Consultant and Clinical Lead in Rehabilitation Medicine

Jo Haworth, Clinical Specialist Physiotherapist

Nicola Branscombe, Band 7 Occupational Therapist

Design technology team members from Citrus Suite:

Chris Morland, Chief Executive, Citrus Suite

Steve Donovan, Chief Commercial Officer, Citrus Suite, Design Technologist Lead

Study Steering Committee:

Suzanne Clarke (Senior UX Designer, BBC Research & Development),

Dr Sue Hunter (Deputy Head of School of Allied Health Professions, Keele University),

Margaret Ogden (PPI whose family member experienced a stroke),

Prof. Fiona Rowe (Professor of Orthoptics and Health Services Research, University of Liverpool),

Suzanne Simpson (Specialist Occupational Therapist, The Walton Centre) (Chair)

Staff and Service users from The Walton Centre:

Staff and service users who contributed to workshop

Service users were involved at the start of the planning for this project. The original idea was conceived by Dr Rachel Stockley (Senior Research Fellow, UCLan) and Dr Ganesh Bavikatte (Consultant and Clinical Lead in Rehabilitation Medicine, The Walton Centre). The initial stages of

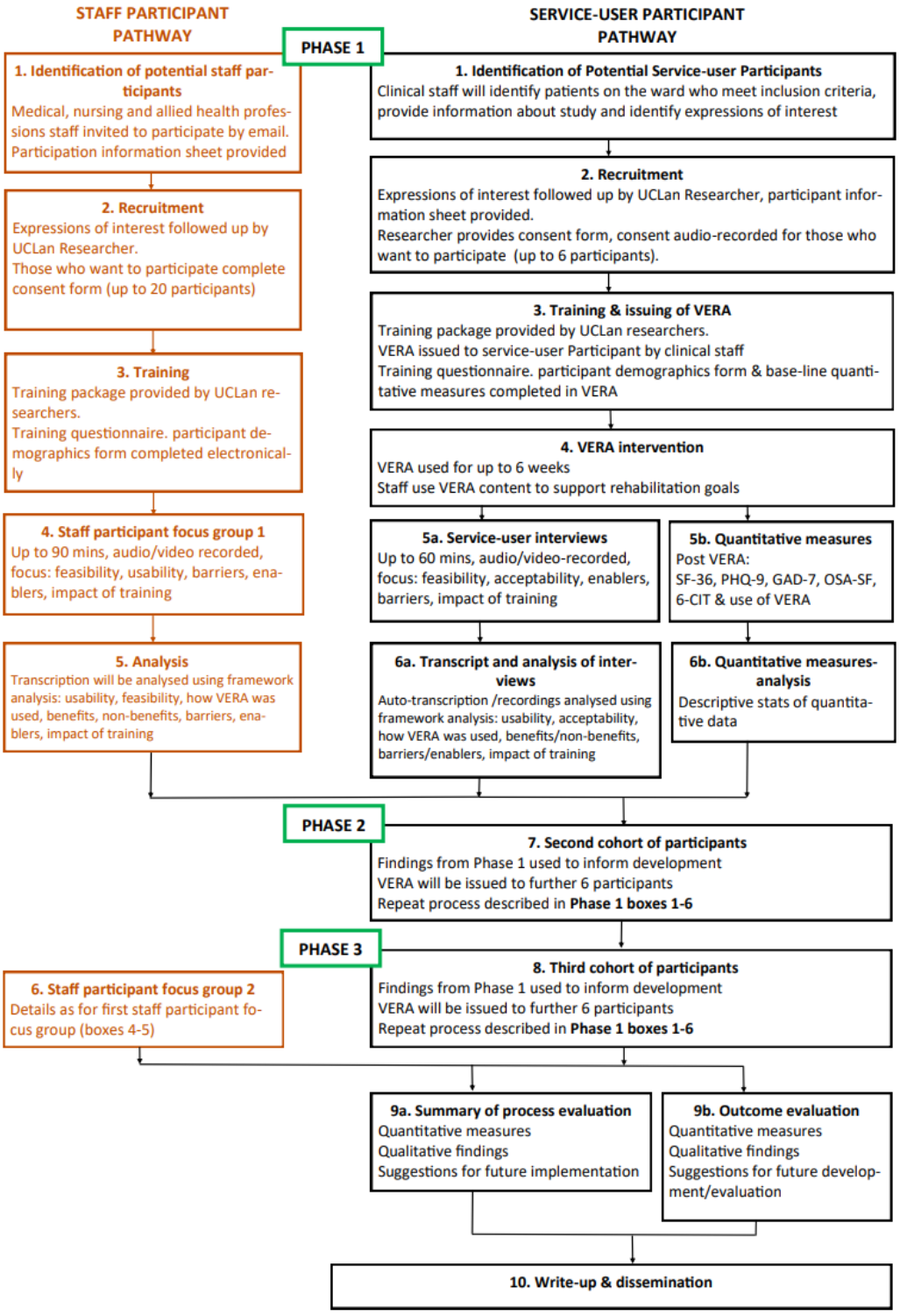
development involved service user (Patient and Public Involvement) and staff workshops (described above). These workshops took place in 2019 and were supported by funding from the NIHR Research Design Service (RDS). The ideas generated at these workshops have shaped the first iteration of VERA and this protocol.

KEY WORDS: rehabilitation, technology, evaluation, implementation, mixed methods, virtual engagement rehabilitation assistant

STUDY FLOW CHART

Please see next page

Figure 1: Summary of staff and service-user VERA evaluation of implementation study



STUDY PROTOCOL

Using digital technology to increase activity during inpatient rehabilitation: initial evaluation of Virtual Engagement Rehabilitation Assistant (VERA)

1 BACKGROUND

The Walton Centre NHS Foundation Trust (The Walton Centre) is a specialist hospital providing rehabilitation to adults with complex neurological needs. Highly qualified staff on the Complex Rehabilitation Unit (CRU) provide specialist rehabilitation, defined as:

> *"process of assessment, treatment and management by which the individual (and their family/carers) are supported to achieve their maximum potential for physical, cognitive, social and psychological function, participation in society and quality of living"* (British Society of Rehabilitation Medicine, 2019, p.2)

This specialist rehabilitation aims to meet the needs of those who meet all the following criteria:

1. have experienced a significant deterioration as a result of complex illness or injury
2. have moderate to severe functional impairment or activity limitation
3. assessment indicates they are likely to improve their functional impairment with access to inpatient rehabilitation.

