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
Acceptability and usability of the Virtual Engagement Rehabilitation Assistant (VERA) for community-based neurological rehabilitation

SHORT STUDY TITLE / ACRONYM

Evaluation of the Virtual Engagement Rehabilitation Assistant (VERA) for community neurological rehabilitation

PROTOCOL VERSION NUMBER AND DATE

Version 3.0 (14th December 2024)

RESEARCH REFERENCE NUMBER

IRAS Number:	330807
SPONSORS Number:	HEALTH 01184 - Sponsor Ethics 7399c1 - Legal and Governance
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Joint-sponsor(s) / co-sponsor(s)	Not applicable
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	The Walton Centre NHS Foundation Trust (The Walton Centre) staff: Dr Ganesh Bavikatte. Nicola Branscombe, Jo Haworth, Charlotte Lawrence, Rachel Saunderson. Citrus Suite staff: Steve Donovan, Chris Morland. Staff and service users who contributed to workshops. Steering Committee: Jonathan Jones, Robbie Jones, Dr Sureshkumar Kamalakannan, Dr Jacqui Morris (Chair), Andrew Russell, Dr Gillian Sweeney.
Committees	Study Steering Committee Chair: Dr Jacqui Morris (J.Y.Morris@dundee.ac.uk) VERA Working Party (Study Management Group) Chair: Dr Ganesh Bavikatte (Ganesh.Bavikatte@the waltoncentre.nhs.uk)

STUDY SUMMARY

Study Title	Acceptability and usability of the Virtual Engagement Rehabilitation Assistant (VERA) for community-based neurological rehabilitation
Internal ref. no. (or short title)	Evaluation of Virtual Engagement Rehabilitation Assistant (VERA) for community neurological rehabilitation
Study Design	Mixed methods, two site implementation evaluation
Study Participants	Community neurological rehabilitation allied health professional staff, and service users
Planned Size of Sample (if applicable)	Up to 20 allied health professional staff Up to 20 service users
Follow up duration (if applicable)	None
Planned Study Period	Once all ethical and organisational approvals are in place, the study will take place over a 7-month period. It is anticipated that the study will start in October 2024 and be complete by 30th April 2025.
Research Question / Aim(s)	This study will evaluate early implementation of the VERA intervention for community neurological rehabilitation. The study will explore: 1. the profiles of service-users along a

	spectrum of benefitting and not benefitting from VERA; 2. the acceptability and usability of this digital technology in a community setting; 3. stakeholder (staff and service users) valued constructs to inform the value proposition of VERA.

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**
NIHR Health Technology Assessment	£97, 765

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 will provide reports and attend progress meetings as set out in the contract between NIHR and the University of Central Lancashire (UCLan). The purpose of these meetings will be to track progress against the planned timeline.

The study sponsor is UCLan, who will assume overall responsibility for the initiation and management of the study.

The UCLan 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

Study Steering Committee

A Study Steering Committee (SSC) has been convened comprising: Patient and Public Involvement (PPI) representatives, and members with multidisciplinary experience in research, rehabilitation, and

technology innovation. The SSC will meet every three months throughout the duration of the study (5 virtual meetings expected (between June 2024 and July 2025). The role of the SSC will be:

- To provide advice through its Chair on all appropriate aspects of the study, including PPI
- To concentrate on progress of the study, 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 study plan
- To agree proposals for substantial protocol amendments
- To provide advice to the investigators on all aspects of the study.

VERA Working Group (Study Management Group)

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

- To facilitate and promote the aims of the study
- To enable the delivery of the study objectives
- To take responsibility for the creation, refinement and adjustment of the study work plan
- To identify issues that arise within the study 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 study, advising on best use of funding and staffing
- To lead on the practical arrangements for study 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 study.

PROTOCOL CONTRIBUTORS

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

UCLan Research team:

Dr Kathryn Jarvis, Senior Research Fellow, UCLan, Chief Investigator.

Dr Julie Cook, Research Fellow, UCLan, Senior Researcher.

Dr Rachel Stockley, Associate Professor in Stroke Recovery and Rehabilitation, UCLan.

Prof. Dame Caroline Watkins, Professor of Stroke and Older People's Care, UCLan

The Walton Centre team:

Rachel Saunderson, Innovation Manager

Dr Ganesh Bavikatte, Consultant and Clinical Lead in Rehabilitation Medicine

Jo Haworth, Clinical Specialist Physiotherapist

Nicola Branscombe, Band 7 Occupational Therapist

Charlotte Lawrence, Speech and Language Therapist

Citrus Suite team:

Chris Morland, Chief Executive, Citrus Suite

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

Staff and Service users:

