NICE National Institute for Health and Care Excellence

Evidence generation plan for virtual reality technologies for treating severe agoraphobic avoidance in people with psychosis

Implementation support

Published: 15 November 2023

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1 Purpose of this document

NICE's early value assessment of virtual reality technologies for treating agoraphobia or agoraphobic avoidance recommends that further evidence is generated while the virtual reality technology gameChangeVR (Oxford VR) is being used in the NHS to treat severe agoraphobic avoidance in people with psychosis aged 16 and over. The other technologies that were assessed can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps.

The company is responsible for ensuring that data collection and analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval. This will be in the form of funding for evidence generation consortia, bringing analytical partners and implementation sites together with developers for evidence generation.

Guidance on commissioning and procurement of the technology will be provided by NHS England, who is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the company does not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years, or sooner if enough evidence is available), the company should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether or not the technology can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The company can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Clinical benefits for severe agoraphobic avoidance in people with psychosis

Evidence on the clinical effectiveness of the technology at 6 months is essential for determining the technology's clinical and cost effectiveness. The committee has highlighted that a self-reported questionnaire such as the Oxford Agoraphobic Avoidance Scale (O-AS) or the Agoraphobia Mobility Inventory (AMI) could be used to assess clinical change in agoraphobic symptoms. Data on any relapse or change in agoraphobic symptoms should be collected to assess if the benefits of treatment are sustained at 6 months.

Level of engagement and adherence

Evidence on engagement and adherence will support the NICE committee in assessing the real-world uptake of the technology and its acceptance by adults with severe agoraphobic avoidance with psychosis.

Healthcare resource use

Several costs are relevant to the overall resource impact of this technology and will be essential in understanding its resource impact and cost effectiveness. The costs include:

- initial upfront costs, such as the licence and virtual reality (VR) headset costs
- healthcare resource use during and after treatment, including healthcare professional grade and time needed to deliver treatment or support
- costs associated with maintenance and lifespan of the hardware
- the cost of extra sessions after the first 6 sessions (the initial full VR therapy intervention).

Adverse effects

Continued reporting of device (VR headset)-related and intervention (VR therapy)-related adverse events is essential to assess any risk involved in the continued use of the technology in the NHS.

2.2 Evidence that further supports committee decision making

Health-related quality of life

This outcome measures a person's perspective on how changes in their health state relate to their quality of life. The EQ-5D is the preferred tool for measuring this outcome but non-standard measures such as the Recovering Quality of Life questionnaire may better capture benefits in people using mental health services within the NHS. This information can be included in health economic evaluations, for which quality of life is an important driver.

Generalisability

It is important to understand the characteristics of people using the technology to understand how the benefits from using the technology will be realised at the population level. This will ensure that appropriate guidance is given on the population group that would most benefit from this technology.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

No ongoing study has been identified that could address the evidence gaps for this technology.

3.2 Data sources

There are several data collections that have different strengths and weaknesses that could potentially support evidence generation. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

Local or regional data collections that have historically supported evidence generation in this clinical area may be able to collect the specific outcome measures needed to support evidence generation. For example, the primary clinical trial that informed NICE's early value assessment guidance on virtual reality technologies for treating agoraphobia or agoraphobic avoidance was done in 9 NHS trusts and the underlying data infrastructure supporting that work could be repurposed.

The Mental Health Services Dataset (MHSDS) is a mandated national data collection that could collect the necessary data. But it may not routinely collect all the outcome measures that were identified in the early value assessment for this evidence generation plan. Also, data may not have been submitted for all people using mental health services and there are potential issues with data quality. NHS England has suggested that modification of the MHSDS could take up to 2 years, so it is unlikely that it could be modified in time to support data collection for this evidence generation plan.

The Clinical Record Interactive Search (CRIS) system is a subnational dataset based on information from the South London and Maudsley NHS Foundation Trust's clinical records. It may include data on clinical outcomes of people with psychotic disorders that could be used to increase and improve the data collected from the study proposed in this plan.

The quality and coverage of real-world data collections are of key importance when used

in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

Real-world comparative study

The suggested approach to addressing the evidence gaps for the technology is a comparative interrupted time series (CITS) study using individual-level data collection. In practice, there is considerable variation across services in the delivery of care for severe agoraphobic avoidance in people with psychosis. Standard care may include cognitive behavioural therapy (CBT), antidepressants or monitoring from community mental health services. A CITS design will allow for evaluation of the technology's effects, controlling for variation across services while limiting the risk of time-varying cofounders. This study design also supports continuous enrolment of people in smaller populations. This study should include people who have severe agoraphobic avoidance with psychosis, and who would be expected to be offered virtual reality (VR) therapy in usual practice.