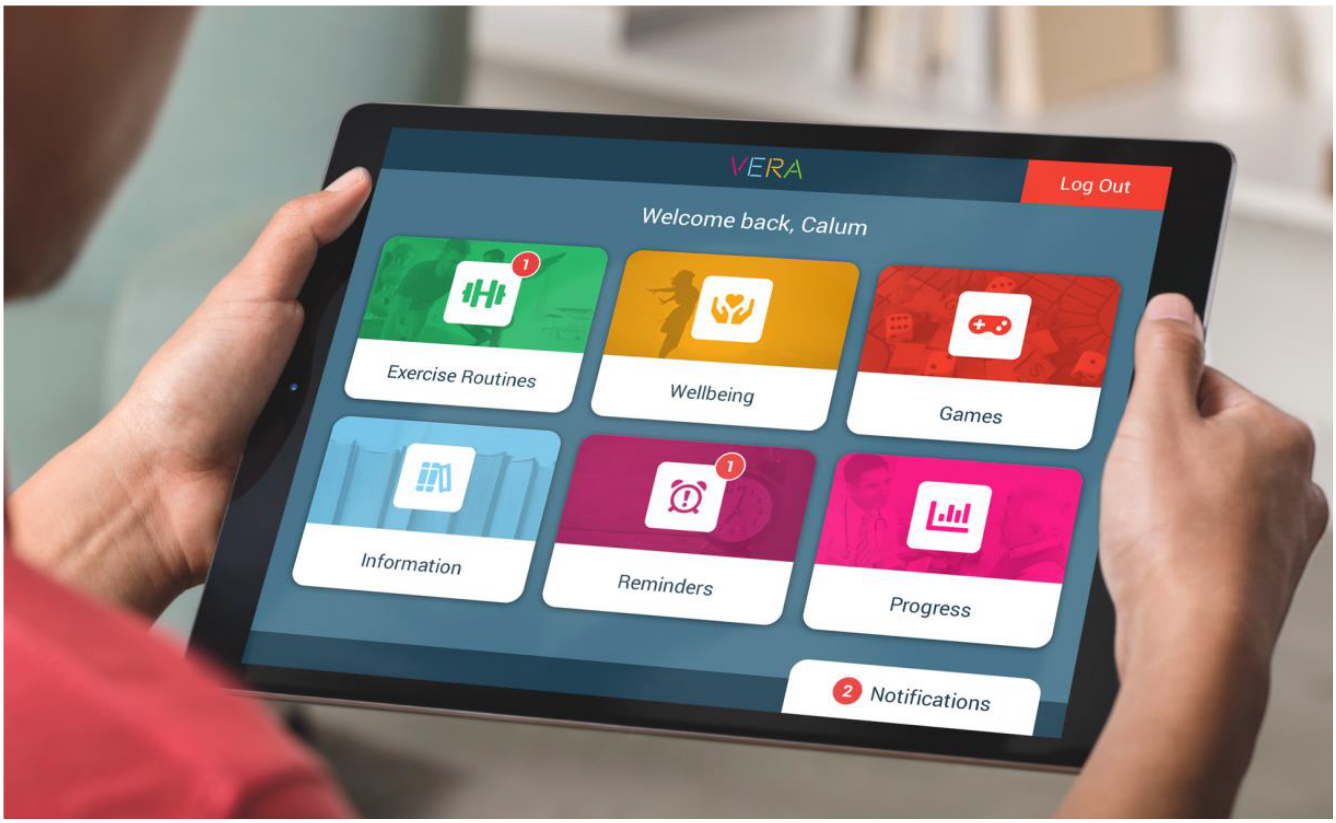
Intensity of activity has been found to improve functional and motor recovery following neurological injury (Intercollegiate Stroke Working Party, 2016; Königs, Beurskens, Snoep, Scherder, & Oosterlaan, 2018; Schneider, Lannin, Ada, & Schmidt, 2016; Teasell et al., 2020), with indications that therapy should be organised in short regular sessions (Bernhardt et al., 2016). However, inactivity is common in hospital admissions (Kunkel, Fitton, Burnett, & Ashburn, 2014; Sheedy et al., 2020), with studies of inpatient rehabilitation units showing that service users spend more than half their time inactive (Bernhardt, Dewey, Thrift, & Donnan, 2004). Current NHS rehabilitation services cannot provide the intensity of therapy which is known to be beneficial due to limited available therapy time. The duration of high intensity interventions has been shown to pose challenges outside a research context (Connell, McMahon, Eng, & Watkins, 2014; Langhorne, Coupar, & Pollock, 2009). Alongside the need for intensity of activity, there is growing evidence that self-management, defined as the ability to respond to the physical and psychosocial impact of one's own condition (Fletcher, Kulnik, Demain, & Jones, 2019), has the potential to improve quality of life and self-efficacy for people with neurological conditions (Fryer, Luker, McDonnell, & Hillier, 2016; Liddy, Blazkho, & Mill, 2014). Founded on this evidence, the VERA was developed to support inpatient rehabilitation at The Walton Centre.

Novel and innovative digital technology offers an opportunity to increase activity in a ward environment outside of formal therapy. Commercially available gaming consoles provide a possible means to improve motor function through provision of targeted games (Iruthayarajah, McIntyre, Cotoi, Macaluso, & Teasell, 2017; Pollock et al., 2014; Trinh, Shiner, Thompson-Butel, & McNulty, 2017). However, technology provides opportunities beyond gaming. Digital technology can be personalised to meet a service user's individual needs and preferences (National Information Board, 2014). A versatile digital platform offers the potential to support rehabilitation goals and increase intensity of therapy, through encouraging engagement in therapeutic activities and reducing inactivity.

A first prototype Virtual Engagement Rehabilitation Assistant (VERA) has been conceived through a collaborative process. Service users, health care professionals and researchers have worked closely with a commercial software design company to realise collaboratively agreed ideas and produce a prototype of VERA.

VERA is a mobile portal which enables portable devices, such as tablets, to access a range of applications and web-based resources. In this study VERA will be housed on an iPad Pro 11" (or equivalent). It will enable a service user to interact with a range of digital resources tailored to their own rehabilitation goals, including timetables and appointments, videos of exercises and activities, reminders, wellbeing questionnaires, games and links to other relevant resources and information.

An example of how VERA will look is given below:



The VERA is not currently being marketed and, therefore, UKCA or CE certification has not yet been sought. Advice has been sought from the Medicines and Healthcare Regulatory Authority (MHRA) who have advised that VERA would not be considered a medical device at this stage of development, based on the functions described in this protocol.

2 RATIONALE

Significant additional funding for rehabilitation services in the NHS is unlikely, so alternative means to be more effective within current resources should be explored. This aspiration is particularly poignant at a time when staff are being redeployed from rehabilitation services to support acute COVID-19 services, leaving less time for staff to spend working on non-COVID-19 rehabilitation (Prvu Bettger et al., 2020). Digital technology may reduce face-to-face contact time between staff and service users, thus enhancing infection control and reducing risk. As there is evidence that service users with complex rehabilitation needs require intense activity to achieve optimal outcomes, the development of cost-effective technology to enable service users to increase the amount of time they are active and increase their engagement with therapeutic tasks with low staff input is both judicious and timely.

The development of VERA has been influenced by the principles of Responsible Research and Innovation (European Commission, 2014; Stilgoe, Owen, & Macnaghten, 2013). Service users and carers have fundamentally shaped VERA, through a co-design process, and will continue to do so through this evaluative study. Further, VERA has been designed to support self-management by empowering service users to have a greater degree of control over their own rehabilitation.

VERA was conceived and developed to meet the needs of service users on a CRU. The first iteration of VERA will, therefore, be implemented and evaluated in this setting. Service users in this setting have a diverse range of rehabilitation needs and receive services from multiple clinical professionals. This study will evaluate early implementation; the profiles of those along a spectrum of benefitting and not benefitting from VERA will be explored, alongside the acceptability, usability and feasibility of introducing this digital technology in a complex inpatient rehabilitation setting.

3 THEORETICAL FRAMEWORK

This study is underpinned by social constructionism, which presumes that knowledge is acquired through the use of language, conversation and social contact with others and that this leads to jointly-constructed understanding (Andrews, 2012, p. 44; Creswell, 2009, p. 8). This implementation study will be a collaborative effort between staff, service users and their families / friends in a clinical environment, staff from a commercial software development company, and academic researchers. It is anticipated that the interactions between the collaborators will be crucial to the development and implementation of VERA.

VERA has a number of interacting components, which define it as a complex intervention (Medical Research Council, 2008). Whilst a range of theoretical frameworks have been developed to support the implementation of complex health interventions (Morris et al., 2019), the Non-adoption, Abandonment, and Challenges to the Scale-up, Spread and Sustainability (NASSS) framework has been developed specifically to address the implementation and sustainability of health and care technologies (Greenhalgh et al., 2017). The NASSS implementation framework, along with the associated qualitative assessment tool, the NASSS-Complexity Assessment Tool (NASSS-CAT) provides the ideal structure on which to develop, implement and evaluate VERA.

There is considerable evidence that the adoption and sustained use of a technology over time is not inevitable, and a range of factors can disrupt this process of implementation. The Non-adoption, Abandonment, and Challenges to the Scale-up, Spread and Sustainability (NASSS) framework (Greenhalgh et al., 2017) is an evidence-based, theory-informed framework comprising seven key

areas that have been found to influence adoption and the sustained implementation of health technologies. These seven key areas or domains are:

1. The condition/s for which the technology seeks to provide benefit
2. The technology itself, including the data it generates and the knowledge required to use the technology
3. The value of the proposition to the service user and the developer
4. The adopters of the technology including staff, service users and, where appropriate, carers / family members
5. The organisation, including its readiness for the technology and its capacity to accommodate the changes required
6. The wider political, regulatory, professional, and socio-cultural systems
7. The scope for embedding the technology over time.

An initial analysis of VERA in relation to the seven key areas using the NASSS-CAT was undertaken as part of the planning for the development of VERA.

The analysis of complexity is summarised below. Areas of high complexity that need addressing as part of this first evaluation are highlighted in red.

NASSS domain	Analysis
1. Condition	The aim is to implement VERA on one Complex Rehabilitation Unit (CRU). Service users will be experiencing a range of conditions / injuries and may also be experiencing co-existing illness and / or impairment. The service users are likely to be diverse. The socio-cultural diversity is wide as the CRU is a regional specialist service, and service users are admitted from a wide geographical area across Cheshire and Merseyside.
2. Technology	The VERA is a digital technology. It is a mobile portal and App which enables service users to access a number of treatment-based features, such as their therapy timetable, videos and instructions of therapy activities to be completed outside of therapy sessions, information about relevant medical conditions, and about the ward and the processes on the ward. These features will be shaped by the implementation process. The performance of VERA is not known. The usability and acceptability to service users and staff is not known. As VERA will need to interact with some components of Information Technology systems at The Walton Centre, data protection is paramount in this implementation.
3. Value of proposition	There is convincing evidence that increased activity leads to better motor control outcomes following brain injury. There is also evidence that service users on wards are often inactive. There appears to be a role for a digital technology that might reduce this gap.