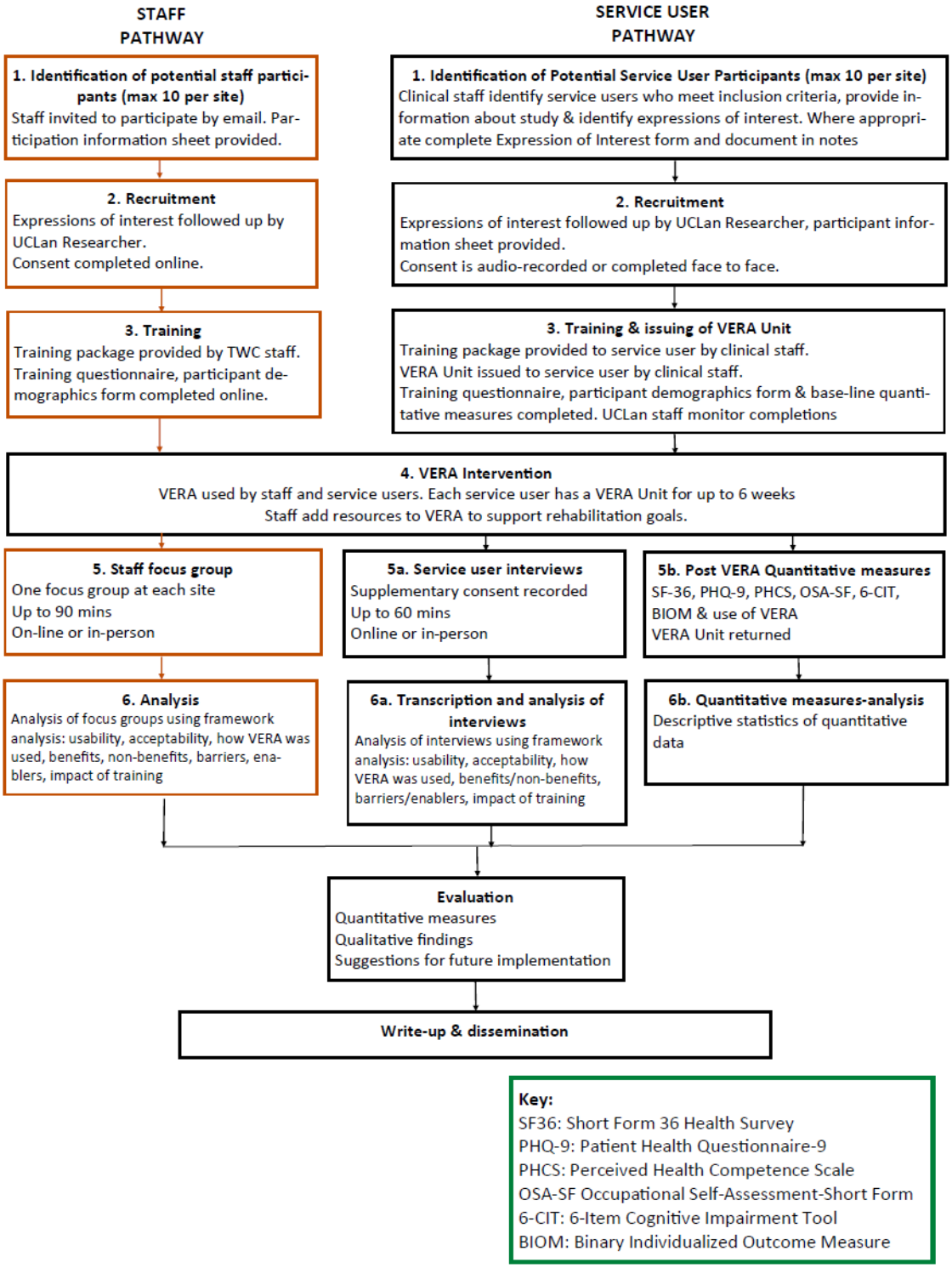
Service users were involved at the start of planning this study. The original idea was conceived by Dr Rachel Stockley (UCLan) and Dr Ganesh Bavikatte (The Walton Centre). The initial stages of development involved service user (Patient and Public Involvement) and staff workshops in 2019, supported by funding from the NIHR Research Design Service (RDS). The ideas generated at these workshops have shaped the first iteration of the VERA technology for an inpatient setting (evaluated 2019-22), and this protocol for the current community-based study.

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

STUDY FLOW CHART

See next page.

Figure 1 : Summary of VERA community neurological rehabilitation evaluation



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STUDY PROTOCOL

Acceptability and usability of the Virtual Engagement Rehabilitation Assistant (VERA) for community-based neurological rehabilitation

VERA Glossary

The VERA technology: a mobile portal comprised of two elements: 1. a web-based VERA staff portal to manage and upload information and digital resources for individual or groups of service-users; 2. a VERA App. downloaded onto a tablet which enables service-users to access and interact with the digital resources (the VERA Unit).

VERA Unit: VERA App. downloaded onto a tablet which enables service-users to access and interact with the digital resources. The App. and the tablet constitute a VERA Unit.

VERA App.: an application (software) that can be downloaded onto a digital device such as a tablet, phone or personal computer, that has the capacity to hold a range of resources that aim to support rehabilitation.

The VERA intervention: the package of the staff and service user VERA training and the associated training materials, the VERA technology and the resources accessed through the VERA App.

Staff VERA training: training provided to staff, and the associated training materials, to provide knowledge and skills required to use the VERA technology.

Service user VERA training: training provided, and the associated training materials, to service users to provide knowledge and skills required to use the VERA Unit.

1 BACKGROUND

It has been estimated that in the United Kingdom (UK), approximately 10 million people are living with a neurological condition (Royal College of Physicians, 2008), and 1.3 million of these people are living with the impact of stroke (National Institute for Health and care Excellence, 2022). Neurological conditions are a leading cause of disability (National Institute for Health and Care Excellence, 2019b) and the number of people affected is set to continue to increase, due primarily to an aging population (Carroll, 2019).

Intensity of activity has been found to improve functional and motor recovery following neurological injury (Intercollegiate Stroke Working Party, 2023; Königs et al., 2018; Schneider et al., 2016; Teasell et al., 2020), with indications that neurological therapy should be organised in short regular sessions (Bernhardt et al., 2016). The duration of high intensity interventions has been shown to pose

challenges beyond the research context (Connell et al., 2014; Langhorne et al., 2009). Current NHS rehabilitation services cannot provide the intensity of activity which is known to be beneficial due to limited available therapy time (Clarke et al., 2018), and this situation has intensified during the recent pandemic (Moore, 2022). 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 et al., 2019), has the potential to improve quality of life and self-efficacy for people with neurological conditions (Fryer et al., 2016; Liddy et al., 2014).

Digital health technology, defined as "apps, programs and software used in the health and social care system" (National Institute for Health and Care Excellence, 2019a, P.45) may revolutionise rehabilitation. The Virtual Engagement Rehabilitation Assistant (VERA) was conceived to harness this potential.

Developed by clinicians, service users, carers and digital technology developers, VERA aims to provide increased opportunities for patients to engage in and self-manage rehabilitation activities. The VERA technology is a cloud-based, mobile portal which can be used on a range of devices (e.g., tablet) to access and interact with digital applications and web-based resources. VERA is distinctive in its operation in practice, as the therapist collaborates with the service user to configure the digital resources to increase the individual's therapeutic activity and reduce inactivity. VERA is configured for each service user by their therapist to provide meaningful, personalised, and appropriately challenging therapeutic activities. Following set-up and training, service users can interact with a range of digital resources through the VERA technology, including timetables and health appointments, videos of exercises, reminders, wellbeing questionnaires, games, and links to other relevant resources and information. This empowers the service user to have a greater degree of control over their own rehabilitation. VERA is currently accessed through an iPad (VERA Unit), but the ultimate aim is for this to be available on a smartphone to improve both accessibility and cost-effectiveness.

VERA is a complex intervention (Skivington et al., 2021) requiring: 1. training of both staff and service users, and 2. the use of the VERA technology to access selected applications and resources (hereafter the VERA Intervention). The intervention has a number of inter-related components, targets a range of behaviours, and may be used by individuals with a range of conditions. It has potential to be linked with a wide range of resources, and it is anticipated that the number of available resources will continue to grow as more Apps and software become available.

