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

Service User Participant Information

Evaluation of the Virtual Engagement Rehabilitation Assistant (VERA)

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends and relatives if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

Who is the sponsor organisation for this study?

The University of Central Lancashire (UCLan) is sponsoring the study. Any reference to 'we' in this information sheet refers to the sponsor.

What is the purpose of the study?

VERA is digital technology which enables portable devices, such as tablets, to access a range of applications (apps) and web-based resources. It has been developed by Citrus Suite, a software development company, and The Walton Centre. These organisations are partners in this study. In this study VERA is housed on an iPad. We are calling this a **VERA Unit**.

We know that intensity of activity has been found to improve functional and motor recovery following neurological injury. But current NHS rehabilitation services cannot provide the intensity of therapy which is known to be beneficial due to limited available therapy time. There is growing evidence that self-management, and the ability to respond to one's own condition, has the potential to improve quality of life and self-efficacy for people with neurological conditions. Founded on this evidence, VERA was developed to support patient rehabilitation. Service users (patients), health care

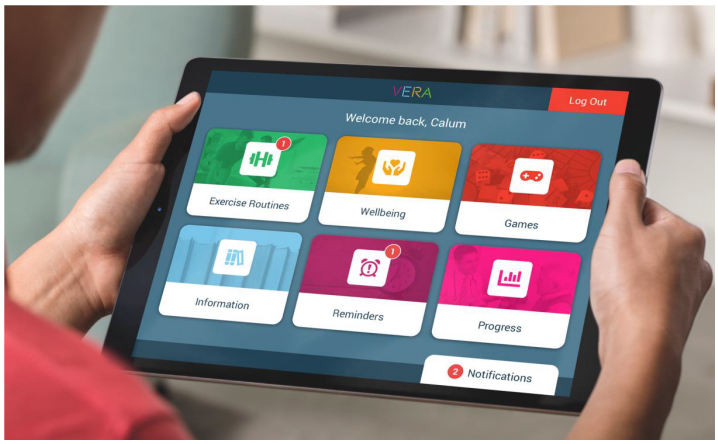
professionals and researchers have worked closely with a commercial software design company to agree ideas and produce a prototype of VERA.

VERA offers an opportunity to increase activity outside of formal therapy. It will enable service users to use a range of digital resources tailored to their own personal rehabilitation goals. This includes timetables and appointments, videos of personal exercises and activities regularly supplied and updated by a service user's own rehabilitation team, reminders, wellbeing questionnaires, games and links to other relevant resources and information.

This study aims to evaluate the process and outcomes of placing the VERA digital technology in a community rehabilitation setting. We intend to explore the adoption of this new technology by both service users and staff. The evaluation is being carried out by researchers from UCLan.

We aim to identify the impact of the VERA training packages, how and when VERA was used, users' perceptions of the benefits and disbenefits of VERA, and any barriers or enablers for using VERA in the community setting.

This is how VERA looks:



Why have I been invited to take part?

You have been invited to take part in this study as you are a community rehabilitation patient in either the Early Supported Discharge service within Liverpool University Hospitals NHS Foundation Trust (LUHFT), or the Lancashire and South Cumbria NHS Foundation Trust (L&SCFT) Community Neurological Rehabilitation Team, and the staff have identified that your rehabilitation goals can be addressed through the activities in VERA. They have assessed that you may be able to interact with and use VERA to do this if you wish. We would like to invite you to take part in the evaluation.

In this study, we aim to recruit up to 20 service users from Liverpool and Lancashire & South Cumbria. Six VERA Units will be available at one time.

Up to 20 staff will also take part in the evaluation.

Do I have to take part?

Participation in the evaluation is completely voluntary. You do not have to take part, and you are free to decline the invitations without any disadvantages or negative consequences from the staff or the UCLan researchers. If you choose not to take part, you will continue to be offered usual rehabilitation.

What will happen if I take part?

You will be asked to complete a consent process. This may be in writing, or by audio-recording. The consent process will be conducted by a UCLan researcher. You will have the opportunity to ask questions and discuss with family / friends prior to consenting.

If you decide to take part, you will be allocated a VERA Unit to use for up to six weeks, or up to discharge from the community rehabilitation team if this is sooner. In total you will not be in the study for more than 3 months, depending on how long each of the steps below takes in your individual case.

It is anticipated that the acceptability and usability of VERA may be affected by the characteristics and beliefs of both the staff and service user participants. This is why your personal information will be collected. This information will be analysed for patterns in adoption of VERA. If you would prefer not to supply this information, which is required for our analysis, then you will not be able to participate in the evaluation.

The information we will be collecting is:

1. Information will be collected for UCLan on a secure online platform called Qualtrics: 1) your age; 2) your medical condition/s; 3) the reason for your referral to the service; 4) the date of your injury / start of your condition; 5) the date of your admission to the community service; 6) any assistance you require in your everyday activities, including communication. With your consent, the clinical staff will input this information from your notes, using the VERA Unit, when they set it up for you.

   You will be invited to self-report the following sensitive personal information yourself online, using VERA: 1) your gender; 2) your ethnicity; and 3) your self-perceived assessment of high / low information technology use and confidence.