	VERA needs evaluation to consider its value to the users of the technology, the healthcare provider and the designer of the VERA mobile portal. There may be a number of differing views, as there are stakeholders with differing motivations and expectations for VERA.
4. Adopters	The main adopters will be service users and staff on the CRU. These stakeholders will be the focus of the first evaluation. However, it is recognised that the adoption of the VERA may be influenced by others supporting the adopters. This support may include service users' family and friends, or Information Technology staff. The evaluation will need to explore the support that was offered to the adopters, as well as the adopters' individual experiences.
5. Organisation	The Walton Centre is the organisation implementing the intervention, The Walton Centre and the staff at The Walton Centre have invested time and money in the technology and appear ready to implement the VERA. Organisational routines and processes will need to change to enable VERA and protect data in line with the UK General Data Protection Regulation (UK GDPR). These will need to be resolved before VERA can be placed on the CRU and therefore will be in place prior to the first VERA evaluation.
6. Wider context	There is evidence that increased activity can lead to better motor control outcomes following brain injury. Also, people in hospital are inactive for large proportions of the day. Digital technology provides a means to increase the amount of activity an individual in hospital undertakes in a day, with the potential that this may impact rehabilitation goal achievement. Additionally, the COVID-19 pandemic has put pressure on rehabilitation services; interventions that can support the rehabilitation provision need exploring and evaluating. This first evaluation will not seek to address the wider context beyond siting the study within this context as described above.
7. Embedding technology over time	There may be challenges to embedding the VERA technology over time due to changes in understanding of the effectiveness of interventions. VERA is a flexible platform; it is likely that it will be possible to adapt VERA through continued co-design process with service users and staff. This will not be a focus for the first evaluation of VERA, but it is recognised that this will be important in the future for sustainability and policymakers.

Table 1: A summary analysis of VERA using NASSS

The analysis in Table 1 indicates that the first four (of seven) NASSS Domains will be key to the initial implementation of VERA. This first evaluative study will, therefore explore:

- **Condition/s:** the individuals, for whom VERA may offer benefit and non-benefit
- **Technology:** the VERA technology, if and how it is used, the data it generates, and the knowledge required to use the technology
- **Value proposition:** the value of VERA to the service user and healthcare provider, which will ultimately inform the development process
- **The adopters:** service user and staff experiences of using VERA

4 RESEARCH QUESTION / AIM(S)

This study aims to evaluate the implementation process and outcomes of placing the VERA digital technology in a complex inpatient rehabilitation setting, and to explore the adoption of the technology by service users and staff. It will do this through a study comprising three phases (summarised in the flow diagram in Figure 1).

4.1 Objectives

The study objectives are:

- To use principles of co-design to foster a collaboration between clinical staff, service users, computer programme developers and researchers to develop and refine a prototype of a Virtual Engagement Rehabilitation Assistant (VERA).
- To develop and produce training packages to support the use of VERA, through collaboration with clinical staff, selected service users, computer programme developers and researchers.
- To explore the acceptability, usability and feasibility of VERA in an inpatient rehabilitation setting.
- To explore the characteristics of the service users who benefit, and do not benefit from VERA.
- To identify barriers and enablers to the implementation of VERA in an inpatient rehabilitation setting.
- To estimate service user engagement with VERA (total time and pattern of usage)

4.2 Outcome

The study will capture both the process and the final outcomes of the implementation of VERA.

Process outcomes

- An exploration of the impact of staff and service user training packages, which will inform production of final VERA training packages.
- Based on the NASSS framework, an exploration of the feasibility, acceptability and usability of VERA to inform further development and implementation of VERA in a complex rehabilitation ward setting.

Final Outcomes

- Production of agreed VERA training packages for both service users (and their families and friends where appropriate) and staff.
- An analysis of how, when and by whom VERA was used in a complex inpatient rehabilitation setting.
- Service users' (and their families' and friends' where appropriate) and professionals' self-perceived benefits or disbenefits of VERA.
- Identification of barriers and enablers to the implementation of VERA for people with complex rehabilitation needs in an inpatient setting.
- A second iteration of VERA.

5 STUDY SETTING

This single-site study will be undertaken on one Complex Rehabilitation Unit (CRU).

The CRU is a 30-bedded unit hosted by The Walton Centre NHS Foundation Trust, and forms part of the Cheshire and Merseyside Rehabilitation Network (https://www.cmrehabnetwork.nhs.uk/). It comprises 20 beds for service users with Level One Rehabilitation needs (highly specialist tertiary rehabilitation), and 10 beds for those with Level Two needs (local specialist rehabilitation). All inpatients are assessed and treated by a highly skilled, multi-disciplinary team, and are provided with individualised treatment programmes which are updated regularly during their stay. Patient-centred care and self-management strategies are an integral part of these treatment programmes.

6 SAMPLE AND RECRUITMENT

6.1 Sampling

6.1.1 Size of sample

Service user sample

Six VERA units will be available on the Complex Rehabilitation Unit at any one time. It is anticipated that each of the six VERA units will be allocated to a different participant in each of the three Phases. It is therefore estimated that, allowing for withdrawal and subsequent replacement, there will be a maximum of 20 service user participants recruited to the study.

Staff sample

There are approximately 50 medical, nursing and allied health professional staff working on the Complex Rehabilitation Unit. In addition to providing demographic data and feedback on the training package for VERA, these staff will be invited to participate in one, or in the case of limited professional group representation, both focus groups. In line with recommendations for focus group size (Krueger & Casey, 2000, p.17), the aim will be to include between six and ten participants with maximum variation and representing the three professional groups in each focus group.

There will, therefore, be a maximum of 20 staff participants. Due to a limited number of staff working on the ward, it is anticipated that the overall number of staff participants is likely to be less than 20, with some staff attending both focus groups.

Programme Management Group sample

The VERA Programme Management Group (PMG) consists of 18 people from across the three collaborating organisations. We aim to recruit up to 10 participants from the PMG, with at least one from each of the three collaborating organisations. Four clinicians who are part of the VERA PMG may also be part of the staff participants cohort. As the data collected in each activity will focus on different aspects of the implementation process, it is both feasible and robust for these clinicians to participate in both the staff and the PMG data collection activities, if they choose to do so (subject to separate recruitment/consent processes). The UCLan research team will also be invited to participate to enable a comprehensive overview of the implementation process.

6.1.2 Sampling technique

Service users

The clinical team will review up to 30 inpatients on the ward at the time of issuing the VERA devices. In collaboration with the Chief Investigator, they will use the study selection criteria and clinical

reasoning to identify the service users they feel will benefit from the programmes available within VERA. This process reflects clinical practice when there are limited resources.

In Phase 1 the inclusion criteria will ensure that participants in the first cohort will be able to use VERA independently. VERA will be implemented with this group before being explored with participants with greater support needs in later phases.

Inclusion criteria - service users

Service user participants will be eligible for inclusion in **Phase 1** if they:

1. have rehabilitation goals that can be addressed through the activities in VERA.
2. have been assessed by a speech and language therapist as able to communicate to allow effective interaction with the VERA unit.
3. are able to use VERA independently (without support from equipment available on the ward, or from another person).
4. are able to understand English language, as the first version of VERA will use English language only.
5. have complex rehabilitation needs described as needing the services of a MDT comprising highly trained professionals due to: 1. High physical dependency; 2. Mixed physical, cognitive / behavioural dependency; 3. Cognitive / behavioural disabilities.

Service user participants will be eligible for inclusion in **Phases 2 and 3** if they:

1. have rehabilitation goals that can be addressed through the activities in VERA.
2. have been assessed by a speech and language therapist as able to communicate to allow effective interaction with the VERA unit independently or with additional equipment or support from another person.
3. are able to understand English language, as the first version of VERA will use English language only.
4. have complex rehabilitation needs described as needing the services of a MDT comprising highly trained professionals due to: 1. High physical dependency; 2. Mixed physical, cognitive / behavioural dependency; 3. Cognitive / behavioural disabilities.

Exclusion criteria - service users

Service users will be excluded in **Phase 1** if they:

1. have been assessed by speech and language therapist as unable to use VERA without support from equipment available on the ward or from another person.

2. do not have mental capacity to engage in the study. This will be assessed through discussion between the service user, the clinical team and the researchers and, where permission is given, with participant-identified family and friends. This discussion will be based on the five principles of the Mental Capacity Act 2005 Code of Practice (Department for Constitutional Affairs, 2007).

Service users will be excluded in **Phases 2 and 3** if they:

1. do not have mental capacity to engage in the study. This will be assessed through discussion between the service user, the clinical team and the researchers and, where permission is given, with participant-identified family and friends. This discussion will be based on the five principles of the Mental Capacity Act 2005 Code of Practice (Department for Constitutional Affairs, 2007).