VERA (Figure 2) has been developed through a collaborative process influenced by the principles of Responsible Research and Innovation (European Commission, 2014; Stilgoe et al., 2013). The current iteration of VERA was designed with and for service users in an inpatient complex rehabilitation unit (CRU). Inpatients and carers have fundamentally shaped VERA through a co-design process with healthcare professionals and innovation leads from The Walton Centre NHS Foundation Trust, researchers from UCLan, and digital designers from Citrus Suite - a commercial software design Small and Medium Enterprise (SME) (Jarvis et al., 2023).

The acceptability and usability of the VERA Intervention as part of a planned rehabilitation programme in the hospital-based setting, was the focus of a study, completed September 2022 (Jarvis et al.,

2024) funded by the Stroke Association and MedCity in the Innovate to Collaborate funding stream (https://www.stroke.org.uk/research/creating-digital-assistant-can-help-rehabilitation-stroke-survivors). Findings indicate that clinical staff and service users adopted the VERA Intervention, successfully engaging with therapeutic rehabilitation activities. They perceive the value of the VERA Intervention to include the individualisation or personalisation of therapeutic interventions, as well as increased opportunity for rehabilitation activity and self-management. The need for the VERA Intervention to be embedded in community rehabilitation settings was a key imperative identified by service users, carers and staff in the hospital-based evaluation (Jarvis et al., 2024).

Figure 2: The home screen of the VERA Unit (service-user view)

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

2 RATIONALE

There is evidence that service users with complex rehabilitation needs require intense activity to achieve optimal outcomes (Intercollegiate Stroke Working Party, 2023). However, significant additional funding for rehabilitation services in the NHS is unlikely, so alternative strategies to be more effective within current resources should be explored. This aspiration is particularly poignant at a time when staffing in the NHS is woefully insufficient (British Medical Association, 2023). Therefore, the development of cost-effective technology which enables service users to increase the amount of time

they are active and their engagement with therapeutic tasks, with low staff input, is both judicious and timely.

VERA was developed to address this need and has been influenced by the principles of Responsible Research and Innovation (European Commission, 2014; Stilgoe et al., 2013). Service users and carers have fundamentally shaped VERA through a co-design process and will continue to do so through this evaluative study.

The provision of high-quality rehabilitation in the community is a priority for health (NHS England, 2023). VERA has been designed to support self-management by empowering service users to have a greater degree of control over their own rehabilitation. This study will evaluate early implementation of VERA for community neurological rehabilitation. The profiles of service-users along a spectrum of benefitting and not benefitting from VERA will be explored, alongside the acceptability and usability of this digital technology in a community 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 a) staff, service users and their families / friends in a community neurological rehabilitation environment, b) staff from a commercial software development company, and c) academic researchers from UCLan. It is anticipated that the interactions between the collaborators will be crucial to the further development and implementation of the VERA intervention.

The VERA intervention 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) and was used in the previous evaluation of VERA in the inpatient hospital-setting (Jarvis et al., 2024). The NASSS implementation framework, along with the associated qualitative assessment tool, the NASSS-Complexity Assessment Tool (NASSS-CAT) therefore provides the ideal structure through which to further develop, implement and evaluate the VERA Intervention in the community setting.

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 the process of implementation. The NASSS framework is an evidence-based, theory-informed framework comprising seven key domains which have been found to influence the adoption and sustained implementation of health technologies:

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.

4 RESEARCH QUESTION / AIM(S)

This study will evaluate early implementation of the VERA intervention for community neurological rehabilitation. The study will explore: 1. the profiles of service-users along a spectrum of benefitting and not benefitting from VERA; 2. the acceptability and usability of this digital technology in a community setting; 3. stakeholder (staff and service users) valued constructs to inform the value proposition of VERA.

4.1 Objectives

The objectives are:

Work stream 1

To identify and engage with VERA stakeholders in a community-based setting.

To complete the Health Equalities Assessment Tool in collaboration with community stakeholders and undertake identified actions to promote equality of access to and use of VERA during the intervention.

Work stream 2

To review, prioritise and undertake changes identified in the first VERA (inpatient setting) study to refine the VERA Intervention in preparation for the current study.

Work stream 3

To utilise findings from Work streams 1 and 2 to modify the VERA Intervention for a community-based neurorehabilitation setting.

Work stream 4 (the evaluation study)

To implement the VERA Intervention in two community-based neurological rehabilitation services.

To investigate staff and service user perceptions of the acceptability and usability of the VERA Intervention in a community-based setting.

To explore staff and service user perceptions of the value proposition of the VERA Intervention.

To investigate the usefulness of the clinical outcomes measures to capture change in key indicators (e.g. mood, cognition and health perception).

4.2 Outcome

The study will capture both the process and the outcomes of the implementation of the VERA intervention in community-based neurological rehabilitation.

- An exploration of the impact of staff and service user training packages, to inform further development.
- Based on the NASSS framework, an exploration of staff and service-user perceptions to understand the acceptability and usability of the VERA intervention in the community setting
- A report on how, when and by whom VERA was used in two community neurological rehabilitation settings.
- Service users' (their families' and friends' where appropriate) and allied health professional staff perceived benefits or disbenefits of the VERA intervention.
- Identification of barriers and enablers to the implementation of the VERA intervention in the community for people with neurological rehabilitation needs.

5 STUDY SETTING

This study will involve two community neurological rehabilitation services, each of which will nominate a site Principal Investigator to co-ordinate between their team and the VERA study Chief Investigator:

1. Early Supported Discharge service within Liverpool University Hospitals NHS Foundation Trust (LUHFT). As VERA has been implemented in an inpatient setting at The Walton Centre in Liverpool previously, this will provide information about the VERA intervention in the community serving a similar geographical area.
2. Lancashire and South Cumbria NHS Foundation Trust (L&SCFT) Community Neurological Rehabilitation Team. This offers a contrast, as staff from the L&SCFT community neurological rehabilitation service had no previous involvement in the design or implementation of the VERA intervention.

6 SAMPLE AND RECRUITMENT

6.1 Sampling

6.1.1 Size of sample

Service user sample

Six VERA Units (i-pads) will be available within each community neurological rehabilitation service at any one time. Up to 10 participants will be recruited from within each service across the period of the study (total n=20).

