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Is the Virtual Engagement Rehabilitation Assistant (VERA) acceptable, and its use feasible, to patients and staff in an inpatient rehabilitation setting?

Submission date
06/06/2022

Recruitment status
No longer recruiting

Registration date
05/07/2022

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The Virtual Engagement Rehabilitation Assistant (VERA), a portable digital technology, allows service users to access a range of digital resources tailored to support the achievement of their individual rehabilitation goals.

The first VERA prototype enables service users to access: information about their timetable and appointments; videos of exercises and activities; reminders; well-being questionnaires; games; and links to other relevant resources and information. In this study, VERA will be housed on an iPad. Staff from a service-user rehabilitation team will provide individualised resources through a portal, accessed through VERA, or through an alternative internet-enabled device.

This study aims to evaluate the implementation process and outcomes of placing the VERA digital technology in a complex inpatient rehabilitation setting and to explore the adoption of the technology by service users and staff.

'Non-adoption, Abandonment, and Challenges to the Scale-up, Spread and Sustainability' (NASSS), a framework designed to evaluate challenges to implementation and adoption of digital technology, will underpin a mixed-methods study.

Who can participate?
Adult service-user participants who have complex rehabilitation goals, including high physical dependency, mixed physical, cognitive/behavioural dependency and/or cognitive/behavioural disabilities, and who are able to use the Evaluation of the Virtual Engagement Rehabilitation Assistant (VERA) independently (phase I) or with greater support needs (phases II and III). Staff participants in a support role.

What does the study involve?
Training and use of VERA for a maximum of six weeks as part of their rehabilitation. Data

collected from service user participants will include demographic information, health and well-being measures, a questionnaire to evaluate the VERA training, and at the end of six weeks using VERA, a semi-structured interview.

Up to 20 staff working in the Complex Rehabilitation Unit, will be invited, following consent, to participate in, and evaluate VERA training, and contribute to a focus group to explore their experiences of using VERA in this setting.

The data analysis will aim to understand the feasibility, acceptability, and usability of VERA and to explore who benefits, and who does not benefit from this novel technology. The VERA training will also be evaluated. The findings from this study will inform the future development of VERA.

What are the possible benefits and risks of participating?
There are no direct benefits to participants from taking part in this study. However, we hope that sharing experiences of the implementation of VERA will be a positive experience for individuals who participate in the study. We do not anticipate that there are any direct risks from taking part in the study. It is possible that VERA may not be as helpful for patients as we think, but this is why the study is being conducted.
It is possible that the health questionnaires may indicate depression, anxiety 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 will follow this up with the relevant participant.

Where is the study run from?
University of Central Lancashire (UK)

When is the study starting and how long is it expected to run for?
September 2020 to September 2022

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Dr Kathryn Jarvis (UK)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293744

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50309, IRAS 293744

Study information

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

Acronym
VERA

Study objectives
This study is a mixed methods study of the acceptability and feasibility of the intervention. To address the aim and objectives, this study will collect information from service users and staff about the acceptability, usability and feasibility of VERA, alongside the barriers to and enablers of using this technology. Additional information will be collected from service-user participants to enable an exploration of who was able to and did, use VERA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2021, Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, Health Research Authority, BS1 6PN, Bristol, United Kingdom; +44 (0)207 104 8085; oxforda.rec@hra.nhs.uk), ref: 21/PR/1141

Study design
Non-randomized feasibility pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stroke

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

A range of theoretical frameworks has been developed to support the implementation of complex health interventions. The Non-adoption, Abandonment, and Challenges to the Scale-up, Spread and Sustainability (NASSS) framework have been developed specifically to address the implementation and sustainability of health and care technologies. The NASSS implementation framework, along with the associated qualitative assessment tool, the NASSS-Complexity Assessment Tool (NASSS-CAT) provides an evidence-based structure on which to develop, implement and evaluate VERA. Further detail about how this has been used is available in the full protocol.

To address the aim and objectives, this study will collect information from service users and staff about the acceptability, usability and feasibility of VERA, alongside the barriers to and enablers of using this technology. Additional information will be collected from service user participants to enable an exploration of who was able to and did, use VERA.

The study has three phases. In each phase, up to six service-user participants will participate (a maximum of 20 service-user participants in the full study). The clinical team in the Complex Rehabilitation Unit will review up to 30 inpatients on the ward at the time of issuing the VERA devices. In collaboration with the Chief Investigator, they will use study selection criteria and clinical reasoning to identify the service users they feel will benefit from the programmes available within VERA. This process reflects clinical practice when there are limited resources. Following consent, and collection of demographic information, service users will be invited to take part in the following:
1. Training to learn how to use VERA
2. Completion of a questionnaire (approximately 10 minutes to complete) to help explore the response to this training
3. Completion of five quantitative measures before using VERA (approximately 35 minutes to complete all five questionnaires):
3.1. Short-form 36 (SF36)
3.2. Patient Health Questionnaire-9 (PHQ-9)