Purposive sampling (Silverman, 2006, p.306) will be employed to gain a maximum variation sample. This aligns with the constructionist theoretical approach, as the study purpose is to construct learning from a range of service users on the CRU. This is a first evaluative study of VERA, therefore the clinical team will seek to be inclusive of as much variation in the study sample as possible. We will aim to include individuals with a range of conditions, including stroke as the benefit of increased activity has been established for stroke survivors. We will aim to gain variety in gender, to include participants who self-identify as Black, Asian, and / or Minority Ethnic, and participants who self-report as being a low user of technology. It may be necessary to adjust our recruitment strategies as the study progresses to achieve this sample; for example, if the participants are mainly male, there would be an aim to recruit females in subsequent phases.

Staff

Medical, nursing and allied health professional staff working on the ward who meet the inclusion criteria will be invited to participate. The Principal Investigator at The Walton Centre will be responsible for distributing information (Appendices 6 and 7), provided by the UCLan VERA Research Team, about the study to all staff working on the ward via email. This will ensure that all staff are aware of the study, and that all relevant staff are invited to participate.

Inclusion criteria - staff

Staff participants will be included if they:

1. are a member of the medical, nursing and allied health professional staff, either a qualified professional or staff working in a support role.
2. have worked in their professional capacity with service users using VERA during the previous six weeks.

Exclusion criteria - staff

Staff participants will be excluded if they:

1. spend less than seven hours a week working with service users on the Complex Rehabilitation Unit
2. have not worked in their professional capacity with any service users who are using VERA

Programme Management Group (PMG) participants

All PMG members (approx. 18) will be invited to participate. The invitation email (Appendix 31) will be sent to the PMG members by an allied health profession student currently studying at UCLan. The PMG Participant Information Sheet (Appendix 32) will be attached to the invitation email. This will ensure that all PMG members are aware of the study and are invited to participate

PMG participants will be included if they have been involved in the development and implementation of VERA for this first evaluative study as part of their role with one of the three collaborating organisations – The Walton Centre, UCLan, or Citrus Suite.

PMG participants may also be staff participants working on the Complex Rehabilitation Unit at The Walton Centre (as identified in 6.1.1).

6.2 Recruitment

6.2.1 Sample identification

Service users

Potential participants will be identified, and an initial approach will be made, by a member of the clinical team working on the rehabilitation ward, as described in section 6.1.2. If a service user is interested in participating, a meeting with a UCLan researcher will be arranged to provide further information, including a Service User Participation Information Sheet (Appendix 2), and to answer any

questions. It is anticipated that this meeting will be via Microsoft Teams given the current restrictions due to COVID-19. However, if infection control measures and research partner protocols for COVID-19 enable face-to-face meetings, these will take place at The Walton Centre. The service user will then be given at least 48 hours to decide if they would like to participate. If a participant requires the information in the Participant Information Sheet in a different format, for example as a video-recording, this will be provided.

No payments or incentives will be made to participants.

Staff

As stated above, all medical, nursing, and allied health professional staff working on the ward who meet the inclusion criteria will be invited to participate. This process is described in section 6.1.2. Staff who express an interest by responding to the recruitment email will be contacted by a UCLan researcher, who will make sure they have received a Staff Participant Information Sheet (Appendix 7) and are given the opportunity to ask questions. It is anticipated that this communication will take place by email, but if a potential participant requests a further / more detailed conversation, then this will be arranged via Microsoft Teams. The member of staff will then be given at least 24 hours to decide if they would like to participate.

As stated in section 6.1.1, the aim will be to recruit staff to attend a focus group of between six and ten participants, at the end of Phase 1, and again at the end of Phase 3. Staff may express an interest to attend both focus groups, or only one. In the unlikely event that there are more than ten staff able / willing to attend the first focus group, staff will be selected based on maximising representation of all three professional groups. Those not invited to attend will be contacted to thank them for their interest and to be advised that a further focus group will take place and every effort will be made to include them in the second focus group (Appendix 9). If the second focus group is also oversubscribed, every attempt will be made to balance the number of participants from each of the three professional groups over the two focus groups. Again, staff who cannot be included in the second group will be contacted and thanked for their interest (Appendix 10).

No payments or incentives will be made to participants. The focus groups will be arranged at times that are identified by the staff as most convenient, for example when competing demands can be minimised.

Programme Management Group

All Programme Management Group members who meet the selection criteria will be invited to participate through the process described in 6.1.2. PMG members who express an interest by responding to the email (Appendix 31) will be contacted by an allied health profession student

currently studying at UCLan who will make sure they have received a PMG Participant Information Sheet (Appendix 32) and are given the opportunity to ask questions. It is anticipated that this communication will take place by email, but if a potential participant requests a further / more detailed conversation, then this will be arranged via Microsoft Teams. The member of staff will then be given at least 24 hours to decide if they would like to participate.

No payments or incentives will be made to participants. The interviews will be arranged at times that are identified by the PMG members as most convenient, for example when competing demands can be minimised.

6.2.2 Consent

Service users

Service users (with mental capacity) opting to participate will undertake a consent process. The consent process will be conducted by a UCLan researcher. Potential participants will have the opportunity to ask questions and discuss with family / friends prior to consenting. To ensure processes are adaptable while remaining governance-compliant in light of COVID-19 restrictions, provision will be made for consent to be documented in written or audio format utilising a consent form (Appendix 3).

Where consent is audio-recorded, this will be via Microsoft Teams (if virtually), or on an encrypted digital recorder (if face-to-face). If undertaken through Microsoft Teams, the consent will be conducted in accordance with UCLan's Remote Research Guidelines (https://www.uclan.ac.uk/students/support/research/ethics.php).

Recordings will be transferred to a secure UCLan Office 365 OneDrive server at the first opportunity, and then deleted from the portable recording device / Microsoft Teams.

Where consent is written, the document will be transferred to an electronic file and stored on a secure UCLan Office 365 OneDrive server separately from any participant data. The original document will be securely destroyed once the document has been transferred.

All participants will be advised verbally and in writing (in the Participant Information Sheet and during the consent process (Appendices 2 and 3) that they are free to withdraw from the evaluation of their use of VERA as part of the study at any time. Ongoing consent will be iterative, as implied by continued use of VERA.

If a service user participant consents and starts to use VERA, but later decides to discontinue its use, the participant will still be invited to complete the quality of life, functional ability, mental health and cognition measures and participate in the Training Questionnaire, and interview (if these have not already been completed), but will be under no obligation to do so. As the focus of the study is to

consider acceptability and feasibility of VERA, it is important to capture the reasons a person chooses to discontinue the use of VERA, if they are willing to provide this information.

If a participant consents and uses VERA, but later decides that they do not want to be interviewed, any pseudonymised data collected up to that point will be included in the analysis. A service user's continued use of VERA for the six weeks allocation is independent of their continued participation in the study or contribution of data.

Each participant will be able to request withdrawal of their interview data for two weeks after the interview. If this is requested, the Chief Investigator will oversee the permanent deletion of the recording and any related analysis. After this time, the data will be anonymised and integrated with findings from other participants and it will not be possible to extract an individual's data. All data presented in the findings of study reports and publications will be anonymised. This will be clearly stated in the Participant Information Sheet (Appendix 2).

Staff

Staff opting to participate will undertake a consent process. The consent process will be conducted by a UCLan researcher. Potential participants will have the opportunity to ask questions prior to consenting. To ensure processes are adaptable while remaining governance-compliant in light of COVID-19 restrictions, provision will be made for consent to be documented electronically through an online consent form utilising Microsoft Forms. (Appendix 8). The consent form will be held securely in UCLan Office 365 OneDrive.

Each participant will be advised verbally and in writing that they are free to withdraw from the study at any time, without giving a reason (Appendices 7 and 8), with no negative consequences from their employer or the UCLan researchers. The data collected up to withdrawal will be retained within the study.

Programme Management Group

Programme Management Group members opting to participate will undertake a consent process. The consent process will be conducted by an allied health profession student currently studying at UCLan who has received training in recording consent. Potential participants will have the opportunity to ask questions prior to consenting. Provision will be made for consent to be documented electronically through an online consent form utilising Microsoft Forms. (Appendix 33). The consent form will be held securely in UCLan Office 365 OneDrive.

Each participant will be advised verbally and in writing that they are free to withdraw from the study at any time, without giving a reason (Appendices 32 and 33), with no negative consequences from their employer or the UCLan staff or students. If this happens, we will ask if we can keep the information we

have collected. With consent, the data collected up to withdrawal will be retained within the study. If a participant does not want us to keep this information, we will permanently delete the information from Microsoft Teams and UCLan's online 365 storage.

7 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

7.1 Study Design

This study is an evaluation of the implementation of a digital technology. It is a mixed methods research design. The quantitative findings will provide context and description to enrich understanding of the qualitative findings and subsequently the implementation process and outcomes.