Staff sample

In line with recommendations for focus group size (Krueger & Casey, 2000, p.17), the aim is to include six to ten participants in a focus group for each site (two in total).

Therefore, there will be a maximum of 20 staff participants across two teams. Due to a limited number of staff working in the community neurological rehabilitation services, this sample is proportionate.

6.1.2 Sampling technique

Service users

When each clinical team receives their six VERA Units, they will review the service users registered to their community neurological rehabilitation service. 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 through the VERA technology, and invite them to take part. This process reflects clinical practice when there are limited resources.

Inclusion criteria - service users

Service user participants will be eligible for inclusion if they:

1. are receiving, or are on a waiting list to receive, rehabilitation to address the impact of a neurological condition.
2. have rehabilitation goals that a therapist identifies can be addressed through the VERA intervention.
3. have communication that supports effective use of the VERA Unit, either independently or with additional equipment/support. Where an individual has a communication impairment, this will be assessed by a speech and language therapist.
4. are able to understand written English language, or have daily access to someone to offer translation support, as VERA is currently only available in the English language.

Exclusion criteria - service users

Service users will be excluded 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). Individuals will be provided with every support possible to consider their involvement in the study (and their subsequent use of VERA) and to make a decision based on the information provided.
2. are under 18 years of age.

Purposive sampling (Silverman, 2006, p.306) will be employed to gain maximum variation. This aligns with the constructionist theoretical approach, as the study purpose is to construct learning from a range of service users allocated a VERA Unit within community neurological rehabilitation. The clinical team will seek to be inclusive of as much variation in the study sample as possible, and will aim to include individuals with a range of conditions, including stroke. We aim to gain variety in self-identified gender, to include participants who self-identify as Black, Asian, and / or Minority Ethnic, and participants who self-report as being low users of technology. It may be necessary to adjust our recruitment strategies as the study progresses in order to achieve this sample; for example, if the participants are mainly White, there would be an aim to recruit more diverse ethnicities in subsequent phases.

Staff

The Principal Investigator in each site will email study information provided by the UCLan Research Team (Appendices 6 and 7) to all allied health professional staff working in their community neurological rehabilitation service, followed by a reminder email after at least 3 weeks. This will ensure that all staff are aware of the study, and that all eligible staff are invited to participate.

Inclusion criteria - staff

Staff participants will be included if they:

1. are a member of the 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 who have been allocated a VERA Unit during the implementation phase.

Exclusion criteria - staff

Staff participants will be excluded if they:

1. spend less than seven hours a week working with service users within the community neurological rehabilitation service.
2. are under 18 years of age.

6.2 Recruitment

6.2.1 Sample identification

Service users

Each clinical team will review all of the service users currently receiving rehabilitation in their community neurological rehabilitation service. In collaboration with the Chief Investigator, study selection criteria and clinical reasoning will inform the identification of service users who are eligible for invitation to participate. An initial approach will be made by a member of the clinical team. If a service user is interested in participating, they will be provided with a Service User Participation Information Sheet (Appendix 2.1) / an Easy Access Service User Participation Information Sheet (Appendix 2.1a) to consider. Time will be allowed for reflection and discussion with others. Where a service user expresses an interest in participating, a member of the clinical team will seek permission to share contact information (name, email and telephone number) with the UCLan VERA research team using a dedicated Microsoft Form (Appendix 11.1). The member of clinical staff will document this permission in the service user's records in line with usual practice. After at least 48 hours, a meeting with a UCLan researcher will be arranged to provide further information, and to answer any questions. It is anticipated that this meeting will be via Microsoft Teams, which is accessible via smartphone as well as laptop/tablet. However, if service user preference, infection control measures, research partner protocols for COVID-19, or lack of access to a stable Teams connection indicate that a face-to-face meeting would be preferable, then this will be arranged to take place at a participant's home. If a potential participant requires the information in the Participant Information Sheet in a different format, for example as a video-recording, this will be provided. Where a person does not have sufficient English language skills to understand all the detailed information about the study, support will be sought from a translator, through the NHS translation services, to explain the terms and requirements of the study and ensure valid consent.

No payments or incentives will be made to service user participants.

Staff

Staff will express an interest in participating by responding to the recruitment email from the site PI. They will be contacted by a UCLan researcher, who will make sure they have received a Staff Participant Information Sheet (Appendix 7.1) and are given the opportunity to ask questions before they decide whether to consent. It is anticipated that this communication will take place by email, but if a potential participant requests a 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 to ten 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.

No payments or incentives will be made to staff participants.

6.2.2 Consent

Service users

Service users who meet the inclusion criteria and opt to participate will undertake a consent process. This will be conducted by a UCLan researcher. Potential participants will have the opportunity to ask additional questions and discuss with family / friends prior to consenting (see section 6.2.1. above). To ensure processes are adaptable while remaining governance-compliant, provision will be made for consent to be documented in written or audio format utilising a consent form (Service User Consent Form, Appendix 3a / Easy Access Service User Consent Form, Appendix 3b). Where a person does not have sufficient English language skills to undertake the consent process, support will be sought from a translator through NHS translation services.

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 Internet Mediated Research Guidelines (Appendix 9) and stored directly on a named VERA study team member's secure and password-protected area in UCLan's Microsoft Office 365 OneDrive (hereafter UCLan OneDrive).

Portable device recordings will be transferred to UCLan OneDrive at the first opportunity, and then deleted from the portable recording device.

Where consent is written (in the home environment only), the document will be securely transported to UCLan by the researcher, and transferred to an electronic file at the first opportunity. It will be stored on UCLan OneDrive separately from any participant data. The original document will be destroyed using UCLan's confidential waste system.

A service user's continued access to the VERA Intervention for the six weeks allocation is independent of their continued participation in the evaluation study or contribution of data.

Participants will be advised verbally and in writing (Service User Participant Information Sheet and during the consent process, Appendices 2 and 3) that they are free to withdraw from the evaluation study at any time, but can continue to use VERA Unit until the end of their six-week allocation if they wish.

If a service user participant consents and starts to use VERA, but later decides to discontinue use, they will still be invited to complete the outcome measures and the interview, but will be under no obligation to do so. As the focus of the study is to consider the acceptability and usability of the VERA Intervention, it is important to capture the reasons a person chooses to discontinue 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 data collected up to that point will be included in the analysis. Participants will be made aware of this verbally and in writing (Service User Participant Information Sheets and during the consent process, Appendices 2.1, 2.1a, and 3).