2. Information about your quality of life, functional ability, mental health and cognition will also be collected, using VERA to access standard questionnaires on Qualtrics.

3. After completing the training package for VERA, an online Training Questionnaire will collect your views about the training package, your learning and its effectiveness.

You will be asked to add your name onto the questionnaires, but your name will be removed once it has been downloaded to the UCLan system to ensure that your responses then become pseudonymised.

The researchers and Citrus Suite staff (the VERA technology developer) will be able to see the information about you that has been added to VERA during the evaluation. Citrus Suite will be able to see your name, email, IP address, and information added to VERA by therapy staff which includes your exercise programmes, goals and appointments.

Interviews

We are also inviting service users to take part in an individual interview with a UCLan researcher. We will explore what you think about the usability, acceptability, and benefits and disbenefits of VERA. Questions will also explore the impact of the VERA training for you, particularly how you think it has changed your behaviour or the outcomes of your rehabilitation.

The interviews will take place in person at your home, or online using Microsoft Teams video calling. Interviews will be audio- or video-recorded using either an encrypted digital audio-recorder or online. Interviews will last approximately 60 minutes and can be organised at a time and date to suit you. At the start of the interview we will review this information sheet and go through an additional consent form about the interview and what will happen to the recordings. We will record your verbal agreement before going ahead.

Interview recordings will be stored in UCLan's password protected secure OneDrive storage along with any notes made during the interview.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information is described in detail on page 4 (above).

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code (PIN) number instead.

We will keep all information about you safe and secure by:

- storing information on secure computer systems
- ensuring only those who should see the information do see it
- anonymising your information at the earliest opportunity

Your data will not be shared outside the UK.

We will keep your study data for a maximum of 7 years. The study data will then be fully anonymized and securely archived or destroyed.

We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep any information about you that we already have. If you take part in an interview, you are free to stop at any point. We would still like to use the interview data you have provided, but that can be discussed and agreed at the time.

- If you decide to stop using VERA, you will still be invited to participate in the Training and Health Questionnaires and interview (if this has not already been completed), but you will be under no obligation to do so. As the focus of the study is to consider the acceptability of VERA, it is important to capture the reasons a person chooses to stop using VERA, if they are willing to provide this information.

- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

If you would like to stop taking part in the study, you can contact Kathryn Jarvis (KJarvis1@uclan.ac.uk) or Julie Cook (JCook11@uclan.ac.uk) directly. Alternatively you can let your therapist know and they will ensure that the researchers know your decision.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to KJarvis1@uclan.ac.uk, who will direct you to the Sponsor's Data Protection Officer if this is appropriate

Are there any risks in taking part?

We do not anticipate that there are any direct risks to you from taking part. It is possible that VERA may not be as helpful for patients as we think, but this is why the study is being conducted. We hope taking part and sharing your thoughts will be a positive experience for you, and will help to develop this technology.

It is possible that the health questionnaires may indicate depression or cognitive impairment. In line with the duty of care, clinical staff will be made aware if a participant's score on any of these measures indicates a potential rehabilitation need, and they will follow this up with you.

Are there any benefits from taking part?

There are no direct benefits to you from taking part in this study. However, we hope that sharing experiences of the implementation of VERA will be a positive experience for service users who participate in the study.

Expenses and / or payments

There will be no expenses incurred or payments made for taking part in the evaluation.

What will happen to the results of the study?

On completion of the study an Executive Summary will be prepared for the organisations involved in the study (The Walton Centre, Early Supported Discharge service within Liverpool University Hospitals NHS Foundation Trust (LUHFT), Lancashire and South Cumbria NHS Foundation Trust (L&SCFT) Community Neurological Rehabilitation Team, Citrus Suite and UCLan).

The Executive Summary will be available on the VERA website, which can be accessed at www.veratechnology.myportfolio.com for those who are interested. All efforts will also be made to publish the findings from this study in a scientific journal. Details will be reported on the website as they become available.

After the study is completed we will send a summary of the research findings to every participant who said they would like to receive this. We will use your email address to do this.

What if I am unhappy or if there is a problem?

This study has been given a favourable opinion by the North-West Preston NHS Ethics Committee and the Health Ethics Panel at the University of Central Lancashire (Health 001184) and approved by the Health Research Authority (IRAS 330807).

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Dr Kathryn Jarvis, kjarvis1@uclan.ac.uk and we will try to help. If you remain unhappy, or have a complaint which you feel you cannot come to us with, then please contact the Research Governance Unit at OfficerForEthics@uclan.ac.uk .

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the university Information Governance and Data Protection Officer by emailing DPFOIA@uclan.ac.uk or calling 01772 892561.

Who can I contact if I have further questions?

Dr Kathryn Jarvis, Senior Research Fellow, School of Nursing and Midwifery, University of Central Lancashire, Preston. PR1 2HE. Tel: 01772 892782, kjarvis1@uclan.ac.uk

Dr Julie Cook, Senior Research Fellow, Applied Health Research Hub, University of Central Lancashire, Preston. PR1 2HE. Jcook11@uclan.ac.uk

The above people can be contacted at any point during your participation in the study.