The intervention in this study is a VERA unit to support rehabilitation goals. Service user participants will be allocated a VERA for six weeks, or until discharge from the CRU, whichever is the shorter.

7.1 Data collection

7.1.1 Anonymisation, transfer, storage and destruction

To enable pseudonymisation of the data files, following consent, service user and staff participants will be allocated a personal identification number (PIN). This will be allocated by the University of Central Lancashire (UCLan) researcher (or allied health profession student for the Programme Management Group participants) for use in all relevant file names. The 'key' document containing the participant's name and PIN (Appendix 11) (and for staff participants a work email contact Appendix 12) will be stored in a password protected file which will be stored separately to all other data collection files. This 'key' document will be stored on the UCLan Office 365 OneDrive.

The 'key' will only be accessible to the UCLan researchers involved in the study, to enable de-anonymisation if necessary.

The allied health profession students for the Programme Management Group participants will only have access to a dedicated Key Document containing the data related to the PMG participants, as necessary to perform their role. They will not have access to staff or service user 'Key' document or other data.

All data collected will be identified only by the participant's PIN.

Where possible, data will be collected by clinical staff and participants (with assistance from family / friends if appropriate). This will be carried out by using the VERA unit to access hyperlinks to the data collection tools, thereby reducing the need for transfer of data. Data collected through the VERA unit and the hyperlinks to the data collection tools will go directly to either the secure Office 365 OneDrive storage of a named member of the VERA team at UCLan, or secure Qualtrics Survey Platform storage. No data will be stored on the VERA Unit.

Where the VERA unit is used to access the Qualtrics Survey Platform (e.g. demographic information, training questionnaire, measures of quality of life, functional ability, mental health and cognition), the pseudonymised data is stored within Qualtrics Survey Platform. This is a GDPR compliant, UCLan approved, web-based survey platform (https://www.qualtrics.com/support/survey-platform/getting-started/data-protection-privacy/). Data is held in a UCLan account, only accessible to specified members of the UCLan VERA research team via password. This data will be analysed in the Qualtrics Survey Platform initially and then transferred to Office 365 OneDrive. Once the data and analysis has been moved to Office 365 OneDrive, they will be deleted from the Qualtrics Survey Platform. The collection of individual data are outlined below in 7.1.2-8.

Data collected through Microsoft Teams (e.g. Interview and Focus Group audio / video recordings) will be downloaded immediately to the secure Office 365 OneDrive storage of a named member of the UCLan VERA research team, and deleted from Microsoft Stream and Microsoft Teams.

Data collected on through Microsoft Forms via hyperlink in the VERA unit (service users) or via email to staff (e.g. Staff consent forms and suggested change forms) will be downloaded immediately to the secure Office 365 OneDrive storage of a named member of the UCLan VERA research team.

Where the data has been collected using an encrypted portable audio-recording device or video camera, the recording will be deleted from the recording device as soon as this data has been transferred to the UCLan Office 365 OneDrive server.

Once data has been analysed and anonymised, the subsequent anonymised reports and analyses will, additionally, be stored on the Faculty of Health & Care dedicated shared drive on the University network for research staff. Each project (including VERA) has a dedicated and individualized folder on the shared drive, which is only accessible, via UCLan password login, to the named research staff on that project. Changes to access must be approved and actioned by named senior research administrators for added security.

Using Office 365 OneDrive will reduce the need for data transfer. However, if there is a need to transfer any data this will be completed through a secure, password protected file transfer.

In line with UCLan policy all the data collected for this study will be kept for five years (unless specified otherwise), after which they will be securely and permanently deleted.

7.1.2 Service user and staff demographic information

It is anticipated that the acceptability and usability of VERA may be affected by the characteristics and beliefs of the staff and service user participants. Demographic information will be collected from both staff and service user participants through tailored Demographic Information Forms (Appendices 13, 14 and 22), which will be analysed for patterns in variation in adoption of VERA. As this is a predominantly a qualitative study, this data will also be used to describe the sample.

Service user demographic information

The following service user participant demographic data will be provided by the clinical staff at The Walton Centre: 1) age; 2) medical condition/s; 3) reason for admission; 4) date of injury / start of condition; 5) date of admission to ward (to give an indication of whether being established on the ward influences VERA usage); 6) independent / supported communication (support may be provided by people or equipment); 7) if supported communication is used, the form of communication used, and where appropriate the type of equipment used to communicate (Appendix 13 Service User Demographic Information Staff-Reported Form). These data will be collected using the VERA unit to access the online Qualtrics Survey Platform. With consent, clinical staff will input the service user participant's demographic information into the VERA unit as they set up the unit for the participant.

To enable self-identification of data that may be sensitive, the following data will be self-reported by service users: 1) gender; 2) ethnicity; 3) self-perceived assessment of high / low technology use and confidence. After they have been allocated a VERA unit and have completed the VERA training package, this information will be entered into a Service User Demographic Information Self-Report Form (Appendix 14) on the online Qualtrics Survey Platform by the participant, using VERA.

Staff demographic information

The information collected from staff participants will be: 1) age; 2) gender; 3) ethnicity; 4) self-perceived assessment of high/low technology use; 5) profession and band / grade; 6) length of time working in rehabilitation; 7) length of time working on ward at The Walton Centre. This data will be collected through the online Qualtrics Survey Platform (Appendix 22). The link for the online Staff Demographic Information Form will be sent by email to the staff participants by a UCLan researcher.

Programme Management Group demographic information

This information will not be collected outside of the interview for the Programme Management Group participants

7.1.3 Service user quantitative measures

Service user participants will be invited to complete a suite of five quantitative measures (1. Short Form-36, 2. Patient Health Questiionnaire-9, 3. General Anxiety Disorder-7, 4. Occupational Self-assessment Short Form, 5. Six-item Cognitive Impairment Tool). These measures have been selected to gain an overview of each service user participant's quality of life, functional ability, mental health and cognition. With the exception of the Six-item Cognitive Impairment Tool, these measures will be completed by the service user participant at the start and end of the VERA intervention period to collect pre- and post-intervention measurements.

The Six-item Cognitive Impairment Tool will be administered by the clinical staff at The Walton Centre at the start and end of the VERA intervention.

These data will be collected through the online Qualtrics Survey Platform.

1. Short Form-36

The Short Form-36 (Ware & Sherbourne, 1992) is a measure of health function and is a measure of health related quality of life (Appendix 15). It has been widely used in health settings (Haan, 2002) and has been found to have acceptable psychometric properties following stroke (Anderson, Laubscher, & Burns, 1996; Hagen, Bugge, & Alexander, 2003) and for people with brain tumours (Bunevicius, 2017). This is a self-administered assessment available online (RAND Corporation) with an established scoring procedure (https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/scoring.htmlassessment).

2. Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) is a short questionnaire to screen for depression (Appendix 16). It can be self-administered and has been shown to be valid in a stroke population (de Man-van Ginkel et al., 2012; Prisnie et al., 2016; Williams et al., 2005). It contains nine questions with a score of 10 or above indicating moderate depression.

3. General Anxiety Disorder-7

The General Anxiety Disorder-7 (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006) is a short questionnaire to screen for generalised anxiety(Appendix 17). It can be self-administered and has been shown to psychometric properties in a healthy population (Löwe et al., 2008) and for individuals with multiple sclerosis (Eccles, Morris, & Kneebone, 2017; Marrie et al., 2018). It contains seven questions and a score of greater than 10 indicates a need for further evaluation.

4. Occupational Self-assessment Short-form

Occupational Self-assessment-Short-form (OSA-SF) (Appendix 18), a shortened version of the validated Occupational Self-assessment (Baron, Kielhofner, Lyenger, Goldhammer, & Wolenski, 1998) assesses self-perceived occupational competence. Service-user participants will respond to 12 questions about their ability to complete everyday activities. This assessment has been chosen, as it can be self-administered, it is quick to complete, the activities described within it are relevant in 2021, and has established validity and reliability in an inpatient rehabilitation setting (Popova, Ostrowski, Wescott, & Taylor, 2019).

5. Six item Cognitive Impairment Test

Six item Cognitive Impairment Test (6CIT) (Brooke & Bullock, 1999) shown in Appendix 19 is a quick screening that has been found to have high sensitivity and specificity (Abdel-Aziz & Larner, 2014) in detecting mild cognitive impairment. The 6-CIT will be administered by the clinical staff at The Walton Centre at the start and end of the VERA intervention using the VERA unit to access the Qualtrics Survey Platform.

7.1.4 Service user and staff Training Questionnaires

Tailored and piloted Training Questionnaires based on Kirkpatrick's model (Kirkpatrick Partners, 2021) will collect data from 1. service users and 2. staff about the initial impact of the training (Appendix 20 and 23). These questionnaires will aim to collect views about the training and the learning that has taken place. The data collected will focus on what was learnt and the effectiveness of the training.