If a participant wants to stop part way through an interview, we will ask the participant if we can keep the interview data collected up to this point. If withdrawal is requested, the Chief Investigator will oversee the permanent deletion of the recording and any related analysis. All data presented in the findings of study reports and publications will be anonymised. This will be clearly stated in the Service User Participant Information Sheets and Consent Form (Appendices 2.1, 2.1a, and 4).

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 (see 6.2.1). Consent will be documented through a Staff Online Consent Form (Appendix 8) utilising Microsoft Forms. An email link to the consent form will be provided by a UCLan researcher, and the completed consent form will be held in UCLan OneDrive, separately from any participant data.

Each staff participant will be advised verbally and in writing that they are free to withdraw from the evaluation study at any time, without giving a reason, with no negative consequences from their employer or the UCLan researchers. Any data collected up to withdrawal will be retained within the study. This will be clearly stated in the Staff Participant Information Sheets and Staff Online Consent Form (Appendices 7.1 and 8).

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 provision of a VERA Unit and appropriate training to enable access to the VERA technology to support rehabilitation goals. Service user participants will be allocated a VERA Unit for six weeks, or until discharge from the community neurological rehabilitation service if sooner.

7.1 Data collection

7.1.1 Anonymisation, transfer, storage and destruction

Following consent, service user and staff participants will be allocated a personal identification number (PIN) by the UCLan researcher for use in all relevant file names.

The 'Key' documents containing a) the service user participants' name, email address and PIN (Appendix 11), and b) staff participants' name, work email contact and PIN (Appendix 12), will be stored in a password protected file separately to all other data collection files on the UCLan OneDrive.

The 'Key' will only be accessible to the UCLan researchers.

It should be noted that as a lesson learned from the VERA inpatient study, service users will be asked to include their name on the quantitative data collection forms, rather than using their UCLan-allocated PIN. This is because previous service users found remembering and entering the correct PINs difficult. This situation can potentially also compromise data integrity. As described below, the quantitative data contributed by service users will only be accessible by UCLan research staff, who will either receive it directly through UCLan One Drive, or download it securely from Qualtrics Survey Platform. In all cases, files will be stored on the UCLan OneDrive with a PIN file name.

Service user data will either be reported by clinical staff or self-reported by service users (with assistance from family / friends if appropriate). During the data collection period, the site PI will regularly prompt team members to complete this data for service users, and to ensure that service users remember to complete it themselves where they wish to do so.

The service users will access the data collection tools through their VERA Unit. Clinical staff and service users will access these tools through hyperlinks, thereby reducing the need for transfer of data. No data will be stored on the VERA Unit.

Where the VERA Unit is used to access the Qualtrics Survey Platform for data collection, 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 the named UCLan research team via password. This data will initially be analysed in the Qualtrics Survey Platform and then transferred to UCLan OneDrive, after which they will be deleted from the Qualtrics Survey Platform. The collection of individual data are outlined in 7.1.2-8.

Data collected through Microsoft Forms is saved automatically to UCLan OneDrive.

Data collected through Microsoft Teams is saved automatically to the UCLan OneDrive.

Where data are collected using an encrypted portable audio-recording device, the recording will be deleted from the recording device as soon as it has been transferred to the UCLan OneDrive.

Using OneDrive reduces the need for data transfer. However, if there is a need to transfer any data between members of the research team and research partners (staff at TWC, LUHFT, LSCFT) 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 seven years (unless specified otherwise), after which they will be securely and permanently deleted.

7.1.2 Service user and staff demographic information

Due to the theoretical underpinning of the study, it is anticipated that the acceptability and usability of the VERA intervention 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 three tailored Demographic Information Forms (Appendices 13, 14 and 22), which will be analysed for patterns in variation in adoption of the VERA Intervention. As this is 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 in each community neurological rehabilitation team: 1) age; 2) medical condition/s and Modified Rankin Scale score; 3) reason for referral to service; 4) date of injury / start of condition; 5) date of admission to community service; 6) independent / supported communication (support 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 Form - Staff-Reported). 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 it up 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 information technology use and confidence. After they have been allocated a VERA Unit and have completed the VERA training package, the participant will use the VERA Unit to enter this information into a Service User Demographic Information Form - Self-Reported (Appendix 14) on the online Qualtrics Survey Platform.

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 in the community neurological rehabilitation team. This data will be collected through the Staff Demographic Information Form (Appendix 22) utilising the online Qualtrics Survey Platform. A UCLan researcher will email the link for the online Staff Demographic Information Form to the staff participants after they have consented to take part in the study.

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 Questionnaire-9, 3. Perceived Health Competence Scale, 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 community neurological rehabilitation team staff at the start and end of the VERA Intervention.

At the end of the VERA Intervention the community neurological rehabilitation team staff will repeat the Modified Rankin Scale to provide a post-study score and complete a Post-study GOAL Binary Individualised Outcome Measure (Appendix 28).

These data will be collected through the online Qualtrics Survey Platform, using the service user participants' VERA Unit.

1. Short Form-36

The Short Form-36 (SF-36) (Ware & Sherbourne, 1992) is a measure of health function and 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 et al., 1996; Hagen et al., 2003) and for people with brain tumours (Bunevicius, 2017). It is a self-administered

assessment with an established scoring procedure (RAND Corporation). 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 et al., 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 (see 8.1 Assessment and management of risk).

3. Perceived Health Competence Scale

The Perceived Health Competence Scale (PHCS) (Appendix 17) is a measure of an individual perception of their control over their own health outcomes (Smith et al., 1995). The scale of eight questions that can be self-administered. The PHCS has been shown to be valid when used in a UK primary care setting (Dempster & Donnelly, 2008).

4. Occupational Self-assessment Short-form

Occupational Self-assessment-Short-form (OSA-SF) (Appendix 18), is a short version of the validated Occupational Self-assessment (Baron et al., 1998), which assesses self-perceived occupational competence. Service-user participants will be asked 12 questions about their ability to complete everyday activities. This assessment has been chosen as it can be self-administered, is quick to complete, the activities described are relevant in 2024, and it has been found to be beneficial in community settings (Nakamura-Thomas & Kyougoku, 2013) and has established validity and reliability in a rehabilitation setting (Popova et al., 2019).

5. Six item Cognitive Impairment Test

Six item Cognitive Impairment Test (6CIT) (Brooke & Bullock, 1999) Appendix 19 is a quick screening tool 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 community neurological rehabilitation team staff.