3.3. General Anxiety Disorder-7 (GAD-7)
3.4. Six-item cognitive impairment test (CIT-6)
3.5. Occupational Self-Assessment-Short-form (OSA-SF)
4. Use of a VERA Unit for up to six weeks to use within their rehabilitation
5. On completion of the use of VERA, an interview of up to 60 minutes, which will be conducted online, or face-to-face if COVID-19 restrictions allow
6. Completion of the five quantitative measures after using VERA: SF36, PHQ-9, GAD-7, CIT-6, (OSA-SF)
7. Debrief
Medical, nursing and allied health professional staff working on the ward who meet the study selection criteria will be invited to participate. The Principal Investigator at The Walton Centre will be responsible for distributing information about the study to all staff working on the ward via email. This will ensure that all of the staff are aware of the study and that all of the relevant staff are invited to participate. Up to 20 staff participants will, following consent and collection of demographic information, will be invited to undertake the following:
7.1. Training to learn how to use VERA
7.2. Completion of a questionnaire to help explore the response to this training
7.3. Contribute to a maximum of two focus groups of up to 90 minutes, participants will be invited to participate in both, depending on availability and professional representation, staff participants may attend one, both, or neither focus group. The Focus Group Discussions will be conducted online, or face-to-face if COVID-19 restrictions allow.

This study is underpinned by Responsible Research and Innovation. Using the principles of co-design, service users, their relatives and clinical staff have been involved in designing VERA and have informed this evaluative study. Study participants will shape the VERA through their involvement. Additionally, there is Patient, Public Involvement (PPI) representation on the Study Steering Committee to ensure a PPI voice in the management of the study.

Intervention Type
Behavioural

Primary outcome measure
A framework analysis (Ritchie and Spencer 1994) was used to analyse the data collected
1. Qualitative component: Exploration of the acceptability, feasibility and usability, and information about who may gain benefit/disbenefit from VERA measured using training questionnaires, service-user interviews and the staff focus groups during the intervention
1.1. Experience of receiving training to use VERA
1.2. Experiences of using VERA
1.3. Facilitators and barriers to using VERA

2. Qualitative component:
Overall total number of minutes of VERA usage recorded at 6 weeks

Secondary outcome measures
1. Health measured using Short Form-35 (SF-35) questionnaire pre- and post- intervention (0 and 6 weeks)
2. Depression measured using the Patient Health Questionnaire-9 (PHQ-9) pre- and post-intervention (0 and 6 weeks)
3. Anxiety measured using General Anxiety Disorder-7 (GAD-7) questionnaire pre- and post-intervention (0 and 6 weeks)
4. Occupational participation measured using the Occupational Self Assessment pre- and post-

intervention (0 and 6 weeks)
5. Cognition measured using the Six-item Cognitive Impairment Test (6CIT) pre- and post-intervention (0 and 6 weeks)

Overall study start date
14/09/2020

Completion date
30/09/2022

Eligibility

Key inclusion criteria
This study comprises three phases. The aim is to recruit six participants for each phase.

Service-user participants in phase I with independent use of Evaluation of the Virtual Engagement Rehabilitation Assistant (VERA):
1. Have rehabilitation goals that can be addressed through the activities in VERA
2. Have been assessed by a speech and language therapist as able to communicate to allow effective interaction with the VERA unit
3. Able to use VERA independently (without support from the equipment available on the ward or from another person)
4. Able to understand the English language, as the first version of VERA will use the English language only
5. Have complex rehabilitation needs described as needing the services of a multidisciplinary team comprising highly trained professionals due to:
5.1. High physical dependency
5.2. Mixed physical, cognitive/behavioural dependency
5.3. Cognitive/behavioural disabilities.

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

Staff participants will be eligible to participate if they:
1. Are a member of the medical, nursing and allied health professional staff, either a qualified professional or staff working in a support role
2. Have worked in their professional capacity with service users using VERA during the previous six weeks

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Service users will be excluded in phase I if they:
1.1 Have been assessed by a speech and language therapist as unable to use VERA without support from the equipment available on the ward or from another person
1.2. Do not have mental capacity to engage in the study. This will be assessed through discussion between the service user, the clinical team and the researchers and, where permission is given, with participant-identified family and friends. This discussion will be based on the five principles of the Mental Capacity Act 2005 Code of Practice (Department for Constitutional Affairs, 2007).

2. Service users will be excluded in Phases II and III if they:
2.1. Do not have the 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).

3. Staff participants will be excluded if they:
3.1. Spend less than seven hours a week working with service users in the Complex Rehabilitation Unit
3.2. Have not worked in their professional capacity with any service users who are using VERA

Date of first enrolment
07/02/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Walton Centre
Lower Lane

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Sponsor information

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ROR
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Funder(s)

Funder type
Charity

Funder Name
Stroke Association; Grant Codes: SA MC 20\100002

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kathryn Jarvis, KJarvis1@uclan.ac.uk. Only anonymised data will be available. This will include the data from the quantitative outcome measures and the full analysis and coding trees of the qualitative data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	28/02/2022	12/02/2024	No	No
Results article		14/05/2024	08/10/2024	Yes	No