The Service User Training Questionnaire (Appendix 20) will be completed by service user participants by accessing the online Qualtrics Survey Platform through VERA. Participating staff will be sent a link to the Staff Training Questionnaire (Appendix 23) on the Qualtrics Survey Platform via email from a UCLan researcher.

The Programme Management Group will not complete a training questionnaire

7.1.5 Usage data direct from VERA

Background analytics will enable the collection of information about the overall length of time VERA was used and the pattern of this usage for each participant. It will be possible to provide an analysis of

the individual programmes that were active, when and for how long. Citrus Suite staff will extract this using Google Analytics. All the data will be anonymised.

7.1.6 Service user interview

Supplementary consent process

A confirmation of specific consent will be undertaken prior to the interview: Service User Interview

Supplementary Consent Form (Appendix 4) may be completed in hard copy if interviews are conducted face-to-face. Consent for face-to-face interviews may also be audio-recorded on an encrypted digital recorder to suit the participant's needs (see below). Consent will be recorded verbally online through Microsoft Teams if the interview is conducted online (see below).

At the start of the interview, the researcher will go through the consent process and form with participants. If verbal consent is being recorded, the researcher will read out the consent statements and ask the participants to verbalise their agreement to each, recording the names of both parties and the date. The consent recording will be kept separate from the main interview recording / transcript following the process outlined below for the interview recording, and linked via participant PIN.

Interview process

Interviews will last up to 60 minutes to allow time to support adapted communication strategies where these are used by a participant. Semi-structured questions, underpinned by the NASSS framework, will explore the usability, acceptability, barriers to and enablers, and the benefits or disbenefits of using VERA (Appendix 21). The interview will also explore the impact of the training, particularly in relation to self-perceived changes in behaviour and outcomes. The interviews will be undertaken by an experienced UCLan researcher. If a participant's speech has been affected, for example by stroke, strategies will be used to facilitate communication, using specialist guidance from the clinical staff on the complex rehabilitation ward. This may include using supporting equipment, alternate methods, or support from another person.

If infection control measures and research partner protocols for COVID-19 enable face-to-face interviews, these will take place at The Walton Centre. They will be recorded on an encrypted digital recorder supplied by UCLan and transferred and stored as described in section 7.1.1.

However, it is anticipated that these interviews will be conducted securely online through Microsoft Teams, using either audio and video, or just audio, depending on participant need and preference. The consent process and interviews will be conducted in accordance with UCLan's Remote Research Guidelines (https://www.uclan.ac.uk/students/support/research/ethics.php).

Recordings, along with any field notes made during the interviews, will be stored as described in section 7.1.1.

With consent, the interviewer will be able to see the participant during the interview and know the participant's first / chosen name. Any identifiers will be removed from the data at the first possible opportunity. The data will be stored in a pseudonymised form and the files with identifiers will be permanently deleted.

7.1.7 Staff focus group

The focus group discussion will last no more than 90 minutes. It will be undertaken by a UCLan researcher, supported by a co-facilitator, who will also be a UCLan researcher. The facilitator will use a semi-structured focus group schedule (Appendix 24) to explore the usability, acceptability, barriers, facilitators, and benefits and disbenefits of VERA. The focus group will also explore the impact of the training, particularly in relation to perceived changes in behaviour and outcomes for staff and service users.

If infection control measures and research partner protocols for COVID-19 enable face-to-face focus groups, these will take place at The Walton Centre. They will be recorded on an encrypted digital recorder supplied by UCLan and transferred and stored as in section 7.1.1.

However, it is anticipated that the focus groups will be conducted online through Microsoft Teams, using video recording, in accordance with UCLan's Remote Research Guidelines (https://www.uclan.ac.uk/students/support/research/ethics.php). Video recording will be used to capture non-verbal communication within the focus group to allow reflection on possible effects such as conformity and censoring which may occur in a focus group (Asbury, 1995; Sim & Wright, 2000, p.58).

The recordings will be stored along with any field notes made during the focus group, pseudonymised by using PINs, as described in section 7.1.1.

The facilitator and co-facilitator will see the participants and know the participants' first / chosen names during the focus group. Any identifiers will be removed from the data at the first possible opportunity. The data will be stored in a pseudonymised form and the files with identifiers permanently deleted.

7.1.8 PMG interview

The interview will last no more than 45 minutes. It will be undertaken by an allied health profession student currently studying at UCLan. The students will receive training and supervision from the UCLan researchers to ensure that they have the knowledge, skills and support to undertake the

interviews. The interviewer will use a semi-structured interview schedule (Appendix 31) to explore the role of the interviewee in developing and implementing VERA into a complex rehabilitation setting.

The interviews will be conducted online through Microsoft Teams, using video recording, in accordance with UCLan's Remote Research Guidelines (https://www.uclan.ac.uk/students/support/research/ethics.php).

The recordings will be stored along with any field notes made during the interview, pseudonymised by using PINs, as described in section 7.1.1.

Identifiers will be removed from the data at the first possible opportunity. The data will be stored in a pseudonymised form and the files with identifiers permanently deleted.

7.1.9 Suggested Changes Form

This is an implementation study and therefore it is anticipated there will be some changes needed to make VERA accessible to individuals on set-up. There will also be reflections on the design during the use of VERA. Key members of the team who are involved in these processes: participants, computer and technology staff at The Walton Centre and Citrus Suite, and members of the research and clinical team will be encouraged to record these changes and reflections on a Suggested Changes Form (Appendix 25). Relatives/friends will be encouraged to suggest changes to users or staff to record. This will enable changes to be tracked, and the opportunity to explore the reason for each suggested or actual change. This anonymised data will form part of the process evaluation. The Suggested Changes Form will be provided as a Microsoft Form. The Microsoft Form will be available on the VERA unit for service user participants and the hyperlink will be made available by email to the staff participants and staff involved in the VERA study. Once submitted through either VERA (service users) or hyperlink (all others) the data will go directly to the secure Office 365 OneDrive storage of a named member of the UCLan VERA research team.

Data Analysis

All analyses and associated documents will be held on the secure UCLan Office 365 OneDrive server. In line with UCLan data protection policy, the analyses and associated documents will be stored for 5 years after the end of the study (April 30th, 2022), after which they will be securely and permanently deleted.

Service user and staff Demographic Information Forms and Training Questionnaires

Data from Demographic Information Forms and Training Questionnaires will be nominal and ordinal. Descriptive analysis will be undertaken by the UCLan VERA research team.

Quantitative data

Analysis of the ordinal quantitative data from the SF-36, PHQ-9, GAD-7, OSA-SF and 6-CIT will also be descriptive in nature. Descriptive analysis including visual representation of the analysed data will be undertaken by a UCLan researcher utilising Qualtrics Survey Platform, IBM SPSS package and Microsoft Excel and will examine the relationship between the pre- and post-VERA data. These quantitative outcomes will be used to provide context to the qualitative data collected through the service user interviews.

Service user interviews

The interviews will be analysed using framework analysis (Furber, 2010; Gale, Heath, Cameron, Rashid, & Redwood, 2013; Ritchie & Spencer, 1994). Framework analysis has five stages: familiarisation with the data, developing a theoretical framework, indexing, charting, and synthesising the data.

In this study the framework will be informed by the NASSS; the analysis framework will be structured based on usability, accessibility, barriers and enablers. Utilising the NASSS Framework and the study objectives, ‘a priori’ codes will be developed. The coding of data, or indexing, will be undertaken from the interview recording (Crichton & Childs, 2005). This approach does not require verbatim transcription; automated transcription software will, however, be used to support coding the data.

Coding from the recording is an established approach in framework analysis (Bazeley, 2021, p.199) and it has been suggested that the original recording can provide a better representation of the data than the written word in a transcript (Parameswaran, Ozawa-Kirk, & Latendresse, 2019). This approach is therefore particularly suitable to coding speech by those who may have communication difficulties, as it retains the integrity of the data, allowing the researcher to engage with meaning and nuance.

If verbatim transcription is required to facilitate coding, it is expected that this will be undertaken by members of the UCLan VERA research team, supported by in-house automated transcription service.

Charting will be used to analyse each service user’s experience of VERA. The charting process will allow the synthesis of the experiences of all participating service users across the ‘a priori’ codes. This will enable examination of similarities and differences in experiences and perceptions which will inform the development and implementation of VERA into the inpatient rehabilitation setting.