6. Modified Rankin Scale

The Modified Rankin Scale (MRS) is a clinician-reported measure of global disability. It requires the clinician to give one score between 0 and 6 to summarise the level of disability. It has been shown to

have good inter-rater and re-test reliability, and construct and convergent validity (Banks & Marotta, 2007).

7. Goal Binary Individualised Outcome Measure (BIOM)

The setting of collaborative goals and the calculation of how many of these goals are achieved in the set timeframe is key to understanding the success of rehabilitation (Spreadbury & Cook, 1995). The goal binary individualised outcome measure will provide information on the success of each service user's rehabilitation programme.

7.1.4 Service user and staff training & Training Questionnaires

Staff in the community neurological rehabilitation services will be trained to use the VERA technology by The Walton Centre clinical staff who have experience of using VERA. They will be supported in their use of VERA by a hard copy Staff Manual.

Service users will receive training to use VERA from staff in the community neurological rehabilitation service who have received the above training. Service users will also have access to a hard copy Service User Manual, and a suite of videos are available through the VERA Unit to support this learning process and encourage engagement.

Tailored and piloted Training Questionnaires based on Kirkpatrick's model (Kirkpatrick Partners, 2021) will collect data from. 1. service users and 2. staff (Appendices 20 and 23) to collect views about the initial impact and effectiveness of the training, and the learning that has taken place.

The Service User Training Questionnaire (Appendix 20) will be completed by accessing the online Qualtrics Survey Platform through their VERA Unit. A UCLan researcher will send participating staff an email link to the Staff Training Questionnaire (Appendix 23) on the Qualtrics Survey Platform

7.1.5 Background analytics

Background analytics will enable the collection of information about the overall length of time VERA Unit was used and the pattern of usage for each service user 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

It is anticipated that the majority of the interviews will be conducted securely online through Microsoft Teams, using either audio and video, or audio only, depending on participant need and preference. The consent process and interviews will be conducted in accordance with UCLan's Internet Mediated Research Guidelines (Appendix 9).

If infection control measures and research partner protocols enable face-to-face interviews, interviews can take place at the service user's home if they wish. Interviews will be recorded on an encrypted digital recorder supplied by UCLan and data transferred and stored as described in section 7.1.1.

Supplementary consent process

A confirmation of specific consent will be undertaken prior to the interview, when the researcher will go through the Supplementary Interview Consent Form (Appendix 4) with participants.

To suit the participant's needs, the Supplementary Interview Consent Form (Appendix 4) will be completed, either: 1) in hard copy if interviews are conducted face-to-face in-person, or 2) audio-recorded on an encrypted digital recorder if interviews are conducted face-to-face in-person, or 3) recorded verbally online through Microsoft Teams if the interview is conducted online (see below).

If verbal consent is recorded, the researcher will read out the consent statements from the Supplementary Interview Consent Form (Appendix 4) and ask the participant to verbalise their agreement to each. The names of both parties and the date will be recorded. The consent recording will be stored separately from the main interview recording / transcript, following the process outlined below for the interview recording.

Interview process

Semi-structured questions, underpinned by the NASSS framework, will explore the usability, acceptability, barriers and enablers, and the benefits or disbenefits of using VERA (Service User Interview Schedule, 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 with a background in the previous inpatient VERA evaluation.

Interviews will last up to 60 minutes to allow time to support any adapted communication strategies. 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 community neurological rehabilitation team. This may include using supporting equipment, alternate methods, or support from another person.

Any identifiers will be removed from the data at the first opportunity. The data will be stored in a pseudonymised form by PIN and any files with identifiers will be permanently deleted.

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

7.1.7 Staff focus group

If infection control measures and research partner protocols enable face-to-face focus groups, these will take place at a time and venue convenient to the staff. They will be recorded on an encrypted digital recorder supplied by UCLan and transferred and stored as in section 7.1.1.

Where focus groups are conducted online, this will be through Microsoft Teams, using video recording, in accordance with UCLan's Internet Mediated Research Guidelines (Appendix 9). 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 (Asbury, 1995; Sim & Wright, 2000, p.58).

The focus group discussion will last no more than 90 minutes. It will be undertaken by two UCLan researchers, as facilitator and co-facilitator. A semi-structured Staff Focus Group Schedule (Appendix 24) will explore the usability, acceptability, barriers, facilitators, and benefits and disbenefits of the VERA Intervention. This will include the impact of the training, particularly in relation to perceived changes in behaviour and outcomes for staff and service users.

Ground rules regarding maintaining respect and confidentiality regarding members' contributions to the discussion will be established at the start. Staff will also be reminded that they should not refer to patients by name. If this occurs, it will redacted from the transcripts during the anonymisation process/transcription, as below.

Recordings, and any field notes made during the focus group, will be stored as described in section 7.1.1.

Any identifiers will be removed from the data at the first opportunity. The data will be stored in a pseudonymised form (PIN) and the files with identifiers permanently deleted.

7.1.8 Suggested Changes Form

This is an implementation study and it is anticipated that adaptations may be needed to make VERA accessible to individual service users on set-up and during use. There will also likely be reflections from participants about the design and potential improvements during the VERA Intervention period. Participants, and members of the research and clinical teams, will be encouraged to record these actual adaptations and reflections on desired changes via a Suggested Changes Form (Appendix 25) utilising Microsoft Forms. Relatives / friends of service users will also be encouraged to suggest changes for users or staff to record.

The Suggested Changes Form will be accessible through the VERA Unit for service user participants. The hyperlink will be made available by email to the research and clinical teams.

This will enable actual adaptations and suggested changes to be captured, and provides an opportunity to explore the reason for each. This anonymised data will form part of the process evaluation. Once submitted, the data will go directly to the UCLan OneDrive.

Data Analysis

All analyses and associated documents will be held on the UCLan OneDrive. In line with UCLan policy, the analyses and associated documents will be stored for 7 years after the end of the study (see below) after which they will be securely and permanently deleted.

Staff and service user participants will be informed of this in the participant information documentation (Appendices 2.1, 2.1a, 3, 4, 7.1, 8)

End of Study

End of study will be December 31st 2025, which is the point that all data will have been collected and analysed and information that is not being stored for 7 years will have been confidentially destroyed.

Service user and staff Demographic Information Forms and Training Questionnaires

Data from service user and staff Demographic Information Forms (Appendices 13, 14 and 22) and Training Questionnaires (Appendices 20 and 23) will be nominal and ordinal. Descriptive analysis will be undertaken by the UCLan research team.