Data should be collected for everyone who has severe agoraphobic avoidance with psychosis, having care in community mental health services that are enrolled in the study. The data collection period should be long enough to ensure there is 6-month follow-up data while people have standard care. People should be offered VR therapy through the technology after 6 months of standard care. Data should then be collected from people offered therapy through the technology for a further 6 months. The study should compare outcomes in the 6 months before offering VR therapy with the 6 months after offering VR therapy. In both observation periods, data should be collected at regular time intervals but must include all of the following:

- the point of entry to the study (the beginning of 6 months of standard care)
- 6 months after standard care but before starting VR therapy
- 6 weeks after starting VR therapy (the point at which VR therapy would be expected to finish)
- 6 months from being offered treatment with the technology.

This study could be done within a single service or, ideally, replicated across multiple

services to show how the technology can be implemented across a range of services, representative of the variety of care in the NHS. Outcomes can reflect other changes that occur over time in the population, unrelated to the interventions. So, additional robustness can be achieved by collecting data from services which have not implemented the technology. These services should be as similar as possible in clinical practice and patient demographics to the services in which the technology has been deployed. This could control for changes in outcomes over time that might have occurred anyway over the same time period.

High-quality data on patient characteristics is needed to assess who the technologies would be suitable for and who engages with the technologies. Important characteristics should be identified with input from clinical experts during the protocol development. Loss to follow up, and reasons for loss to follow up over the data collection period should be reported.

Data collection could be approached using multiple sources, for example:

- engagement and drop-out information generated through the technology
- some information collected through suitable real-world data sources
- other information collected by clinicians and research staff working with the person, for example clinical measures and quality-of-life data.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of the data collection. NICE's real-world evidence framework provides guidance on the planning, conduct, and reporting of real-world evidence studies of comparative treatment effects and outlines potential sources of bias. Guidance from the NICE real-world evidence framework also includes reporting standards for interrupted time series studies.

3.4 Data to be collected

The following information has been prioritised for collection:

- At baseline, clinical diagnosis for agoraphobia in people with psychosis who are having difficulty leaving the house, as assessed in line with the World Health Organization's International Classification of Diseases (ICD)-10.

- Information on standard care provided in the mental health services. Standard care may include CBT, antidepressants or monitoring from community mental health services. Details of processes and NHS staff should also be collected because they may vary between services.
- In people having VR therapy with the technology, the number of extra sessions delivered beyond the standard 6-week therapy.
- The Oxford Agoraphobic Avoidance Scale (O-AS) or the Agoraphobia Mobility Inventory (AMI) score at regular time intervals (see section 3.3).
- Changes in agoraphobic symptoms, defined according to a standardised measure.
- Recovery, defined according to a standardised measure of agoraphobic symptoms, with a predefined threshold, at regular time intervals (see section 3.3).
- Relapse to severe agoraphobic symptoms, that is, the number of people with previous recovery who relapse to severe agoraphobic avoidance at a later time point.
- EQ-5D or Recovering Quality of Life questionnaire scores at regular time intervals.
- Any adverse events through use of the technology or VR therapy.
- Access and uptake: this should include the number and proportion of people who were able to access treatment for severe agoraphobic avoidance before and after deployment of the technology in the service.
- Engagement and information on stopping VR therapy, including reasons for stopping. This should include the number of people starting VR therapy, the number of sessions completed, and whether it was stopped because of improvements in symptoms, adverse effects, or other reasons.
- Information about individual characteristics at baseline, including sex, age, ethnicity, clinical diagnosis, medicines, comorbidities and past medical history including previous interaction with tiered mental health services, and other important characteristics identified with input from clinical experts.
- Costs of VR therapy with the technology, including any costs associated with providing the VR headset, licence fees, maintenance and replacement of the hardware, and costs associated with the delivery of extra sessions when needed.
- Other health service use costs including NHS staff grade and time needed to support

the use of the technology, and cost and time associated with staff training.

3.5 Evidence generation period

The evidence generation period should be 3 years, or sooner if enough evidence is available. This will be enough time to implement the evidence generation study, collect the necessary information and analyse the collected data.

4 Monitoring

The company must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The company should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the company should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

- The company should provide training for staff to support use of the technology.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners, and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff, and by using suitable real-world data to collect information when possible.
- There is a wide variation in standard care for severe agoraphobic avoidance in people with psychosis within the NHS. Contributing services should be chosen to maximise the generalisability of evidence generated, both in terms of the populations covered and the standard care delivered.
- Careful planning of the approach to information governance is vital. Implementers should ensure that appropriate structures and policies are in place to ensure that the data is handled in a confidential and secure manner and to appropriate ethical and quality standards.
- Using the EQ-5D requires a licence, with an associated cost.
- The Oxford Agoraphobic Avoidance Scale (O-AS) outcomes measure is not routinely used in the NHS. It was developed by researchers who were also involved in the development of the technology.
- Sufficient retention of people is needed over the required follow-up period, and people having standard care alone may need motivation or incentivisation to remain in the study. To encourage retention, the company should consider offering virtual reality (VR) therapy to people after they have taken part in in the study in services which have not yet implemented the technology (control services).

ISBN: 978-1-4731-7737-6