To ensure rigour in the data analysis, several processes will be undertaken. Researchers will familiarise themselves with the data using the audio recording, and where it is helpful to increase understanding of the data, the automated transcription. Two researchers will be involved in the creation of the coding system by independently coding three interviews from the first phase, and an additional interview from subsequent phases, and comparing results. This agreed coding scheme will then be used by one researcher to code the remaining interviews. All data that is coded will be transcribed to provide evidence of dependency of the data. Researchers will keep an anonymised reflexive journal, field notes and an audit trail of decisions. NVivo will support management, analysis, and retrieval of the data.

Staff focus groups

The audio- or video-recordings will be transcribed to enable the interactions between the different staff to be analysed for consensus and conformity (Asbury, 1995, p.58; Sim & Wright, 2000) alongside coding the data. It is expected that this will be undertaken by members of the UCLan VERA research team supported by in-house automated transcription service.

The transcripts will be analysed independently by two researchers, this will include the focus group facilitator where possible. Mirroring the service user interviews, ‘a priori’ codes will inform the structure for a framework analysis; NVivo coding will support data management, analysis, and retrieval. Also, researcher reflexive journal, field notes and an audit trail of decisions will support a rigorous analysis.

Programme Management Group interviews

A framework analysis as described above for service user interviews will be used to analyse the Programme Management Group interviews. However, for these interviews the recordings will be transcribed (intelligent verbatim) and analysed from the transcripts. This is for two reasons. Firstly it is anticipated that the Programme Management Group will not be experiencing communication difficulties and therefore analysis should be possible without the need for the additional non-verbal information provided by the recording. Secondly, as the allied health profession students will be undertaking the analysis, it is anticipated that taking a mainstream approach to the analysis (working from a transcript) will enable them to use a wide range of resources to support their learning, providing a more robust analysis.

UCLan researchers and allied health professional students will undertake the analysis. The students will receive supervision throughout the analysis process to ensure a robust interpretation of the data collected.

Suggested Changes Form

The information in the Suggested Changes Forms will be used to track ideas for changes and actual changes.

The analysis of the Suggested Changes Forms will be descriptive in nature to help describe the process undertaken during the study. The suggested and actual changes will be summarised and tabulated chronologically to identify which changes were made to VERA across the three phases of the study. This table will identify which changes were made and the reasons for the change/s.

The forms will be collated in the three phases to see progression across the phases and to inform the second iteration of VERA.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Legislation and requirements:

Medicines and Healthcare Regulatory Authority (MHRA) have advised that VERA would not be considered a medical device at this stage of development, based on the functions described in this protocol.

This study will recruit participants from the NHS and will therefore require Health Research Authority NHS Ethics Service approval and approval from The Walton Centre. All UCLan staff who will have contact with service-users and / or the primary data will hold honorary research contracts with The Walton Centre

Dignity of participants:

The technology has been developed with the aim of supporting rehabilitation and promoting self-management. One of the objectives of the study is to establish the benefits and disbenefits of VERA; understanding these will be a key outcome of this investigation. Dignity will be preserved throughout the data collection process. The Service User Demographic Information Form (Appendix 13) and one questionnaire (Six-item Cognitive Impairment Test) will be administered by a member of staff. Service-user participants will complete the remainder of the questionnaires themselves, using VERA. This

process will be within their control and at a time that is convenient to the participant. In the interviews, service users will be asked for their perceptions and opinions of VERA.

Similarly, the staff participants will have control of the data they submit via questionnaires and during the focus groups.

PMG members will be able to complete the consent procedures at a time of their choosing and the interview will be arranged at a time convenient to them.

8.1 Assessment and management of risk

Protection of the data collected by VERA

Protecting the participants' data requires substantial consideration due to the use of digital technology that will collect data. This is further complicated by having three organisations, The Walton Centre, the University of Central Lancashire, and Citrus Suite, involved and responsible for different aspects of the data. A Data Protection Impact Assessment has been undertaken by The Walton Centre.

Risks to security of data stored on VERA

There is risk of loss of data, stolen data, breach of data (from UCLan One Drive, Qualtrics Survey Platform where the study data will be stored or AWS Cloud Servers, where the clinical data will be stored). These risks will be reduced as described below.

AWS Cloud Server: Data will be secured and encrypted during transfer. Data held on the cloud server will be encrypted and secured. Usernames and Passwords will be required to access data. Access will only be permitted to trained staff.

UCLan One Drive and Qualtrics Survey Platform: PIN numbers allocated to participating staff and patients will be used on all data collection documents, thereby pseudonymising data. The data will be available only to the UCLan VERA research team. Usernames and Passwords will ensure controlled access. Access will only be permitted to trained staff.

Unauthorised access to VERA

The VERA units will be password protected to control access. The VERA training will include the need to protect the VERA, emphasising that it contains personal information. Training will include advice about keeping passwords protected from others. Staff will be able to access VERA through a portal, or through a separate log-in process to that of the service-user.

Unauthorised disclosure of data

There is a risk of unauthorised disclosure of data. To reduce the risk of a member of the VERA team disclosing data without authorisation there will be contractual arrangements in place between partners and pseudonymisation of the evaluation datasets. Additionally, the research staff employed by UCLan collecting and analysing data will be trained in Good Clinical Practice and data protection.

The allied health profession students will only have access to the PMG interview data.

Identification of a service user occurring, if someone is determined to re-identify a participant

It is anticipated that this might occur if someone on the team set out to identify a participant. The risk will be reduced through staff training, contractual arrangements between partners and pseudonymisation of the evaluation datasets.

Identification of depression, anxiety or cognitive impairment from the quantitative measures

It is possible that the quantitative measures may indicate depression, anxiety, or cognitive impairment. In line with the assessment scoring guidance, clinical staff will be made aware if a participant scores:

- more than ten (indicating moderate / severe depression) on the completed PHQ-9
- more than ten (indicating a need for further evaluation) on the completed GAD-7
- more than eight on the completed 6-CIT

The need for this information to be made available to the clinical team will explained in the Participant Information Sheet.

Changes to health condition

If a service-user's health condition changes during the time of the study, they will be able to continue to participate if they choose to do so and they continue to meet the requirements of the selection criteria. Clinical staff will be asked to advise research staff of changes that mean that the participant no longer meets the selection criteria.

Clinical time

There is a risk that the evaluation of VERA may take time that clinical staff would otherwise spend undertaking other duties. In the evaluation study, the additional time involved will be completion of a Staff Demographic Information Questionnaire, a Staff Training Questionnaire, and a maximum of two focus groups, as well as potentially providing support to service users undertaking interviews. In

collaboration with the clinical team, the focus groups will be timed to run within a part of the day that is considered least disruptive to the staff.

The staff will, additionally, be involved in designing, developing and implementing VERA. The introduction of VERA to the rehabilitation unit has been sought by the staff within the clinical setting and is a key component of the service development on the Complex Rehabilitation Unit.

Risk of unprofessional practice disclosure

In the unlikely event that a member of staff reported unprofessional practice by any party during a focus group, there would be an obligation to report this to the appropriate Manager for further investigation. This will be stated on Participant Information Sheet.

Identification of a staff participant occurring in reports / publications

It is anticipated that the incidental identification of a staff participant might occur in reports / publication if there are only a few staff participants from one professional group. The risk will be reduced through awareness of this risk, and careful reporting of findings. The UCLan VERA research team have experience in this area.

Risk of low uptake

There is a risk of low uptake of VERA that would undermine the evaluation findings. It is anticipated that it will be possible to recruit six participants for each phase of the study from approximately 30 individuals who are inpatients on the CRU at any given time. If it is not possible to recruit six participants, the predominantly qualitative findings will continue to have value. The diversity of the sample is, however, likely to be affected. The impact of this would be reflected in the interpretation of the findings

Risk of students not complying with required procedures/policies/legislation

There may be areas where the students are developing their research knowledge and skills during the study. Supervision will be a feature of the students' work on the project. This will provide opportunity to discuss and clarify the processes. This will reduce the risk of non-compliance with procedures/policies and legislation. The students will have a formal weekly supervision session, there will also be informal supervision sessions during the week to maintain a clear line of responsibility to the Chief Investigator. The students will have a means to contact the Chief Investigator if they have queries that arise outside the supervision sessions. Relevant training will be undertaken by the students prior to any contact with potential participants.

Risk that PMG participants will be concerned about providing data

As the PMG includes the UCLan researchers, additional measures have been taken to reduce associated risks. The Participant Information Sheet identifies the involvement of the UCLan researchers in the data collection and analysis. It also provides an additional contact for PMG members to direct questions or to discuss their participation.

The Participant Information Sheet and the Consent Form clearly state that participation is voluntary and that there will be no disadvantage or negative consequences from the staff from The Walton Centre or Citrus Suit or the UCLan researchers if a PMG member decides not to participate.

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

Before the start of the study, a favourable opinion will be required from the UK Health Research Authority NHS Ethics Service.