Quantitative data

Service Users

The ordinal quantitative data from the SF-36, PHQ-9, PHCS, OSA-SF, 6-CIT and MRS and goal Binary Individualised Outcome Measure will be subject to descriptive analysis including visual representation. This 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-intervention data. These quantitative outcomes will be used to provide context to the qualitative data collected through the service user interviews.

Service user interviews

The interview data will be analysed using framework analysis (Furber, 2010; Gale et al., 2013; Ritchie & Spencer, 1994) . Informed by the NASSS, the analysis framework will be structured based on

usability, accessibility, barriers and enablers. Framework analysis has five stages: familiarisation with the data, developing a theoretical framework, indexing, charting, and synthesising the data.

The interviews will be transcribed by the UCLan research team, with the assistance of MS Teams transcription software.

Researchers will familiarise themselves with the data using the audio / video recording alongside the transcription. This is helpful to increase understanding of the data. The approach is 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 (Parameswaran et al., 2019).

Two researchers will utilise the study objectives and the NASSS Framework to develop 'a priori' codes. They will independently code three interviews and compare results. This agreed coding scheme will then be used to code the remaining interviews.

A 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 to inform the development and implementation of the VERA intervention.

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) as part of coding the data. This will be undertaken by members of the UCLan research team supported by MS Teams transcription.

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

Suggested Changes Form

The information collected in the Suggested Changes Forms (Appendix 25) will be used to track actual adaptations as well as ideas for future changes. The analysis will be descriptive in nature.

The actual adaptations will be summarised and tabulated chronologically to identify which changes were made to the VERA Intervention across the study, and the reasons for this.

The forms will be collated for the two sites to see similarities and differences between the settings to inform the development of VERA.

PGR Student access to anonymised dataset

It is possible that postgraduate students under the supervision of the Chief Investigator may have limited access to specific aspects of the anonymised dataset during the study period. This would be for the purposes of their study, in order to both enhance their exposure to research, and maximise use of the study data. As UCLan students, they would also be trained and bound by GDPR and study protocols.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Legislation and requirements:

The Medicines and Healthcare Regulatory Authority (MHRA) has 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 staff and service user participants from the NHS and will therefore require Health Research Authority NHS Ethics Service approval, and approval from both Liverpool University Hospitals NHS Foundation Trust (LUHFT), and Lancashire and South Cumbria (L&SC) NHS Foundation Trust. All UCLan staff who will have contact with service-users and / or the primary data will hold Letters of Access from the partner organisations.

Dignity of participants:

The VERA 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 the VERA Intervention; understanding these will be a key outcome of this investigation. Dignity of participants will be preserved throughout the data collection process. The Service User Demographic Information Form - Staff-reported (Appendix 13) and one questionnaire (Six-item Cognitive Impairment Test, Appendix 19) will be administered by a member of clinical staff. To protect sensitive information, service-user participants will complete the remainder of the questionnaires themselves, using their VERA Unit. This process will be within their control at a convenient time. In the interviews, service users will be asked about their perceptions and opinions of the VERA intervention.

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

8.1 Assessment and management of risk

Protection of the data collected during the study

Protecting the participants' data requires substantial consideration due to the use of digital technology to collect the data. This is further complicated by five organisations having responsibility for different aspects of the data: The Walton Centre, Lancashire and South Cumbria NHS Foundation Trust, Liverpool University Hospitals NHS Foundation Trust, the University of Central Lancashire, and Citrus Suite. A Data Protection Impact Assessment will be undertaken by Lancashire and South Cumbria NHS Foundation Trust and Liverpool University Hospitals NHS Foundation Trust, supported by a previous VERA Data Protection Impact Assessment undertaken by The Walton Centre in relation to the inpatient study.

Risks to security of data

There is risk of loss of data, stolen data, and breach of data (from UCLan One Drive, Qualtrics Survey Platform, or Amazon Web Services (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. Access will only be permitted to clinical staff trained in the use of VERA. Usernames and Passwords will be required to access data.

UCLan One Drive and Qualtrics Survey Platform: PIN numbers allocated to staff and service users will be used to identify all data collection documents. The data will be available only to the UCLan research team. Usernames and Passwords will ensure controlled access.

Unauthorised access to the VERA Unit

The VERA Units (i-pads) will be password protected to control access. The VERA training for staff and service users will include the need to protect the VERA Unit, emphasising that personal information could be accessed through the VERA Unit. Training will include advice about keeping passwords protected from others. Staff will be able to access the content of an individual service user's VERA App. through a staff portal, or via the VERA Unit 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 study team disclosing data without authorisation, contractual arrangements will be in place between partners. Additionally, the UCLan research staff who collect and analyse data are trained in Good Clinical Practice and GDPR.

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

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

Identification of depression, or cognitive impairment from the quantitative measures

It is possible that the quantitative measures may indicate depression or cognitive impairment (see 7.1.3 Service user quantitative measures).

These data collection instruments will be managed within the UCLan researchers' Qualtrics and One Drive accounts. The UCLan researchers will monitor the relevant submissions weekly. In line with the assessment scoring guidance, UCLan researchers will make nominated clinical staff in the relevant community team aware if a participant scores:

- more than ten (indicating moderate / severe depression) on the completed PHQ-9
- more than eight on the completed 6-CIT

The need for this information to be made available to the clinical team in order to provide relevant support will be explained in the Service User Participant Information Sheets and Consent Forms (Appendices 2.1, 2.1a, 3, 4).

Appropriate records will be kept on any such referrals.

Risk assessments for home visits

UCLan researchers may be required to conduct home visits to obtain consent or carry out interviews with service users.

A risk assessment (Appendix 10) for home visits to research participants will be applied for all such visits.

UCLan staff will also follow standard UCLan procedures for travel and lone working. Additionally, they will consult in advance with the community neurological team caring for the specific service user, to identify any further risks and mitigation.

If it is felt for any reason that a home visit is not advisable, then the team will not present this an option for the particular user.

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, provided they continue to meet the inclusion criteria. Clinical staff will be asked to advise research staff of changes that mean the participant no longer meets the inclusion criteria.

Clinical time

There is a risk that the evaluation of the VERA Intervention may take time that clinical staff would otherwise spend undertaking other duties. The additional time involved will be required, 1. to undertake VERA training, 2. to set-up the VERA Unit for service users, and 3. potentially to support service users to submit their own personal data and undertake evaluation interviews.

Staff who consent to participate in the research element of the study will be asked to complete a Staff Demographic Information Questionnaire, a Staff Training Questionnaire, and participate in a focus group. 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.

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 in the Staff Participant Information Sheet (Appendix 7.1).

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, and careful reporting of findings. The UCLan research team have experience in this area.

Risk of low uptake

There is a risk of low uptake of the VERA Intervention that would undermine the evaluation findings. It is anticipated that it will be possible to recruit between six and ten service user participants from each

community neurological rehabilitation service. 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.

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.
- 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.
- The Chief Investigator will notify the REC of the end of the study.
- 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 service users into the study, the Chief Investigator (study) / Principal Investigator (site) or designee will ensure that appropriate approvals from participating organisations are in place. This will include, 1. Liverpool University Hospitals NHS Foundation Trust (LUHFT), and 2. Lancashire and South Cumbria NHS Foundation Trust (L&SCFT).

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 / site PI) 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 study 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 Liverpool University Hospitals NHS Foundation Trust (LUHFT), and Lancashire and South Cumbria NHS Foundation Trust (L&SCFT) to assess whether the amendment affects the NHS permission.

8.3 Peer review

This study has gained funding from the National Institute of Health and Care Research Health Technology Assessment Programme 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 development of VERA and the planning for this study. Service users, and where appropriate their families and friends, will continue to be integral to the implementation and development of VERA, through both formal data collection and their interactions with the staff as the VERA Unit is allocated and set up for each service user 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 to be included in the VERA intervention. The information from these workshops informed the first prototype of VERA. The first inpatient evaluation, supported by PPI and participant data, has

continued to support the acceptability of the research. A further series of workshops are planned as part of the current community-based VERA study.

- **Design of the research** – the design of this study is based on development work and an initial evaluation of VERA in an inpatient complex rehabilitation unit, which is underpinned by PPI as described above. The design of this community evaluation has been influenced further through the involvement of two additional PPI representatives. Both commented on the planned research, and one was a co-applicant on the successful bid submitted for National Institute for Health and Care Research (NIHR) funding.
- **Management of the research** - a PPI co-applicant contributed to the successful funding application and to the design and planned management of the study. At the time of the funding application, one PPI representative had agreed to be a member of the Study Steering Committee. To strengthen the PPI contributions, we have successfully sought a further PPI representative, and the Study Steering Committee now comprises one third PPI representatives.
- **Undertaking the research** – service user views will be instrumental to the community evaluation of the VERA Intervention and the subsequent development. It is anticipated that changes will be made to the design based on the data collected from both service users and the staff from the community neurological the rehabilitation services.
- **Dissemination of findings** - opportunities will be sought to include interested service users in dissemination opportunities, including conference presentations. The Service User Participant Debrief (Appendix 5) 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 documented on the relevant forms and reported to the Chief Investigator and Sponsor for appropriate response.

8.6 Data protection and service user confidentiality

The arrangements to address service user confidentiality and the appropriate management (collection, storage, processing and disclosure) of personal information have been designed 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 Research Fellow, 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.

It is likely that the data collected in this study may be beneficial in future studies to further develop the VERA technology and Intervention. The Staff and Service User Participant Information Sheets and Consent Forms (Appendices 2.1, 2.1a, 3, 4, 7.1 and 8) will state that for seven years after the end of the study, data may be used to further develop 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, 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 website and will be stored on the University of Central Lancashire Online Knowledge (CLoK) repository, to enable open access.

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

In a debrief at the end of the study, service user 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 indicates interest, they will be asked to supply an email address or telephone number to enable future contact.

A lay summary of the findings will be available after completion of the study. All patient participants will be informed of this via the PIS (Appendices 2.1, 2.1a) and Debrief (Appendix 5), and will have the option to consent (Appendices App. 3, 3a) to receive this by email in due course.

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.

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.

10. APPENDICIES

10.1 Summary of appendices for HRA Ethics Services

Document	Who for?	Format/notes	Appendix Number
Protocol			**1**
Participant Communications / Information Sheets / Consent Forms			
Service users			
Service User PIS	Service user participants	Written	2.1
Service User PIS (Easy Use)	Service User Participants	Written	2.1a
Service User Consent Form	Service user participants	Written - Likely that verbal consent will be audio / video recorded through Teams	3
Service User Supplementary Interview Consent Form	Service user participants	Written - Likely that verbal consent will be audio / video recorded through Teams	4
Debrief for participants (as they leave study)	Service user participants	Written	5
Staff			
Invitation email	Staff on community team	Written	6
Staff PIS	Staff participants	Written	7.1

Staff Consent Form	Staff participants	MS Forms	8
Guidance for researchers			
UCLan's Internet Mediated Research Guidelines	Researchers	Written	9
Home visit risk assessment	Researchers	Written	10
Research data record			
'Key' document with service-user participants' name, email and PIN	Researchers	Written	11
Expression of interest form	Staff	MS Forms	11.1
'Key' document with staff participants' name, email and PIN	Researchers	Written	12
Data Collection Instruments			
Service users			
Service User Demographic Information Form (including modified Rankin score) - Staff-Reported	Completed by Community clinical staff	Qualtrics	13
Service User Demographic Information Form - Self-Reported	Service user participants	Qualtrics	14
SF-36	Service user participants	Qualtrics	15
PHQ-9	Service user participants	Qualtrics	16

Perceived Health Competence Scale	Service user participants	Qualtrics	17
OSA	Service user participants	Qualtrics	18
6-CIT	Community clinical staff	Qualtrics	19
Post-study GOAL Binary Individualised Outcome Measure & Modified Rankin Scale	Community clinical staff	Qualtrics	28
Service User Training Questionnaire	Service user participants	Qualtrics	20
Service User Interview Schedule	Service user participants	Written	21
Staff			
Staff Demographic Information Form	Staff participants	Qualtrics	22
Staff Training Questionnaire	Staff participants	Qualtrics	23
Staff Focus Group Schedule	Staff participants	Written	24
Suggested Changes Form	Researchers & Community clinical staff	MS Forms	25
Other			
Study Flow Diagram			26
Certificate/s of Insurance/Indemnity			27
Modified Rankin Scale & Goal Binary Individualised Outcome Measure			28

Organisational Information Document			29
Chief Investigator CV			30

10.2 Appendices for HRA Ethics Services

Please refer to separate document files

10.3 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	

11 AMENDMENTS

11.1 Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

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