As this will be NHS REC reviewed research, the following will be adhered to:

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- 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.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications / abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator / Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. This will include gaining approval from The Walton Centre.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

Amendments

If the Sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the Sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. The Sponsor will decide if an amendment is substantial or non-substantial for the purposes of submission to the REC.

Any substantive changes will be communicated to relevant stakeholders.

Once agreed the amended documents will be held in the study file with the new version clearly stated. All members of the VERA research team will be advised of the changes. Where the amendment involves clinical staff, all relevant clinical staff will be advised. The information will be provided by email with a 'read' receipt and a request to respond to the email to confirm receipt.

Amendments will be notified to The Walton Centre research team to assess whether the amendment affects the NHS permission.

8.3 Peer review

This study has gained funding from the Stroke Association / MedCity and has, therefore, been exposed to a high-quality peer review (independent, expert and proportionate for the size of the study).

8.4 Patient & Public Involvement

Patient and public involvement has been fundamental to the planning for this study. Service users, and where appropriate their families and friends, will continue to be integral to implementation and the development of VERA, both through formal data collection, but also through their interactions with the staff as VERA is allocated and set up for each participant.

PPI involvement is summarised below:

- **The acceptability of the research** - workshops were completed in 2019 to gain feedback on initial ideas and to explore what service users wanted included in VERA. The information from these workshops have informed the first prototype of VERA
- **Design of the research** - the aim was to undertake a second round of workshops at The Walton Centre to discuss the study design and the planned content of VERA. However, due to the COVID-19 pandemic this has not been possible. A PPI member of the Study Steering Committee has provided comments on the research protocol and this dialogue has informed the protocol. If infection control measures and research partner protocols for COVID-19 enable a second round of workshops / discussions with service-users and their carers, prior to the start of the formal evaluation, these will be undertaken. The focus of these discussions will be the content of VERA.
- **Management of the research** - there is active PPI membership in the Study Steering Committee
- **Undertaking the research** – service user views will be instrumental to the evaluation of VERA and the subsequent development. It is anticipated that changes will be made to the design based on the data collected from service users along with the staff on the rehabilitation unit.
- **Dissemination of findings** - opportunities will be sought to include interested service users in dissemination opportunities, including conference presentations. This will be dependent on whether this is something the participating individual service users would like to be involved with, and the Service User Participant Debrief will offer the opportunity to supply contact details for this follow-up activity.

8.5 Protocol compliance

All efforts will be made to ensure protocol compliance through training and mentoring. It is recognised that accidental protocol deviations can happen at any time. If there are deviations from the protocol, these will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor for appropriate response.

8.6 Data protection and patient confidentiality

The arrangements to address service user confidentiality and the appropriate management (collection, storage, processing and disclosure) of personal information to meet the General Data Protection Regulation (2018).

All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2018) in regards to the collection, storage, processing and disclosure of personal information and will uphold the Guidelines' core principles

These processes have been described in detail in sections 6 and 7 of the protocol.

The data custodian is:

Dr Kathryn Jarvis (Senior Lecturer in Occupational Therapy, UCLan)

8.7 Indemnity

Insurance / indemnity from Sponsor will cover:

1. The potential legal liability of the sponsor for harm to participants arising from the management of the research
2. The potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research

The NHS indemnity scheme will provide cover in respect to:

3. The potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.

8.8 Access to the final study dataset

The research team at UCLan will have access to the final study dataset. The Study Steering Committee will also have access to anonymised and analysed data.

As this is a first evaluation study, it is likely that the data collected in this study may be beneficial in future studies to further develop the VERA. The Staff and Service User Participant Information Sheet and Consent Forms (Appendices 2, 3, 7 and 8) will reflect that, until five years after the end of the study, the data from this study may be used in future studies to further develop the VERA.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The responsibility for the data collected from this study will lie with UCLan. On completion of the study, the data will be analysed, and a Final Study Report prepared. All efforts will be made to publish the findings from this study, which will ensure the report is available in a peer-reviewed journal. It will be possible to access the Executive Summary of the full study report by contacting the Chief Investigator. It will also be available on the VERA project website, and will be stored on the University of Central Lancashire Online Knowledge (CLoK) web-pages, to enable open access.

Funders, and others supporting the study will be acknowledged in any reports. The final report will have been reviewed by a representative from all three organisations involved and will be made available by agreement on a specifically designated webpage for the VERA study.

At debrief, at the end of the study, participants will be advised how they can access the Executive Summary of the final report (Appendix 5). They will also be asked if they would like to be involved in dissemination opportunities, including conference presentations. Where a participant does indicate interest, they will be asked to supply an email address or telephone number to enable future contact.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of any publications arising from the Research Project will be decided in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines on the authorship of medical publications (International Committee of Medical Journal Editors, 2021). In line with these International Author Guidelines, authorship will be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of 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 appropriately investigated and resolved.

In addition to being accountable for the parts of the work an author has undertaken themselves, an author will be able to identify which co-authors are responsible for specific other parts of the work. Each author will have confidence in the integrity of the contributions of their co-authors.

It is anticipated that authorship of any reports, papers and presentations will include representatives from The Walton Centre and UCLan. Authors will have made a significant contribution to the study through development of the protocol, data collection, data analysis and / or writing up of the study for publication. Where others, for example employees of Citrus Suite and PPI representatives, contribute significantly to the study outputs they will also form part of the authorship.

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11. APPENDICIES

11.1 Summary of appendices for HRA Ethics Services

Document	Who for?	Format/notes	Appendix Number
Protocol			**1**
Amended protocol			**35**
Participant Communications / Information Sheets / Consent Forms			
Service users			
PIS	Service user participant	Written	2
Consent form	Service user participant	Written - Likely that consent will be audio / video recorded through Teams	3
Supplementary interview consent form	Service user participant	Written - Likely that consent will be audio / video recorded through Teams	4
Debrief for participants as they leave study/ward.	Service user participant	Written	5
Staff			
Invitation email	Staff on ward	Written	6
PIS	Staff participants	Written	7
Consent form	Staff participants	MS Forms	8

Letter if there are too many staff for 1st focus group?	Staff participants	Written	9
Letter if there are too many staff for 2nd focus group?	Staff participants	Written	10
Research data record			
'key' document with service-user participants' name and PIN	Researchers	Written	11
'key' document with staff participants' names and PIN	Researchers	Written	12
Data Collection Instruments			
Service users			
Demographic collection service-user form	Completed by TWC staff	Questions only as will be put into VERA	13
Demographic collection service-user form – self-reported	Service user participant	Questions only as will be put into VERA	14
SF-36	Service user participant	Qualtrics	15
PHQ-9	Service user participant	Qualtrics	16
GAD-7	Service user participant	Qualtrics	17
OSA	Service user participant	Qualtrics	18
6-CIT	Service user participant	Qualtrics	19

Service-user training questionnaire	Service user participant	Qualtrics	20
Interview schedule	Service user participant	Written	21
Staff			
Demographics from staff participants	Staff participants	Questions only as will be put into VERA	22
Staff training questionnaire	Staff participants	Qualtrics	23
Focus group schedule	Staff participants	Written	24
Suggested changes form	Researchers & TWC staff	MS Forms	25
Other			
Study Flow Diagram			26
Certificate/s of Insurance/Indemnity			27
Additional documentation to support amendment			
Programme Management Group invitation email	PMG members	Written	31
Programme Management Group PIS	PMG participant	Written	32
Programme Management Group consent form	PMG participant	MS Forms	33
Programme Management Group interview schedule	Researchers and allied health professional students	Written	34

11.2 Appendices for HRA Ethics Services

Please refer to separate document files

11.3 Chief Investigator CV

11.4 Schedule of Procedures

Procedures – Service user participants	**Visits (insert visit numbers as appropriate)**		
	Screening	**Baseline**	**Week 6**
Informed consent	x		x prior to interview
Demographic Information Form		x	
Training Questionnaire		x	
Quantitative measures		x	x
Interview			x
Suggested changes form		Throughout study	

Procedures - Staff participants	**Visits (insert visit numbers as appropriate)**		
	Screening	**Baseline**	**Week 6**
Informed consent	x		
Demographic Information Form		x	
Training Questionnaire		x	
Focus group			x

Suggested changes form		Throughout study

Procedures – Programme management Group participants	**Visits (insert visit numbers as appropriate)**		
	Screening	**Baseline**	**Week 6**
Informed consent			x
Interview			x
Suggested changes form		Throughout study	

12 AMENDMENTS

12.1 Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2.0		Kathryn Jarvis & Julie Cook	As this is a new digital technology we would like to interview the Programme Management Group about the development process as we believe it will help us deepen our understanding of the process involved in implementing a new digital health technology. We are confident that this amendment will not significantly alter the main research design, but will provide a further data collection stream to better inform the evaluation of the process and assist in meeting the objective of understanding the barriers and enablers to implementing a new digital health technology in an in-patient rehabilitation setting.